**As filed with the Securities and Exchange Commission on October 13, 2021**

**Registration No. 333-259065**

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

AMENDMENT NO. 1
TO

# Form S-4

**REGISTRATION STATEMENT**
***UNDER***
***THE SECURITIES ACT OF 1933***

# Advaxis, Inc.

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **2834** | **02-0563870** |
|---|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(Primary Standard Industrial Classification Code Number)** | **(I.R.S. Employer Identification Number)** |

**9 Deer Park Drive, Suite K-1**
**Monmouth Junction, New Jersey 08852**
**(609) 452-9813**
**(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)**

**Kenneth A. Berlin**
**President and Chief Executive Officer**
**Interim Chief Financial Officer**
**Advaxis, Inc.**
**9 Deer Park Drive, Suite K-1**
**Monmouth Junction, New Jersey 08852**
**(609) 452-9813**
**(Name, address, including zip code, and telephone number, including area code, of agent for service)**

***Copies to:***

| **Robert W. Dickey** | **Dr. Ruth Ben Yakar** | **Tali Sealman, Esq.** |
|---|---|---|
| **Morgan, Lewis & Bockius LLP** | **Biosight Chief Executive Officer** | **Colin Diamond, Esq.** |
| **101 Park Avenue** | **Biosight Ltd.** | **White & Case LLP** |
| **New York, New York 10178-0060** | **3 Hayarden St., Airport City** | **3000 El Camino Real** |
| **(212) 309-6000** | **P.O.B. 1083** | **2 Palo Alto Square, Suite 900** |
| | **Lod 7019802 Israel** | **Palo Alto, California 94306-2019** |
| | **+972 (3) 656 8669** | **(650) 213-0315** |

**Approximate date of commencement of proposed sale to the public:** As soon as practicable after the effective date of this registration statement and the satisfaction or waiver of all other conditions under the Merger Agreement described herein.

If the securities being registered on this Form are being offered in connection with the formation of a holding company and there is compliance with General Instruction G, check the following box: ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☐ |

| | | | |
|---|---|---|---|
| Non-accelerated filer | ☒ | Smaller reporting company | ☒ |
| | | Emerging growth company | ☐ |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

If applicable, place an X in the box to designate the appropriate rule provision relied upon in conducting this transaction:

Exchange Act Rule 13e-4(i) (Cross-Border Issuer Tender Offer) ☐

Exchange Act Rule 14d-1(d) (Cross-Border Third-Party Tender Offer) ☐

**CALCULATION OF REGISTRATION FEE**

| Title of each class of securities to be registered | Amount to be registered(1) | Proposed maximum offering price per share | Proposed maximum aggregate offering price(2) | Amount of registration fee(3) |
|---|---|---|---|---|
| Common stock, par value $0.001 per share | 44,205,068 | N/A | $ 45,677.10 | $ 4.98 |

(1) Relates to common stock, $0.001 par value per share, of Advaxis, Inc., a Delaware corporation, or Advaxis, issuable to holders of the ordinary and preferred shares, par or nominal value NIS 0.01 per share, and warrants of Biosight Ltd., a company organized under the laws of the State of Israel, or Biosight, in the proposed merger of Advaxis Ltd., a company organized under the laws of the State of Israel and a direct, wholly owned subsidiary of Advaxis, with and into Biosight, with Biosight continuing as a wholly owned subsidiary of Advaxis and the surviving corporation of the merger. The amount of Advaxis common stock to be registered is based on the estimated number of shares of Advaxis common stock that are expected to be issued pursuant to the merger, taking into account the effect of a reverse stock split of Advaxis common stock on a 10 to 1 basis, assuming a pre-split exchange ratio of approximately 118.2009 shares of Advaxis common stock for each outstanding Biosight ordinary share. The estimated exchange ratio contained herein is subject to adjustment prior to the closing of the merger.

(2) Estimated solely for the purpose of calculating the registration fee and computed pursuant to Rule 457(f)(2) under the Securities Act of 1933. Biosight is a private company, no market exists for its securities, and Biosight has an accumulated capital deficit. As such, the aggregate offering price of the common stock shares was calculated as follows: (a) 44,205,068, the estimated number of ordinary shares to be exchanged and cancelled for the Registrant's common stock shares, multiplied by (b) $0.0031, the book value per share of the securities.

(3) Determined in accordance with Section 6(b) of the Securities Act of 1933, as amended, at a rate equal to $109.10 per $1,000,000 of the proposed maximum aggregate offering price.

**The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

**The information in this proxy statement/prospectus/information statement is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This proxy statement/prospectus/information statement is not an offer to sell and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.**

**SUBJECT TO COMPLETION, DATED OCTOBER [●], 2021**

**PROPOSED MERGER**
**YOUR VOTE IS VERY IMPORTANT**

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To the Stockholders of Advaxis, Inc. and the Shareholders of Biosight Ltd.,

Advaxis, Inc., a Delaware corporation, or Advaxis, and Biosight Ltd., a company organized under the laws of the State of Israel, or Biosight, entered into an Agreement and Plan of Merger and Reorganization, or the Merger Agreement, on July 4, 2021, pursuant to which a direct, wholly owned subsidiary of Advaxis, Advaxis Ltd., or Merger Sub, will merge with and into Biosight, with Biosight surviving as a wholly owned subsidiary of Advaxis, and the surviving company of the merger, which transaction is referred to herein as the merger. Advaxis following the merger is referred to herein as the combined company.

At the effective time of the merger each of Biosight's ordinary and preferred shares, par or nominal value NIS 0.01 per share, collectively referred to herein as the Biosight shares, will be converted into the right to receive a number of shares of Advaxis common stock, par value $0.001 per share, referred to herein as the Advaxis common stock, equal to the exchange ratio, 118.2009 shares of Advaxis common stock per Biosight share (subject to adjustment to account for the proposed Advaxis reverse stock split), described in more detail in the section titled "*The Merger Agreement—Merger Consideration*" beginning on page 108 of the accompanying proxy statement/prospectus/information statement.

Prior to the merger, each of Biosight and Advaxis shall take all actions necessary to provide that each option for Biosight shares, or Biosight option, outstanding and unexercised immediately before the effective time of the merger, automatically and without any action on the part of the holder thereof, be assumed by Advaxis and converted into an option for Advaxis common stock, or Advaxis option, with the number of shares subject to and per share exercise price of the option adjusted to reflect the exchange ratio. Each such substituted Advaxis option shall continue to have, and shall be subject to, the same terms and conditions (including the applicable time-vesting and/or performance-vesting conditions) as applied to the corresponding Biosight option immediately prior to the effective time of the merger. All other securities of Biosight shall be cancelled and shall be of no further force and effect from the effective time of the merger and shall not be assumed or converted into a right to receive any shares of Advaxis common stock.

Each share of Advaxis common stock and option to purchase Advaxis common stock that is issued and outstanding at the effective time of the merger will remain issued and outstanding, and such shares will be unaffected by the merger. Immediately after the merger, Advaxis stockholders as of immediately prior to the merger are expected to own approximately 25% of the outstanding shares of the combined company and former Biosight shareholders are expected to own approximately 75% of the outstanding shares of the combined company.

Shares of Advaxis common stock are currently listed on The Nasdaq Capital Market under the symbol "ADXS." Advaxis will file an initial listing application for the combined company with The Nasdaq Stock Market Inc., or Nasdaq. After completion of the merger, Advaxis will be renamed "Biosight Therapeutics Inc." and it is expected that the common stock of the combined company will trade on The Nasdaq Capital Market under the symbol "BSTX." On August 24, 2021, the last trading day before the date of the accompanying proxy statement/prospectus/information statement, the closing sale price of Advaxis common stock was $0.42 per share.

Advaxis stockholders are cordially invited to attend the special meeting of Advaxis stockholders. Advaxis is holding its special meeting of stockholders, or the Advaxis special meeting, on November 16, 2021, at 10:00 a.m. Eastern Time, unless postponed or adjourned to a later date, in order to obtain the stockholder approvals necessary to complete the merger and related matters. The Advaxis special meeting will be held entirely online. Advaxis stockholders will be able to attend and participate in the Advaxis special meeting online by visiting www.virtualshareholdermeeting.com/ADXS2021SM where they will be able to listen to the meeting live, submit questions and vote. At the Advaxis special meeting, Advaxis will ask its stockholders to:

1. Approve the issuance of shares of common stock of Advaxis to shareholders of Biosight, pursuant to the terms of the Merger Agreement, a copy of which is attached as *Annex A* to the accompanying proxy statement/prospectus/information statement, and the change of control resulting from the merger;

2. Approve an amendment to the amended and restated certificate of incorporation of Advaxis to effect a reverse stock split of Advaxis' issued and outstanding common stock within a range, as determined by the Advaxis board of directors and agreed to by Biosight, of one new share of Advaxis common stock for every 10 to 30 shares (or any number in between) of outstanding Advaxis common stock in the form attached as *Annex E* to the accompanying proxy statement/prospectus/information statement;

3. Approve an amendment to the amended and restated certificate of incorporation of Advaxis to change the corporate name from Advaxis, Inc. to "Biosight Therapeutics Inc." in the form attached as *Annex F* to the accompanying proxy statement/prospectus/information statement;

4. Approve, on a non-binding, advisory basis, the compensation that will or may become payable by Advaxis to its named executive officers in connection with the merger;

5. Consider and vote upon an adjournment of the Advaxis special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposal Nos. 1, 2 and 3; and

6. Transact such other business as may properly come before the stockholders at the Advaxis special meeting or any adjournment or postponement thereof.

As described in the accompanying proxy statement/prospectus/information statement, certain Advaxis stockholders who in the aggregate own less than 1% of the outstanding shares of Advaxis as of July 31, 2021, and certain Biosight shareholders who in the aggregate own approximately 25.9% of the ordinary shares of Biosight as of August 24, 2021, are parties to support agreements with Advaxis and Biosight, respectively, whereby such stockholders and shareholders have agreed to vote in favor of, and to adopt and approve, the merger, the Merger Agreement and the related transactions at any meeting of Advaxis' stockholders or Biosight's shareholders, as applicable (or any adjournment or postponement thereof), subject to the terms of the support agreements. Following the effectiveness of the registration statement on Form S-4 of which the accompanying proxy statement/prospectus/information statement is a part and pursuant to the Merger Agreement, Biosight shall either hold, as promptly as practicable, a special meeting of Biosight shareholders to approve, or seek approval by written consent of its shareholders of, the Merger Agreement and the transactions contemplated therein.

After careful consideration, each of the Advaxis and Biosight boards of directors have approved the Merger Agreement and have determined that it is advisable to consummate the merger. Advaxis' board of directors has approved the proposals described in the accompanying proxy statement/prospectus/information statement and unanimously recommends that its stockholders vote "FOR" the proposals described in the accompanying proxy statement/prospectus/information statement.

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**More information about Advaxis, Biosight, the Merger Agreement and transactions contemplated thereby and the foregoing proposals is contained in the accompanying proxy statement/prospectus/information statement. Advaxis urges you to read the accompanying proxy statement/prospectus/information statement carefully and in its entirety. IN PARTICULAR, YOU SHOULD CAREFULLY CONSIDER THE MATTERS DISCUSSED UNDER "RISK FACTORS" BEGINNING ON PAGE 19 OF THE ACCOMPANYING PROXY STATEMENT/PROSPECTUS/INFORMATION STATEMENT.**

Advaxis and Biosight are excited about the opportunities the merger brings to Advaxis' stockholders and Biosight's shareholders and thank you for your consideration and continued support.
Sincerely,

Kenneth A. Berlin
*President and Chief Executive Officer*
*Interim Chief Financial Officer*
Advaxis, Inc.

Dr. Ruth Ben Yakar
*Chief Executive Officer*
Biosight Ltd.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of the accompanying proxy statement/prospectus/information statement. Any representation to the contrary is a criminal offense.**

The accompanying proxy statement/prospectus/information statement is dated , 2021 and is first being mailed to Advaxis stockholders on or about , 2021.

**ADVAXIS, INC.**
**9 Deer Park Drive, Suite K-1**
**Monmouth Junction, New Jersey 08852**
**(609) 452-9813**

## NOTICE OF SPECIAL MEETING OF STOCKHOLDERS

To the stockholders of Advaxis, Inc.:

**NOTICE IS HEREBY GIVEN** that a virtual special meeting of stockholders, or the Advaxis special meeting, will be held on November 16, 2021, at 10:00 a.m. Eastern Time, unless postponed or adjourned to a later date. The Advaxis special meeting will be held entirely online. You will be able to attend and participate in the Advaxis special meeting online by visiting www.virtualshareholdermeeting.com/ADXS2021SM, where you will be able to listen to the meeting live, submit questions and vote.

**The Advaxis special meeting will be held for the following purposes:**

1. To approve the issuance of shares of common stock of Advaxis, Inc., or Advaxis, to stockholders of Biosight Ltd., or Biosight, pursuant to the terms of the Agreement and Plan of Merger and Reorganization among Advaxis, Biosight and Advaxis Ltd., or Merger Sub, dated as of July 4, 2021, a copy of which is attached as *Annex A* to the accompanying proxy statement/prospectus/information statement, which is referred to in this Notice as the Merger Agreement, and the change of control resulting from the merger;

2. To approve an amendment to the amended and restated certificate of incorporation of Advaxis to effect a reverse stock split of Advaxis' issued and outstanding common stock within a range, as determined by the Advaxis board of directors and agreed to by Biosight, of one new share of Advaxis common stock for every 10 to 30 shares (or any number in between) of outstanding Advaxis common stock in the form attached as *Annex E* to the accompanying proxy statement/prospectus/information statement;

3. To approve an amendment to the amended and restated certificate of incorporation of Advaxis to change the corporate name from Advaxis, Inc. to "Biosight Therapeutics Inc.," in the form attached as *Annex F* to the accompanying proxy statement/prospectus/information statement;

4. To approve, on a non-binding, advisory basis, the compensation that will or may become payable by Advaxis to its named executive officers in connection with the merger;

5. To consider and vote upon an adjournment of the Advaxis special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposal Nos. 1, 2 and 3; and

6. To transact such other business as may properly come before the stockholders at the Advaxis special meeting or any adjournment or postponement thereof.

**Record Date:** Advaxis' board of directors has fixed September 17, 2021 as the record date for the determination of stockholders entitled to notice of, and to vote at, the Advaxis special meeting and any adjournment or postponement thereof. Only holders of record of shares of Advaxis common stock at the close of business on the record date are entitled to notice of, and to vote at, the Advaxis special meeting. At the close of business on the record date, Advaxis had 145,638,459 shares of common stock outstanding and entitled to vote.

**Your vote is important. The affirmative vote of the holders of a majority of the outstanding shares of Advaxis common stock entitled to vote at the special meeting is required for approval of Proposal Nos. 1, 2 and 3. The affirmative vote of the holders of a majority of shares virtually present in person or represented by proxy at the Advaxis special meeting and entitled to vote on the subject matter, assuming a quorum is present, is required for approval of Proposal Nos. 4 and 5. Approval of each of Proposal No. 1, referred to as the merger proposal, Proposal No. 2, referred to as the reverse stock split proposal, Proposal No. 3, referred to as the certificate of incorporation amendment proposal, is a condition to the completion of the merger. Therefore, the merger cannot be consummated without the approval of Proposal Nos. 1, 2 and 3.**

**Even if you plan to virtually attend the Advaxis special meeting, Advaxis requests that you sign and return the enclosed proxy or vote by mail or online to ensure that your shares will be represented at the Advaxis special meeting if you are unable to virtually attend. You may change or revoke your proxy at any time before it is voted at the Advaxis special meeting.**

**ADVAXIS' BOARD OF DIRECTORS HAS DETERMINED AND BELIEVES THAT EACH OF THE PROPOSALS OUTLINED ABOVE IS FAIR TO, IN THE BEST INTERESTS OF, AND ADVISABLE TO ADVAXIS AND ITS STOCKHOLDERS AND HAS APPROVED EACH SUCH PROPOSAL. ADVAXIS' BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT ADVAXIS STOCKHOLDERS VOTE "FOR" EACH SUCH PROPOSAL.**

**Important Notice Regarding the Availability of Proxy Materials for the Stockholders' Meeting to Be Held on November 16, 2021 at 10:00 a.m. Eastern Time, Via the Internet**

The proxy statement/prospectus/information statement and annual report to stockholders are available at www.virtualshareholdermeeting.com/ADXS2021SM

By Order of Advaxis' Board of Directors,

Kenneth A. Berlin
*President and Chief Executive Officer, Interim Chief Financial Officer*
Monmouth Junction, New Jersey
, 2021

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## QUESTIONS AND ANSWERS ABOUT THE MERGER

*Except where specifically noted, the following information and all other information contained in this proxy statement/prospectus/information statement does not give effect to the proposed reverse stock split described in Proposal No. 2 of this proxy statement/prospectus/information statement.*

The following section provides answers to frequently asked questions about the merger. This section, however, provides only summary information. For a more complete response to these questions and for additional information, please refer to the cross-referenced sections.

**Q: What is the merger?**

**A:** Advaxis, Inc., or Advaxis, also referred to herein as "we," "us," "our," and the "Company," and Biosight Ltd., or Biosight, have entered into an Agreement and Plan of Merger, or the Agreement, dated as of July 4, 2021, a copy of which is attached as *Annex A* to this proxy statement/prospectus/information statement. The Merger Agreement contains the terms and conditions of the proposed business combination of Advaxis and Biosight. Pursuant to the Merger Agreement, Advaxis Ltd., or Merger Sub, a direct, wholly owned subsidiary of Advaxis, will merge with and into Biosight, with Biosight surviving as a wholly owned subsidiary of Advaxis. This transaction is referred to in this proxy statement/prospectus/information statement as the merger. Advaxis following the merger is referred to herein as the combined company. After the completion of the merger, the combined company will change its corporate name to "Biosight Therapeutics Inc."

Immediately prior to the effective time of the merger, the outstanding Biosight shares will be converted into the right to receive a number of shares of Advaxis common stock equal to the exchange ratio described in more detail in the section titled "*The Merger Agreement—Merger Consideration*" beginning on page 108 of this proxy statement/prospectus/information statement.

In connection with the merger, each outstanding and unexercised option to purchase Biosight's ordinary shares will be assumed by Advaxis and will be converted into an option to purchase shares of Advaxis' common stock, with necessary adjustments to reflect the exchange ratio.

Each share of Advaxis common stock and warrant or option to purchase Advaxis common stock that is issued and outstanding at the effective time of the merger will remain issued and outstanding and such shares, warrants and options will be unaffected by the merger. If any holder of a warrant to purchase Advaxis common stock issued in connection with Advaxis' September 2018 offering properly exercises such holder's right to receive a cash payment in connection with the merger pursuant to the terms and conditions of the underlying agreement governing such warrant, Advaxis shall promptly pay such cash payment to such holder, in each case in such amount as determined in accordance with, and pursuant to the procedures set forth in, such agreement governing such warrant.

**Q: What will happen to Advaxis if, for any reason, the merger does not close?**

**A:** Advaxis has invested significant time and incurred, and expects to continue to incur, significant expenses related to the merger. In the event the merger does not close, the Advaxis board of directors may elect, among other things, to attempt to complete another strategic transaction or the Advaxis board of directors may instead divest all or a portion of Advaxis' business or assets if a viable alternative strategic transaction is not available. Under certain circumstances, Biosight and Advaxis may be obligated to pay the other party a termination fee of $7,500,000 or reimburse certain expenses of the other party, as more fully described in the section titled "*The Merger Agreement—Termination*" beginning on page 121 and the section titled "*The Merger Agreement—Termination Fee*" beginning on page 121 of this proxy statement/prospectus/information statement.

**Q: Why are the two companies proposing to merge?**

**A:** Advaxis and Biosight believe that combining the two companies will result in a company with a robust pipeline, strong leadership team and substantial capital resources, which will better position it to advance the research, development and commercialization of therapies for cancer. For a more complete description of the reasons for the merger, please see the sections titled "*The Merger—Advaxis Reasons for the Merger*" and "*The Merger—Biosight Reasons for the Merger*" beginning on pages 85 and 88, respectively, of this proxy statement/prospectus/information statement.

**Q: Why am I receiving this proxy statement/prospectus/information statement?**

**A:** You are receiving this proxy statement/prospectus/information statement because you have been identified as a stockholder of Advaxis as of September 17, 2021, the record date for the special meeting, and you are entitled to vote at the Advaxis special meeting to approve the matters set forth herein. This document serves as:

- a proxy statement of Advaxis used to solicit proxies for the Advaxis special meeting to vote on the matters set forth herein and an information statement for the shareholders of Biosight for their special meeting or written consent; and

- a prospectus of Advaxis used to offer shares of Advaxis common stock in exchange for ordinary shares and preferred shares of Biosight in the merger.

**Q: What proposals will be voted on at the Advaxis special meeting, the approval of which are conditions to the closing of the merger?**

**A:** Pursuant to the terms of the Merger Agreement, the following proposals must be approved by the requisite stockholder vote at the Advaxis special meeting in order for the merger to close:

- Proposal No. 1 to approve the issuance of shares of Advaxis common stock to Biosight shareholders pursuant to the Merger Agreement and the change of control resulting from the merger;

- Proposal No. 2 to approve an amendment to the amended and restated certificate of incorporation of Advaxis to effect a reverse stock split of Advaxis' issued and outstanding common stock within a range, as determined by the Advaxis board of directors and agreed to by Biosight, of one new share of Advaxis common stock for every 10 to 30 shares (or any number in between) of outstanding Advaxis common stock, which is referred to herein as the reverse stock split, in the form attached as *Annex E* to this proxy statement/prospectus/information statement; and

- Proposal No. 3 to approve an amendment to the amended and restated certificate of incorporation of Advaxis to change the corporate name from Advaxis, Inc. to "Biosight Therapeutics Inc." in the form attached as *Annex F* to the accompanying proxy statement/prospectus/information statement.

Proposal No. 1 is referred to herein as the merger proposal. Proposal No. 2 is referred to herein as the reverse stock split proposal. Proposal No. 3 is referred to herein as the certificate of incorporation amendment proposal. The approval of the merger proposal, the reverse stock split proposal and the certificate of incorporation amendment proposal are all conditions to the completion of the merger. The issuance of Advaxis common stock in connection with the merger and the change of control resulting from the merger, or Proposal No. 1, and the amendment to the amended and restated certificate of incorporation of Advaxis, as amended, to change the corporate name from Advaxis, Inc. to "Biosight Therapeutics Inc.," or Proposal No. 3, will not take place unless they are approved by Advaxis stockholders and the merger is consummated.

In addition to the requirement of obtaining Advaxis stockholder approval, each of the other closing conditions set forth in the Merger Agreement must be satisfied or waived. For a more complete description of the closing conditions under the Merger Agreement, please see the section titled "*The Merger Agreement—Conditions to the Completion of the Merger*" beginning on page 110 of this proxy statement/prospectus/information statement.

**Q: What proposals are to be voted on at the Advaxis special meeting, other than the merger proposal, the reverse stock split proposal and the certificate of incorporation amendment proposal?**

**A:** At the Advaxis special meeting, the holders of Advaxis common stock will also be asked to consider the following proposals:

- Proposal No. 4 to approve, on a non-binding advisory vote basis, compensation that will or may become payable by Advaxis to its named executive officers in connection with the merger; and

- Proposal No. 5 to approve an adjournment of the Advaxis special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposal Nos. 1, 2 and 3.

The approvals of Proposal Nos. 4 and 5 are not conditions to the merger. Such proposals, together with the merger proposal, the reverse stock split proposal, and the certificate of incorporation amendment proposal, are referred to collectively in this proxy statement/prospectus/information statement as the proposals.

**Q: What stockholder presence is required for quorum at the Advaxis special meeting?**

**A:** The presence, by accessing online or being represented by proxy, at the Advaxis special meeting of the holders of a one-third of the shares of Advaxis common stock outstanding, or equal to 48,546,153 shares, is necessary to constitute a quorum at the meeting for the purpose of approving the proposals.

**Q: What stockholder votes are required to approve the proposals at the Advaxis special meeting?**

**A:** The affirmative vote of the holders of a majority of the outstanding shares of Advaxis common stock entitled to vote thereon is required for approval of Proposal Nos.1, 2 and 3. The affirmative vote of the holders of a majority of shares present in person or represented by proxy at the Advaxis special meeting and entitled to vote on the subject matter, assuming a quorum is present, is required for approval of Proposal Nos. 4 and 5.

Votes will be counted by the inspector of election appointed for the meeting, who will separately count “FOR” and “AGAINST” votes, abstentions and any broker non-votes. Abstentions and broker non-votes will be treated as shares present for the purpose of determining the presence of a quorum for the transaction of business at the special meeting. Abstentions will be counted toward the vote totals for each proposal and will have the same effect as “AGAINST” votes. Broker non-votes will have no effect on Proposals Nos. 1, 4 and 5, but will have the same effect as votes “AGAINST” Proposal Nos. 2 and 3.

As of July 31, 2021, the directors and certain executive officers of Advaxis owned or controlled less than 1% of the outstanding shares of Advaxis common stock entitled to vote at the Advaxis special meeting. As of July 31, 2021, the Advaxis stockholders that are party to support agreements, including the directors and certain executive officers of Advaxis, owned an aggregate of 70,715 shares of Advaxis common stock representing approximately less than 1% of the outstanding shares of Advaxis common stock. Pursuant to the support agreements, these stockholders, including the directors and certain executive officers of Advaxis, have agreed to vote all shares of Advaxis common stock owned by them as of the record date in favor of all the proposals.

**Q: Other than the approval by Advaxis’ stockholders of Proposal Nos. 1, 2 and 3, what else is required to consummate the merger?**

**A:** The consummation of the merger requires, among other things, the satisfaction or waiver of certain conditions on or prior to the closing pursuant to the terms set forth in the Merger Agreement, including the following:

- the approval by the Biosight shareholders of the merger, the Merger Agreement, and the other transactions contemplated thereby;

- the registration statement, of which this proxy statement/prospectus/information statement is a part, must have become effective in accordance with the provisions of the Securities Act and must not be subject to any stop order or proceeding, or any proceeding threatened by the SEC, seeking a stop order with respect to the registration statement that has not been withdrawn;

- each of Advaxis and Biosight must have performed or complied in all material respects with all covenants and obligations in the Merger Agreement required to be performed or complied with by it on or before the consummation of the merger;

- there shall not have occurred any material adverse effect on Biosight (as it relates to Advaxis' obligations to consummate the merger) or material adverse effect on Advaxis (as it relates to Biosight's obligations to consummate the merger), in each case, that is continuing;

- Advaxis must have delivered a duly executed copy of the IIA Undertaking (as defined in the Merger Agreement); and

- Nasdaq shall not have rejected Advaxis' appeal to its determination by the Listing Qualifications Department of The Nasdaq Stock Market LLC that Advaxis is not in compliance with Nasdaq Listing Rule 5550(a)(2), and the shares of Advaxis common stock to be issued in the merger shall be approved for listing (subject to official notice of issuance) on the Nasdaq Capital Market as of the effective time of the merger.

**Q: What will Biosight shareholders and optionholders receive in the merger?**

**A:** Biosight shareholders holding issued and outstanding Biosight shares immediately prior to the effective time of the merger will receive shares of Advaxis common stock, and Biosight optionholders holding Biosight options that are outstanding and unexercised immediately prior to the effective time of the merger will receive options to purchase Advaxis common stock. Applying the exchange ratio, the former Biosight shareholders immediately before the merger are expected to own approximately 75% of the aggregate number of shares of the combined company's common stock immediately following the merger and pre-merger Advaxis stockholders are expected to own approximately 25% of the aggregate number of shares of the combined company common stock immediately following the merger.

In connection with the merger, each outstanding and unexercised option to purchase Biosight's ordinary shares will be converted into an option to purchase Advaxis common stock, with the number of shares and exercise price being appropriately adjusted to reflect the exchange ratio between Biosight's shares and Advaxis' common stock as determined in accordance with the Merger Agreement. Unvested options held by service providers shall become fully vested at the effective time of the merger.

For a more complete description of what Biosight shareholders and optionholders will receive in the merger, please see the sections titled "*The Merger Agreement—Merger Consideration*" and "*The Merger Agreement—Treatment of Biosight Options*" beginning on pages 107 and 108, respectively, of this proxy statement/prospectus/information statement.

**Q: Will the common stock of the combined company trade on an exchange?**

**A:** Shares of Advaxis common stock are currently listed on The Nasdaq Capital Market under the symbol "ADXS." Advaxis will file an initial listing application for the combined company with Nasdaq. After completion of the merger, Advaxis will be renamed "Biosight Therapeutics Inc." and it is expected that the common stock of the combined company will trade on The Nasdaq Capital Market under the symbol "BSTX." On August 24, 2021, the last trading day before the date of this proxy statement/prospectus/information statement, the closing sale price of Advaxis common stock was $0.42 per share.

**Q: Who will be the directors of the combined company following the merger?**

**A:** Immediately following the merger, the combined company's board of directors will be composed of nine members: six designated by Biosight (Pini Orbach, Aaron Sasson, Briggs Morrison, Gary Gordon, Gary Titus and Yuval Cabilly), and three by Advaxis (Kenneth A. Berlin, David Sidransky and Dr. Samir Khleif), with David Sidransky to be nominated as Chairman of the board of directors.

**Q: Who will be the executive officers of the combined company immediately following the merger?**

**A:** Immediately following the merger, the executive management team of the combined company is expected to consist of members of both of the Advaxis and Biosight executive management teams prior to the merger. Advaxis' Chief Executive Officer, Kenneth A. Berlin, will lead the combined company, with Andres Gutierrez, M.D., Ph.D. (of Advaxis) serving as Chief Medical Officer and Roy Golan, CPA, LLM (of Biosight), serving as Chief Financial Officer.

**Q: As an Advaxis stockholder, how does Advaxis' board of directors recommend that I vote?**

**A:** After careful consideration, Advaxis' board of directors unanimously recommends that Advaxis stockholders vote "FOR" all of the proposals.

**Q: Do persons involved in the merger have interests that may conflict with mine as an Advaxis stockholder?**

**A:** Yes. In considering the recommendation of the Advaxis special committee with respect to issuing shares of Advaxis common stock pursuant to the Merger Agreement and the other matters to be acted upon by Advaxis stockholders at the special meeting, Advaxis stockholders should be aware that certain members of the Advaxis board of directors and executive officers of Advaxis have interests in the merger that may be different from, or in addition to, interests they have as Advaxis stockholders.

Advaxis' executive officers, including Kenneth Berlin, its Chief Executive Officer, who also serves on Advaxis' board of directors, and Andres Gutierrez, Advaxis' Chief Medical Officer, are contractually entitled to severance payments, including a cash severance payment equal to a multiple of each person's base salary (1.75 and 1.0 times the base salary for Mr. Berlin and Mr. Gutierrez, respectively). Mr. Gutierrez, would receive his cash severance in equal monthly installments (12 months) and would also receive a target bonus for the fiscal year in which the termination occurs, and health benefit continuation (up to 12 months) if terminated after the merger. Mr. Berlin would receive his cash severance in a single lump sum within 60 days of the termination. Mr. Berlin would also be entitled to a bonus payment for the year in which the employment is terminated equal to the target bonus percentage, multiplied by the base salary in effect at the time of termination, multiplied by a fraction, the numerator of which is the number of calendar days Mr. Berlin was employed during such year and the denominator of which is 365, continued health and welfare benefits for 21 months, and full vesting and exercisability of all stock options and stock awards.

In addition, Mr. Berlin is also entitled to full accelerated vesting of all outstanding equity awards upon a change in control, as defined in his employment agreements, regardless of whether he is terminated.

Based on the terms of their respective employment agreements, Advaxis' current executive officers would be entitled to receive a total value of approximately $2.5 million (collectively, not individually) in connection with the consummation of the merger under certain conditions (i.e., termination), which includes the value associated with the acceleration of outstanding equity awards. Such compensation is the subject of Proposal No. 4.

Additionally, pursuant to the terms of the Merger Agreement, David Sidransky, Mr. Berlin and Dr. Samir Khleif, who are currently directors of Advaxis, will continue as directors of the combined organization after the closing of the merger and Dr. Sidransky and Dr. Samir Khleif will be due certain compensation as non-employee directors.

As of July 31, 2021, the directors and executive officers of Advaxis owned, in the aggregate, less than 1% of the outstanding voting shares of Advaxis common stock and have agreed to vote in favor of the merger and related transactions. The voting agreements are discussed in greater detail in the section titled "*Agreements Related to the Merger*" in this proxy statement/prospectus/information statement.

The Advaxis board of directors was aware of these interests and considered them, among other matters, in the decision to approve the Merger Agreement. For more information, please see the section titled "*The Merger — Interests of the Advaxis Directors and Executive Officers in the Merger*" in this proxy statement/prospectus/information statement.

**Q: Why am I being asked to cast a non-binding, advisory vote regarding compensation that will or may become payable by Advaxis to its named executive officers in connection with the merger?**

**A:** SEC rules require Advaxis to seek a non-binding, advisory vote regarding compensation that will or may become payable by Advaxis to its named executive officers in connection with the merger.

**Q: What will happen if stockholders do not approve the compensation that will or may become payable by Advaxis to its named executive officers in connection with the merger at the special meeting?**

**A:** Approval of the compensation that will or may become payable by Advaxis to its named executive officers in connection with the merger (and any associated termination from the combined company) is not a condition to completion of the merger. The vote with respect to the compensation that will or may become payable by Advaxis to its named executive officers in connection with the merger is an advisory vote and will not be binding on Advaxis. Accordingly, regardless of the outcome of the advisory vote, if the Merger Agreement is adopted by the stockholders and the merger is completed, Advaxis' named executive officers will be eligible to receive their respective compensation that is based on or otherwise relates to the merger.

**Q: What risks should I consider in deciding whether to vote in favor of the merger?**

**A:** You should carefully review the section titled "*Risk Factors*" beginning on page 19 of this proxy statement/prospectus/information statement and the annexes attached hereto, which set forth certain risks and uncertainties related to the merger, risks and uncertainties to which the combined company's business will be subject, and risks and uncertainties to which each of Advaxis and Biosight, as independent companies, are subject.

**Q: When do you expect the merger to be consummated?**

**A:** The merger is anticipated to close promptly after the Advaxis special meeting scheduled to be held on November 16, 2021, but the exact timing cannot be predicted. For more information, please see the section titled "*The Merger Agreement—Conditions to the Completion of the Merger*" beginning on page 110 of this proxy statement/prospectus/information statement.

**Q: What do I need to do now?**

**A:** Advaxis urges you to read this proxy statement/prospectus/information statement carefully, including the annexes attached hereto, and to consider how the merger affects you.

If you are an Advaxis stockholder of record, you may provide your proxy instructions in one of four different ways:

- You can attend the Advaxis special meeting online and vote online during the special meeting.
- You can mail your signed proxy card in the enclosed return envelope.
- You can provide your proxy instructions via telephone by following the instructions on your proxy card.
- You can provide your proxy instructions via the internet by following the instructions on your proxy card.

Your signed proxy card, telephonic proxy instructions, or internet proxy instructions must be received by November 15, 2021, 11:59 p.m. Eastern Time, to be counted.

If you hold your shares in "street name" (as described below), you may provide your proxy instructions via telephone or the internet by following the instructions on your vote instruction form. Please provide your proxy instructions only once, unless you are revoking a previously delivered proxy instruction, and as soon as possible so that your shares can be voted at the Advaxis special meeting.

**Q: What happens if I do not return a proxy card or otherwise vote or provide proxy instructions, as applicable?**

**A:** If you are an Advaxis stockholder, the failure to return your proxy card or otherwise vote or provide proxy instructions will reduce the aggregate number of votes required to approve any of the proposals. Also, your shares will not be counted for purposes of determining whether a quorum is present at the Advaxis special meeting unless your broker has discretionary authority to vote on certain matters.

**Q: May I attend the Advaxis special meeting and vote in person?**

**A:** In light of the coronavirus, or COVID-19, outbreak, and in the best interests of public health and the health and safety of Advaxis' board of directors and stockholders, the Advaxis special meeting will be held entirely online. Stockholders of record as of September 17, 2021, will be able to attend and participate in the Advaxis special meeting online by accessing www.virtualshareholdermeeting.com/ADXS2021SM. To join the Advaxis special meeting, you will need to have your 16-digit control number that is included on your Notice of Internet Availability of Proxy Materials and your proxy card. If your shares are held in "street name," you should contact your bank, broker or other nominee to obtain your 16-digit control number or otherwise vote through your bank, broker or other nominee.

**Q: Who counts the votes?**

**A:** Broadridge Financial Solutions, or Broadridge, will be engaged as Advaxis' independent agent to tabulate stockholder votes, which Advaxis refers to as the inspector of election. If you are a stockholder of record, your executed proxy card is returned directly to Broadridge for tabulation. If you hold your shares through a broker, your broker returns one proxy card to Broadridge on behalf of all its clients.

**Q: If my Advaxis shares are held in "street name" by my broker, will my broker vote my shares for me?**

**A:** Unless your broker has discretionary authority to vote on certain matters, your broker will not be able to vote your shares of Advaxis common stock on matters requiring discretionary authority without instructions from you. If you do not give instructions to your broker, your broker can vote your Advaxis shares with respect to "discretionary," routine items but not with respect to "non-discretionary," non-routine items. Discretionary items are proposals considered routine under Rule 452 of the New York Stock Exchange on which your broker may vote shares held in "street name" in the absence of your voting instructions. Proposal Nos. 2 and 3 will be routine matters. With respect to non-routine items for which you do not give your broker instructions, your Advaxis shares will be treated as broker non-votes. To make sure that your vote is counted, you should instruct your broker to vote your shares, following the procedures provided by your broker.

**Q: What are broker non-votes and do they count for determining a quorum?**

**A:** Generally, broker non-votes occur when shares held by a broker in "street name" for a beneficial owner are not voted with respect to a particular proposal because the broker (i) has not received voting instructions from the beneficial owner and (ii) lacks discretionary voting power to vote those shares. A broker is entitled to vote shares held for a beneficial owner on routine matters without instructions from the beneficial owner of those shares. On the other hand, absent instructions from the beneficial owner of such shares, a broker is not entitled to vote shares held for a beneficial owner on non-routine matters.

Broker non-votes will be treated as shares present for the purpose of determining the presence of a quorum for the transaction of business at the Advaxis special meeting. Broker non-votes will not be treated as votes cast for or against a proposal and accordingly will not have any effect with respect to the outcome of Proposal Nos. 4, 5 and 6 and will have the same effect as "AGAINST" votes for Proposal Nos. 1, 2 and 3.

**Q: May I change my vote after I have submitted a proxy or provided proxy instructions?**

**A:** Advaxis stockholders of record, unless such stockholder's vote is subject to a support agreement, may change their vote at any time before their proxy is voted at the Advaxis special meeting in one of four ways:

- You may submit another properly completed proxy with a later date by mail or via the internet.
- You can provide your proxy instructions via telephone at a later date.
- You may send a written notice that you are revoking your proxy to Advaxis, Inc., 9 Deer Park Drive, Suite K-1, Monmouth Junction, NJ 08852, Attention: Igor Gitelman, VP of Finance and Chief Accounting Officer.
- You may attend the Advaxis special meeting online and vote by following the instructions at www.virtualshareholdermeeting.com/ADXS2021SM. Simply attending the Advaxis special meeting will not, by itself, revoke your proxy.

Your signed proxy card, telephonic proxy instructions, internet proxy instructions, or written notice must be received by November 15, 2021, 11:59 p.m. Eastern Time, to be counted.

If an Advaxis stockholder that owns Advaxis shares in "street name" has instructed a broker to vote its shares of Advaxis common stock, the stockholder must follow directions received from its broker to change those instructions.

**Q: Who is paying for this proxy solicitation?**

**A:** Advaxis and Biosight will share equally the cost of printing and filing of this proxy statement/prospectus/information statement and the proxy card. Arrangements will also be made with brokerage firms and other custodians, nominees and fiduciaries who are record holders of Advaxis common stock for the forwarding of solicitation materials to the beneficial owners of Advaxis common stock. Advaxis will reimburse these brokers, custodians, nominees and fiduciaries for the reasonable out-of-pocket expenses they incur in connection with the forwarding of solicitation materials. Advaxis will retain Kingsdale Advisors to assist it in soliciting proxies using the means referred to above. Advaxis will pay the fees of Kingsdale Advisors, which Advaxis expects to be approximately $250,000, plus reimbursement of out-of-pocket expenses.

**Q: Who can help answer my questions?**

**A:** If you are an Advaxis stockholder and would like additional copies of this proxy statement/prospectus/information statement without charge or if you have questions about the merger, including the procedures for voting your shares, you should contact:

Advaxis, Inc.
9 Deer Park Drive, Suite K-1
Monmouth Junction, New Jersey 08852
Attention: Igor Gitelman, VP of Finance and Chief Accounting Officer
Telephone: (609) 452-9813

## PROSPECTUS SUMMARY

*This summary highlights selected information from this proxy statement/prospectus/information statement and may not contain all of the information that is important to you. To better understand the merger and the proposals being considered at the Advaxis special meeting, you should read this entire proxy statement/prospectus/information statement carefully, including the Merger Agreement and the other annexes to which you are referred in this proxy statement/prospectus/information statement. For more information, please see the section titled "Where You Can Find More Information" beginning on page 238 of this proxy statement/prospectus/information statement. Except where specifically noted, the following information and all other information contained in this proxy statement/prospectus/information statement does not give effect to the proposed reverse stock split described in Proposal No. 2 of this proxy statement/prospectus/information statement.*

**The Companies**

Advaxis, Inc.

9 Deer Park Drive, Suite K-1
Monmouth Junction, New Jersey 08852
Telephone: (609) 452-9813

Advaxis is a clinical-stage biotechnology company focused on the development and commercialization of proprietary *Lm* Technology antigen delivery products based on a platform technology that utilizes live attenuated *Listeria monocytogenes*, or *Lm*, bioengineered to secrete antigen/adjuvant fusion proteins. These Lm-based strains are believed to be a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy by accessing and directing antigen-presenting cells, or APCs, to stimulate anti-tumor T cell immunity, stimulate and activate the innate immune system with the equivalent of multiple adjuvants, and simultaneously reduce tumor protection in the tumor micro-environment, or TME, to enable the T cells to attack tumor cells.

The Company believes that its current pipeline evaluating off-the shelf, neoantigen-directed immunotherapies (i.e., our HOT program) can address significant unmet needs in the current oncology treatment landscape. Specifically, our first drug construct from the HOT program is ADXS-503 (HOT Lung), which has been designed to treat non-small cell lung cancer (NSCLC), and has the potential to optimize checkpoint inhibitors' performance in NSCLC, while having a generally well-tolerated safety profile. On July 15, 2021, the Company announced the initiation of a Phase 1 clinical study evaluating the second drug construct from our HOT program, ADXS-504 (HOT Prostate), in patients with biochemically recurrent prostate cancer. The study, being conducted at Columbia University Irving Medical Center, is the first clinical evaluation of ADXS-504 for the treatment of early prostate cancer.

Advaxis has completed and closed out clinical studies of *Lm* Technology immunotherapies in several program areas including the following:

- Human Papilloma Virus ("HPV") associated cancers
- Personalized neoantigen-directed therapies
- Prostate-specific antigen ("PSA") directed therapy

While we have been winding down clinical studies of *Lm* Technology immunotherapies in these program areas, our license agreements continue with OS Therapies, LLC for ADXS-HER2 and with Global BioPharma, or GBP, for the exclusive license for the development and commercialization of ADXS-HPV or AXAL in Asia, Africa, and the former USSR territory, exclusive of India and certain other countries.

During the period of 2020-2021, Advaxis undertook a confidential, strategic review process, which was intended to result in an actionable plan that leverages its assets, capital and capabilities to maximize stockholder value. Following an extensive process of evaluating strategic alternatives and identifying and reviewing potential candidates for a strategic acquisition or other transaction, on July 4, 2021, Advaxis entered into the Merger Agreement with Biosight, under which a wholly owned subsidiary of Advaxis will merge with and into the privately held Biosight. If the merger is completed, the business of Biosight will continue as the business of the combined organization.

Biosight Ltd.

3 Hayarden St., Airport City
P.O.B. 1083
Lod 7019802
Israel
Telephone: +972 (3) 656 8669

Biosight is a private Phase 2 clinical-stage biotechnology company developing an innovative therapeutic for hematological malignancies and disorders. Biosight's investigational product, aspacytarabine (BST-236), is an innovative, proprietary anti-metabolite that seeks to address unmet medical needs by enabling high-dose chemotherapy with reduced systemic toxicity. BST-236 is currently being evaluated as a single agent in a Phase 2b clinical trial, which recently completed enrollment, for the first-line treatment of acute myeloid leukemia ("AML"). Interim results demonstrate tolerability with promising efficacy among the challenging population of AML patients who are unfit for intensive standard-of-care chemotherapy. An additional Phase 2 study in patients with relapsed/refractory AML and myelodysplastic syndrome ("MDS") in collaboration with the European Myelodysplastic Syndrome Cooperative Group was recently launched. A similar Phase 2 study is to be initiated in the US in 2021.

Advaxis Ltd.
9 Deer Park Drive, Suite K-1
Monmouth Junction, New Jersey 08852
(609) 452-9813
Merger Sub is a direct, wholly owned subsidiary of Advaxis and was formed solely for the purpose of carrying out the merger.

**The Merger (see page 73)**

If the merger is completed, Merger Sub will merge with and into Biosight, with Biosight surviving the merger as a wholly owned subsidiary of Advaxis.

Subject to the terms and conditions of the Merger Agreement, at the closing of the merger, (a) each then issued and outstanding share of Biosight's share capital will be converted into the right to receive a number of shares of Advaxis common stock, after giving effect to a reverse stock split of Advaxis common stock described below, calculated in accordance with the exchange ratio set forth in the Merger Agreement; and (b) each then outstanding and unexercised Biosight option to purchase Biosight ordinary shares will be assumed by Advaxis with the number of shares subject to such option and its exercise price being adjusted as set forth in the Merger Agreement.

Under the exchange ratio formula in the Merger Agreement, upon the closing of the merger, on a pro forma basis and based upon the number of shares of Advaxis common stock expected to be issued in the merger, pre-merger Advaxis stockholders will own approximately 25% of the combined company and pre-merger Biosight shareholders will own approximately 75% of the combined company.

Each share of Advaxis common stock issued and outstanding at the time of the merger will remain issued and outstanding and such shares will be appropriately adjusted to reflect the proposed reverse stock split of Advaxis common stock. In addition, each option and warrant to purchase shares of Advaxis common stock that is outstanding immediately prior to the effective time of the merger, whether vested or unvested, will survive the closing and remain outstanding in accordance with its terms. The number of shares of Advaxis common stock underlying such options and warrants, and the exercise prices for such stock options, will be appropriately adjusted to reflect the proposed reverse stock split of Advaxis common stock. If any holder of a warrant to purchase Advaxis common stock issued in connection with Advaxis' September 2018 offering properly exercises such holder's right to receive a cash payment in connection with the merger pursuant to the terms and conditions of the underlying agreement governing such warrant, Advaxis shall promptly pay such cash payment to such holder, in each case in such amount as determined in accordance with, and pursuant to the procedures set forth in, such agreement governing such warrant.

For a more complete description of the merger and the exchange ratio, please see the section titled "*The Merger Agreement*" in this proxy statement/prospectus/information statement.

The merger will be completed as promptly as practicable, but in no event later than the second ($2^{nd}$) business day after all of the conditions to consummation of the merger set forth in the Merger Agreement are satisfied or waived (save and except for those conditions that by their nature are to be satisfied at the closing, but subject to the satisfaction or waiver of each of such conditions), including the adoption of the Merger Agreement by the Biosight shareholders and the approval by the Advaxis stockholders of the issuance of Advaxis common stock in the merger and the reverse stock split of Advaxis common stock. The merger is anticipated to close promptly after the Advaxis special meeting scheduled to be held on November 16, 2021. However, Advaxis and Biosight cannot predict the exact timing of the completion of the merger because it is subject to the satisfaction or waiver of various conditions. After completion of the merger, assuming that Advaxis receives the required stockholder approval, Advaxis will be renamed "Biosight Therapeutics Inc."

**Reasons for the Merger (see pages 85 and 88)**

After consideration and consultation with its senior management and its financial and legal advisors, the Advaxis board of directors unanimously determined that the Merger Agreement, the merger and other transactions contemplated thereby are advisable, fair to and in the best interests of Advaxis and its stockholders. The Advaxis board of directors considered various reasons to reach its determination. For example:

- During its evaluation of the Merger Agreement and the transactions contemplated by the Merger Agreement, the Advaxis board of directors considered several factors in its decision to approve the Merger Agreement with Biosight.

- The Advaxis board of directors assessed the financial condition and prospects of Advaxis and risks associated with continued operations; considered the expected cash resources of the combined company and the likelihood the combined company would possess sufficient cash resources to fund future product development; and analyzed the potential strategic alternatives of other merger partner candidates. Further, Advaxis management conducted scientific, regulatory, and technical due diligence of the regulatory pathway for, and market opportunity of, Biosight's product candidates. The current financial market conditions and historical market prices, volatility, and trading information for Advaxis common stock was considered by the Advaxis board of directors as well.

- The Advaxis board of directors considered the experience of the senior management team and board of directors of the combined company, which will consist of experienced representatives from both the current Advaxis and Biosight management team and board of directors.

- The Advaxis board of directors reviewed the terms of the Merger Agreement and related transaction documents, concluding the terms, in the aggregate, were reasonable. The Advaxis board of directors considered the fairness opinion provided by LifeSci Capital LLC, which included its financial analysis, from a financial point of view, of the exchange ratio to be paid by Advaxis pursuant to the Merger Agreement terms.

- The Advaxis board of directors also considered, in its deliberations, the variety of risks and other countervailing factors related to entering into the Merger Agreement, including the potential effect of the termination fee; substantial expense incurred in connection with the merger; the scientific, technical, regulatory and other risks and uncertainties associated with the development and commercialization of Biosight's product candidates; the risk of a lack of available sources of financing necessary to fund product development; and various other risks.

- The Advaxis board of directors consider the factors overall to be favorable to, and to support, its determination of approval of the Merger Agreement.

The Biosight board of directors has unanimously approved the Merger Agreement, the merger and the transactions contemplated thereby. The Biosight board of directors reviewed several factors in reaching its decision and believes that the Merger Agreement, the merger and the transactions contemplated thereby are in the best interests of Biosight and its stockholders. Several factors considered by the Biosight board of directors included:

- the potential increased access to sources of capital and a broader range of investors to support the clinical development of its product candidates following consummation of the transaction compared to if Biosight continued to operate as a privately held company;

- the cash resources of the combined organization, with $78.3 million of cash and cash equivalents on a pro forma basis as of April 30, 2021 after giving effect to the merger, which Biosight believes is sufficient to enable Biosight to pursue its near term clinical trials and business plans; and

- the expectation that the merger with Advaxis would be a more time- and cost-effective means to access capital than other options considered by the Biosight board, including additional private financings or an initial public offering.

For a more complete description of the reasons for the merger, please see the sections titled “The Merger—Advaxis Reasons for the Merger” and “The Merger—Biosight Reasons for the Merger” beginning on pages 85 and 88, respectively, of this proxy statement/prospectus/information statement.

**Opinion of the Advaxis Financial Advisor (see page 89)**

LifeSci Capital rendered its opinion to the Advaxis board of directors that, as of July 2, 2021, based on and subject to the factors and assumptions set forth in the opinion, the exchange ratio was fair, from a financial point of view, to the holders of shares of Advaxis. For a more complete description of the opinion of the Advaxis financial advisor, please see the section titled “The Merger—Opinion of the Advaxis Financial Advisor” beginning on page 89.

**Interests of Certain Directors, Officers and Affiliates of Advaxis and Biosight (see pages 97 and 101)**

In considering the recommendation of the Advaxis board of directors with respect to issuing shares of Advaxis common stock pursuant to the Merger Agreement and the other matters to be acted upon by Advaxis stockholders at the Advaxis special meeting, Advaxis stockholders should be aware that certain members of the Advaxis board of directors and executive officers of Advaxis have interests in the merger that may be different from, or in addition to, interests they have as Advaxis stockholders. Advaxis’ executive officers, including Kenneth Berlin, its Chief Executive Officer, who also serves on Advaxis’ board of directors, and Andres Gutierrez, Advaxis’ Chief Medical Officer, are contractually entitled to severance payments, including a cash severance payment equal to a multiple of each person’s base salary (1.75 and 1.0 times the base salary for Mr. Berlin and Mr. Gutierrez, respectively) paid in equal monthly installments (21 and 12 months for Mr. Berlin and Mr. Gutierrez, respectively), plus a target bonus for the fiscal year in which the termination occurs, and health benefit continuation (up to 21 and 12 months for Mr. Berlin and Mr. Gutierrez, respectively) if terminated after the merger.

In addition, Mr. Berlin is also entitled to full accelerated vesting of all outstanding equity awards upon a change in control, as defined in his employment agreements, regardless of whether he is terminated.

Based on the terms of their respective employment agreements, Advaxis’ current executive officers would be entitled to receive a total value of approximately $2.5 million (collectively, not individually) in connection with the consummation of the merger (under certain conditions) which includes the value associated with the acceleration of outstanding equity awards. Such compensation is the subject of Proposal No. 4.
Additionally:

- Kenneth A. Berlin, Dr. David Sidransky and Dr. Samir Khleif, members of the Advaxis board of directors, will continue as directors after the merger, and, following the closing of the merger, Dr. Sidransky and Dr. Samir Khleif will be eligible to be compensated as directors of Advaxis pursuant to the Advaxis compensation policy that is expected to remain in place following the merger. Under the Merger Agreement, Advaxis’ directors and executive officers are entitled to continued indemnification, expense advancement and insurance coverage.

- Dr. David Sidransky, a member of the Advaxis board of directors, is a co-founder and owner of Israeli Biotech Fund. Israeli Biotech Fund is an owner of shares of share capital (or options to purchase capital stock) of Biosight. Israeli Biotech Fund I, L.P. and Israeli Biotech Fund II, L.P. collectively own an aggregate of 371,608 of Biosight's preferred C shares and warrants to purchase up to 48,774 of Biosight's preferred C shares, which represent, in the aggregate, ownership of approximately 10% of Biosight calculated on a fully diluted basis.

- The vesting of approximately 73,777 options granted to Kenneth A. Berlin will accelerate in connection with the closing of the merger.

As of July 31, 2021, the directors and executive officers of Advaxis owned, in the aggregate, less than 1% of the outstanding voting shares of Advaxis common stock. Each of the Advaxis' officers and directors has entered into support agreements in connection with the merger. The support agreements are discussed in greater detail in the section titled "*Agreements Related to the Merger*" in this proxy statement/prospectus/information statement. The Advaxis board of directors was aware of these interests and considered them, among other matters, in the decision to approve the Merger Agreement. For more information, please see the section titled "*The Merger — Interests of the Advaxis Directors and Executive Officers in the Merger*" of this proxy statement/prospectus/information statement.

In considering the recommendation of the Biosight board with respect to the merger proposal, Biosight shareholders should be aware that the executive officers and directors of Biosight have certain interests in the merger that may be different from, or in addition to, the interests of Biosight shareholders generally. The Biosight board was aware of these interests and considered them, among other matters, in approving the merger agreement and the transactions contemplated thereby and making its recommendation that Biosight shareholders vote in favor of the merger proposal.
These interests include, among others:

- as of August 24, 2021, all current directors and executive officers of Biosight, together with their affiliates, owned approximately 25.9% of Biosight's outstanding share capital which will, at the effective time of the merger, be automatically converted into the right to receive an amount of registered shares of Advaxis common stock equal to the Exchange Ratio; certain Biosight officers and directors, and their affiliates, have also entered into support agreements in connection with the merger. The support agreements are discussed in greater detail in the section titled "*Agreements Related to the Merger — Support Agreements*" in this proxy statement/prospectus/information statement;

- certain of Biosight's current executive officers and directors hold options to purchase Biosight shares that are outstanding and unexercised immediately prior to the effective time of the merger, which will, at the effective time of the merger, be automatically converted into options to purchase Advaxis common stock. Unvested options held by service providers shall become fully vested at the effective time of the merger;

- as of August 24, 2021, certain of Biosight's directors and executive officers hold 243,296 warrants;

- certain of Biosight's current executive officers and directors are expected to become executive officers and directors of Advaxis upon the closing of the merger; and

- Biosight's current executive officers and directors are entitled to certain liability insurance coverage pursuant to the terms of the Directors and Officers Insurance Policy of Biosight.

**Management Following the Merger (see page 199)**

Effective as of the closing of the merger, the combined company's executive officers are expected to be certain members of the Advaxis and Biosight executive management teams prior to the merger, including:

| Name | Title |
|---|---|
| Kenneth Berlin | President and Chief Executive Officer |
| Roy Golan, CPA, LLM | Chief Financial Officer |
| Andres Gutierrez, M.D., Ph.D. | Co-Chief Medical Officer |

**Potential PIPE Financing**

In connection with the merger, Advaxis may seek investments from sources to provide capital for the combined company. Advaxis began fundraising efforts in September 2021 and is seeking to raise at least an aggregate of $25 million in capital to close concurrently with the merger.

**Overview of the Merger Agreement and Agreements Related to the Merger Agreement**

**Merger Consideration and Adjustment** (see page 107)

At the effective time of the merger, each share of share capital of Biosight that is issued and outstanding immediately prior to the effective time of the merger will be converted into the right to receive a number of shares of Advaxis common stock.

The Merger Agreement does not provide for any adjustment (other than an adjustment as a result of the proposed reverse stock split of Advaxis common stock) to the total number of shares of Advaxis common stock that Biosight shareholders will be entitled to receive as part of the merger, including for changes in the market price of Advaxis common stock. Accordingly, the market value of the shares of Advaxis common stock issued pursuant to the merger will depend on the market value of the shares of Advaxis common stock at the time the merger closes, and could vary significantly from the market value of the shares of Advaxis common stock on the date of this proxy statement/prospectus/information statement.

At the effective time of the merger:

- each issued and outstanding share of share capital of Biosight (excluding certain Biosight shares that may be cancelled pursuant to the terms and conditions of the Merger Agreement) shall, by virtue of the merger and without any action on the part of the holder thereof, be deemed to have been transferred to Biosight in exchange for the right to receive 118.2009 shares of Advaxis common stock (the "Exchange Ratio") (subject to adjustment to account for the proposed Advaxis reverse stock split) and, with respect to 102 Biosight Shares (as defined in the Merger Agreement), in exchange for the right to receive 102 Advaxis Shares (as defined in the Merger Agreement);

- each ordinary share, par value one Israeli Agora (NIS 0.01) per share, of Merger Sub issued and outstanding immediately prior to the effective time of the merger shall be automatically and without further action converted into and become one validly issued, fully paid and nonassessable ordinary share, par value one Israeli Agora (NIS 0.01) per share, of the surviving company of the merger; and

- each option to purchase Biosight shares of share capital outstanding and unexercised immediately prior to the effective time of the merger will be assumed by Advaxis and will become an option to purchase (A) that number of shares of Advaxis common stock (rounded down to the nearest whole share) equal to the product obtained by multiplying (i) the total number of Biosight shares subject to such Biosight option immediately prior to the effective time of the merger by (ii) the Exchange Ratio, (B) at a per share exercise price (rounded up to the nearest whole cent) equal to the quotient obtained by dividing (i) the exercise price per share of a Biosight share at which such Biosight option was exercisable immediately prior to the effective time of the merger by (ii) the Exchange Ratio (rounding the resulting exercise price up to the nearest whole cent), with the Exchange Ratio, in each case, subject to adjustment to account for the proposed Advaxis reverse stock split.

**Conditions to the Completion of the Merger** (see page 110)

To consummate the merger, Advaxis stockholders must approve the issuance of shares of Advaxis common stock in the merger to the Biosight shareholders and approve the amendment to the amended and restated certificate of incorporation of Advaxis increasing the number of authorized shares of common stock, if necessary, and effecting the Advaxis reverse stock split. Additionally, the Biosight shareholders must approve the merger and adopt the Merger Agreement and the related transactions. In addition to obtaining such securityholder approvals and appropriate regulatory approvals, each of the other closing conditions set forth in the Merger Agreement must be satisfied or waived, including, among other things:

- the registration statement, of which this proxy statement/prospectus/information statement is a part, must have become effective in accordance with the provisions of the Securities Act and must not be subject to any stop order or proceeding, or any proceeding threatened by the SEC, seeking a stop order with respect to the registration statement that has not been withdrawn; and

- Nasdaq shall not have rejected Advaxis' appeal to its determination by the Listing Qualifications Department of The Nasdaq Stock Market LLC that Advaxis is not in compliance with Nasdaq Listing Rule 5550(a)(2), and the shares of Advaxis common stock to be issued in the merger shall be approved for listing (subject to official notice of issuance) on the Nasdaq Capital Market as of the effective time of the merger.

**No Solicitation (**see page 114)

Each of Advaxis and Biosight agreed that, subject to limited exceptions, Advaxis and Biosight and any of their respective subsidiaries will not, and each party will not authorize or permit any of its officers, directors, employees, investment bankers, attorneys, accountants, representatives, consultants or other agents retained by it or any of its subsidiaries to, directly or indirectly:

- solicit, initiate, encourage, induce or knowingly facilitate the communication, making, submission or announcement of, any "acquisition proposal," as defined in the Merger Agreement, or take any action that could reasonably be expected to lead to an acquisition proposal;
- furnish to any person any non-public information or data with respect to, or cooperate in any way that would otherwise reasonably be expected to lead to, any proposal or inquiry that constitutes, or would reasonably be expected to lead to any acquisition proposal;
- enter into, continue or otherwise engage in any discussions or negotiations with any person with respect to any acquisition proposal or any proposal or inquiry that would reasonably be expected to lead to any acquisition proposal;
- submit to the stockholders of Advaxis or the shareholders of Biosight, as applicable, for their approval or adoption any acquisition proposal;
- approve, declare advisable, adopt or recommend, or publicly propose to approve, declare advisable, adopt or recommend, or allow Advaxis or Biosight, as applicable, or any of their respective subsidiaries, to execute or enter into any binding or non-binding letter of intent, agreement in principle, memorandum of understanding, merger agreement, acquisition agreement, option agreement, joint venture agreement, partnership agreement or other agreement contemplating or otherwise in connection with, or that is intended to or would reasonably be expected to lead to any acquisition proposal;
- grant any waiver or release under any confidentiality, standstill or similar agreement, other than to either Advaxis or Biosight, as applicable; or
- agree or publicly announce an intention to take any of the foregoing actions.

**Termination** (see page 121)

Either Advaxis or Biosight can terminate the Merger Agreement under certain circumstances, which would prevent the merger from being consummated.

**Termination Fee** (see page 121)

If the Merger Agreement is terminated under certain circumstances, Advaxis or Biosight, as applicable, will be required to pay the other party a termination fee equal to $7,500,000. In addition, upon termination of the Merger Agreement under certain circumstances, and provided that Advaxis has not paid the $7,500,000 termination fee, Advaxis will be required to pay up to $2,000,000 to Biosight for reimbursement of expenses.

**Material U.S. Federal Income Tax Consequences of the Merger (see page 102)**

As discussed in detail in the section titled "*The Merger—Material U.S. Federal Income Tax Consequences of the Merger*," Advaxis and Biosight intend the merger to qualify as a "reorganization" within the meaning of Section 368(a) of the Code and the Treasury Regulations promulgated thereunder. In general, and subject to the qualifications and limitations set forth in the section titled "*The Merger—Material U.S. Federal Income Tax Consequences of the Merger*," if the merger qualifies as a "reorganization" within the meaning of Section 368(a) of the Code and the Treasury Regulations promulgated thereunder, the material U.S. federal income tax consequences to a U.S. Holder (as defined in the section titled "*The Merger—Material U.S. Federal Income Tax Consequences of the Merger*") of Biosight share capital will be as follows:

- such Biosight shareholder will not recognize gain or loss upon the exchange of Biosight share capital for Advaxis common stock pursuant to the merger, except with respect to cash received in lieu of a fractional share of Advaxis common stock;

- such Biosight shareholder's aggregate tax basis for the shares of Advaxis common stock received in the merger will equal the stockholder's aggregate tax basis in the shares of Biosight share capital surrendered in the merger reduced by the basis allocable to any fractional share of Advaxis common stock for which cash is received; and

- the holding period of the shares of Advaxis common stock received by such Biosight shareholder in the merger will include the holding period of the shares of Biosight share capital surrendered in exchange therefor.

If the merger does not qualify as a "reorganization" within the meaning of Section 368(a) of the Code and the Treasury Regulations promulgated thereunder, then each U.S. Holder of Biosight share capital would recognize gain or loss for U.S. federal income tax purposes on the exchange of Biosight shares for Advaxis common stock in the merger equal to the difference between such Biosight shareholder's adjusted tax basis in the shares of Biosight share capital surrendered in the merger and the amount of cash and fair market value of the shares of Advaxis common stock received in exchange therefor. Determining the actual tax consequences of the merger to you may be complex and will depend on the facts of your own situation. You should consult your tax advisors to fully understand the tax consequences to you of the merger, including the estate, gift, state, local or non-U.S. tax consequences of the merger.

**Nasdaq Stock Market Listing (see page 106)**

Advaxis will file an initial listing application for the combined company common stock with Nasdaq. If such application is accepted, Advaxis anticipates that the common stock of the combined company will be listed on The Nasdaq Capital Market following the closing of the merger under the trading symbol "BSTX."

**Anticipated Accounting Treatment (see page 105)**

The merger will be accounted for as a reverse recapitalization in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. Under this method of accounting, Biosight will be deemed to be the accounting acquirer for financial reporting purposes. As a result of the merger, the net assets of Advaxis will be recorded at their acquisition-date fair value in the financial statements of Biosight and the reported operating results prior to the merger will be those of Biosight.

**Appraisal Rights and Dissenters' Rights (see page 106)**

Under the Delaware General Corporation Law ("DGCL"), Advaxis stockholders are not entitled to appraisal rights in connection with the merger.

**Comparison of Rights of Holders of Shares (see page 224)**

Advaxis is incorporated under the laws of the State of Delaware and Biosight is a company organized under the laws of Israel. If the merger is completed, Biosight shareholders will become holders of Advaxis common stock and will have different rights as holders of Advaxis common stock than they had as holders of Biosight ordinary shares or preferred shares. The differences between the rights of these respective holders result from the differences between (1) Israeli and Delaware law and (2) the respective governing documents of Biosight and Advaxis, as the same may be amended in connection with the merger. For additional information, see the section titled "*Comparison of Rights of Holders of Advaxis Capital Stock and Biosight Share Capital*" beginning on page 223 of this proxy statement/prospectus/information statement.

**Risk Factors (see page 19)**

Both Advaxis and Biosight are subject to various risks associated with their businesses and their industries. In addition, the merger, including the possibility that the merger may not be completed, poses a number of risks to each company and its respective securityholders, including, without limitation, the following risks:

- The exchange ratio will not be adjusted based on the market price of Advaxis common stock, so the merger consideration at the closing may have a greater or lesser value than at the time the Merger Agreement was signed;
- Failure to complete the merger may result in Advaxis or Biosight paying a termination fee or Advaxis reimbursing expenses of Biosight, which could harm the common stock price of Advaxis and the future business and operations of each company;
- If the conditions to the merger are not satisfied or waived, the merger will not occur;
- The merger may be completed even though material adverse effects may result from the announcement of the merger, changes in or affecting the industries in which Advaxis or Biosight operate and other causes;
- If Advaxis and Biosight complete the merger, the combined company will need to raise additional capital by issuing equity securities or incurring additional debt or by entering into licensing arrangements, which may cause significant dilution to the combined company's stockholders or restrict the combined company's operations;
- Some Advaxis and Biosight executive officers and directors have interests in the merger that are different from yours and that may influence them to support or approve the merger without regard to your interests;
- Advaxis' stockholders may not realize a benefit from the merger commensurate with the ownership dilution they will experience in connection with the merger; and
- If the merger is not completed, Advaxis' stock price may fluctuate significantly.

These risks and other risks are discussed in greater detail under the section titled "*Risk Factors*" beginning on page 19 of this proxy statement/prospectus/information statement. Advaxis and Biosight both encourage you to read and consider all of these risks carefully.

## MARKET PRICE AND DIVIDEND INFORMATION

The closing price of Advaxis common stock on July 2, 2021, the last trading day prior to the public announcement of the merger, was $0.47 per share, and the closing price of Advaxis common stock on August 24, 2021 was $0.42 per share, in each case as reported on The Nasdaq Capital Market. As of September 17, 2021, there were approximately 95 holders of record of Advaxis' common stock.

Because the market price of Advaxis common stock is subject to fluctuation, the market value of the shares of Advaxis common stock that Biosight shareholders will be entitled to receive in the merger may increase or decrease.

Biosight is a private company and its shares of ordinary shares and preferred shares are not publicly traded.

**Dividends**

Advaxis has never declared or paid cash dividends on its capital stock and does not anticipate paying any cash dividends in the foreseeable future. Biosight has never paid or declared any cash dividends on its share capital. Biosight intends to retain all available funds and any future earnings for use in the operation of its business and does not anticipate paying any cash dividends on its share capital in the foreseeable future. Notwithstanding the foregoing, any determination to pay cash dividends subsequent to the merger will be at the discretion of the combined company's board of directors and will depend upon a number of factors, including the combined company's results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors the combined company's board of directors deems relevant.

## RISK FACTORS

*The combined company (for the purpose of this "Risk Factors" section, "we," "us" and "our") will be faced with a market environment that cannot be predicted and that involves significant risks and uncertainties, many of which will be beyond our control. You should carefully consider all of the information set forth in this proxy statement/prospectus/information statement. The combined company's business, financial condition and results of operations could be materially and adversely affected by any of these risks. In that event, the trading price of our ordinary shares would likely decline and you might lose all or part of your investment. In addition to the other information contained in this proxy statement/prospectus/information statement, you should carefully consider the material risks described below before deciding how to vote your shares of Advaxis common stock. You should also read and consider the other information in this proxy statement/prospectus/information statement and additional information about Advaxis set forth in its Annual Report on Form 10-K for the fiscal year ended October 31, 2020, which is filed with the Securities and Exchange Commission, or the SEC, as updated by its Quarterly Reports on Form 10-Q. Please see the section titled "Where You Can Find More Information" beginning on page 238 of this proxy statement/prospectus/information statement for further information. This proxy statement/prospectus/information statement also contains forward-looking statements that involve risks and uncertainties. Our results could materially differ from those anticipated in these forward-looking statements, as a result of certain factors including the risks described below and elsewhere in this report and our other SEC filings. See also "Special Note Regarding Forward-Looking Statements" on page 67 of this proxy statement/prospectus/information statement.*

***Summary of Risk Factors***

*The summary below provides a high-level overview of the risks that the combined company faces, as well as those faced by our industry, and is intended to enhance the readability and accessibility of our disclosures. These risks include, but are not limited to:*

***Risks Related to the Merger***

- The exchange ratio will not be adjusted based on the market price of Advaxis common stock, so the merger consideration at the closing may have a greater or lesser value than at the time the Merger Agreement was signed.
- Failure to complete the merger may result in either Advaxis or Biosight paying a termination fee or reimbursing expenses to the other party, which could harm the common stock price of Advaxis and future business and operations of each company.
- If the conditions to the merger are not satisfied or waived, the merger may not occur.
- The merger may be completed even though a material adverse effect may result from the announcement of the merger, industry wide changes or other causes.

***Risks Related to the Proposed Reverse Stock Split***

- The reverse stock split may not increase the combined company's stock price over the long term.
- The reverse stock split may decrease the liquidity of the combined company's common stock.
- The reverse stock split may lead to a decrease in the combined company's overall market capitalization.

***Risks Related to the Combined Company***

- The combined company (for the purpose of this "Risk Factors" section, "we," "us" and "our") will need substantial additional funding before we can complete the development of our product candidates. If we are unable to obtain such additional capital on favorable terms, or at all, we would be forced to delay, reduce or eliminate our product development and clinical programs and may not have the capital required to otherwise operate our business.

- We may be exposed to increased litigation, including stockholder litigation, which could have an adverse effect on our business and operations.

***Risks Relating to Our Business and Capital Requirements***

- Our limited operating history and lack of any product revenue;
- Impacts of the COVID-19 pandemic;
- Our recurring losses from operations that raise substantial doubt about our ability to continue as a going concern;
- Our ability to establish sales, marketing and distribution capabilities on our own or in collaboration with third parties;
- Our need for substantial additional capital to fund our development and commercialization efforts;

***Risks Related to the Discovery and Clinical Development of Our Product Candidates***

- Our dependence on the success of our investigational product candidate, BST-236;
- Substantial costs and difficult implementation of the clinical studies required for our product candidates;
- Our ability to successfully enroll and retain patients in our clinical trials;
- Outcomes of our preclinical studies as compared to the success of our later clinical studies;
- Our success in identifying patients and achieving a significant market share for our product candidates despite a small target patient population;
- The extent to which our product candidates receive broad market acceptance by the medical community, patients and third-party payors;
- Our failure to capitalize on successful product candidates;
- The extent to which we can successfully identify, discover or maintain rights to new or additional product candidates;

***Risks Related to the Marketing and Other Regulatory Approval of Our Product Candidates***

- Maintaining compliance with the requisite regulatory requirements on an ongoing basis;
- Obtaining marketing approval in every jurisdiction where we seek to market and commercialize our product candidates;
- Exposure to fraud and abuse and other healthcare law violations as a result of our relationships with collaborators and customers;

- Our ability to maintain and benefit from the regulatory fast track and orphan drug designations for our product candidates;
- Effects of our product candidates on pricing regulations, reimbursement practices or healthcare reform initiatives;

***Risks Related to Our Dependence on Third Parties***

- Our dependence on third-party collaborators with respect to clinical trials and the manufacturing of our product candidates;

***Risks Related to Legal and Compliance Requirements***

- Compliance with government regulations in the United States and abroad, including extensive environmental, health and safety requirements;
- Exposure to product liability claims;

***Risks Related to Our Intellectual Property***

- Obtaining and maintaining sufficient protection of our proprietary rights, including our patents and other intellectual property for our product candidates;
- Protection of our intellectual property rights in the United States and abroad; and
- Successfully enforcing our patent and intellectual property rights against competitors, as well as defending ourselves in potential infringement litigation.

**Risks Related to the Merger**

***The exchange ratio will not be adjusted based on the market price of Advaxis common stock, so the merger consideration at the closing may have a greater or lesser value than at the time the Merger Agreement was signed.***

At the effective time of the merger, outstanding Biosight share capital will be converted into shares of the combined company's common stock. Applying the exchange ratio, the former Biosight shareholders immediately before the merger are expected to own approximately 75% of the aggregate number of shares of the combined company's common stock following the merger, and Advaxis stockholders immediately before the merger are expected to own approximately 25% of the aggregate number of shares of the combined company's common stock following the merger, subject to certain assumptions.

Any changes in the market price of Advaxis stock before the completion of the merger will not affect the number of shares Biosight shareholders will be entitled to receive pursuant to the Merger Agreement. Therefore, if before the completion of the merger, the market price of Advaxis common stock increases from the market price on the date of the Merger Agreement, then Biosight shareholders could receive merger consideration with substantially more value for their Biosight shares than the parties had negotiated when they established the exchange ratio. Similarly, if before the completion of the merger the market price of Advaxis common stock declines from the market price on the date of the Merger Agreement, then Biosight shareholders could receive merger consideration with substantially lower value. The Merger Agreement does not include a price-based termination right.

***If the conditions to the merger are not satisfied or waived, the merger may not occur.***

Even if the Merger Agreement is adopted by the stockholders of Biosight and Proposal Nos. 1, 2 and 3 as described in this proxy statement/prospectus/information statement are approved by the Advaxis stockholders, specified conditions must be satisfied or waived to complete the merger. These conditions are set forth in the Merger Agreement and described in the section titled "*The Merger Agreement—Conditions to the Completion of the Merger*" beginning on page 110 of this proxy statement/prospectus/information statement. Advaxis and Biosight cannot assure you that all of the conditions to the consummation of the merger will be satisfied or waived. If the conditions are not satisfied or waived, the merger may not occur or the closing may be delayed, and Advaxis and Biosight each may lose some or all of the intended benefits of the merger.

***The merger may be completed even though a material adverse effect may result from the announcement of the merger, industry wide changes or other causes.***

In general, neither Advaxis nor Biosight is obligated to complete the merger if there is a material adverse effect affecting the other party between July 4, 2021, the date of the Merger Agreement, and the closing of the merger. However, certain types of changes are excluded from the concept of a "material adverse effect." Such exclusions include but are not limited to changes in general economic or market conditions, industry wide changes, changes in U.S. GAAP, changes in laws, rules or regulations of general applicability or interpretations thereof, natural disasters, pandemics (including the COVID-19 pandemic), outbreaks of hostilities or acts of terrorism, changes resulting from the announcement, performance or pendency of the merger, changes in the price or trading volume of Advaxis common stock, and failures to meet internal or third-party guidance or forecasts. Therefore, if any of these events were to occur, impacting Advaxis or Biosight, the other party would still be obliged to consummate the closing of the merger. If any such adverse changes occur and Advaxis and Biosight consummate the closing of the merger, the stock price of the combined company may suffer. This in turn may reduce the value of the merger to the stockholders of Advaxis, Biosight or both. For a more complete discussion of what constitutes a material adverse effect on Advaxis or Biosight, see the section titled "*The Merger Agreement—Representations and Warranties*" beginning on page 113 of this proxy statement/prospectus/information statement.

***If Advaxis and Biosight complete the merger, the combined company will need to raise additional capital by issuing equity securities or additional debt or through licensing arrangements, which may cause significant dilution to the combined company's stockholders or restrict the combined company's operations.***

Additional financing may not be available to the combined company when it is needed or may not be available on favorable terms. To the extent that the combined company raises additional capital by issuing equity securities, such financing will cause additional dilution to all securityholders of the combined company, including Advaxis' pre-merger stockholders and Biosight's former shareholders. It is also possible that the terms of any new equity securities may have preferences over the combined company's common stock. Any debt financing the combined company enters into may involve covenants that restrict its operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of the combined company's assets, as well as prohibitions on its ability to create liens, pay dividends, redeem its stock or make investments. In addition, if the combined company raises additional funds through licensing arrangements, it may be necessary to grant licenses on terms that are not favorable to the combined company. Alternatively, in connection with the Merger, Advaxis may seek investments from outside sources to provide capital for the combined company.

***Advaxis and Biosight directors and executive officers have interests in the merger that are different from yours and that may influence them to support or approve the merger without regard to your interests.***

Directors and executive officers of Advaxis and Biosight have interests in the merger that are different from, or in addition to, the interests of other Advaxis stockholders generally. These interests with respect to Advaxis' directors and executive officers may include, among others, acceleration of equity award vesting and severance payments if employment is terminated in a qualifying termination in connection with the merger. Three current member of the Advaxis board of directors will continue as directors of the combined company after the effective time of the merger, and, following the closing of the merger, two will be eligible to be compensated as non-employee directors of the combined company pursuant to the Advaxis non-employee director compensation policy that is expected to remain in place following the effective time of the merger, and current members of the Advaxis executive management team will continue with the combined company. These interests with respect to Biosight's directors and executive officers may include, among others, that certain of Biosight's directors and executive officers have options, subject to vesting, to purchase shares of Biosight ordinary shares which, at the effective time of the merger, will be converted into and become fully vested options to purchase shares of the common stock of the combined company; Biosight's executive officers are expected to continue as executive officers of the combined company after the effective time of the merger; and all of Biosight's directors and executive officers are entitled to certain indemnification and liability insurance coverage pursuant to the terms of the Merger Agreement. Further, certain current members of Biosight's board of directors will continue as directors of the combined company after the effective time of the merger, and, following the closing of the merger, will be eligible to be compensated as non-employee directors of the combined company pursuant to the Advaxis non-employee director compensation policy that is expected to remain in place following the effective time of the merger. Certain directors and executive officers own options to purchase the shares of their respective companies.

The Advaxis and Biosight boards of directors were aware of and considered those interests, among other matters, in reaching their decisions to approve and adopt the Merger Agreement, approve the merger, and recommend the approval of the Merger Agreement to Advaxis and Biosight shareholders. These interests, among other factors, may have influenced the directors and executive officers of Advaxis and Biosight to support or approve the merger.

For more information regarding the interests of Advaxis and Biosight directors and executive officers in the merger, please see the sections titled "*The Merger—Interests of Advaxis Directors and Executive Officers in the Merger*" beginning on page 97 and "*The Merger—Interests of Biosight Directors and Executive Officers in the Merger*" beginning on page 101 of this proxy statement/prospectus/information statement.

***Advaxis stockholders may not realize a benefit from the merger commensurate with the ownership dilution they will experience in connection with the merger.***

During the period of 2020-2021, Advaxis undertook a confidential, strategic review process, which was intended to result in an actionable plan that leverages its assets, capital and capabilities to maximize stockholder value. Following an extensive process of evaluating strategic alternatives and identifying and reviewing potential candidates for a strategic acquisition or other transaction, on July 4, 2021, Advaxis entered into a Merger Agreement with Biosight, under which the privately held Biosight will merge with a wholly-owned subsidiary of Advaxis. Pre-merger Advaxis shareholders will own approximately 25% of the combined company and pre-merger Biosight shareholders will own approximately 75% of the combined company. Advaxis is devoting substantially all of its time and resources to consummating this transaction; however, there can be no assurance that such activities will result in the consummation of this transaction or that such transaction will deliver the anticipated benefits or enhance stockholder value. If the combined company is unable to realize the full strategic and financial benefits currently anticipated from the merger, Advaxis stockholders will have experienced substantial dilution of their ownership interests without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the combined company is able to realize only part of the strategic and financial benefits currently anticipated from the merger.

***If the merger is not completed, Advaxis' stock price may fluctuate significantly.***

The market price of Advaxis' common stock is subject to significant fluctuations. During the 12-month period ended August 24, 2021, the closing sales price of Advaxis' common stock on The Nasdaq Capital Market ranged from a high of $1.41 on February 17, 2021, to a low of $0.28 on November 24, 2020. Market prices for securities of pharmaceutical, biotechnology and other life science companies have historically been particularly volatile. In addition, the market price of Advaxis common stock will likely be volatile based on whether stockholders and other investors believe that Advaxis can complete the merger or otherwise raise additional capital to support Advaxis' operations if the merger is not consummated and another strategic transaction cannot be identified, negotiated and consummated in a timely manner, if at all. The volatility of the market price of Advaxis common stock is exacerbated by low trading volume. Additional factors that may cause the market price of Advaxis common stock to fluctuate include:

- the initiation of, material developments in, or conclusion of litigation to enforce or defend its intellectual property rights or defend against claims involving the intellectual property rights of others;
- the entry into, or termination of, key agreements, including commercial partner agreements;
- announcements by commercial partners or competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- the introduction of technological innovations or new therapies that compete with its future products;

- the loss of key employees;
- future sales of its common stock;
- general and industry-specific economic conditions that may affect its research and development expenditures;
- the failure to meet industry analyst expectations; and
- period-to-period fluctuations in financial results.

Moreover, the stock markets in general have at times experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of Advaxis common stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies.

***Advaxis stockholders and Biosight shareholders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the completion of the merger as compared to their current ownership and voting interests in the respective companies.***

After the completion of the merger, the current stockholders of Advaxis and shareholders of Biosight will own a smaller percentage of the combined company than their ownership of their respective companies prior to the merger. Immediately after the merger, Advaxis stockholders as of immediately prior to the merger are expected to own approximately 25% of the outstanding shares of the combined company and former Biosight shareholders are expected to own approximately 75% of the outstanding shares of the combined company.

***During the pendency of the merger, Advaxis and Biosight may not be able to enter into a business combination with another party on more favorable terms because of restrictions in the Merger Agreement, which could adversely affect their respective business prospects.***

Covenants in the Merger Agreement impede the ability of Advaxis and Biosight to make acquisitions during the pendency of the merger, subject to specified exceptions. As a result, if the merger is not completed, the parties may be at a disadvantage to their competitors during that period. In addition, while the Merger Agreement is in effect, each party is generally prohibited from soliciting, proposing, seeking or knowingly encouraging, facilitating or supporting any inquiries, indications of interest, proposals or offers that constitute or may reasonably be expected to lead to certain transactions involving a third party, including a merger, sale of assets or other business combination, subject to specified exceptions. Any such transactions could be favorable to such party's stockholders, but the parties may be unable to pursue them. For more information, see the section titled "*The Merger Agreement—Non-Solicitation*."

***Certain provisions of the Merger Agreement may discourage third parties from submitting competing proposals, including proposals that may be superior to the transactions contemplated by the Merger Agreement.***

The terms of the Merger Agreement prohibit each of Advaxis and Biosight from soliciting or engaging in discussions with third parties regarding alternative acquisition proposals, except in limited circumstances when such party's board of directors determines in good faith that an unsolicited acquisition proposal constitutes or could reasonably be expected to lead to a superior proposal and that failure to take such action would reasonably be expected to be inconsistent with its fiduciary duties under applicable law, as described in further detail in the section titled "*The Merger Agreement—Non-Solicitation*." In addition, if the Merger Agreement is terminated by Advaxis or Biosight under certain circumstances, including because of a decision of Advaxis' board of directors to accept a superior proposal, Advaxis would be required to pay Biosight a termination fee of $7.5 million or reimburse Biosight's expenses up to a maximum of $2.0 million. This termination fee may discourage third parties from submitting alternative takeover proposals to Advaxis or its stockholders, and may cause Advaxis' board of directors to be less inclined to recommend an alternative proposal.

***Because the lack of a public market for Biosight's shares makes it difficult to evaluate the fair market value of Biosight's share capital, Advaxis may pay more than the fair market value of Biosight's share capital and/or the shareholders of Biosight may receive consideration in the merger that is less than the fair market value of Biosight's share capital.***

The outstanding share capital of Biosight is privately held and is not traded in any public market. The lack of a public market makes it difficult to determine the fair market value of Biosight's share capital. Because the percentage of Advaxis equity to be issued to Biosight shareholders was determined based on negotiations between the parties, it is possible that the value of the Advaxis common stock to be received by Biosight shareholders will be less than the fair market value of Biosight's capital stock, or Advaxis may pay more than the aggregate fair market value for Biosight's share capital.

***The merger may fail to qualify as a "reorganization" for U.S. federal income tax purposes, resulting in recognition of taxable gain or loss by Biosight shareholders in respect of their Biosight capital stock.***

Advaxis and Biosight intend for the merger to qualify as a "reorganization" within the meaning of Section 368(a) of the Code and the Treasury Regulations promulgated thereunder, as described in the section titled "*The Merger—Material U.S. Federal Income Tax Consequences of the Merger*" in this proxy statement/prospectus/information statement. In the event that the merger does not qualify as a "reorganization," the merger would result in taxable gain or loss for U.S. federal income tax purposes for each Biosight shareholder, with the amount of such gain or loss determined by the amount that each such Biosight shareholder's adjusted U.S. federal income tax basis in the Biosight capital stock surrendered is less or more than the fair market value of the Advaxis common stock and any cash in lieu of a fractional share received in exchange therefor. Each holder of Biosight capital stock is urged to consult with his, her or its own tax advisor with respect to the tax consequences of the merger.

***The announcement and pendency of the merger, whether or not consummated, may adversely affect the trading price of Advaxis' common stock and its business prospects.***

The announcement and pendency of the merger, whether or not consummated, may adversely affect the trading price of Advaxis' common stock and its business prospects. In the event that the merger is not completed, the announcement of the termination of the Merger Agreement may also adversely affect the trading price of Advaxis' common stock and its business prospects.

***Biosight received a letter from counsel to an Israeli company, claiming that such company is entitled to an amount equal to 4.8% of the share capital to be allocated and/or issued to Biosight shareholders in connection with the merger pursuant to a purported agreement between Biosight and such company allegedly entered into in 2011.***

On or about October 5, 2021, Biosight received a letter from counsel to Foodronix Ltd., an Israeli company ("Foodronix"), claiming that Foodronix is entitled to an amount equal to 4.8% of the share capital to be allocated and/or issued to Biosight shareholders in connection with the merger. The asserted entitlement is alleged to arise pursuant to a purported agreement between Biosight and Foodronix, which Foodronix claims was entered into in 2011.

Biosight believes that during March 2011, meetings were held by Biosight's former chief executive officer with several companies in an effort to identify a shell company listed on the Tel Aviv Stock Exchange to merge with Biosight in order for Biosight to become public. While no such transaction occurred, and Foodronix has had no involvement with the merger, if Foodronix is found to have some entitlement to compensation as a result of its alleged claims, the combined company could be subject to damages, which could have an adverse effect on the combined company's operating results and financial condition, or the combined company's shareholders could be subject to substantial dilution without receiving any commensurate benefit. The combined company's management may also be distracted from operations in addressing the claims of the letter.

For additional information regarding the claim from Foodronix, please see the section titled "*Biosight's Business—Legal Proceedings*" beginning on page 175 of this proxy statement/prospectus/information statement.

***Failure to consummate the merger may result in Advaxis paying a termination fee to Biosight and could harm Advaxis' common stock price and its future business and operations.***

The merger will not be consummated if the conditions precedent to the consummation of the transaction are not satisfied or waived, or if the Merger Agreement is terminated in accordance with its terms. If the merger is not consummated, Advaxis is subject to the following risks:

- if the Merger Agreement is terminated under certain circumstances, Advaxis will be required to pay Biosight a termination fee of $7.5 million or reimburse Biosight's expenses up to a maximum of $2.0 million; and

- the price of Advaxis' common stock may decline and remain volatile.

If the merger does not close for any reason, Advaxis' board of directors may elect to, among other things, attempt to complete another strategic transaction, attempt to sell or otherwise dispose of Advaxis' various assets, dissolve or liquidate its assets, declare bankruptcy or seek to continue to operate its business. If Advaxis seeks another strategic transaction or attempts to sell or otherwise dispose of its various assets, there is no assurance that it will be able to do so, that the terms would be equal to or superior to the terms of the merger or as to the timing of such transaction. If Advaxis decides to dissolve and liquidates its assets, Advaxis would be required to pay all of its debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurance as to the amount or timing of available cash left to distribute to stockholders after paying its debts and other obligations and setting aside funds for reserves.

If Advaxis was to seek to continue its business, it would need to determine whether to acquire one or more other product candidates. Advaxis would also need to raise funds to support continued operations and re-assess its workforce requirements in consideration of its reduced workforce.

If the merger is not consummated, Advaxis may be unable to retain the services of key remaining members of its management team and, as a result, may be unable to seek or consummate another strategic transaction, properly dissolve and liquidate its assets or continue its business.

***If Advaxis does not successfully consummate the transaction with Biosight, Advaxis' board of directors may dissolve or liquidate its assets to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to Advaxis' stockholders will depend heavily on the timing of such transaction or liquidation.***

If the merger does not close for any reason, Advaxis' board of directors may elect to, among other things, dissolve or liquidate its assets, which may include seeking protection from creditors in a bankruptcy proceeding. If Advaxis decides to dissolve and liquidate its assets, Advaxis would be required to pay all of its debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurances as to the amount or timing of available cash left to distribute to stockholders after paying its debts and other obligations and setting aside funds for reserves.

In the event of a dissolution and liquidation, the amount of cash available for distribution to Advaxis' stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as Advaxis funds its operations in preparation for the consummation of the merger. Further, the Merger Agreement contains certain termination rights for each party, and provides that, upon termination under specified circumstances, Advaxis may be required to pay Biosight a termination fee of $7.5 million or reimburse Biosight's expenses up to a maximum of $2.0 million, which would further decrease Advaxis' available cash resources. If Advaxis' board of directors were to approve and recommend, and its stockholders were to approve, a dissolution and liquidation, Advaxis would be required under Delaware corporate law to pay its outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to its stockholders. Advaxis' commitments and contingent liabilities may include (i) regulatory and clinical obligations remaining under its clinical trials; (ii) obligations under its employment, separation and retention agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control of Advaxis; and (iii) potential litigation against Advaxis, and other various claims and legal actions arising in the ordinary course of business. As a result of this requirement, a portion of Advaxis' assets may need to be reserved pending the resolution of such obligations. In addition, Advaxis may be subject to litigation or other claims related to a dissolution and liquidation of Advaxis. If a dissolution and liquidation were pursued, Advaxis' board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of Advaxis common stock could lose all or a significant portion of their investment in the event of its liquidation, dissolution or winding up.

**Risks Related to the Proposed Reverse Stock Split**

***Advaxis is seeking stockholder approval of a reverse stock split of Advaxis common stock for the purpose of maintaining the listing of Advaxis common stock on Nasdaq and as a condition of the merger, but Advaxis may not obtain stockholder approval or it may not have the desired result.***

Advaxis is seeking stockholder approval of a reverse stock split of Advaxis common stock for the purpose of raising the per share trading price of the Advaxis common stock and maintaining the listing of Advaxis common stock on Nasdaq and as a condition of the merger. However, there is no assurance that Advaxis' stockholders will approve the reverse stock split proposal, or even if they do, that it will have the desired result and that Advaxis will be able to maintain its listing on Nasdaq. Even if Advaxis effects the reverse stock split and maintains its listing, shares of Advaxis common stock may still have a relatively low trading price, which could hinder Advaxis' ability to attract institutional or other potential investors. Furthermore, the price per share of Advaxis common stock after the reverse stock split, if approved and implemented, may not reflect the reverse stock split and the price per share following the effective time of the reverse stock split may not be maintained for any period following the reverse stock split. In many cases, the market price of a company's shares declines after a reverse stock split. Accordingly, the total market capitalization of Advaxis common stock following the contemplated reverse stock split may be lower than before the reverse stock split. Similarly, the trading liquidity of the Advaxis common stock could be adversely affected by the reduced number of shares outstanding after the reverse stock split. If Advaxis does not maintain compliance with the Nasdaq minimum bid price prior to the merger and this reverse stock split proposal is not approved by Advaxis' stockholders and the parties waive this closing condition, the combined company resulting from the merger will likely not be able to obtain compliance with the minimum bid price requirement for an initial listing on The Nasdaq Capital Market and, as a consequence, Nasdaq will immediately provide the combined company with written notification that the common stock will be delisted.

If Advaxis' common stock is delisted, Advaxis would expect Advaxis' common stock to be traded in the over-the-counter market, which could adversely affect the liquidity of Advaxis' common stock. Additionally, Advaxis could face significant material adverse consequences, including:

- a limited availability of market quotations for Advaxis' common stock;
- a reduced amount of news and analyst coverage for Advaxis;
- a decreased ability to issue additional securities and a concomitant substantial impairment in Advaxis' ability to obtain sufficient additional capital to fund Advaxis' operations and to continue as a going concern;
- reduced liquidity for Advaxis' stockholders;
- potential loss of confidence by employees and potential future partners or collaborators; and
- loss of institutional investor interest and fewer business development opportunities.

***The reverse stock split may not increase the combined company's stock price over the long term.***

The principal purpose of the reverse stock split is to increase the per share market price of Advaxis' common stock above the minimum bid price requirement under the Nasdaq rules so that the listing of Advaxis and the shares of Advaxis common stock being issued in the merger on Nasdaq will be approved. It cannot be assured, however, that the reverse stock split will accomplish this objective for any meaningful period. While it is expected that the reduction in the number of outstanding shares of common stock will proportionally increase the market price of Advaxis' common stock, it cannot be assured that the reverse stock split will increase the market price of its common stock by a multiple of the reverse stock split ratio mutually agreed by Advaxis and Biosight, or result in any permanent or sustained increase in the market price of Advaxis' common stock, which is dependent upon many factors, including Advaxis' business and financial performance, general market conditions and prospects for future success. Thus, while the stock price of Advaxis might meet the listing requirements for Nasdaq initially, it cannot be assured that it will continue to do so.

***The reverse stock split may decrease the liquidity of the combined company's common stock.***

Although the Advaxis board of directors believes that the anticipated increase in the market price of the combined company's common stock resulting from the proposed reverse stock split could encourage interest in its common stock and possibly promote greater liquidity for its stockholders, such liquidity could also be adversely affected by the reduced number of shares outstanding after the reverse stock split. The reduction in the number of outstanding shares may lead to reduced trading and a smaller number of market makers for the combined company's common stock. In addition, the reverse stock split may not result in an increase in the combined company's stock price necessary to satisfy Nasdaq's initial listing requirements for the combined company.

***The reverse stock split may lead to a decrease in the combined company's overall market capitalization.***

Should the market price of the combined company's common stock decline after the reverse stock split, the percentage decline may be greater, due to the smaller number of shares outstanding, than it would have been prior to the reverse stock split. A reverse stock split is often viewed negatively by the market and, consequently, can lead to a decrease in the combined company's overall market capitalization. If the per share market price does not increase in proportion to the reverse stock split ratio, then the value of the combined company, as measured by its stock capitalization, will be reduced. In some cases, the per share stock price of companies that have effected reverse stock splits subsequently declined back to pre-reverse split levels, and accordingly, it cannot be assured that the total market value of the combined company's common stock will remain the same after the reverse stock split is effected, or that the reverse stock split will not have an adverse effect on the combined company's stock price due to the reduced number of shares outstanding after the reverse stock split.

**Risks Related to Ownership of Advaxis' Common Stock and Its Status as a Public Company**

***Sales of additional equity securities may adversely affect the market price of Advaxis' common stock and your rights may be reduced.***

Advaxis expects to continue to incur drug development and selling, general and administrative costs, and to satisfy its funding requirements, it will need to sell additional equity securities, which may be subject to registration rights and warrants with anti-dilutive protective provisions. The sale or the proposed sale of substantial amounts of Advaxis common stock or other equity securities in the public markets may adversely affect the market price of Advaxis common stock and Advaxis' stock price may decline substantially. Advaxis' shareholders may experience substantial dilution and a reduction in the price that they are able to obtain upon sale of their shares. Also, new equity securities issued may have greater rights, preferences or privileges than Advaxis' existing common stock.

***The price of Advaxis' common stock and warrants may be volatile.***

The trading price of Advaxis' common stock and warrants may fluctuate substantially. The price of Advaxis' common stock and warrants that will prevail in the market may be higher or lower than the price you have paid, depending on many factors, some of which are beyond Advaxis' control and may not be related to its operating performance. These fluctuations could cause you to lose part or all of your investment in Advaxis' common stock and warrants. Those factors that could cause fluctuations include, but are not limited to, the following:

- price and volume fluctuations in the overall stock market from time to time;
- fluctuations in stock market prices and trading volumes of similar companies;
- actual or anticipated changes in Advaxis' net loss or fluctuations in its operating results or in the expectations of securities analysts;
- the issuance of new equity securities pursuant to a future offering, including issuances of preferred stock;
- general economic conditions and trends;
- positive and negative events relating to healthcare and the overall pharmaceutical and biotech sector;
- major catastrophic events;
- sales of large blocks of Advaxis' stock;
- significant dilution caused by the anti-dilutive clauses in Advaxis' financial agreements;
- departures of key personnel;
- changes in the regulatory status of Advaxis' immunotherapies, including results of its clinical trials;
- events affecting University of Pennsylvania ("Penn") or any current or future collaborators;

- announcements of new products or technologies, commercial relationships or other events by Advaxis or its competitors;
- regulatory developments in the United States and other countries;
- failure of Advaxis' common stock or warrants to be listed or quoted on The Nasdaq Stock Market, NYSE Amex Equities or other national market system;
- changes in accounting principles; and
- discussion of Advaxis or its stock price by the financial and scientific press and in online investor communities.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Due to the potential volatility of Advaxis' stock price, it may therefore be the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from Advaxis' business.

***A limited public trading market may cause volatility in the price of Advaxis' common stock.***

The quotation of Advaxis' common stock on Nasdaq does not assure that a meaningful, consistent and liquid trading market currently exists, and in recent years such market has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies like Advaxis. Advaxis' common stock is thus subject to this volatility. Sales of substantial amounts of common stock, or the perception that such sales might occur, could adversely affect prevailing market prices of Advaxis' common stock and its stock price may decline substantially in a short time and its shareholders could suffer losses or be unable to liquidate their holdings.

***The market prices for Advaxis' common stock may be adversely impacted by future events.***

Advaxis' common stock began trading on the over-the-counter-markets on July 28, 2005 and is currently quoted on the Nasdaq Capital Market under the symbol ADXS. Market prices for Advaxis' common stock and warrants will be influenced by a number of factors, including:

- the issuance of new equity securities pursuant to a future offering, including issuances of preferred stock;
- changes in interest rates;
- significant dilution caused by the anti-dilutive clauses in Advaxis' financial agreements;
- competitive developments, including announcements by competitors of new products or services or significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- variations in quarterly operating results;
- change in financial estimates by securities analysts;
- the depth and liquidity of the market for Advaxis' common stock and warrants;
- investor perceptions of Advaxis and the pharmaceutical and biotech industries generally; and
- general economic and other national conditions.

***Advaxis is not currently in compliance with the continued listing requirements for Nasdaq. If the price of Advaxis' common stock continues to trade below $1.00 per share for a sustained period or it does not meet other continued listing requirements, its common stock may be delisted from the Nasdaq Capital Market, which could affect the market price and liquidity for its common stock and reduce its ability to raise additional capital.***

In order to maintain listing on the Nasdaq Capital Market, Advaxis must satisfy minimum financial and other requirements including, without limitation, a requirement that its closing bid price be at least $1.00 per share. On April 8, 2020, Advaxis received written notice from Nasdaq indicating that Advaxis was not in compliance with this minimum bid price requirement because its common stock had closed below $1.00 per share for the previous 30 consecutive business days. On April 17, 2020, Advaxis received an additional notice from Nasdaq indicating that, due to extraordinary market conditions, Nasdaq had tolled the compliance period for the bid-price requirement through June 30, 2020 (the "tolling period") and that on April 16, 2020, Nasdaq filed an immediately effective rule change with the SEC to implement the tolling period. In accordance with the April 17, 2020 notice from Nasdaq, Advaxis had until December 21, 2020 to regain compliance with the minimum bid price requirement.

As of December 21, 2020, Advaxis was yet to be in compliance with the minimum bid requirement as discussed above. On December 22, 2020, Advaxis received notification from Nasdaq that its application to transfer the listing of its common stock from the Nasdaq Global Select Market to the Nasdaq Capital Market had been approved. Advaxis' securities were transferred to the Nasdaq Capital Market at the opening of business on December 24, 2020 and it had an additional 180 days, or until June 21, 2021, to regain compliance with the minimum bid price per share requirement.

On June 22, 2021, Advaxis received notification from Nasdaq that the Company had not regained compliance with the minimum bid price per share requirement. The notification indicated that the Company's common stock would be subject to delisting unless the Company timely requested a hearing before a Nasdaq Hearing Panel (the "Panel"). The Company timely requested a hearing and the hearing was scheduled for July 29, 2021. The hearing request stayed any suspension or delisting action pending the hearing and the expiration of any additional extension period granted by the Panel following the hearing. On August 11, 2021, Advaxis issued a press release announcing that it has received a letter indicating that following the Company's hearing before the Panel, the Panel determined to grant the Company an extension through November 22, 2021, to evidence compliance with Nasdaq's $1.00 Minimum Bid Price Rule and complete its previously announced merger transaction with Biosight. Pursuant to the Nasdaq Listing Rules, the combined company will be required to meet all applicable initial listing requirements upon the closing of the merger, including the $4 per share price requirement.

***Unless Advaxis' common stock continues to be listed on a national securities exchange it will become subject to the so-called "penny stock" rules that impose restrictive sales practice requirements.***

If Advaxis is unable to maintain the listing of its common stock on The Nasdaq Capital Market or another national securities exchange, its common stock could become subject to the so-called "penny stock" rules if the shares have a market value of less than $5.00 per share. The SEC has adopted regulations that define a penny stock to include any stock that has a market price of less than $5.00 per share, subject to certain exceptions, including an exception for stock traded on a national securities exchange. The SEC regulations impose restrictive sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. An accredited investor generally is a person whose individual annual income exceeded $200,000, or whose joint annual income with a spouse exceeded $300,000 during the past two years and who expects their annual income to exceed the applicable level during the current year, or a person with net worth in excess of $1.0 million, not including the value of the investor's principal residence and excluding mortgage debt secured by the investor's principal residence up to the estimated fair market value of the home, except that any mortgage debt incurred by the investor within 60 days prior to the date of the transaction shall not be excluded from the determination of the investor's net worth unless the mortgage debt was incurred to acquire the residence. For transactions covered by this rule, the broker-dealer must make a special suitability determination for the purchaser and must have received the purchaser's written consent to the transaction prior to sale. This means that if Advaxis is unable maintain the listing of its common stock on a national securities exchange, the ability of stockholders to sell their common stock in the secondary market could be adversely affected.

If a transaction involving a penny stock is not exempt from the SEC's rule, a broker-dealer must deliver a disclosure schedule relating to the penny stock market to each investor prior to a transaction. The broker-dealer also must disclose the commissions payable to both the broker-dealer and its registered representative, current quotations for the penny stock, and, if the broker-dealer is the sole market-maker, the broker-dealer must disclose this fact and the broker-dealer's presumed control over the market. Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the customer's account and information on the limited market in penny stocks.

***If Advaxis fails to remain current with its listing requirements, it could be removed from the Nasdaq Capital Market, which would limit the ability of broker-dealers to sell its securities and the ability of shareholders to sell their securities in the secondary market.***

Companies trading on the Nasdaq Marketplace, such as Advaxis, must be reporting issuers under Section 12 of the Exchange Act, as amended, and Advaxis must meet the listing requirements in order to maintain the listing of its common stock on the Nasdaq Capital Market. If Advaxis does not meet these requirements, the market liquidity for its securities could be severely adversely affected by limiting the ability of broker-dealers to sell its securities and the ability of shareholders to sell their securities in the secondary market.

***Advaxis may be at an increased risk of securities litigation, which is expensive and could divert management attention.***

The market price of Advaxis' common stock may be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. Advaxis may be the target of this type of litigation in the future. Securities litigation against Advaxis could result in substantial costs and divert its management's attention from other business concerns, which could seriously harm its business.

***Advaxis does not intend to pay cash dividends.***

Advaxis has not declared or paid any cash dividends on its common stock, and it does not anticipate declaring or paying cash dividends for the foreseeable future. Any future determination as to the payment of cash dividends on Advaxis' common stock will be at its board of directors' discretion and will depend on its financial condition, operating results, capital requirements and other factors that its board of directors considers to be relevant.

**Risks Related to the Combined Company**

In determining whether you should approve the issuance of shares of Advaxis common stock, the change of control resulting from the merger and other matters related to the merger, as applicable, you should carefully read the following risk factors in addition to the risks described above.

***The market price of our common stock is expected to be volatile, and the market price of the common stock may drop following the merger.***

The market price of our common stock following the merger could be subject to significant fluctuations. Some of the factors that may cause the market price of our common stock to fluctuate include:

- results of clinical trials and preclinical studies of our product candidates, or those of our competitors or our existing or future collaborators;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- if we do not achieve the perceived benefits of the merger as rapidly or to the extent anticipated by financial or industry analysts;

- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading opinions regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions or market conditions in the pharmaceutical and biotechnology sectors;
- sales of securities by us or our securityholders in the future;
- if we fail to raise an adequate amount of capital to fund our operations and continued development of our product candidates;
- trading volume of our common stock;
- announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to precision medicine product candidates, including with respect to other products in such markets;
- the introduction of technological innovations or new therapies that compete with our products and services; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have at times experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In addition, a recession, depression or other sustained adverse market event resulting from the spread of COVID-19 or otherwise could materially and adversely affect our business and the value of our common stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies. Furthermore, market volatility may lead to increased shareholder activism if we experience a market valuation that activists believe is not reflective of our intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition.

***Following the merger, we may be unable to integrate successfully and realize the anticipated benefits of the merger.***

The merger involves the combination of two companies that currently operate as independent companies. We may fail to realize some or all of the anticipated benefits of the merger if the integration process takes longer than expected or is more costly than expected. In addition, Advaxis and Biosight have operated and, until the completion of the merger, will continue to operate, independently. It is possible that the integration process also could result in the diversion of each company's management's attention, the disruption or interruption of, or the loss of momentum in, each company's ongoing businesses or inconsistencies in standards, controls, procedures and policies, any of which could adversely affect our ability to maintain relationships with customers, suppliers and employees or the ability to achieve the anticipated benefits of the merger, or could otherwise adversely affect our business and financial results.

***We will need substantial additional funding before we can complete the development of our product candidates. If we are unable to obtain such additional capital on favorable terms, on a timely basis or at all, we would be forced to delay, reduce or eliminate our product development and clinical programs and may not have the capital required to otherwise operate our business.***

Developing therapies, including conducting pre-clinical studies and clinical trials and establishing manufacturing capabilities, is expensive. We have not generated any revenues from the commercial sale of products and will not be able to generate any product revenues until, and only if, we receive approval to sell our product candidates from the Federal Drug Administration ("FDA") or other regulatory authorities. The cash expected from both Advaxis and Biosight at closing is expected to fund the further development of our programs. However, we may need to raise substantial additional capital in order to fund our general corporate activities and to fund our research and development, including our currently planned clinical trials and plans for new clinical trials and product development.

We may seek to raise additional funds through various potential sources, such as equity and debt financings, or through strategic collaborations and license agreements. We can give no assurances that we will be able to secure such additional sources of funds to support our operations or, if such funds are available, that such additional financing will be sufficient to meet our needs. Moreover, to the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or product candidates, or grant licenses on terms that may not be favorable.

Given our capital constraints, we will need to prioritize spending on our clinical and pre-clinical programs. If we are unable to raise sufficient funds to support our current and planned operations, we may elect to discontinue certain of our ongoing activities or programs. Our inability to raise additional funds could also prevent us from taking advantage of opportunities to pursue existing or promising new programs in the future.

Our forecasts regarding our beliefs in the sufficiency of our financial resources to support our current and planned operations are forward-looking statements and involve significant risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. These estimates are based on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than currently expected.

***We will incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies.***

We will incur significant legal, accounting and other expenses as a public company that Biosight did not incur as a private company, including costs associated with public company reporting obligations under the Securities Exchange Act of 1934, as amended, (the "Exchange Act"). Our management team will consist of certain executive officers of both Advaxis and Biosight prior to the merger. At least some of these executive officers and other personnel will need to devote substantial time to gaining expertise related to public company reporting requirements and compliance with applicable laws and regulations to ensure that we comply with all of these requirements. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on the board of directors or on board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

***Once we are no longer a smaller reporting company or otherwise no longer qualify for applicable exemptions, we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results.***

We will be subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition as well as other disclosure and corporate governance requirements. However, as a "smaller reporting company" we may take advantage of certain exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. Once we are no longer a smaller reporting company or otherwise qualify for these exemptions, we will be required to comply with these additional legal and regulatory requirements applicable to public companies and will incur significant legal, accounting and other expenses to do so. If we are not able to comply with the requirements in a timely manner or at all, our financial condition or the market price of our common stock may be harmed. For example, if we or our independent auditor identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, we could face additional costs to remedy those deficiencies, the market price of our stock could decline or we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

***The unaudited pro forma condensed combined financial data for Advaxis and Biosight included in this proxy statement/prospectus/information statement is preliminary, and our actual financial position and operations after the merger may differ materially from the unaudited pro forma financial data included in this proxy statement/prospectus/information statement.***

The unaudited pro forma financial data for Advaxis and Biosight included in this proxy statement/prospectus/information statement is presented for illustrative purposes only and is not necessarily indicative of our actual financial condition or results of operations of future periods, or the financial condition or results of operations that would have been realized had the entities been combined during the periods presented. The unaudited pro forma financial statements have been derived from the historical financial statements of Advaxis and Biosight and adjustments and assumptions have been made regarding the combined company after giving effect to the transaction. The information upon which these adjustments and assumptions have been made is preliminary, and these kinds of adjustments and assumptions are difficult to make with accuracy. Moreover, the unaudited pro forma financial statements do not reflect all costs that are expected to be incurred by us in connection with the transactions or that have been incurred since the date of such unaudited pro forma financial statements. The assumptions used in preparing the unaudited pro forma financial information may not prove to be accurate, and other factors may affect our financial condition following the transaction. For more information see the section titled "*Unaudited Pro Forma Condensed Combined Financial Information*" beginning on page 207.

***Advaxis' certificate of incorporation, bylaws and Delaware law have anti-takeover provisions that could discourage, delay or prevent a change in control of the combined company, which may cause our stock price to decline.***

Advaxis' amended and restated certificate of incorporation, second amended and restated bylaws and Delaware law contain provisions which could make it more difficult for a third party to acquire Advaxis, even if closing such a transaction would be beneficial to Advaxis' shareholders, which provisions will remain in place for the combined company. To date, Advaxis has not issued shares of preferred stock; however, Advaxis is authorized to issue up to 5,000,000 shares of preferred stock. This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our board of directors without further action by shareholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third party and thereby preserve control by then-present management.

Provisions of Advaxis' certificate of incorporation, bylaws and Delaware law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a shareholder might consider favorable. Such provisions may also prevent or frustrate attempts by our shareholders to replace or remove our management. In particular, the amended and restated certificate of incorporation, second amended and restated bylaws and Delaware law, as applicable, among other things; provide the board of directors with the ability to alter the second amended and restated bylaws without shareholder approval and provide that vacancies on the board of directors may be filled by a majority of directors in office, and less than a quorum.

Advaxis is also subject to Section 203 of the Delaware General Corporation Law, which, subject to certain exceptions, prohibits "business combinations" between a publicly-held Delaware corporation and an "interested shareholder," which is generally defined as a shareholder who becomes a beneficial owner of 15% or more of a Delaware corporation's voting stock for a three-year period following the date that such shareholder became an interested shareholder.

These provisions are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of Advaxis to first negotiate with Advaxis' board. These provisions may delay or prevent someone from acquiring or merging with us, which may cause the market price of our common stock to decline.

***Our ability to utilize our respective net operating loss carryforwards and tax credit carryforwards may be subject to limitations.***

Our ability to use our respective federal and state net operating losses ("NOLs") to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, and neither Advaxis nor Biosight can predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOLs.

Under Section 382 and Section 383 of the Code and corresponding provisions of state law, if a corporation undergoes an "ownership change," its ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. A Section 382 "ownership change" is generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period. Advaxis believes that it has experienced an ownership change in the past, and may experience subsequent ownership changes in the future due to subsequent shifts in our stock ownership (some of which are outside of our control). Biosight may have experienced ownership changes in the past, may experience an ownership change as a result of the merger, and may experience ownership changes in the future due to subsequent shifts in our stock ownership (some of which are outside of our control). Furthermore, the merger, if consummated, will constitute an ownership change (within the meaning of Section 382 of the Code) of Advaxis which could eliminate or otherwise substantially limit Advaxis' ability to use its federal and state NOLs to offset its future taxable income. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of Biosight's or Advaxis' NOL carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations. Similar provisions of state tax law may also apply to limit the use of accumulated state tax attributes. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

***Changes in tax laws or regulations could materially adversely affect us.***

New tax laws or regulations could be enacted at any time, and existing tax laws or regulations could be interpreted, modified or applied in a manner that is adverse to us, which could adversely affect our business and financial condition.

***Advaxis and Biosight do not anticipate that we will pay any cash dividends in the foreseeable future.***

The current expectation is that we will retain our future earnings, if any, to fund the growth of our business as opposed to paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain, if any, for the foreseeable future.

***An active trading market for our common stock may not develop and our stockholders may not be able to resell their shares of common stock for a profit, if at all.***

Prior to the merger, there had been no public market for Biosight's share capital. An active trading market for our shares of common stock may never develop or be sustained. If an active market for our common stock does not develop or is not sustained, it may be difficult for our stockholders to sell their shares at an attractive price or at all.

***Future sales of shares by existing stockholders could cause our stock price to decline.***

If existing securityholders of Advaxis and Biosight sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. Based on shares outstanding as of September 17, 2021, and the shares expected to be issued upon completion of the merger, we are expected to have outstanding a total of approximately 145,638,459 shares of common stock immediately following the completion of the merger. Shares of common stock that are subject to outstanding options of Biosight will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act. If these shares are sold, the trading price of our common stock could decline.

***After completion of the merger, our executive officers, directors and principal stockholders will have the ability to control or significantly influence all matters submitted to our stockholders for approval.***

Upon the completion of the merger, it is anticipated that our executive officers, directors and principal stockholders will, in the aggregate, beneficially own less than 1% of our outstanding shares of common stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of the combined company on terms that other stockholders may desire.

***We may be exposed to increased litigation, including stockholder litigation, which could have an adverse effect on our business and operations.***

We may be exposed to increased litigation from stockholders, customers, suppliers, consumers and other third parties due to the combination of Advaxis' business and Biosight's business following the merger. Such litigation may have an adverse impact on our business and results of operations or may cause disruptions to our operations. In addition, in the past, stockholders have initiated class action lawsuits against biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

We may be exposed to litigation resulting from the transactions contemplated herein. Such lawsuits could cause us to incur substantial costs and divert management's attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

***If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.***

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock after the completion of the merger, and such lack of research coverage may adversely affect the market price of our common stock. In the event we have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

***We will have broad discretion in the use of our cash and cash equivalents and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.***

We will have broad discretion over the use of our cash and cash equivalents. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. Our failure to apply these resources effectively could compromise our ability to pursue our growth strategy and, we might not be able to yield a significant return, if any, on our investment of these net proceeds. You will not have the opportunity to influence our decisions on how to use our cash resources.

***Our internal control over financial reporting may not meet the standards required by Section 404 of the Sarbanes-Oxley Act, and failure to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and share price.***

As a privately held company, Biosight was not required to evaluate its internal control over financial reporting in a manner that meets the standards of publicly traded companies required by Section 404 of the Sarbanes-Oxley Act, or Section 404. Following the merger, our management will be required to report on the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation.

We cannot assure you that any material weaknesses identified at the combined company will be remediated by us and/or that there will not be additional material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain effective internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

***Risks Relating to Our Combined Businesses and Capital Requirements***

***We have a limited operating history and have never generated any product revenue.***

Both Advaxis and Biosight are clinical-stage biotechnology companies with limited operating history. Biosight was formed on November 10, 1999, and since inception, has incurred significant net losses and has financed its operations with $68.5 million through capital contributions. As of June 30, 2021, Biosight had an accumulated deficit of $45.0 million. Similarly, Advaxis has not generated any revenue from product sales. As of July 31, 2021, Advaxis had cash and cash equivalents of $45.3 million.

To date, both Advaxis and Biosight's operations have been limited to organizing and staffing the respective companies, raising capital, developing therapeutic product candidates and advancing those candidates through clinical development and trials. Neither Advaxis nor Biosight has demonstrated the ability to successfully complete a registration-enabling clinical pivotal trial, obtain marketing approval, manufacture a clinical-stage or commercial-scale product (or arrange for a third party to do so on either company's behalf), or conduct sales and marketing activities necessary for successful, full-scale product commercialization. Therefore, we have no meaningful operations upon which to evaluate our business, and any predictions about our future success, viability or profitability would not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing therapeutic pharmaceutical products.

Our ability to generate product revenue and become profitable depends on our ability to successfully complete the development of, and obtain regulatory approvals for, our product candidates, including BST-236. We have never been profitable, have no products currently approved for commercial sale, and have not generated any revenue from product sales. Even if we receive regulatory approval for our product candidates, we do not know when or if such candidates will generate product revenue. Our ability to generate product revenue depends on a number of factors, including, but not limited to, our ability to:

- successfully complete pre-clinical studies and clinical trials;
- obtain and maintain regulatory approval for the marketing of our product candidates;
- add operational, financial and management information systems personnel, including support for our clinical, manufacturing and planned future commercialization efforts;
- establish or maintain collaborations, licensing or other arrangements;
- initiate and continue relationships with third-party suppliers and manufacturers and have commercial quantities of our product candidates manufactured at acceptable cost and quality levels and in compliance with FDA and other regulatory requirements;
- launch commercial sales of our products, whether alone or in collaboration with others;
- set an acceptable price for approved product candidates, obtain coverage and obtain adequate reimbursement;
- compete with other biotechnology products that target oncology and hematological malignancies;
- achieve broad market acceptance in the medical community, with third-party payors and consumers; and
- maintain, expand and protect our intellectual property portfolio.

Because of the numerous risks and uncertainties associated with biotechnology product development, we are unable to predict the timing or amount of increased expenses, or the extent to which we will be able to achieve or maintain profitability. Our expenses could increase beyond expectations if we are required by the FDA, European Medicines Agency ("EMA") or comparable regulatory authorities in other countries to perform studies or clinical trials in addition to those that we currently anticipate. Even if our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with their commercial launch. If we cannot successfully execute any one of the foregoing, our business may be unsuccessful, and your investment will be adversely affected.

***Our combined business, operations and clinical development plans and timelines could be adversely impacted by the effects of health epidemics, including the recent COVID-19 pandemic.***

Our combined business could be harmed by health epidemics wherever we have clinical trial sites or conduct operations performed by us or by third parties with whom we conduct business, including contract manufacturers, CROs, shippers and others. In December 2019, a novel strain of coronavirus, SARS-CoV-2, causing a disease referred to as COVID-19, surfaced in Wuhan, China and has since spread to multiple countries worldwide, including the United States, Israel and Europe. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic.

Our combined company will have business operations in Israel, the United States and Europe. Certain of our contract manufacturers are located in the United States and Europe. The Israeli, United States and European governments have imposed a variety of continuing aggressive orders, health directives and recommendations to reduce the spread of the disease, including shelter-in-place directives and executive orders directing that all non-essential businesses close their physical operations and implement work-from-home schedules. The effects of these orders and our work-from-home policies could negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition. In addition, COVID-19 infection of any members of our workforce could result in a temporary disruption in our business activities, including manufacturing and other functions. Further, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce our ability to access capital, which could negatively affect our short-term and long-term liquidity. Additionally, the stock market has been unusually volatile during the COVID-19 outbreak and such volatility may continue. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, financing or clinical trial activities, or on healthcare systems or the global economy as a whole. However, these effects could have a material impact on our liquidity, capital resources, operations and business and those of the third parties on which we rely.

We are dependent on an international supply chain for products to be used in our clinical trials and, if approved by the regulatory authorities, for commercialization. Quarantines, shelter-in-place and similar government orders, or the expectation that such orders, shutdowns or other restrictions could occur, whether related to COVID-19 or other infectious diseases, could impact personnel at third-party manufacturing facilities or the availability or cost of materials. Any manufacturing supply interruption of our product candidates could harm our ability to conduct ongoing and future clinical trials of our product candidates. In addition, closures of transportation carriers and modal hubs could materially impact our clinical development and any future commercialization timelines.

If our relationships with our third-party manufacturers, suppliers or other vendors are terminated or scaled back as a result of the COVID-19 pandemic or other health epidemics, we may be unable to enter into arrangements with alternative suppliers or vendors or do so on commercially reasonable terms or in a timely manner. There is a natural transition period when a new supplier or vendor commences work. As a result, delays occur, which could adversely impact our ability to meet our desired clinical development and any future commercialization timelines.

In addition, our clinical trials have been affected by the COVID-19 pandemic and could continue to be affected in the future. Clinical trial progression, dosing, patient enrollment and related activities have been delayed, and could continue to be delayed, due to prioritization of hospital resources toward the COVID-19 pandemic or concerns among patients about participating in clinical trials during a pandemic, and reporting of some clinical data could be incomplete or delayed if patients enrolled in our clinical trials are unable to fully participate as a result of any such hospital resource prioritization, patient participation concerns or other factors. Federal, state, and local guidelines for reopening in Israel, the United States and Europe, where our clinical trials are being run, could negatively impact our ability to enroll additional patients in any of our clinical programs. Some patients could have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. For example, patients in our clinical trials for BST-236 are elderly adults, often with advanced disease who could not be able to safely participate in clinical trials for this product candidate during the COVID-19 pandemic. Similarly, our inability to successfully recruit and retain patients and principal investigators and site staff who, as healthcare providers, could have heightened exposure to COVID-19 or experience additional restrictions by their institutions or local, state or national governments, could adversely impact our clinical trial operations. In addition, the COVID-19 pandemic has affected the operations of the FDA and other health authorities, which can result in delays of reviews and approvals, including with respect to our product candidates.

The spread of COVID-19, which has caused a broad impact globally, could materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 could be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could harm our business and the value of our common shares.

***We expect to incur significant losses for the foreseeable future and could never achieve or maintain profitability. Biosight's independent registered public accounting firm has expressed substantial doubt about its ability to continue as a going concern.***

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or fail to become commercially viable. Both Advaxis and Biosight have never generated any product revenue, and we cannot estimate with precision the extent of our future losses. We do not currently have any products that are available for commercial sale and could never generate product revenue or achieve profitability. As of June 30, 2021, Biosight had an accumulated deficit of $45.0 million.

We expect to continue to incur substantial and increasing losses through the commercialization of any current or future candidates if they receive approval. Our product candidates, including BST-236, the investigational product candidate, have not been approved for marketing anywhere in the world, and it is likely that they could never receive such approval. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain profitability. Our ability to generate product revenue and achieve profitability is dependent on our ability to complete the development of BST-236, continue developing new product candidates, obtain necessary regulatory approvals for such product candidates and manufacture and successfully market our product candidates. There can be no assurance that we will be profitable even if we successfully commercialize BST-236 or any current and future product candidates we develop. If we do obtain regulatory approval to market any of our product candidates, our revenue will be dependent upon, in part and among other things, the size of the markets in the territories for which we gain regulatory approval, the number of competitors in those markets, the accepted price for any such product candidate and whether we own the commercial rights for those territories. If the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we would not generate significant revenue from sales of any of our product candidates, even if they receive approval. Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Any failure to become and remain profitable could adversely impact the market price of our ordinary shares and our ability to raise capital and continue operations. A decline in the shares' value also could cause the stockholders to lose all or part of their investment.

We expect our research and development expenses in connection with development programs for BST-236 and any current and future product candidates to be significant. In addition, if we obtain regulatory approval for our product candidates, we expect to incur increased sales, marketing and manufacturing expenses. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have harmed and will continue to harm our results of operations, financial position and working capital.

***Biosight's independent registered public accounting firm has issued a going concern opinion on Biosight's financial statements as of December 31, 2020, expressing substantial doubt as to Biosight's ability to continue as a going concern. Biosight's consolidated financial statements do not include any adjustments that could result from the outcome of this uncertainty***.

Management believes that, after completion of the merger, with the receipt of the cash available to Advaxis, the combined company's cash will be sufficient to fund the combined company's project operations through the 4$^{th}$ quarter of 2022. We continually assess multiple options to obtain additional funding to support our operations, including proceeds from offerings of our equity securities or debt, or transactions involving product development, technology licensing or collaboration arrangements or other sources of capital to complete our currently planned development programs. Additional capital may not be available in sufficient amounts or on reasonable terms, if at all, and our ability to raise additional capital could be adversely impacted by potentially worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic.

***We face significant competition, and our commercial opportunities will be negatively affected if our competitors develop and market products that are more effective, safer or less expensive than the products we develop.***

The biotechnology and pharmaceutical industry is highly competitive. We are currently developing advanced therapeutical products to treat oncology and hematological malignancies and life-threatening diseases in patients who are elderly or are medically unfit to undergo standard chemotherapy treatments. As a significant unmet medical need exists in this market, there are several large and small pharmaceutical companies that may be focused on developing therapeutics for the treatment of these life-threatening diseases. Therefore, the product candidates that we develop, if they receive regulatory approval, will compete with those products currently available, in development, or that will be developed in the future.

We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities and other research institutions. In particular, there are a number of companies that are developing or marketing treatments for oncology and hematological malignancies. A number of biotechnology companies are developing treatments for our target markets. Many of our competitors have significantly greater financial, manufacturing, marketing, product development, technical and human resources than we do, and may also use more effective or advanced technology to develop their product candidates, which could render our products obsolete, less competitive or not economical.

Large pharmaceutical companies have many capabilities that exceed our own, such as extensive experience in clinical testing, obtaining marketing approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research and marketing capabilities than we do, with products in the late stages of development or which are already approved, as well as collaborative development arrangements with leading organizations. Large pharmaceutical companies also have greater resources and can invest heavily to accelerate discovery and development. Smaller and other early-stage companies could also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Finally, mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. As a result of all of these factors, our competitors and particularly, larger pharmaceutical companies, could succeed in discovering, developing, receiving marketing approval for and commercializing product candidates in our target markets before we are able.

We could lose or have reduced commercial opportunities if any competitors successfully develop and commercialize products that are safer, more effective, have fewer or less-severe effects, are more convenient, have a broader label, are marketed more effectively, are reimbursed or are less expensive than any product candidate that we develop. Our competitors also may obtain marketing approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we can enter the market. Even if the product candidates we develop receive marketing approval, they may be priced at a significant premium over competitive products that have already received approval, which will further reduce our competitive position.

***If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we could be unsuccessful in commercializing our product candidates and generating product revenues.***

We do not have an infrastructure for the sales, marketing or distribution of our product candidates if they receive regulatory approval for marketing and commercialization, and the cost of establishing and maintaining such capabilities could exceed the cost-effectiveness of doing so. In order to market any product for which we receive approval, we must build our sales, distribution, marketing, managerial and other non-technical capabilities, or alternatively make arrangements with third parties to obtain the requisite licenses and perform these services on our behalf.

We currently plan to commercialize our product candidates initially in the United States, Israel and Europe. If we receive regulatory approval in those jurisdictions to market our products, including the investigational product candidate, BST-236, we may build a focused sales, distribution and marketing infrastructure to market them. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including the ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities, or to obtain and maintain the requisite licenses, could delay product launches and adversely impact the commercialization of our product candidates.

In lieu of establishing our own sales, marketing and distribution capabilities ourselves, we could enter into arrangements with collaborative partners or other third parties. Any terms of these arrangements could be unfavorable to us, and we could be unable to enter into any arrangements at all. If we are unable to build our own sales force or negotiate a collaborative relationship with a third party, we could be forced to delay the potential commercialization of such products or reduce the scope of our sales or marketing activities. If we increase our expenditures to fund commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market or generate product revenue.

***We will require substantial additional capital to fund our operations. If we are unable to raise sufficient capital, we could be forced to delay, reduce or eliminate our product discovery, development programs or commercialization efforts.***

The development, marketing and commercialization of pharmaceutical products require a substantial amount of capital. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue ongoing Phase 2b clinical trials, seek marketing approval for our investigational product candidate, BST-236, as well as initiate new research and preclinical development efforts for any current and future product candidates. If we obtain marketing approval for BST-236, we could incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such capabilities are not the responsibility of a third party collaborator. In addition, after completion of the merger, we expect to incur substantial additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding to continue our operations, and any failure to receive a sufficient amount of funding will hinder our ability to effectively market and commercialize BST-236, as well as develop any new product candidates in the future.

We will be required to expend significant funds in order to advance the development of the product candidates in our pipeline, as well as other product candidates we may seek to develop. Biosight expects that its existing cash will be sufficient to fund our operating expenses and capital expenditure requirements through the middle of 2022. However, existing cash will not be sufficient to fund all of the efforts that we plan to undertake or to fund the completion of development of any of our product candidates. Even if we seek to enter into, and are successful in securing, collaborative agreements for development of product candidates, we do not expect to enter into agreements for every product. Accordingly, we will need to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements, among other sources. Adequate additional funding may not be available to us on acceptable terms or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or product candidates or one or more of our other research and development initiatives. Our failure to raise any necessary capital could have a negative impact on our financial condition and our ability to develop product candidates in line with our business strategy and product pipeline.

Because the length of time and the activities associated with our product candidates are highly uncertain, we cannot estimate the actual funds we will require for developing and the extent and costs of our marketing and commercialization efforts, if any. The estimates of what activities our existing cash will cover could prove to be inaccurate, and we could use our available capital resources sooner than we currently expect. We could also need additional funding sooner than we expect as a result of changing circumstances, some of which are beyond our control, which could cause us to consume capital significantly faster than we anticipate. Our future funding requirements, both short-term and long-term, will depend on many factors, including:

- the timing, progress, costs and results of clinical trials of our product candidates, including phase 3 clinical trials of BST-236;
- future clinical development plans we establish for our product candidates;
- the number and characteristics of product candidates that we develop or may in-license;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or any of our current or future product candidates;
- the effect of competing market developments;
- the cost and timing of completion of commercial-scale manufacturing activities;

- the cost of establishing sales, marketing and distribution capabilities for our products in regions where we choose to commercialize our products on our own; and

- the initiation, progress, timing and results of the commercialization of our product candidates, if approved for commercial sale.

***We have received and may receive in the future Israeli governmental grants to assist in the funding of our research and development activities.***

Through the date hereof, we had received an aggregate of $2.4 million in the form of grants from the Israel Innovation Authority, previously known as the Office of the Chief Scientist (the "IIA"). The requirements and restrictions for such grants are found in the Law for Encouragement of Industrial Research and Development—1984 (the "Research Law"). Under the Research Law, royalties of 3% to 3.5% on the revenues derived from sales of products or services developed in whole or in part using these IIA grants are payable to the Israeli government. We developed our investigational product candidate, BST-236, at least in part, with funds from these grants, and accordingly we would be obligated to pay these royalties on sales of any of our product candidates that achieve regulatory approval. The maximum aggregate royalties paid generally cannot exceed 100% of the grants made to us, plus annual interest equal to the 12-month LIBOR applicable to dollar deposits, as published on the first business day of each calendar year. As of June 30, 2021, we had not paid any royalties to the IIA.

***The Israeli government grants we have received for research and development expenditures restrict our ability to manufacture products and transfer technologies outside of Israel and require us to satisfy specified conditions. If we fail to satisfy these conditions, we may be required to refund grants previously received together with interest and penalties.***

Our research and development efforts have been financed, in part, through the grants that we have received from the IIA. Therefore, we must comply with the requirements of the Research Law. Under the Research Law, we are prohibited from manufacturing products developed using these grants outside of the State of Israel without special approvals. We may not receive the required approvals for any proposed transfer of manufacturing activities. Even if we do receive approval to manufacture products developed with government grants outside of Israel, the royalty rate may increase, and we may be required to pay up to 300% of the grant amounts plus interest, depending on the manufacturing volume that is performed outside of Israel. This restriction may impair our ability to outsource manufacturing or engage in our own manufacturing operations for those products or technologies.

Additionally, under the Research Law, we are prohibited from transferring, including by way of license, the IIA-financed technologies and related intellectual property rights and know-how outside of the State of Israel, except under limited circumstances and only with the approval of the IIA Research Committee. We may not receive the required approvals for any proposed transfer and, even if received, we may be required to pay the IIA a portion of the consideration that we receive upon any sale of such technology to a non-Israeli entity, up to 600% of the grant amounts plus interest. The scope of the support received, the royalties that we have already paid to the IIA, the amount of time that has elapsed between the date on which the know-how or the related intellectual property rights were transferred and the date on which the IIA grants were received, the sale price and the form of transaction will be taken into account in order to calculate the amount of the payment to the IIA. Approval of the transfer of technology to residents of the State of Israel is required, and may be granted only if the recipient abides by the provisions of applicable laws, including the restrictions on the transfer of know-how and the obligation to pay royalties. There is no assurance that approval of any such transfer, if requested, will be granted.

These restrictions may impair our ability to sell our technology assets, to perform or outsource manufacturing outside of Israel, to engage in change of control transactions or to otherwise transfer our know-how outside of Israel and may require us to obtain the approval of the IIA for certain actions and transactions and to pay additional royalties and other amounts to the IIA. In addition, any change of control and any change of ownership of our shares that would make a non-Israeli citizen or resident an "interested party," as defined in the Research Law (such as the change of ownership which will take place as a result of the merger contemplated herein) requires prior written notice to the IIA, and our failure to comply with this requirement could result in criminal liability. These restrictions will continue to apply even after we have repaid the full amount of royalties on the grants. If we fail to satisfy the conditions of the Research Law, we may be required to repay certain grants previously received together with interest and penalties, and may become subject to criminal charges.

***Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.***

We are highly dependent on principal members of our executive team listed under "Management" herein, including Dr. Ruth Ben Yakar, Biosight's current chief executive officer and a member of Biosight's Board until the closing of the merger completed herein, the loss of whose services may adversely impact the achievement of our objectives. Biosight and Dr. Ben Yakar have negotiated a separation agreement pursuant to which Dr. Ben Yakar shall resign from her position in Biosight and, effective as of the closing of the merger, Dr. Ben Yakar shall not act as a Board member or officer of Biosight. Biosight and Dr. Ben Yakar have agreed to the principal terms of the separation agreement, which have also been approved by Biosight's board of directors, subject to the approval of Biosight's shareholders, but the parties have not executed the separation agreement yet.

While we have entered into employment agreements with each of our executive officers, any of them could leave our employment at any time, as all of our employees are "at will" employees. Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense, and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. In addition, failure to succeed in pre-clinical studies or clinical trials may make it more challenging to recruit and retain qualified personnel. The inability to recruit or loss of the services of any executive, key employee, consultant or advisor may impede the progress of our research, development and commercialization objectives.

***Our employees, independent contractors, consultants, commercial partners, principal investigators, or CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.***

We are exposed to the risk of employee and third party fraud or other misconduct. Misconduct by employees, independent contractors, consultants, commercial partners, manufacturers, investigators, or contract research organizations ("CROs") could include intentional, reckless, negligent, or unintentional failures to comply with FDA regulations, comply with applicable fraud and abuse laws, provide accurate information to the FDA, properly calculate pricing information required by federal programs, comply with federal procurement rules or contract terms, report financial information or data accurately or disclose unauthorized activities to us. This misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter this type of misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Moreover, it is possible for a whistleblower to pursue a False Claims Act case against us even if the government considers the claim unmeritorious and declines to intervene, which could require us to incur costs defending against such a claim. Further, due to the risk that a judgment in an FCA case could result in exclusion from federal health programs or debarment from government contracts, whistleblower cases often result in large settlements. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, and results of operations, including the imposition of significant fines or other sanctions.

***Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.***

Our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we are not aware of any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

***We may be exposed to significant foreign exchange risk.***

We incur significant portions of our expenses, and may in the future derive revenue, in currencies other than the U.S. dollar, in particular, the euro and the Israeli Shekel. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. Any fluctuation in the exchange rate of these foreign currencies may negatively impact our business, financial condition and operating results. Global economic events, such as the COVID-19 pandemic, have and may continue to significantly impact local economies and the foreign exchange markets, which may increase the risks associated with sales denominated in foreign currencies. We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates. Therefore, for example, an increase in the value of the euro against the U.S. dollar could be expected to have a negative impact on our operating expenses as euro denominated expenses, if any, would be translated into U.S. dollars at an increased value. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows.

***Risks Related to the Discovery and Clinical Development of Our Product Candidates***

***Our business is heavily dependent on the successful development, regulatory approval and commercialization of our investigational product candidates, BST-236, ADXS-503 and ADXS-504.***

Currently, none of our product candidates has received approval for commercial sale. As a result, we were not able to develop a marketable product. We expect a substantial portion of our efforts and expenditures to be devoted to the continued clinical evaluation of BST-236 and its commercialization following regulatory approval, if received, as well as the development, manufacture, preclinical and clinical evaluation of any other product candidates. Therefore, our business depends significantly on the successful completion of clinical trials, regulatory approval and commercialization for BST-236, as well as any product candidates that we seek to develop in the future.

We cannot be certain that BST-236 or any of our future product candidates will receive regulatory approval or will be successfully commercialized even if they receive approval. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of our product candidates are, and will remain, subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, each of which has different regulations. We have not completed Phase 2b or any later-stage clinical trials for BST-236 and will not be permitted to market BST-236 or any other product candidate in the United States until we receive approval of a new drug application ("NDA"), or in any foreign country until we receive the requisite marketing approval or authorization. Even if we do receive regulatory approval to market BST-236 or any other product candidate, such approval could be subject to limitations on the indicated uses or patient for which we are able to market the product.

We have not submitted an NDA to the FDA or any comparable application to another regulatory authority in any other country. Obtaining approval of an NDA or similar regulatory approval is an extensive, lengthy, expensive and inherently uncertain process. The FDA or relevant foreign regulatory authority may delay, limit or deny approval of BST-236 or our *Lm*-LLO immunotherapies product candidates, including axalimogene filolisbac ("AXAL"), ADXS-PSA, ADXS-503, ADXS-504, ADXS-HER2 or any of our future product candidates for many reasons, including, but not limited to:

- our failure to demonstrate that our product candidates are safe or effective as a treatment for any of our currently targeted indications to the satisfaction of the relevant regulatory authority;

- requirements by the relevant regulatory authority for additional pre-approval studies or clinical trials;

- the results of our clinical trials do not meet the requisite level of statistical or clinical significance;
- disagreement by the relevant regulatory authority with the way we conduct our clinical trials;
- actions taken, or errors or breaches of protocols committed by, the CROs we retain to conduct clinical trials which are outside of our control and adversely impact our clinical trials and ability to obtain market approvals;
- findings by the relevant regulatory authority that the data from nonclinical studies or clinical trials is not sufficient to demonstrate that the benefits of our products outweigh any safety risks;
- disagreement by the relevant regulatory authority with our interpretation of data or significance of results from the nonclinical studies and clinical trials of any product candidate;
- refusal by the relevant regulatory authority to accept data generated from our clinical trial sites;
- if our NDA or other application is being reviewed by an advisory committee, any difficulties that may arise from scheduling an advisory committee meeting in a timely manner, as well the advisory committee's recommendations against approval or that the FDA or relevant regulatory authority require, as a condition for approval, additional nonclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- requirement to develop a risk evaluation and mitigation strategy ("REMS"), or its equivalent;
- requirements for additional post-marketing studies or a patient registry;
- findings that the chemistry, manufacturing and controls are insufficient to support the quality of our products;
- findings of deficiencies in the manufacturing processes or facilities of our manufacturers; or
- changes to the policies of, or the adoption of new regulations by, the relevant regulatory authority.

***Clinical studies required for our product candidates are expensive, time-consuming, difficult to design and implement and involve uncertain outcomes.***

Obtaining marketing approvals, both in the United States and abroad, is lengthy, time-consuming and expensive. It may take many years or more per study, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of our product candidates. To secure marketing approval, we must conduct preclinical and clinical trials and submit extensive data to the relevant regulatory authorities in order to establish the product candidate's safety and efficacy. We could experience delays in the commencement and rate of completion of clinical studies due to a number of factors, including, for example: the inability to manufacture sufficient quantities of stable and qualified materials under the relevant regulatory standards for use in clinical studies; slower than expected rates of patient recruitment and enrollment; modification of clinical study protocols; changes in regulatory requirements for clinical studies; the lack of effectiveness during clinical studies; the emergence of unforeseen safety issues; and government or regulatory delays which could require us to suspend or terminate the studies. For example, in June 2019, Advaxis announced that it was closing its AIM2CERV Phase 3 clinical trial with AXAL in cervical cancer due to the delays it incurred as a result of the recent FDA partial clinical hold on the trial, as well as the estimated cost and time to completion of the trial. This Phase 3 clinical trial with ADXS-HPV (AXAL) in cervical cancer was closed on June 11, 2021. Furthermore, Advaxis has completed the clinical study report from Part A of the ADXS-NEO study and closed the study and IND closure has been requested.

The results of any clinical studies we conduct are uncertain. In particular, the results we obtain from early clinical studies are not predictive of the results we will obtain in later clinical studies. It is also possible that clinical studies will fail to demonstrate the safety and effectiveness required to obtain the relevant regulatory approvals to market and commercialize our product candidates. Any failure to demonstrate safety and effectiveness could harm the development of that product candidate and others that we may develop in the future, particularly because it may cause us to abandon the development of that product candidate or significantly delay plans to develop other product candidates. Delaying or terminating our clinical studies will delay the filing of our NDAs, or their foreign equivalents, and will also hinder our ability to commercialize our product candidates and generate product revenues. In addition to the foregoing, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

***Enrollment and retention of patients in clinical trials could be made more difficult or rendered impossible by multiple factors that are outside our control.***

We have completed enrollment into our Phase 2b clinical trial for our investigational product candidate, BST-236, as a first-line, single-agent treatment for patients with AML, are currently enrolling patients into the Phase 2 trial sponsored by the Groupe Francophone des Myélodysplasies ("GFM"), and expect to enroll patients into additional clinical trials by the end of 2021. We could encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials. Even once we enroll patients, we could be unable to retain the number of patients necessary to complete any of our trials.

Our ability to enroll and retain patients in clinical trials depends on many factors, including: the size of the patient population; the nature of the trial protocol; the effectiveness of our patient recruitment efforts; delays in enrollment due to travel or quarantine policies, or other factors, related to COVID-19; the existing body of safety and efficacy data with respect to the study candidate; the perceived risks and benefits of cytarabine for the treatment of hematological diseases; the number and nature of competing existing treatments for our target indications, the number and nature of ongoing trials for other product candidates in development for our target markets; any pre-existing conditions in patients that preclude participation; the proximity of patients to clinical sites; and the eligibility criteria for the study.

Delays or failures in planned patient enrollment or retention may result in increased costs and program delays, which could have an adverse effect on our ability to develop our product candidates or could render further development impossible. In addition, we expect to rely on CROs and clinical trial sites to ensure that clinical trials are conducted under proper conditions, and, while we have entered into agreements governing their services, we will be limited in our ability to control their actual performance.

***Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials.***

The outcome of preclinical studies and early clinical trials are not always predictive of the success of later clinical trials, and interim results of clinical trials do not necessarily predict success in the results of completed clinical trials. For example, even though our Phase 1/2a and Phase 2 clinical trials provided promising data that our investigational product candidate, BST-236, has safe and effective qualities in the treatment of AML, these results may not be indicative of any results we achieve in future randomized Phase 3 clinical trials that may be conducted with a different patient pool.

Preclinical and clinical data are susceptible to varying interpretations and analyses. Even if we, or any collaborators, believe that the results of clinical trials for our product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities could disagree and reject marketing approval. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and the rate of dropout among clinical trial participants. If we fail to receive positive results in clinical trials, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects would be negatively impacted.

***The results of clinical trials conducted at clinical trial sites outside the United States might not be accepted by the FDA, and data developed outside of a foreign jurisdiction similarly might not be accepted by such foreign regulatory authority.***

Some of the clinical trials for our product candidates that are being or will be conducted through our partnerships and collaborations may be conducted outside the United States, and we intend in the future to conduct additional clinical trials outside the United States. Although the FDA, EMA or comparable foreign regulatory authorities may accept data from clinical trials conducted outside the relevant jurisdiction, acceptance of these data is subject to certain conditions. For example, the FDA requires that the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles such as institutional review board ("IRB") or ethics committee approval and informed consent, the trial population must adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, acceptance of the data by the FDA will be dependent upon its determination that the trials were conducted consistent with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the United States as adequate support of a marketing application. Similarly, we must also ensure that any data submitted to foreign regulatory authorities adheres to their standards and requirements for clinical trials and there can be no assurance a comparable foreign regulatory authority would accept data from trials conducted outside of its jurisdiction.

***Because the target patient populations for many of the product candidates we may develop are small, we must be able to successfully identify patients and achieve a significant market share to achieve and maintain profitability and growth.***

BST-236 seeks to address a highly unmet need by developing therapeutic products for rare, oncology and hematological illnesses among a small subset of affected patients. We focus our research and product development on treatments for diseases such as, but not limited to, AML, acute lymphoblastic leukemia ("ALL"), and MDS. We have also conducted clinical studies of *Lm* Technology immunotherapies in non-small cell lung cancer and other solid tumor types, prostate cancer and HPV-associated cancers.

Our investigational product candidate, BST-236, targets elderly patients, who are more likely to develop these diseases, or patients who cannot tolerate the high levels of toxicity associated with standard chemotherapy commonly used to treat these conditions. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with the product candidates we may develop, are based on estimates. These estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence of these diseases. The number of patients in the United States, Israel, Europe and elsewhere may turn out to be lower than expected. In addition, patients may not be amenable to treatment with our products, or may become increasingly difficult to identify or gain access to. If the market opportunities for any product candidates we may develop are smaller than we believe they are, our revenues, if any, may be adversely affected, and our ability to locate and enroll eligible patients, conduct clinical trials and perform other necessary requirements needed for marketing and commercialization approval may suffer.

In addition, cancer therapies are sometimes characterized as first-line, second-line, or third-line, and the FDA often approves new therapies initially only for third-line use. When cancer is detected early enough, first-line therapy, usually chemotherapy, hormone therapy, surgery, radiation therapy, immunotherapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. We are seeking approval of our investigational product candidate, BST-236, for patients who have received one or more prior treatments. If BST-236 proves to be sufficiently beneficial, we would expect to seek approval potentially as a first-line therapy, but there is no guarantee that product candidates we develop, even if approved, would be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials. Even if we obtain a significant market share for BST-236, or any other product candidate and the potential target populations are small, we could fail to achieve profitability without obtaining marketing approval for additional indications, including use as first- or second-line therapy.

***We may not be successful in our efforts to identify, discover or maintain certain rights to additional product candidates.***

Although we intend to explore other therapeutic opportunities in addition to our investigational product candidate, BST-236, as well as our other current product candidates such as AXAL, ADXS-PSA, ADXS-503 and ADXS-504, we could fail to identify additional product candidates for clinical development for several reasons. For example, our research methodology could be unsuccessful in identifying potential product candidates. In addition, any product candidates we identify could have harmful side effects that make them unmarketable or unlikely to receive regulatory approval. Additional product candidates will require additional, time-consuming development efforts prior to commercialization, including preclinical studies, clinical trials and approval by the relevant regulatory authorities. Moreover, all product candidates are prone to risks of failure that are inherent in therapeutic product development, and our failure to successfully identify, develop, market and commercialize product candidates in the future will adversely affect our ability to grow our business and generate product revenue.

Additionally, we could be required to relinquish valuable or beneficial rights to product candidates in connection with collaborative agreements we enter into with third parties to develop and commercialize our product candidates in the United States, Israel, Europe or other countries or territories of the world. For instance, since July 2020 we have been working with the French Study Group of the European Myelodysplastic Syndrome Cooperative Group, led by GFM, to continue our research and development efforts of BST-236. In our collaboration with GFM and any future collaboration with another third party in the future, we can expect to lose some or all of the control over the future success of that product candidate to the third party.

***The commercial success of any current or future product candidate will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.***

We are currently investigating BST-236 as a single-agent, first-line treatment in a Phase 2b clinical study, and aim to launch a Phase 3 trial and submit our NDA application to the FDA and seek marketing approval from other regulatory authorities by 2024. In addition, we closed the Phase 1/2 study with ADXS-PSA ± pembrolizumab in metastatic castration resistant prostate cancer patients on January 25, 2021. The MEDI Phase 2 combo study (AZ) with AXAL ± durvalumab in Cervical and Head and Neck Cancer and the AIM2CERV Phase 3 clinical trial with ADXS-HPV (AXAL) in cervical cancer were closed August 22, 2019 and June 11, 2021, respectively. The study with personalized neoantigen-directed therapies (ADXS-NEO) was closed on May 22, 2020 and the NEO program-IND inactivation request was submitted to FDA on May 10, 2021.

Accordingly, we have never commercialized a product, and even if we obtain any regulatory approval for BST-236 or other product candidates, their commercial success will depend in part on the medical community, patients and third-party payors accepting them as effective, safe and cost-effective. Any product that we bring to the market could fail to gain market acceptance by those in the medical community. For instance, physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Patients could acclimate to the therapies that they are currently taking and do not want to switch unless their physicians recommend doing so or they are required to switch therapies due to lack of reimbursement for existing therapies. If approved for commercial sale by the FDA and other relevant regulatory authorities, the degree to which the medical community and other stakeholders accept BST-236 and other product candidates we develop will depend on, among other factors:

- the potential efficacy and potential advantages over alternative treatments;
- the frequency and severity of any side effects, including limitations or warnings contained in the product's approved labeling, or side effects resulting from follow-up requirements for the administration of our products;
- the relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe them;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments; and
- sufficient third-party insurance coverage and adequate reimbursement.

Even if a product candidate displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product, if approved for commercial sale, will not be known until after it is launched. For example, initial Phase 1/2a clinical trials for BST-236 indicate that the treatment is safe and well-tolerated amongst the patients in our target population who are older adults or those not fit for intensive chemotherapy. Our efforts to educate the medical community and third-party payors on these benefits of BST-236, or any of the product candidates we may develop in the future, will likely require significant resources and their success is uncertain. If we are unable to receive an adequate level of acceptability for BST-236 and any other product candidates, we could be unable to generate significant product revenue and become profitable.

***We could expend our limited resources to pursue a product candidate and fail to capitalize on other product candidates that are more profitable or for which there is a greater likelihood of success.***

We have limited financial and managerial resources and intend to focus on developing product candidates for specific indications that we identify as most likely to succeed, in terms of both their potential for marketing approval and commercialization. Currently, we are prioritizing the development of BST-236, our investigational product candidate that seeks to treat patients with AML and other related hematological malignancies and who are older and susceptible to experiencing severe side effects associated with standard chemotherapy, or who have already responded poorly to prior chemotherapy treatments. In prioritizing our efforts on BST-236, we could forego or delay pursuing opportunities with other product candidates or for other indications that could prove to have greater potential for commercialization. Additionally, our resource allocation decisions could cause us to fail to capitalize on viable commercial products or profitable market opportunities. The spending decisions we do choose to make with respect to research and development programs could fail to yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we could relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements.

***Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of its product candidates in other jurisdictions.***

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, the EMA or comparable foreign regulatory authorities must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

***Risks Related to the Marketing and Other Regulatory Approval of Our Product Candidates***

***If we are not able to obtain required regulatory approvals, or if we or our third-party collaborators fail to comply with the requisite regulatory requirements, we will not be able to commercialize our product candidates and generate product revenue.***

We have not received approval from any regulatory authority to market our product candidates in any jurisdiction. We are currently conducting Phase 2b clinical trials in the United States and Israel for our investigational product candidate, BST-236, and plan to launch a Phase 3 study in 2022, and expect to submit an NDA to the FDA for accelerated market approval by 2024, provided we can demonstrate that BST-236 provides a clinical benefit at the time of submission. We cannot make the necessary submissions to seek regulatory approvals unless and until we successfully complete pivotal clinical trials that indicate the safety and efficacy of the treatment. It is possible that BST-236, or any other product candidates we may develop in the future, will never obtain the appropriate regulatory approvals necessary for us to commence product sales as anticipated.

Our activities in connection with developing and commercializing our product candidates, such as the design, research, testing, manufacture, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation in the United States and abroad, including the FDA, the EMA and similar foreign regulatory authorities. We, or the third-party CROs with whom we expect to rely on and collaborate, cannot successfully commercialize our product candidates if we do not obtain marketing approval from these regulators or fail to comply with the requisite regulatory requirements on an ongoing basis. Securing marketing approval requires that we submit extensive nonclinical and clinical data and supporting information for our product candidates for each therapeutic indication to establish safety and efficacy of the product candidate for that indication. We must also submit information about the product manufacturing process to, and arrange for the inspection of manufacturing facilities by, the relevant regulatory authorities. Delays or errors in the submission of applications for marketing approval or issues, including those related to gathering the appropriate data and the inspection process, will ultimately delay or affect our ability to obtain regulatory approval, commercialize our product candidates and generate product revenue.

***Even if we obtain marketing approval for our product candidates in one jurisdiction, we may never obtain marketing approval for them in any other jurisdiction, which would limit our ability to realize their full market potential.***

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

We and any third-party collaborators, our CROs and contract manufacturers must establish and comply with numerous and varying regulatory requirements on a country-by-country basis in order to market our product candidates in any particular jurisdiction. Regulatory approval in one country does not guarantee regulatory approval in any other country. As part of the regulatory approval process in certain jurisdictions, we must conduct preclinical and clinical trials of our product candidates to prove their safety and efficacy. However, the preclinical or clinical trials that we conduct in one country will not necessarily be accepted by regulatory authorities in other countries. In addition, the approval processes vary by country and can involve additional product testing and validation, as well as prolonged administrative review periods. Seeking foreign regulatory approval could result in difficulties and extraneous costs, such as, for example, requirements to conduct additional nonclinical or clinical trials above and beyond the studies we have already performed. The variation of regulatory approval requirements in different countries could delay or prevent us from introducing our product candidates in those countries. We are currently conducting Phase 2b clinical trials in the United States and Israel for our investigational product candidate, BST-236 and plan to launch a Phase 3 study in 2022, and expect to submit an NDA to the FDA for accelerated market approval by 2024, provided we can demonstrate that BST-236 provides a clinical benefit at the time of submission. If the FDA approves our NDA and permits us to market BST-236 in the United States, any such approval will not ensure that regulatory authorities in other countries or jurisdictions will provide similar approval.

We do not currently have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

***Our current and future relationships with healthcare providers, customers and third-party payors could be subject to fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Members of the medical community, such as healthcare providers and physicians, as well as patients and third-party payors, will play a primary role in recommending BST-236 or any other product candidates for which we obtain marketing approval, if any. Any relationships that we enter into with healthcare providers, patients and third-party payors could expose us to fraud and abuse and other healthcare laws and regulations. These requirements could constrain the arrangements and relationships that we use to market, sell and distribute BST-236 or any product candidates for which we obtain marketing approval. In the United States, where we intend to seek marketing approval of BST-236, we will face restrictions under applicable federal and state healthcare laws and regulations, including the following:

- the Anti-Kickback Statute, which prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- the federal civil and criminal false claims laws (including the False Claims Act, which is enforceable by civil whistleblower or qui tam actions on behalf of the government), and the civil monetary penalties law, which prohibit individuals or entities from knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal government program, or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing a money obligation to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, which impose criminal and civil liability for executing schemes to defraud any healthcare benefit program and impose obligations with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

- the federal transparency requirements under the Affordable Care Act, (the "ACA"), as amended by the Health Care and Education Reconciliation Act of 2010, which requires manufacturers of drugs, devices, biologics and medical supplies to report information related to physician payments and other transfers of value and ownership and investment interests held by physicians and their immediate family members; and

- analogous state laws and regulations, which apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance regulations promulgated by the federal government and may require drug manufacturers to report information relating to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing. State and local laws require the registration of pharmaceutical sales and medical representatives. State and non-United States laws also govern the privacy and security of health information in some circumstances, and can differ from each other in significant ways and complicate compliance efforts.

We will likely incur substantial costs by taking efforts to ensure that our arrangements with healthcare providers, patients and third-party payors will comply with applicable healthcare laws and regulations so that we can ensure that we obtain and maintain marketing approval. It is possible that governmental authorities, both in the United States or in any foreign country or territory where we conduct business, will conclude that our business practices do not comply with current or future fraud and abuse or other healthcare laws and regulations. If government authorities determine that our operations violate any of the requirements that apply to us, we could lose or fail to obtain marketing approval for our product candidate.

We could also be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs (such as, in the United States, Medicare and Medicaid and other federal healthcare programs), contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our business and results of operations. If any of the healthcare providers, physicians or entities with whom we expect to do business is found to be not in compliance with applicable laws, they could be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which could have a material adverse effect on our business and results of operations. Even the mere issuance of a subpoena or the fact of an investigation alone, regardless of the merit, may lead to negative publicity, a drop in our share price, and other harms to our business.

***Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.***

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval.

For example, in March 2010, the ACA was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The law has continued the downward pressure on pharmaceutical pricing, especially under the Medicare program, and increased the industry's regulatory burdens and operating costs. Among the provisions of the ACA of importance to our product candidates are the following:

- an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer point-of-sale discounts of 70% off negotiated prices of applicable brand drugs to eligible beneficiaries under their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs in certain states;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a licensure framework for follow on biologic products;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There remain judicial, Congressional, and other challenges to certain aspects of the ACA. In January 2017, the former President of the United States signed Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA's "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax.

Further, the Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In addition, the federal government eliminated federal cost-sharing reduction ("CSR") payments to insurance companies. The loss of such federal CSR payments has resulted in increased premiums on certain policies issued by qualified health plans under the ACA. Moreover, in December 2018, the U.S. Centers for Medicare and Medicaid Services, or CMS, published a new final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On April 27, 2020, the United States Supreme Court reversed a Federal Circuit decision that previously upheld Congress' denial of $12 billion in "risk corridor" funding. On December 14, 2018, a United States District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act of 2017, the remaining provisions of the ACA are invalid as well. In December 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and our business. The ACA is likely to continue the downward pressure on pharmaceutical pricing and may also increase our regulatory burdens and operating costs. We continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This included further reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act ("CARES Act"), which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period in which the government may recover overpayments to providers from three to five years.

Further, there have been several recent United States Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the out-of-pocket cost of prescription drugs and reform government program reimbursement methodologies for drugs. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to pharmaceutical product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the current administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the United States presidential administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases.

Additionally, on May 11, 2018, the then President of the United States laid out his administration's "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" to reduce the cost of prescription drugs while preserving innovation and cures. The Department of Health and Human Services has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Congress and the United States presidential administration under President Trump each indicated that they would continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Additionally, on July 24, 2020, then President Trump announced four executive orders related to prescription drug pricing that attempt to implement several of the Trump administration proposals, including (i) a policy that would tie certain Medicare Part B drug prices to international drug prices, or the "most favored nation price," the details of which were released on September 13, 2020 and also expanded the policy to cover certain Part D drugs; (ii) an order that directs HHS to finalize the Canadian drug importation proposed rule previously issued by HHS and makes other changes allowing for personal importation of drugs from Canada; (iii) an order that directs HHS to finalize the rulemaking process on modifying the Anti-Kickback Statute safe harbors for discounts for plans, pharmacies, and pharmaceutical benefit managers; and (iv) a policy that reduces costs of insulin and EpiPen's to patients of federally qualified health centers. The FDA also recently released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, whether the current regulations, guidance or interpretations will be changed, or what the impact of such changes on our business, if any, may be. In addition, increased scrutiny by the United States Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. In addition, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

***The FDA has granted BST-236, AXAL and ADXS-HER2 fast track designations. Any such designation or grant of priority review status by the FDA or comparable foreign regulatory authority does not guarantee a faster development, regulatory review or approval process and will not assure approval of our product candidates.***

Fast track designation by the FDA, or an equivalent designation by a comparable foreign authority, will not always lead to accelerated approval of a product candidate, or approval at all. The FDA will grant a product candidate with fast track designation, or designate it for priority review, if it determines that the product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness. Such designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Additionally, even if we do receive a priority review designation, it does not result in expedited development and does not necessarily result in an expedited regulatory review or approval process. Moreover, such designation does not necessarily confer any advantage with respect to approval compared to conventional FDA procedures. The FDA may also withdraw the designation if it believes that the designation is no longer supported by data from our clinical development program.

In July 2020, the FDA granted our investigational product candidate, BST-236, with fast track designation for the treatment of patients with AML who are unfit for standard chemotherapy. As a result, we intend to submit an NDA to the FDA for marketing approval of BST-236 on an accelerated timeline, following the completion of our Phase 2b clinical trials in 2022. The FDA has also granted Fast Track Designation for AXAL for adjuvant therapy for high-risk locally advanced cervical cancer patients, and has granted Fast Track Designation for ADXS-HER2 for patients with newly-diagnosed, non-metastatic, surgically-respectable osteosarcoma. We could request priority review for any other product candidates we are developing or that we will develop in the future. Even though we have received fast track designation for BST-236, there is no guarantee that the FDA will approve our NDA at all, or within the six-month review cycle after we submit the NDA.

***BST-236, AXAL and ADXS-HER2 have received orphan drug designations by the FDA and orphan medicinal product designation by the EMA. There is no guarantee that we will be able to maintain these designations, receive these designations for any of our other product candidates, or receive or maintain any corresponding benefits, including periods of exclusivity.***

Product candidates that receive orphan drug designations by the FDA or orphan drug medicinal product designations by the EMA are entitled to certain benefits, including, for example, tax credits, reduced fees and clinical trial assistance. Additionally, if a product candidate with either designation subsequently receives marketing approval before another product that the FDA or the EMA considers to be the same product for the same indication, the product candidate can receive a period of marketing exclusivity. The marketing exclusivity period precludes the FDA or the EMA from approving another marketing application for the same product for the same indication for a specified time period. The applicable periods are seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a product candidate no longer meets the criteria for orphan drug medicinal product designation, or if the product is sufficiently profitable such that market exclusivity is no longer justified.

We received orphan drug designation from the FDA in May 2019, and orphan medicinal product designation from the EMA in November 2020 for our investigational product candidate, BST-236. In addition, the FDA has granted orphan drug designation for AXAL for use in the treatment of anal cancer, HPV-associated head and neck cancer, Stage II-IV invasive cervical cancer and for ADXS-HER2 for the treatment of osteosarcoma in the United States, as well as EMA orphan drug designation for AXAL for the treatment of anal cancer and for ADXS-HER2 for the treatment of osteosarcoma in the EU. However, we cannot guarantee that we will obtain any orphan drug designations or orphan drug medicinal product designations for any future product candidates. In addition, orphan drug designation and orphan drug medicinal product designation by the FDA and the EMA, respectively, neither shorten the development time or regulatory review time of a product candidate, nor provide a product candidate with any advantage in the regulatory review or approval process. Therefore, even with these designations, we cannot guarantee that we will be able to successfully develop BST-236 or any other product candidates, or that we will be able to maintain any orphan drug or orphan drug medicinal product designations we have already received. For instance, the FDA may revoke its orphan drug designation if the FDA finds that the request for designation contained an untrue statement of material fact or omitted material information, or if the FDA finds that the product candidate was not eligible for designation at the time of the submission of the request.

Even if we maintain our orphan drug and orphan drug medicinal product designations, we may not receive any period of regulatory exclusivity if BST-236 or any other product candidate is approved. Any exclusivity period that we receive for BST-236, or any other product candidates, could not effectively protect us from competition. Even if we obtain exclusivity, the FDA could subsequently approve another product containing the same principal molecular features for the same condition if the FDA concludes that the later drug is clinically superior to ours in that it is shown to be safer, more effective or makes a major contribution to patient care. A competitor also may receive approval of different products for the same indication for which our orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Moreover, we may not be able to maintain our orphan drug designation or exclusivity and our product candidates would not be eligible for exclusivity if the approved indication is broader than the orphan drug designation. For example, it is possible that product candidates will still be approved either for the same condition that BST-236 seeks to treat, such as AML, or which are the same products as BST-236 but seek to treat different conditions.

In addition, the European exclusivity period is ten years but can be reduced to six years if the drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

***Our product candidates could become subject to unfavorable pricing regulations, third-party payor reimbursement practices or healthcare reform initiatives that could harm our ability to successfully commercialize our product candidates.***

Our ability to commercialize our investigational product candidate, BST-236, or any other product candidates, will depend substantially on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities (such as, in the United States, Medicare and Medicaid), private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our products. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish and maintain pricing sufficient to realize meaningful revenue.

Government authorities and third-party payors decide which medications they will cover and establish reimbursement levels. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, and could view our products as not being cost-effective. As a result, coverage and reimbursement could be unavailable to our customers, or be insufficient to allow our products to be competitively marketed. If the prices for our products, if any, decrease or if governmental and other third-party payors do not provide adequate coverage or reimbursement, our prospects for revenue and profitability will suffer.

There is also significant uncertainty related to third-party payor coverage and reimbursement of newly-approved product candidates because pricing and reimbursement for new product candidates vary widely by country. Some countries require approval of the sale price of a product candidate before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. In addition, increasingly, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. We cannot be sure that coverage will be available for any product candidate that we may commercialize and, if available, that the reimbursement rates will be adequate.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates, once approved. Patients are unlikely to use our product candidates, once approved, unless coverage is provided and reimbursement is adequate

There could also be delays in obtaining coverage and reimbursement for newly approved drugs, and coverage can be more limited than the indications for which the drug is approved by the FDA or comparable foreign regulatory authorities. Even if our products are eligible for reimbursement, such eligibility does not imply that they will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Reimbursement rates can vary, for example, according to the use of the drug and the clinical setting in which it is used, or can in some cases be based on reimbursement levels that have already been set for lower-cost drugs. As a result, we could obtain marketing approval for a product in a particular country, but then be subject to reimbursement delays that prolong the commercial launch of the product, possibly for lengthy time periods, which can negatively impact product revenues we are able to generate from sales in that country.

**Risks Related to Our Dependence on Third Parties**

***We depend on third-party collaborators to develop and conduct clinical trials with, obtain regulatory approvals for, and if approved, market and sell product candidates.***

For our current investigational product candidate, BST-236, we depend on our third-party collaborator, GFM, to conduct a clinical trial in Europe. We may in the future form additional collaborations and may depend on other third-parties to develop, conduct clinical trials of, and, if approved, commercialize that product candidate. Our current and any future collaborations that we enter into are subject to numerous risks, including the following:

- collaborators have significant discretion in determining the efforts and resources they apply to collaborations;
- collaborators could fail to perform their obligations or fulfill their responsibilities in a timely manner;
- collaborators could fail to develop or commercialize our product candidates that achieve regulatory approval or may elect not to continue or renew such programs based on trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition;
- collaborators could delay preclinical studies or clinical trials, provide insufficient funding for clinical trials, stop a preclinical study or clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- we do not always have access to, or could be restricted from disclosing, certain information about our product candidates under a collaboration and, in such cases, would have limited information to relay to our shareholders about the status of such product candidates;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under more economically attractive terms than ours;
- collaborations do not always result in product candidates that we can develop or market, and preclinical studies or clinical trials that we conduct as part of the collaborations will not always be successful;
- collaborators stop commercializing our product candidates if they view the product candidates we develop with them as competing with their own product candidates;
- collaborators with marketing and distribution rights to any of our product candidates that achieve regulatory approval could refuse to commit sufficient resources to the marketing and distribution of that product; and
- collaborators could fail to properly maintain or defend our patent and intellectual property rights and could use such information in a way that exposes us to litigation or jeopardizes or invalidates our intellectual property.

In addition, certain collaboration agreements provide our collaborators with rights to terminate such agreements, which rights may or may not be subject to conditions, and, if exercised, would adversely affect our product development efforts and make it difficult for us to attract new collaborators. Our rights to recover tangible and intangible assets and intellectual property rights needed to advance a product candidate or product after termination of a collaboration are, in some cases, limited by contract, in those cases we would not be able to advance a program post-termination. If a collaborator terminates its agreement with us, we would likely be required to limit the size and scope of efforts for the development and commercialization of such product candidates or products or be required to seek additional financing to fund further development or identify alternative strategic collaborations. Moreover, our potential to generate future revenue from such product candidates would be significantly reduced.

***We intend to rely on third parties to manufacture product candidates, which increases the risk that we will not have sufficient quantities of such product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.***

We will depend on third-party manufacturers to supply our clinical materials. We do not own or operate manufacturing facilities for the production of clinical or commercial supplies of our investigational product candidate, BST-236. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We rely on third parties for the supply of our product candidates, and our strategy is to outsource all manufacturing of our product candidates to third parties. We use contract manufacturing operations in the United States and Europe to supply the requisite doses of BST-236 for our ongoing, Phase 2b clinical studies in the United States, Israel and Europe.

In order to conduct clinical trials of product candidates, including for BST-236, we need to have them manufactured in potentially large quantities. Our contract manufacturing organizations may be unable to successfully increase the manufacturing capacity for BST-236 or any of our current and future product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities and at any other time. For example, ongoing data on the stability of our product candidates may shorten the expiry of our product candidates and lead to clinical trial material supply shortages, and potentially clinical trial delays. In addition, there could be solubility and stability issues in the manufacturing of BST-236. We had issues in the past relating to the solubility and stability of BST-236, which led to modification in the manufacturing of the active pharmaceutical ingredient ("API"), drug product, and the formulation. These issues may occur again. If these contract manufacturers are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of that product candidate may be delayed or not obtained, which could significantly harm our business and results of operations.

If we hire new contract manufacturers, we increase the risk that we will experience delays in production or receive insufficient supplies of our product candidates, because we will be required to transfer our manufacturing technology to these manufacturers and allow them to gain experience manufacturing our product candidates. Even after gaining such experience, there can be no assurance that a contract manufacturer will produce sufficient quantities of our product candidates in a timely manner or continuously over time, or at all. In addition, if any of our contract manufacturers should cease to continue producing our product candidates, we will likely experience delays in advancing our preclinical and clinical studies while we seek replacement manufacturers. We may be unable to obtain replacement supplies on terms that are favorable to us, or else be unable to obtain adequate supplies of our product candidates.

We contract with licensed pharmaceutical manufacturers which are compliant with the FDA's current good manufacturing practices ("cGMP"). While we have engaged several third-party vendors to provide clinical and non-clinical supplies and fill-finish services, we do not currently have any agreements with third-party manufacturers for long-term commercial supplies. In the future, we may fail to enter into agreements with third-party manufacturers for commercial supplies of any product candidate that we develop, or may be unable to do so on acceptable terms. Even if we are able to establish and maintain arrangements with third-party manufacturers, our reliance on them entails risks, including:

- reliance on third parties for manufacturing process development, regulatory compliance and quality assurance;
- limitations on supply availability resulting from capacity and scheduling constraints of third parties;
- breach of manufacturing agreements by third parties due to factors beyond our control; and
- termination or non-renewal of the manufacturing agreements by the third party, at a time that is costly or inconvenient to us.

Contract manufacturers may not be able to comply with cGMP requirements or similar regulatory requirements outside of the United States. Our failure, or the failure of our contract manufacturers, to comply with applicable requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and/or criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates.

In addition to the cGMP requirements, the production and manufacturing of BST-236 require our contract manufacturers to handle toxic or hazardous substances. In order to handle toxic or hazardous substances, our contract manufacturers may need to obtain certifications and meet other regulatory requirements.

BST-236 and any current or future product candidates that we develop will likely compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP requirements that are capable of manufacturing for us and our products. Our current and anticipated future dependence upon third parties for the manufacture of our product candidates may adversely affect our future profit margins, our ability to develop product candidates and our success in commercializing product candidates that receive marketing approval.

***Risks Related to Legal and Compliance Requirements***

***Our operations and product candidates are subject to extensive and costly government regulation in the United States and abroad.***

We and our third party collaborators, including our CROs and contract manufacturing organizations, are subject to extensive government regulation in the United States, Israel, Europe and various other countries or territories. In the United States, we and our third-party collaborators are subject to regulatory oversight by federal authorities, such the FDA, CMS, other divisions of the United States Department of Health and Human Services, the United States Department of Justice, as well as state and local governments. In Europe, we are subject to regulatory oversight by the EMA and its various regulatory networks, including the European Commission through the Centralized Procedure, the National Competent Authority. We are also subject to the respective equivalents of these authorities in any foreign country or territory where we or our third-party collaborators research and develop product candidates, conduct clinical trials and seek to market and commercialize our products. Such foreign regulation may be equally or more demanding than corresponding United States regulation.

Government regulation substantially increases the cost and risk of researching, developing, manufacturing, marketing and commercializing of our product candidates. The regulatory review and approval process, which includes preclinical and nonclinical testing and clinical studies of each product candidate, is lengthy, expensive and uncertain. We and our collaborators, if any, must obtain and maintain regulatory authorization to conduct clinical studies and must

obtain regulatory approval for each product that we intend to market. In addition, the facilities that we or our collaborators use to manufacture our product candidates must be inspected and meet legal requirements. In order to secure regulatory approval, we must submit extensive preclinical, nonclinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish the product's safety and efficacy. The development and approval process takes many years, requires substantial resources and may never lead to the approval of a product.

If we, our collaborators, or the contract manufacturers upon which we rely fail to comply with applicable regulatory requirements at any stage during the regulatory oversight or approval process, such noncompliance could result in various penalties or consequences, including: delays in, or refusal by the relevant regulatory agency to review, the approval of applications or supplements to approved applications; warning letters; fines; import or export restrictions; product recalls or seizures; injunctions or suspensions of manufacturing; withdrawals of previously-approved marketing applications or licenses; recommendations by the relevant regulatory authorities against our ability to enter into governmental contracts; civil penalties; and criminal prosecutions.

In addition, any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and comparable foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and good clinical practice requirements for any clinical trials that we conduct post-approval.

Even if we successfully obtain regulatory approval for a particular product candidate, such approval could limit the indicated medical uses for the product, otherwise limit our ability to promote, sell and distribute the product, require that we conduct costly post-marketing surveillance, and require that we conduct ongoing, post-marketing studies. We could be required to undergo additional regulatory review and approval if we make changes to an approved product, such as, for example, by making formulation or manufacturing changes or revising our labeling of the product. Even if we receive regulatory approval for our product candidate, the relevant regulatory authority can withdraw its approval, such as, for example, if there is a later discovery of previously unknown problems or safety issues with the product.

The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by the FDA or suspension or revocation of license approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The policies of the FDA, EMA and comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we have obtained and we may not achieve or sustain profitability.

***We are subject to extensive environmental, health and safety laws and regulations and our failure to comply with these requirements could subject us to substantial fines, penalties, or costs.***

We and the CROs, contract manufacturers and other third parties with which we collaborate are subject to numerous environmental, health and safety laws and regulations in the United States, Israel, Europe and the jurisdictions where we operate. These requirements include, but are not limited to, those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations, particularly the development, formulation and testing of our product candidates, involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent over time. We cannot predict how and the extent to which such changes will impact our ability to operate, develop product candidates and conduct clinical trials, and cannot be certain of our future compliance.

In addition, we could incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

***We face potential product liability claims that, if successful, would subject us to substantial liability and costs, as well as potential revocation or other negative impacts to any regulatory approvals we receive.***

The use of our product candidates in clinical trials and the sale of any product candidate for which we obtain marketing approval expose us to the inherent risk of product liability claims, and we will face an even greater risk if the approved products are sold commercially. We may receive product liability claims from patients, healthcare providers, pharmaceutical companies or other third parties that sell or otherwise come into contact with our products. In addition, our investigational product candidate, BST-236, or any other product candidates we are developing now or in the future, may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. Product liability claims, regardless of their merit or eventual outcome, may result in the following:

- decreased demand for our products;
- impairment to our business reputation;
- withdrawal of clinical trial participants;
- substantial monetary awards to patients or other claimants;
- costs due to related litigation;
- distraction of management’s attention from our primary business;
- loss of revenues;
- the inability to commercialize our product candidates, in particular, BST-236; and
- decreased demand for BST-236 or any other product candidates we develop, if approved for commercial sale.

Patients with the diseases that our investigational product candidate, BST-236, targets, including AML, ALL and MDS, are often already in severe and advanced stages of their disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. For example, our target population for BST-236 includes older adults who are more susceptible to extreme side effects, including bone marrow suppression and infections, as well as adults whose medical conditions preclude their ability to handle the highly toxic effects of standard chemotherapy. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to BST-236 or any other product candidates we are developing now or may develop in the future. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our product candidates, the investigation into the circumstances may be expensive, time-consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval process or impact and limit the type of regulatory approvals our product candidates receive or maintain. A product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

We have acquired product liability insurance coverage, which includes coverage for human clinical trials, in Israel and in the US for our Phase 1/2a and Phase 2b studies, for BST-236; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage each time we commercialize an additional product; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business. Further, we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

***Risks Related to Our Intellectual Property***

***If we are unable to obtain and maintain patent and other intellectual property protection for our product candidates, or if the scope of protection obtained is not sufficiently broad, we could be unable to compete effectively in our markets.***

Our ability to compete effectively will depend, in part, on our ability to maintain the proprietary nature of the formulations, technology and manufacturing processes of the product candidates we are currently developing and will develop in the future. We rely on patents to establish our intellectual property rights and protect our product candidates. These legal means, however, afford only limited protection and may not adequately protect our rights. In certain situations and as considered appropriate, we have sought, and we intend to continue to seek to protect our proprietary position by filing patent applications in the United States and one or more countries outside the United States relating to current and future product candidates that are important to our business.

As of July 30, 2021, Biosight's intellectual property portfolio consisted of 49 Patents/Patent Applications. Biosight currently owns all of its intellectual property. Biosight has filed patent applications in Australia, Brazil, Canada, China, Europe, France, Germany, India, Israel, Italy, Japan, Korea, Netherlands, Russia, Switzerland, United Kingdom, and the United States for Biosight's investigational product candidate, BST-236. Biosight has filed patent applications in the US, EU, Israel, Australia, Brazil, Russia, India, Canada, China, Japan and Korea and intends to file additional applications in the US, EU, Israel, Australia, Brazil, Russia, India, Canada, China, Japan and Korea. Biosight's patents in Australia, Europe, France, Germany, India, Israel, Italy, Netherlands, Russia, Switzerland, United Kingdom, and the United States have been granted, and Biosight's patents in Australia, Brazil, Canada, China, Europe, Israel, Japan, Korea, and the United States remain pending. In addition, Advaxis owns or has the rights to several hundred patents and applications, which are owned, licensed from, or co-owned with Penn and Merck. Advaxis has obtained the rights to all future patent applications in this field originating in the laboratories of Dr. Yvonne Paterson and Dr. Fred Frankel, at Penn. However, we cannot predict whether these applications and others we pursue will issue as patents, or whether the claims of any resulting patents will give us a competitive advantage or whether we will be able to successfully pursue patent applications in the future.

The patent application and approval process is expensive and time-consuming. We could fail to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We or any of our current and future third-party collaborators could fail to identify patentable aspects of inventions before it is too late to obtain patent protection on them. In such cases, we will miss potential opportunities to seek additional patent protection. It is possible that defects of form in the preparation or filing of patent applications could exist, such as, for example, with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we fail to establish, maintain or protect patents and other intellectual property rights, they could be reduced or eliminated. If there are material defects in the form, preparation, prosecution or enforcement of our patents or patent applications, they could be invalid or unenforceable. Even if unchallenged, our patents and patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims. For example, a third party could develop a competitive therapy that provides benefits similar to BST-236 but that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue are not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected.

Other parties and competitors, many of whom have greater resources and have made significant investments in advanced technologies, have developed or plan to develop product candidates that are competitive with ours. These parties could file patent applications with claims that overlap or conflict with our applications, such as by claiming the same compositions, formulations or methods or by claiming subject matter. Our competitors could also seek to market generic versions of any approved products by submitting NDAs to the FDA in which they claim that our patents are invalid, unenforceable or not infringed. In these circumstances, we could be required to defend or assert our patents by filing lawsuits alleging patent infringement. A court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not protect us from competitive product candidates.

The patent position of biotechnology companies is highly uncertain. In the United States and many foreign jurisdictions, there is no consistent policy regarding the breadth of claims allowed for biotechnology patents. In addition, determining patent rights for biotechnology and pharmaceutical compounds commonly involves complex legal and factual questions, which have, in recent years, been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. As a result, any patents we obtain may not provide us with patent protection sufficient to exclude others from commercializing product candidates similar to ours.

In the future, we and third parties may collaborate to in-license one or more of our product candidates. In some cases, the availability and scope of potential patent protection is limited based on prior decisions by our licensors or the inventors, such as decisions on when or whether to file patent applications. Our failure to obtain, maintain, enforce or defend such intellectual property rights, for any reason, could allow third parties to make competing products or impact our ability to develop, manufacture and market our products and product candidates, even if approved, on a commercially viable basis, if at all, which could have a material adverse effect on our business.

In addition to patent protection, we expect to rely on research, manufacturing and other know-how, trade secrets, license agreements and contractual provisions, many of which are difficult to protect. We seek protection in part by entering into confidentiality agreements with third parties who have access to proprietary information, but we cannot be certain that these agreements will not be breached, adequate remedies for any breach would be available, or our information will not otherwise become known to or be independently developed by our competitors. If we cannot protect our intellectual property rights, our product sales could suffer and we could fail to generate sufficient product revenue.

***We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.***

We also rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

***Some of the products developed by Advaxis are dependent upon a license agreement with Penn; if we breach the license agreement and/or fail to make payments due and owing to Penn under the license agreement, our development may be materially and adversely affected.***

Pursuant to the terms of Advaxis' license agreement with Penn, which has been amended from time to time, Advaxis has acquired exclusive worldwide licenses for patents and patent applications related to its proprietary Listeria vaccine technology. The license provides Advaxis with the exclusive commercial rights to the patent portfolio developed at Penn as of the effective date of the license, in connection with Dr. Paterson and requires Advaxis to pay various milestone, legal, filing and licensing payments to commercialize the technology. As of October 31, 2020, Advaxis did not have outstanding payables to Penn. We can provide no assurance that we will be able to make all future payments due and owing thereunder, that such licenses will not be terminated or expire during critical periods, that we will be able to obtain licenses from Penn for other rights that may be important to us, or, if obtained, that such licenses will be obtained on commercially reasonable terms. The loss of any current or future licenses from Penn or the exclusivity rights provided therein could materially harm our business, financial condition and operating results.

***If we are unable to obtain licenses needed for product candidates developed by Advaxis, or if we breach any of the agreements under which Advaxis has licensed rights to patents or other intellectual property from third parties, we could lose license rights that are important to our business.***

If we are unable to maintain and/or obtain licenses needed for the development of product candidates developed by Advaxis in the future, we may have to develop alternatives to avoid infringing on the patents of others, potentially causing increased costs and delays in drug development and introduction or precluding the development, manufacture, or sale of planned products. Some of the licenses that Advaxis has obtained provide for limited periods of exclusivity that require minimum license fees and payments and/or may be extended only with the consent of the licensor. We can provide no assurance that we will be able to meet these minimum license fees in the future or that these third parties will grant extensions on any or all such licenses. This same restriction may be contained in licenses obtained in the future.

Additionally, we can provide no assurance that the patents underlying any licenses will be valid and enforceable. To the extent any products developed by Advaxis are based on licensed technology, royalty payments on the licenses will reduce our gross profit from such product sales and may render the sales of such products uneconomical. In addition, the loss of any current or future licenses or the exclusivity rights provided therein could materially harm our business, financial condition and its operations.

***Obtaining and maintaining patent protection depends on our ability to comply with various requirements of governmental patent agencies and, in some cases, receiving patent term extensions.***

We are required to comply with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued in the United States and the foreign jurisdictions where we seek patent rights. For example, we are required to pay periodic maintenance fees, renewal fees, annuity fees and various other governmental fees to the United States Patent and Trademark Office (the "USPTO") in the United States, as well as foreign governmental patent agencies, in several stages over the lifetime of the patents and applications. Our failure to comply can result in abandonment or lapse of the patent or patent application, which will result in partial or complete loss of patent rights in the relevant jurisdiction. In addition, the terms of any licenses we may enter into in the future may not give us the ability to maintain or prosecute patents in the portfolio, and in such cases, we will have to rely on third parties to prosecute on our behalf.

In some cases, we will seek to maintain our patent protection by extending the term of our issued patents. Patents and the protection they afford have a limited lifespan. For example, in the United States, if we timely pay all maintenance fees, the natural expiration of a patent is generally 20 years from its earliest United States non-provisional filing date. Once the life of any patent issued for a product candidate expires, that product candidate will become susceptible to competition from similar products, or products that seek to treat the same conditions. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents could expire before or shortly after we begin to commercialize those products, and in such cases, we will be unable to exclude our competitors from commercializing products similar or identical to ours.

Any issued patents covering BST-236 or our current and future product candidates could be eligible for limited patent extension in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. The remaining term of a patent cannot be extended beyond a total of 14 years from the date of product approval, and can only be extended once and based on a single approved product. We could fail to receive an extension if we do not satisfy applicable requirements, including, for example, if we fail to: obtain a granted patent before approval of a product candidate; exercise due diligence during the testing phase or regulatory review process; apply within applicable deadlines; or apply prior to expiration of relevant patents. Moreover, the time period or the scope of patent protection we are afforded, if any, could be less than we request. If we do not obtain patent term extension or the term is less than we request, our competitors could obtain approval of competing product candidates following our patent expiration, and the competitiveness of our products could be significantly reduced. The expiration of our owned or licensed patents before completing the research and development of our product candidates and receiving all required approvals in order to sell and distribute the products on a commercial scale can adversely affect our business and results of operations.

***We may not be able to protect our intellectual property rights throughout the world.***

Biosight has filed patent applications in multiple jurisdictions, including Australia, Brazil, Canada, China, Europe, India, Japan, Israel, Russia and the United States, as well as under the Patent Cooperation Treaty. Biosight has been issued five patents in United States, two in Europe and one in each of Australia, India, Israel and Russia. The requirements for patentability differ in certain countries, thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover our products or protect our patent rights to the same extent as other countries where we seek protection. Consequently, we may not be able to prevent third parties, including competitors from producing our products in all countries or from selling or importing products made using our formulations in and into the United States or foreign jurisdictions. These products may compete with our product candidates and our intellectual property rights may not be effective or sufficient to prevent them from competing.

We could also encounter problems protecting and defending our intellectual property rights in foreign jurisdictions. The legal systems of certain countries do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop infringement or violation of our intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. We could be unsuccessful in proceedings to enforce our intellectual property rights. Even if obtained, protection of such rights could result in substantial costs, divert our management's efforts and attention from other aspects of our business or development of other product candidates, put our patents at risk of being invalidated or interpreted narrowly, put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage.

***We could be required to protect or enforce our patents and other intellectual property rights, which could be expensive, time-consuming and, if unsuccessful, put our products at a competitive disadvantage.***

Competitors may infringe on the patents or other intellectual property we hold in connection with our product candidates. To protect or enforce our proprietary rights, we may file infringement claims, which can be expensive, time-consuming and divert the time and attention of our management and scientific personnel. Our patents could also become involved in inventorship, priority or validity disputes. To counter or defend against such claims is also expensive and time-consuming, and our adversaries could be able to dedicate substantially greater resources to prosecuting these legal actions than we can. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us, alleging that we infringe their patents and that our patents are invalid, unenforceable or both.

If a court in an infringement proceeding decides that our patent is invalid or unenforceable, or refuses to stop the other party from using the product at issue, we would be unable to prevent that party or others from infringing on or misappropriating the proprietary rights we own or control. An adverse result in any proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Intellectual property litigation also requires a substantial amount of discovery, which increases the risk that some of our confidential information could be disclosed and compromised. Even if intellectual property litigation is resolved in our favor, a court could decide not to grant an injunction against further infringing activity and instead award only monetary damages, which is not always an adequate remedy. We could incur substantial expenses from defending our intellectual property rights in litigation or related proceedings. In addition, there could be public announcements of the results of such proceedings, which could lead to a decline in the price of our ordinary shares if securities analysts or investors perceive the results to be negative, could substantially increase our operating losses, reduce the resources available for development, future sales, marketing or distribution of our product candidates and negatively impact our ability to successfully compete in our target market. In addition, proceedings involving our patents or patent applications or those of others could result in adverse decisions regarding:

- the patentability of our inventions relating to our product candidates; and/or

- the enforceability, validity or scope of protection offered by our patents relating to our product candidates.

***We could be sued for infringing the intellectual property rights of third parties, which could be costly and disrupt our efforts to develop or commercialize our product candidates.***

Third parties could have issued United States and foreign patents and pending patent applications relating to compounds, methods of manufacturing compounds or methods of use for the treatment of the diseases for which we are developing our own product candidates. While we aim to develop, manufacture, market and sell our product candidates without infringing the intellectual property and other proprietary rights of third parties, we may become party to, or threatened with, such claims by way of litigation or other adversarial proceedings, including interference and post-grant proceedings before the USPTO.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, the outcome of which is subject to uncertainties that cannot be adequately quantified in advance. The scope of protection afforded by a patent is subject to interpretation by the courts, which is not always uniform. Moreover, in defending ourselves in a patent infringement claim, we would have to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, which would be very difficult. Even if we are successful in these proceedings, we could incur substantial costs and may not have sufficient resources to bring these actions to a successful conclusion. Any involvement in infringement proceedings could cause management and scientific personnel to divert their time and resources away from other, critical business and the development of our product candidates.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate. We could also be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. We cannot guarantee that a license will be available on commercially reasonable terms, or at all. A license could be non-exclusive, giving our competitors access to the same technologies licensed to us, or could include terms that impede or destroy our ability to compete successfully in our target markets. Finally, we could be found liable for substantial monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of liability for infringement or misappropriating confidential information or trade secrets could prevent us from commercializing our product candidates or force us to cease some of our business operations.

***Conditions in Israel could materially and adversely affect our business.***

Most of Biosight's employees operate from our offices that are located in near Tel Aviv, Israel. Accordingly, political, economic, and military conditions in Israel and the surrounding region may directly affect our business and operations. In recent years, Israel has been engaged in sporadic armed conflicts with Hamas, an Islamist terrorist group that controls the Gaza Strip, with Hezbollah, an Islamist terrorist group that controls large portions of southern Lebanon, and with Iranian-backed military forces in Syria. In addition, Iran has threatened to attack Israel and may be developing nuclear weapons. Some of these hostilities were accompanied by missiles being fired from the Gaza Strip against civilian targets in various parts of Israel, including areas in which our employees are located, and negatively affected business conditions in Israel. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its trading partners could adversely affect the development of our business.

Biosight's commercial insurance does not cover losses that may occur as a result of events associated with war and terrorism. Although the Israeli government currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained or that it will sufficiently cover our potential damages. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflicts or political instability in the region would likely negatively affect business conditions and could harm our results of operations.

Further, in the past, the State of Israel and Israeli companies have been subjected to economic boycotts. Several countries still restrict business with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our results of operations, financial condition or the expansion of our business. A campaign of boycotts, divestment, and sanctions has been undertaken against Israel, which could also adversely affect our business. Actual or perceived political instability in Israel or any negative changes in the political environment, may individually or in the aggregate adversely affect the Israeli economy and, in turn, our business, financial condition, results of operations, and prospects.

In addition, many Israeli citizens are obligated to perform several weeks of annual military reserve duty each year until they reach the age of 40 (or older, for reservists who are military officers or who have certain occupations) and, in the event of a military conflict, may be called to active duty. In response to increases in terrorist activity, there have been periods of significant call-ups of military reservists. It is possible that there will be military reserve duty call-ups in the future. Our operations could be disrupted by such call-ups, which may include the call-up of members of our management. Such disruption could materially adversely affect our business, prospects, financial condition, and results of operations.

## CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This proxy statement/prospectus/information statement contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding future financial condition, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “anticipate,” “believe,” “continue,” “could,” “design,” “estimate,” “expect,” “intend,” “may,” “plan,” “potentially,” “predict,” “seek,” “should,” “will” or the negative of these terms or other similar expressions.

All statements other than statements of historical fact are statements that could be deemed forward-looking statements. For example, forward-looking statements include any statements of the plans, strategies and objectives of management for future operations, including the execution of integration and restructuring plans and the anticipated timing of filings; any statements concerning proposed new products, services or developments; any statements regarding future economic conditions or performance; statements of belief and any statement of assumptions underlying any of the foregoing. Forward-looking statements may also include any statements of the plans, strategies and objectives of management with respect to the approval and consummation of the merger, Advaxis’ ability to solicit a sufficient number of proxies to approve the merger and other matters related to the consummation of the merger.

For a discussion of the factors that may cause Advaxis, Biosight or the combined organization’s actual results, performance or achievements to differ materially from any future results, performance or achievements expressed or implied in such forward-looking statements, or for a discussion of risk associated with the ability of Advaxis and Biosight to complete the merger and the effect of the merger on the business of Advaxis, Biosight and the combined organization, see the section titled “*Risk Factors*” in this proxy statement/prospectus/information statement.

These forward-looking statements include, but are not limited to, statements concerning the following:

- the expected benefits of and potential value created by the merger for the stockholders of Advaxis and Biosight;
- likelihood of the satisfaction of certain conditions to the completion of the merger and whether and when the merger will be consummated;
- Advaxis’ ability to control and correctly estimate its operating expenses and its expenses associated with the merger;
- any statements of the plans, strategies and objectives of management for future operations, including the execution of integration plans and the anticipated timing of filings;
- any statements of plans to develop and commercialize products;
- any statements concerning the attraction and retention of highly qualified personnel;
- any statements concerning the ability to protect and enhance the combined organization’s products, product candidates and intellectual property;
- any statements regarding expectations concerning Biosight’s relationships and actions with third parties; and
- future regulatory, judicial and legislative changes in Biosight’s industry.

You should not rely upon forward-looking statements as predictions of future events. Neither Advaxis nor Biosight can assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur. In addition, statements that "we believe" and similar statements reflect the beliefs and opinions on the relevant subject of Advaxis, Biosight or the combined organization, as applicable. These statements are based upon information available as of the date of this prospectus, and while Advaxis, Biosight or the combined organization, as applicable, believes such information forms a reasonable basis for such statements, such information may be limited or incomplete.

Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation, the risk that the conditions to the closing are not satisfied, including the failure to timely, or at all, obtain stockholder approval for the merger; uncertainties as to the timing of the consummation of the merger; risks related to Advaxis' ability to correctly estimate its operating expenses and its expenses associated with the merger; the ability of Advaxis, Biosight or the combined organization to protect its intellectual property rights; competitive responses to the merger; unexpected costs, charges or expenses resulting from the merger; potential adverse reactions or changes to business relationships resulting from the announcement or completion of the merger; and legislative, regulatory, political and economic developments. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere.

If any of these risks or uncertainties materializes or any of these assumptions proves incorrect, the results of Advaxis, Biosight or the combined organization could differ materially from the forward-looking statements. All forward-looking statements in this proxy statement/prospectus/information statement are current only as of the date on which the statements were made. Advaxis and Biosight do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any statement is made or to reflect the occurrence of unanticipated events, except as otherwise required by the federal securities laws.

## THE SPECIAL MEETING OF ADVAXIS STOCKHOLDERS

### Date, Time and Place

The Advaxis special meeting will be held on November 16, 2021, commencing at 10:00 a.m. Eastern Time, unless postponed or adjourned to a later date. The Advaxis special meeting will be held entirely online. Advaxis is sending this proxy statement/prospectus/information statement to its stockholders in connection with the solicitation of proxies by Advaxis' board of directors for use at the Advaxis special meeting and any adjournments or postponements of the Advaxis special meeting. This proxy statement/prospectus/information statement is first being furnished to Advaxis stockholders on or about _____, 2021.

### Purposes of the Advaxis Special Meeting

The purposes of the Advaxis special meeting are:

1. To approve the issuance of shares of common stock of Advaxis, Inc., or Advaxis, to stockholders of Biosight Ltd., or Biosight, pursuant to the terms of the Agreement and Plan of Merger and Reorganization among Advaxis, Biosight and Advaxis Ltd., or Merger Sub, dated as of July 4, 2021, a copy of which is attached as *Annex A* to this proxy statement/prospectus/information statement, and the change of control resulting from the merger;

2. To approve an amendment to the amended and restated certificate of incorporation, as amended, of Advaxis to effect a reverse stock split of Advaxis' issued and outstanding common stock within a range, as determined by the Advaxis board of directors and agreed to by Biosight, of one new share of Advaxis common stock for every 10 to 30 shares (or any number in between) of outstanding Advaxis common stock in the form attached as *Annex E* to this proxy statement/prospectus/information statement;

3. To approve an amendment to the amended and restated certificate of incorporation of Advaxis to change the corporate name from Advaxis, Inc. to "Biosight Therapeutics Inc." in the form attached as *Annex F* to this proxy statement/prospectus/information statement;

4. To approve, on a nonbinding, advisory basis, the compensation that will or may become payable by Advaxis to its named executive officers in connection with the merger;

5. To consider and vote upon an adjournment of the Advaxis special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposal Nos. 1, 2 and 3; and

6. To transact such other business as may properly come before the stockholders at the Advaxis special meeting or any adjournment or postponement thereof.

Proposal No. 1 is referred to herein as the merger proposal. Proposal No. 2 is referred to herein as the reverse stock split proposal. Proposal No. 3 is referred to herein as the certificate of incorporation amendment proposal. The approval of the merger proposal, the reverse stock split proposal and the certificate of incorporation amendment proposal are all conditions to the completion of the merger. The issuance of Advaxis common stock in connection with the merger and the change of control resulting from the merger, or Proposal No. 1, and the amendment to the amended and restated certificate of incorporation of Advaxis, as amended, to change the corporate name from Advaxis, Inc. to "Biosight Therapeutics Inc.," or Proposal No. 3, will not take place unless they are approved by Advaxis stockholders and the merger is consummated.

**Recommendation of Advaxis' Board of Directors**

- Advaxis' board of directors has determined and believes that the issuance of shares of Advaxis' common stock pursuant to the Merger Agreement is fair to, in the best interests of, and advisable to, Advaxis and its stockholders and has approved such issuance. Advaxis' board of directors unanimously recommends that Advaxis stockholders vote "FOR" Proposal No. 1 to approve the issuance of shares of Advaxis common stock pursuant to the Merger Agreement and the change of control resulting from the merger.

- Advaxis' board of directors has determined and believes that it is fair to, in the best interests of, and advisable to, Advaxis and its stockholders to approve the amendment to the amended and restated certificate of incorporation of Advaxis to effect the reverse stock split of Advaxis common stock, as described in this proxy statement/prospectus/information statement. Advaxis' board of directors unanimously recommends that Advaxis stockholders vote "FOR" Proposal No. 2 to approve the reverse stock split of Advaxis common stock.

- Advaxis' board of directors has determined and believes that it is fair to, in the best interests of, and advisable to, Advaxis and its stockholders to approve the amendment to the amended and restated certificate of incorporation of Advaxis as amended to change the corporate name from Advaxis, Inc. to "Biosight Therapeutics Inc.," as described in this proxy statement/prospectus/information statement. Advaxis' board of directors unanimously recommends that Advaxis stockholders vote "FOR" Proposal No. 3 to change the corporate name from Advaxis, Inc. to "Biosight Therapeutics Inc."

- Advaxis' board of directors has determined and believes that it is fair to, in the best interests of, and advisable to, Advaxis and its stockholders to approve, on a nonbinding advisory vote basis, compensation that will or may become payable by Advaxis to its named executive officers in connection with the merger. Advaxis' board of directors unanimously recommends that Advaxis stockholders vote "FOR" Proposal No. 4.

- Advaxis' board of directors has determined and believes that adjourning the Advaxis special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposal Nos. 1, 2 and 3 is fair to, in the best interests of, and advisable to, Advaxis and its stockholders and has approved and adopted the proposal. Advaxis' board of directors unanimously recommends that Advaxis stockholders vote "FOR" Proposal No. 5 to adjourn the Advaxis special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposal Nos. 1, 2 and 3.

**Record Date and Voting Power**

Only holders of record of Advaxis common stock at the close of business on the record date September 17, 2021, are entitled to notice of, and to vote at, the Advaxis special meeting. At the close of business on the record date, there were registered holders of record of Advaxis common stock and there were _____ shares of Advaxis common stock issued and outstanding. Each share of Advaxis common stock entitles the holder thereof to one vote on each matter submitted for stockholder approval.

**Voting and Revocation of Proxies**

The proxy accompanying this proxy statement/prospectus/information statement is solicited on behalf of Advaxis' board of directors for use at the Advaxis special meeting.

If, as of the record date referred to above, your shares were registered directly in your name with the transfer agent for Advaxis common stock, Continental Stock Transfer and Trust Company, then you are a stockholder of record. Whether or not you plan to attend the Advaxis special meeting online, Advaxis urges you to fill out and return the proxy card or vote by proxy over the telephone or on the internet as instructed below to ensure your vote is counted.

The procedures for voting are as follows:

If you are a stockholder of record, you may vote at the Advaxis special meeting. Alternatively, you may vote by proxy by using the accompanying proxy card, over the internet or by telephone. Whether or not you plan to attend the Advaxis special meeting, Advaxis encourages you to vote by proxy to ensure your vote is counted. Even if you have submitted a proxy before the Advaxis special meeting, you may still attend the Advaxis special meeting and vote during the virtual meeting. In such case, your previously submitted proxy will be disregarded.

- To vote at the Advaxis special meeting, attend the Advaxis special meeting online and follow the instructions posted at www.virtualshareholdermeeting.com/ADXS2021SM.

- To vote using the proxy card, simply complete, sign and date the accompanying proxy card and return it promptly in the envelope provided. If you return your signed proxy card before the Advaxis special meeting, Advaxis will vote your shares in accordance with the proxy card.

- To vote by proxy over the internet, follow the instructions provided on the Notice of Internet Availability.

- To vote by telephone, you may vote by proxy by calling the toll-free number found on the Notice of Internet Availability.

If you are a beneficial owner of shares registered in the name of your broker, bank or other agent, you should have received a voting instruction card and voting instructions with these proxy materials from that organization rather than from us. Simply complete and mail the voting instruction card to ensure that your vote is counted. To vote in person at the Advaxis special meeting, you must obtain a valid proxy from your broker, bank or other agent. Follow the instructions from your broker, bank or other agent included with these proxy materials, or contact your broker, bank or other agent to request a proxy.

Advaxis provides internet proxy voting to allow you to vote your shares online, with procedures designed to ensure the authenticity and correctness of your proxy vote instructions. However, please be aware that you must bear any costs associated with your internet access, such as usage charges from internet access providers and telephone companies.

If you do not give instructions to your broker, your broker can not vote your Advaxis shares during the Special Meeting for anything besides Proposal Nos. 2 and 3 because all the other proposals are considered “non-discretionary,” non-routine items.

All properly executed proxies that are not revoked will be voted at the Advaxis special meeting and at any adjournments or postponements of the Advaxis special meeting in accordance with the instructions contained in the proxy. **If a holder of Advaxis common stock executes and returns a proxy and does not specify otherwise, the shares represented by that proxy will be voted “FOR” all of the proposals in accordance with the recommendation of Advaxis’ board of directors.**

If you are a stockholder of record of Advaxis and you have not executed a support agreement, you may change your vote at any time before your proxy is voted at the Advaxis special meeting in any one of the following ways:

- You may submit another properly completed proxy with a later date by mail or via the internet.

- You can provide your proxy instructions via telephone at a later date.

- You may send a written notice that you are revoking your proxy to Advaxis, Inc., 9 Deer Park Drive, Suite K-1, Monmouth Junction, New Jersey 08852, Attention: Igor Gitelman, VP of Finance and Chief Accounting Officer.

- You may attend the Advaxis special meeting online and vote by following the instructions at www.virtualshareholdermeeting.com/ADXS2021SM. Simply attending the Advaxis special meeting will not, by itself, revoke your proxy.

If your shares are held by your broker, bank or other agent, you should follow the instructions provided by them.

**Required Vote**

The affirmative vote of the holders of a majority of shares present in person or represented by proxy at the Advaxis special meeting and entitled to vote on the subject matter, assuming a quorum is present, is required for approval of Proposal Nos. 4 and 5. The affirmative vote of the holders of a majority of the outstanding shares of Advaxis common stock entitled to vote thereon is required for approval of Proposal Nos. 1, 2 and 3. Proposal No. 1 is referred to herein as the merger proposal. Proposal No. 2 is referred to herein as the reverse stock split proposal. Proposal No. 3 is referred to herein as the certificate of incorporation amendment proposal. The approval of the merger proposal, the reverse stock split proposal and the certificate of incorporation amendment proposal are all conditions to the completion of the merger. The issuance of Advaxis common stock in connection with the merger and the change of control resulting from the merger, or Proposal No. 1, and the amendment to the amended and restated certificate of incorporation of Advaxis, as amended, to change the corporate name from Advaxis, Inc. to "Biosight Therapeutics Inc.," or Proposal No. 3, will not take place unless they are approved by Advaxis stockholders and the merger is consummated.

Votes will be counted by the inspector of election appointed for the meeting, who will separately count "FOR" and "AGAINST" votes, abstentions and broker non-votes. Abstentions and broker non-votes will also be treated as shares present for the purpose of determining the presence of a quorum for the transaction of business at the special meeting. Abstentions will be counted toward the vote totals for each proposal, and will have the same effect as "AGAINST" votes. Broker non-votes will not be treated as votes cast for or against a proposal and accordingly will not have any effect with respect to the outcome of Proposal Nos. 1, 4 and 5, and will have the same effect as "AGAINST" votes for Proposal Nos. 2 and 3.

As of July 31, 2021, the directors and certain executive officers of Advaxis owned or controlled less than 1% of the outstanding shares of Advaxis common stock entitled to vote at the Advaxis special meeting. As of July 31, 2021, the Advaxis stockholders that are party to a support agreement, including the directors and certain executive officers of Advaxis, owned an aggregate of 70,715 shares of Advaxis common stock representing less than 1% of the outstanding shares of Advaxis common stock. Each stockholder that entered into a support agreement, including the directors and certain executive officers of Advaxis, has agreed to vote all shares of Advaxis common stock owned by him or her as of the record date in favor of Proposal Nos. 1, 2, and 3, and against any competing "Acquisition Proposal" (as defined in the Merger Agreement).

**Solicitation of Proxies**

In addition to solicitation by mail, the directors, officers, employees and agents of Advaxis may solicit proxies from Advaxis stockholders by personal interview, telephone, email, fax or otherwise. Advaxis and Biosight will share equally the costs of printing and filing this proxy statement/prospectus/information statement and proxy card. Arrangements will also be made with brokerage firms and other custodians, nominees and fiduciaries who are record holders of Advaxis common stock for the forwarding of solicitation materials to the beneficial owners of Advaxis common stock. Advaxis will reimburse these brokers, custodians, nominees and fiduciaries for the reasonable out-of-pocket expenses they incur in connection with the forwarding of solicitation materials. Advaxis has retained Kingsdale Advisors to assist it in soliciting proxies using the means referred to above. Advaxis will pay the fees of Kingsdale Advisors, which Advaxis expects to be approximately $250,000, plus reimbursement of out-of-pocket expenses.

**Other Matters**

As of the date of this proxy statement/prospectus/information statement, Advaxis' board of directors does not know of any business to be presented at the Advaxis special meeting other than as set forth in the notice accompanying this proxy statement/prospectus/information statement. If any other matters should properly come before the Advaxis special meeting, it is intended that the shares represented by proxies will be voted with respect to such matters in accordance with the judgment of the persons voting the proxies.

## THE MERGER

*This section and the section titled "The Merger Agreement" beginning on page 107 of this proxy statement/prospectus/information statement describe the material aspects of the merger and the Merger Agreement. While Advaxis and Biosight believe that this description covers the material terms of the merger and the Merger Agreement, it may not contain all of the information that is important to you. You should read carefully this entire proxy statement/prospectus/information statement for a more complete understanding of the merger and the Merger Agreement and the other documents to which you are referred in this proxy statement/prospectus/information statement. See the section titled "Where You Can Find More Information" beginning on page 238 of this proxy statement/prospectus/information statement.*

**Background of the Merger**

Advaxis' board of directors and executive management regularly review Advaxis' operating and strategic plans, both near-term and long-term, as well as potential partnerships in an effort to enhance stockholder value. These reviews and discussions focus, among other things, on the opportunities and risks associated with Advaxis' business and financial condition and strategic relationships, and due to the capital-intensive nature of its business of developing and commercializing products, also on methods to increase capital in order to advance and strengthen its business and mitigate risks, and, consequently, enhance stockholder value. In furtherance of this endeavor, Advaxis has periodically considered various strategic alternatives, which have included licensing or acquiring rights to product candidates, divesting certain product candidates, equity financings (including potential PIPE transactions), debt financings, and acquisitions of, or mergers with, other companies with other technologies, products, or product candidates.

In 2018, the Advaxis board of directors conducted a review of strategic options and its product pipeline. In connection with such review, Advaxis streamlined its pipeline to focus on the highest value opportunities and continued its pursuit of opportunities to monetize its drug candidates that target human papilloma virus and prostate specific antigens.

In early January, 2019, Advaxis entered into a Finder's Agreement with a financial advisor to facilitate introductions between Advaxis and potential investors and strategic partners. In February, 2019, Advaxis engaged another financial advisor ("Financial Advisor A") with experience in the biotech field, knowledge of the life sciences industry, and familiarity with Advaxis, to initiate a formal strategic process and provide transaction advisory services, with broad direction to find ways to enhance Advaxis' product portfolio through in-licensing and potential M&A transactions.

Over the next 12 months, Advaxis management and Financial Advisor A corresponded with more than 200 potential transaction counterparties on a broad variety of transaction types, including potential M&A, in-licensing and out-licensing transactions. Various strategic alternatives were discussed, over 20 nondisclosure agreements were entered into, and certain due diligence information was exchanged with certain of the potential counterparties.

On June 27, 2019, Advaxis announced by press release the increased focus on neoantigen-directed immunotherapies and closure of the AIM2CERV Phase 3 clinical trial with axalimogene filolisbac (AXAL) in high-risk locally advanced cervical cancer. The study was terminated early due to resource and funding constraints, and Advaxis would continue to pursue monetization opportunities for AXAL.

On October 11, 2019, management notified the Advaxis board of directors that discussions were progressing regarding a potential PIPE transaction with a potential strategic counterparty ("Party A"), which had been previously discussed with the board, and was expected to lead to a proposal.

On October 28, 2019 a letter of intent was provided by Party A contemplating an initial PIPE investment followed by a subsequent stock based business combination transaction between Advaxis and Party A with an ownership ratio to be discussed as part of future discussions. The draft letter of intent was not executed by Party A and Advaxis, and in furtherance of its need for additional capital, Advaxis continued to advance discussions regarding the PIPE investment.

On November 11, 2019, Party A provided Advaxis with an initial draft of a Securities Purchase Agreement relating to the potential PIPE investment for review while discussions continued between Party A and Advaxis regarding a potential business combination transaction.

From December 13 to December 15, 2019, members of Advaxis management met socially with members of management of Party A in Luxembourg. On the last day of the meetings, a potential business combination transaction was discussed generally by members of management of each of Party A and Advaxis, although the parties did not discuss any specific terms.

On December 18, 2019, following additional discussions between Party A and Advaxis, a revised draft of the Securities Purchase Agreement was received from Party A.

At the December 19, 2019 meeting of the Advaxis board of directors, the board discussed recent strategic activities, including the potential PIPE investment by Party A, and the board received updates about recent discussions with multiple potential transaction counterparties, all of which were preliminary in nature. The board authorized Advaxis management to execute a revised letter of intent with Party A, providing for a merger between Advaxis and Party A, or a subsidiary of Party A, with Party A's stockholders owning 90% of the combined company and Advaxis' stockholders owning 10% of the combined company. The letter of intent also provided that upon signing of the definitive agreement, Party A would make, or cause to be made, a $10 million or $15 million investment in Advaxis in the form of a PIPE, a debt investment or other mutually agreeable form.

On December 25, 2019, Advaxis received a final, signed letter of intent from Party A, and on December 26, 2019 Advaxis signed and returned the fully executed letter of intent to Party A, which provided for Party A's stockholders owning 90% of the combined company, Advaxis' stockholders owning 10% of the combined company, and Party A making a $10 million or $15 million investment in Advaxis in the form of a PIPE, a debt investment or other mutually agreeable form upon signing of a definitive agreement. Over the following weeks, the parties began exchanging due diligence information.

At the January 17, 2020 meeting of the Advaxis board of directors, the board decided to terminate the letter of intent with Party A and authorized Advaxis to consummate a registered offering and private placement of up to $11 million in shares of its common stock and a private placement of warrants to purchase shares of common stock in an amount of up to half of the number of shares issued in the registered offering.

On January 16, 2020, a potential counterparty ("Party B") tendered a letter of intent for the license of ADXS-504 (HOT Prostate) and ADVAXIS-PSA. A nondisclosure agreement was signed on January 21, 2020 and access was provided to Advaxis' due diligence information. Advaxis and Party B conducted a few in person meetings among members of management but no additional definitive transaction terms were agreed to between Advaxis and Party B and the letter of intent was not executed by Advaxis.

On January 19, 2020, Advaxis terminated the letter of intent with Party A in order to proceed with an alternative financing transaction (further described below) as instructed by the board.

On January 21, 2020, Advaxis announced the pricing of a $10.5 million registered direct offering and that Advaxis had entered into a definitive agreement with two institutional investors for the purchase and sale of 10,000,000 shares of common stock at an offering price of $1.05 per share, for gross proceeds of $10.5 million before expenses. The net proceeds were intended to fund research and development initiatives in the product pipeline, including the Advaxis HOT program and potential new studies for Advaxis-PSA, and for general corporate purposes.

From February 2019 to February 2020, in accordance with its engagement, Financial Advisor A conducted a broad search and initiated outreach to identify and evaluate prospects for potential strategic alliances, mergers and acquisitions, and other business combinations. Many prospects were responsive to the outreach and engaged by expressing various levels of interest, including meetings with Advaxis management. In addition to the other letters of intent described herein, one other potential counterparty submitted a non-binding proposal for a merger with Advaxis. Ultimately, however, the Advaxis board of directors did not believe such non-binding proposal would enhance stockholder value. No other definitive proposals were received that the Advaxis board of directors believed would be a viable transaction option for such enhancement of value, and Advaxis terminated Financial Advisor A's engagement.

On February 25, 2020, Advaxis management was contacted by Party A with an interest to resume discussions regarding a potential business combination. Party A proposed a transaction structure on substantially the same terms as the executed letter of intent in which Party A's stockholders would own 90% of a combined company, with Advaxis' stockholders owning 10% with a concurrent PIPE investment.

At the March 3, 2020 Advaxis board of directors meeting, the board discussed and evaluated potential transaction counterparties, including Party A, Party B and four others.

During March and April 2020, Advaxis continued to engage in discussions with multiple potential counterparties, and due diligence information was shared with Advaxis and certain of such counterparties.

On April 8, 2020, Advaxis received a letter from Nasdaq indicating that Advaxis no longer met its requirement to maintain a minimum bid price of $1 per share and that, according to its Listing Rules, Advaxis would have a period of 180 days in which to regain compliance. On April 20, 2020, in response to the unprecedented turmoil in U.S. and world financial markets, Nasdaq informed Advaxis that it had determined to toll compliance periods through June 30, 2020, and, therefore, Advaxis would have until December 21, 2020 to regain compliance.

At the April 21, 2020 Advaxis board of directors meeting, the board authorized the entry into a Sales Agreement with A.G.P./Alliance Global Partners, as sales agent ("A.G.P."), for the issuance and sale to the public by Advaxis of up to $40,000,000 of shares of Advaxis' common stock in an at-the-market transaction. A.G.P. had a previous relationship with Advaxis and was not introduced to Advaxis in connection with LifeSci Capital's engagement. On May 8, 2020, Advaxis announced its entry into the Sales Agreement with A.G.P.

At the May 4, 2020 Advaxis board of directors meeting, the board discussed engaging LifeSci Capital LLC ("LifeSci Capital"), a financial advisor with experience in the life sciences industry, to serve as financial advisor in connection with potential M&A and in-licensing transactions and management provided an update on continued discussions regarding strategic alternatives. The board authorized management to continue ongoing due diligence efforts and review of certain potential partners or acquirors. Following the board meeting, LifeSci Capital was engaged by Advaxis to serve as financial advisor.

During May 2020, members of Advaxis management continued to engage in discussions with multiple potential counterparties, and due diligence information was shared with Advaxis and certain of such counterparties.

At the June 1, 2020 Advaxis board of directors meeting, the board discussed a potential merger transaction with one potential counterparty ("Party C"). Management reported to the board that significant scientific and clinical due diligence had been completed in connection with such potential merger transaction, and legal and financial due diligence remained outstanding. Management described for the board the proposed contemplated transaction, which could include a financing component. The Board discussed that such financing could foster greater interest from larger, fundamental biotechnology institutional funds in the near- or medium-term and add capital to the combined company.

The board discussed the potential lead investor, which was also an investor in Party C. Director Dr. Sidransky, who is also a principal of the potential investor, discussed anticipated plans for financing. Current valuation of Party C was discussed in the context of a valuation split for the merger transaction that involved Advaxis stockholders owning between 40% and 60% of a combined company. In view of his relationship with the potential investor, following this discussion, Dr. Sidransky recused himself from decisions regarding Party C and left the meeting.

Based on the relative valuations of Advaxis and Party C, the Board authorized Advaxis management to negotiate a letter of intent with Party C with a valuation split involving Advaxis stockholders owning between 40% and 50% of a combined company.

On June 11, 2020, Advaxis released financial results for the second quarter ended April 30, 2020 and hosted a conference call to provide a business update.

On June 25, 2020, Party C notified Advaxis that it declined to continue transaction discussions and would put its consideration of strategic options aside in favor of focusing on obtaining financing.

At the July 16, 2020 Advaxis board of directors meeting, the board authorized management to expand the ongoing search for M&A opportunities to also include potential transactions in which Advaxis might be acquired, as opposed to mergers of equals. The board also authorized management, with the assistance of counsel, to negotiate terms of principal documentation for an equity line with Lincoln Park Capital Fund LLC ("Lincoln Park"), pursuant to which Advaxis would be able to require Lincoln Park to purchase shares of Advaxis' common stock during a specified term, up to a maximum commitment amount, all in accordance with the specific terms to be set forth in an Equity Commitment Purchase Agreement.

On August 3, 2020, Advaxis announced that it had entered into a common stock purchase agreement for up to $20 million with Lincoln Park. Lincoln Park made an initial purchase of $2 million of Advaxis common stock at $0.57 per share. Under the terms, Advaxis had the right, at its sole discretion, to sell to Lincoln Park up to $20 million worth of shares over the 36-month term of the agreement, subject to certain conditions. The purchase price of the shares would be based on prevailing market prices at the time of each sale, with no upper limits to the price per share. Advaxis controlled the timing and amount of any future sales of its stock to Lincoln Park. There were no warrants, derivatives, financial or business covenants associated with the agreement, and Lincoln Park agreed not to cause or engage in any direct or indirect short selling or hedging of Advaxis' common stock. Advaxis had the right to terminate the purchase agreement at any time without cost or penalty. In consideration for Lincoln Park entering into the purchase agreement, Advaxis issued 1,084,266 shares of its common stock to Lincoln Park as a fee for Lincoln Park's obligation to purchase shares at Advaxis' discretion.

Party A contacted Advaxis regarding re-engaging in connection with negotiating and consummating a business combination transaction, and on August 4, 2020, a draft letter of intent was received from Party A regarding a potential merger. The letter of intent proposed relative valuations of Advaxis and Party A that would have resulted in Party A's stockholders owning at least 80% of the combined entity.

At the August 4, 2020 Advaxis board of directors meeting, management updated the Board regarding the letter of intent received from Party A with respect to a potential merger transaction. The board authorized management to negotiate the terms of a letter of intent between Party A and Advaxis regarding a potential strategic transaction on a non-exclusive basis. Management updated the board with respect to the ongoing activities of LifeSci Capital and that the availability of other options for M&A transactions was limited. The board instructed management to continue exploring strategic transactions with the support of LifeSci Capital in parallel with negotiating the letter of intent with Party A.

On August 4, 2020, Director Sidransky provided an introduction to Biosight, the parties thereafter entered into a customary nondisclosure agreement prohibiting each party from disclosing material nonpublic information obtained from the other, with no standstill provisions with customary standstill provisions and don't ask-don't waive terms.

On August 5, 2020, the letter of intent with Party A was executed providing for a merger transaction in which Party A's stockholders would own at least 80% of the combined entity as well as the consummation of a concurrent $80 to $100 million investment in the combined entity in the form of a PIPE, a debt investment or other mutually agreeable form. The letter of intent with Party A did not contain any exclusivity provisions so that Advaxis could continue to work with LifeSci Capital on exploring other strategic alternatives as directed by the board.

On August 6, 2020, the nondisclosure agreement with Biosight was executed, and Biosight provided a confidential corporate presentation.

From August 6 through August 23, 2020, Advaxis continued to engage in discussions with Party A and Biosight.

On August 23, 2020, Advaxis received a draft proposal from Biosight with proposed terms for a merger transaction, including exclusivity provisions that would require termination of discussions with Party A. The proposal provided that Biosight would be prepared to enter a merger transaction that valued Biosight at $120 million and Advaxis at $35 million, which would imply Biosight shareholders owning 77.5% and Advaxis stockholders owning 22.5% of the combined company and requiring that Advaxis have at least $15 million in "net cash" at closing of a transaction.

On August 24, 2020, management notified the board that a draft letter of intent was received from Biosight and scheduled a meeting with the board to review. Additional information for the Biosight and Party A opportunities with preliminary evaluation of each of the opportunities was provided to the board.

At the August 25, 2020 Advaxis board of directors meeting, management described Biosight to the board as a potential new M&A partner. It was disclosed that Israeli Biotech Fund, an investment fund co-founded by Director Sidransky, had an investment in Biosight. Dr. Sidransky provided insight and his opinion on Biosight, explaining that following a merger between Advaxis and Biosight, the combined company would have three product candidates. Dr. Sidransky then recused himself from further discussion regarding the strategic process and left the meeting.

Management provided an update on the status of the potential strategic transaction with Party A, which was conducting additional scientific due diligence.

Advantages and disadvantages of both potential opportunities involving Biosight and Party A were discussed by the Board. The Board then instructed management to proceed with the process and authorized management to begin negotiation of a potential transaction with Biosight, without committing to exclusivity.

Following the board of directors meeting, management discussed with Biosight key issues in the draft proposal, including valuation and exclusivity.

On August 27, 2020, Advaxis provided to Biosight a counterproposal to the letter of intent. From August 27, 2020 through September 16, 2020, Advaxis and Biosight continued to exchange due diligence information and negotiate the letter of intent.

On August 28, 2020, management updated the board that discussions were progressing with Biosight towards key terms of the letter of intent, and discussions with Party A were progressing towards a first draft of a merger agreement.

On August 29, 2020, Morgan, Lewis & Bockius LLP (“Morgan Lewis”), counsel to Advaxis, received the initial draft of a merger agreement from Party A.

On September 3, 2020, one of the members of the board proposed another potential merger counterparty (“Party D”) to management.

In parallel, Advaxis continued to exchange due diligence information with Biosight and Party A.

On September 8, 2020, Biosight requested the ability to disclose the identity of Advaxis for evaluation by two potential venture capital firms interested in investing in Biosight, which request was approved by Advaxis. Additionally, Biosight sent an updated letter of intent to Advaxis that proposed relative valuations of Advaxis and Biosight that would have resulted in Advaxis’ stockholders owning 20% of the combined company, and Biosight’s shareholders owning 80%.

On September 10, 2020, a nondisclosure agreement with Party D was executed and Party D was provided access to due diligence materials regarding Advaxis. From September 10 to September 24, 2020, Advaxis engaged in discussions with and provided due diligence information to Party D.

On September 11, 2020, management updated the board that cash at closing was a focal point in strategic discussions with both Biosight and Party A, and suggested utilizing the at the market program to raise additional funds. All of the members of the board confirmed their approval of this approach by email.

On September 15, 2020, management updated the board as to the status of the strategic discussions.

At the September 17, 2020 Advaxis board of directors meeting, Advaxis’ financing needs were discussed, including the at the market offering program with A.G.P. and the equity line with Lincoln Park. The board approved an offer and sale under the at the market program of shares of Advaxis’ common stock with a maximum aggregate offering price of up to $5,000,000, for an offering price per share of no less than $0.40 during the period commencing on September 11, 2020 and terminating on November 13, 2020. The board further approved an offer and sale under the equity line to Lincoln Park of offered shares having a maximum aggregate offering price of up to $6,000,000, for an offering price per share of greater than or equal to $0.40, during the period commencing on September 16, 2020 and terminating on November 13, 2020.

Management provided an update on strategic alternatives, noting continued interest from various third parties, including continued engagement with Biosight and Party A. The board discussed concerns about the ability of Party A to consummate a transaction successfully, and that, in comparison to Party A, Biosight's products had more promise of a successful development and commercialization, Biosight appeared to have greater potential to raise capital, and the respective businesses of Advaxis and Biosight were more aligned in nature and scope. Following this discussion, the board authorized management, on behalf of Advaxis, to execute a letter of intent with Biosight, setting forth certain preliminary terms of a potential merger transaction between Advaxis and Biosight which would have resulted in Advaxis' stockholders owning 20% of the combined company and Biosight's shareholders owning 80% of the combined company, as adjusted for the amount of cash held by Advaxis.

The board also discussed the susceptibility of Advaxis under current conditions to a hostile takeover. The risks and benefits associated with implementing a stockholder rights plan were reviewed. Advaxis counsel reviewed the fiduciary duties of directors applicable to adoption of a stockholder rights plan and the board authorized management, on behalf of Advaxis, to take all actions necessary to effect implementation of a stockholder rights plan in order to allow the board to make informed decisions in the best long term interests of Advaxis and its stockholders.

On September 21, 2020, Biosight notified Advaxis that it did not envision proceeding towards a potential merger transaction and instead, based on recent data, intended to pursue an initial public offering. Management of Advaxis updated the board as to Biosight's plans and the status of other ongoing opportunities with Party A and Party D.

On September 23, 2020, Biosight contacted Advaxis and indicated that, notwithstanding recent communications, it remained interested in pursuing a potential transaction with Advaxis. Biosight and Advaxis management spoke to discuss Biosight's ongoing interest and current clinical summary. A revised draft of the letter of intent was submitted to Advaxis, which was shared with the Advaxis board. The letter of intent proposed relative valuations of Advaxis and Biosight that would have resulted in Advaxis' stockholders owning 10% of the combined company and Biosight's shareholders owning 90%, which ratio would be adjusted downwards depending on the amount of cash Advaxis held at the closing of the potential transaction.

On September 23, 2020, a proposal was received from Party D regarding a potential license to the HOT program with stock consideration and shared with the Advaxis board.

At the September 24, 2020 Advaxis board of directors meeting, the board was updated as to financing activities with sales made under the Lincoln Park equity line of 4 million shares, for a total capital raise of approximately $2 million, in accordance with the board's prior authorization to sell up to $6 million of shares at a price per share of no less than $0.40. Sales under the at the market program with A.G.P. had not been conducted.

The board authorized the offer and sale to Lincoln Park under the equity line of up to 15,000,000 shares of Advaxis' common stock, for an offering price per share of greater than or equal to $0.40, during the period commencing September 24, 2020 and terminating on November 13, 2020.

The board authorized the sale under the at the market program of additional offered shares having a maximum aggregate offering price of up to $10,000,000, for an offering price per share of no less than $0.40, during the period commencing September 24, 2020 and terminating on November 13, 2020.

The Advaxis board was updated with respect to strategic alternatives, and Party D's interest, technology and product pipeline were discussed. An update was provided on continuing discussions with Biosight. Director Sidransky recused himself from further discussions regarding the strategic process and temporarily left the meeting, and both Director Sidransky and Director Appel abstained from the matter. Director Appel did not give a reason for his abstention. The board authorized management, for and on behalf of Advaxis, to pursue the execution of a letter of intent for a potential transaction with Biosight, optimizing the terms of the potential deal to include a carveout to out-license material assets of Advaxis and ensure the Advaxis stockholders receive the value of such carveout, and further authorized management to pursue an out-license opportunity with Party D. The letter of intent contemplated exclusivity for a period of 45 days.

Representatives of Morgan Lewis led a discussion regarding potential adoption of a stockholder rights plan, potential amendments to Advaxis' bylaws, and the fiduciary duties of directors applicable to the adoption of a stockholder rights plan and bylaw amendments. Following discussion, the board authorized management to engage an investment bank for assistance with preparation and implementation of a stockholder rights plan. The board agreed to reconvene on September 29, 2020 to discuss the stockholder rights plan further. Thereafter, LifeSci Capital was engaged to assist Advaxis with the stockholder rights plan and prepare a presentation for the September 29, 2020 board meeting.

On September 24, 2020, Advaxis announced that the U.S. Food and Drug Administration (FDA) had cleared a new Investigational New Drug (IND) application for the initiation of an Investigator Sponsored Phase 1 clinical study of ADXS-504, Advaxis' off-the-shelf neoantigen Advaxis HOT candidate for prostate cancer.

From September 24, 2020 until September 30, 2020, Advaxis and Biosight continued to exchange due diligence information and negotiate the letter of intent. Advaxis and Party D also continued to discuss the out-license opportunity.

At the September 29, 2020 Advaxis board of directors meeting, in response to the general view of the Advaxis position in the market and its resulting vulnerability to a hostile takeover, the board approved the form, terms and provisions of the Rights Agreement respecting the stockholder rights plan, and also approved and adopted the Amended and Restated By-laws of Advaxis. The adoption of the rights plan was announced in a press release later that day.

On September 30, 2020, Advaxis requested, and Biosight confirmed, that Advaxis could continue certain other monetization discussions of the HOT platform during the exclusivity period under the letter of intent. On September 30, 2020, the letter of intent between Advaxis and Biosight was executed, which included exclusivity for a period of 30 days. Thereafter, access to Advaxis' due diligence information continued to be provided to Biosight, and the respective legal teams were introduced.

On October 2, 2020, Advaxis notified Party A that Advaxis had entered into exclusive discussions with another party, and that the letter of intent between Advaxis and Party A was terminated.

From September 30 until late December, Advaxis and Biosight exchanged due diligence information.

On October 5, 2020, a draft letter of intent was received from Party D for an out-licensing deal to purchase the HOT platform. Director Sidransky was updated by management. From October 5, 2020 until November 19, 2020, Advaxis and Party D negotiated the letter of intent with respect to the sale of the HOT program.

On October 7, 2020, after receiving authorization by the board, Advaxis re-engaged LifeSci Capital to advise with respect to a potential transaction with Party D in addition to the financial advisory services already being provided.

On October 9, 2020, Advaxis and Party D management discussed structure and financial terms.

On October 13, 2020, a revised draft of the letter of intent was sent to Party D.

On October 15, 2020, Advaxis entered into private exchange agreements with two warrant holders from the January 2020 public offering, pursuant to which such holders sold 3 million shares in exchange for 5 million warrants.

On October 18, 2020, management updated the Advaxis board on the status of each of the Biosight and Party D discussions.

On October 26, 2020, Advaxis announced updated clinical results from the combination arm of Advaxis' ongoing Phase 1/2 study evaluating ADXS-503 in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy in non-small cell lung cancer (NSCLC).

On November 9, 2020, Advaxis announced that it had presented updated data from its ongoing ADXS-503 Phase 1/2 Lung Cancer Trial at the 2020 Society for Immunotherapy of Cancer (SITC) Annual Meeting. The data presented across three cohorts; Part A monotherapy, Part B combination with KEYTRUDA® and Part C combination with KEYTRUDA® in the first line setting for patients with NSCLC with PD-L1 expression ≥ 1% or who are unfit for chemotherapy, together, demonstrated that ADXS-503 was safe and well tolerated, and may restore or enhance sensitivity to checkpoint inhibitors as an off-the-shelf, neoantigen immunotherapy.

On November 10, 2020, management updated the Advaxis board on transaction discussions.

On November 11, 2020, an initial draft of the Merger Agreement was sent by White & Case LLP ("White & Case"), counsel to Biosight, to Morgan Lewis. Thereafter, the parties and their respective counsel began to negotiate the Merger Agreement and continued to exchange due diligence information.

At the November 16, 2020 Advaxis board of directors meeting, management updated the board on negotiations regarding a potential merger transaction with Biosight. Before further discussion, Dr. Sidransky reminded the board of his indirect relationship with Biosight. Management observed that although the exclusivity period had expired, Advaxis and Biosight had recently re engaged in further discussions and that a draft Merger Agreement was received by Advaxis on November 11, 2020. The board discussed the terms of the draft Merger Agreement and the various revisions that would be necessary in order to reach a more definitive agreement. No further action was taken at this time with respect to the transaction with Biosight by the board of Advaxis.

Management updated the board on the potential transaction for the out-license of the HOT program. Diligence was not yet conducted, and the current status of the letter of intent related to the transaction was discussed. The board authorized management to continue negotiations with respect to the out-license transaction of the HOT program.

At the November 16, 2020 Advaxis board of directors meeting, the board deemed it advisable and in the best interest of the stockholders of Advaxis that Advaxis make a public offering of up to $10,000,000 in shares of Advaxis common stock, together with warrants to purchase shares of Advaxis common stock in an amount equal to up to half of the number of shares issued in the offering, at a price per share and an exercise price, respectively, to be subsequently determined by a named Pricing Committee.

The Advaxis board also authorized any action deemed necessary to effect and keep effective the listing of the Advaxis common stock on Nasdaq.

After further discussion, the Advaxis board recommended that management engage in discussions directly with the board of directors of Biosight in an effort to expedite negotiations. Additionally, a financial analysis presentation, including the anticipated impact of the various transaction alternatives, was requested at the board's next meeting to be held on November 25, 2020.

On November 19, 2020, the letter of intent relating to the potential outlicensing of the HOT program between Advaxis and Party D was executed. Thereafter, Advaxis and Party D engaged in discussions regarding the potential transaction and exchanged due diligence information. Also on November 19, 2020, Morgan Lewis sent a revised draft of the Merger Agreement to White & Case.

On November 27, 2020, Advaxis announced the closing of a $9.2 million public offering. The net proceeds from the offering would be used to fund continued research and development initiatives in its product pipeline including, but not limited to, investment in its Advaxis HOT program and for general corporate purposes. Advaxis also indicated that it might use a portion of the net proceeds to acquire or invest in other businesses, products and technologies. The offering was made pursuant to an effective shelf registration statement on Form S-3 (File No. 333-226988) previously filed with the U.S. Securities and Exchange Commission (the "SEC"), which became effective upon filing on August 30, 2018.

On December 7, 2020, Advaxis sent to Party D an initial draft of a license agreement.

Between December 7, 2020 and late January, 2021, Advaxis and Party D negotiated the license agreement and related documents and continued to exchange due diligence information.

On December 22, 2020, White & Case sent a revised draft of the Merger Agreement to Morgan Lewis.

On December 22, 2020, Advaxis announced that the Nasdaq Stock Market had granted approval of Advaxis' request to transfer its listing to the Nasdaq Capital Market from the Nasdaq Global Select Market, effective on December 24, 2020, because the stock price traded below the minimum bid price necessary to maintain its listing on the Nasdaq Global Select Market.

On December 29, 2020, Biosight and Advaxis conducted a teleconference with Biosight and Advaxis management members, Director Patton and respective counsel and financial advisors to discuss business, legal and tax matters related to the Merger Agreement.

On December 30, 2020, a telephone meeting of the Advaxis board of directors was held to discuss the terms, process and timing of the potential transaction with Biosight.

Thereafter, on January 7, 2021, Morgan Lewis sent a revised draft of the Merger Agreement to White & Case.

On January 19, 2021, Advaxis announced the first milestone payment related to the licensing agreement for ADVAXIS31-164, known as OST-HER2, with OS Therapies for evaluation in the treatment of osteosarcoma in humans. Under the terms of the licensing agreement, OS Therapies, in collaboration with the Children's Oncology Group, was responsible for the conduct and funding of a clinical study evaluating ADXS-HER2 in recurrent, completely resected osteosarcoma and Advaxis was entitled to receive additional clinical, regulatory, and sales-based milestone payments as well as royalties on future product sales. The second milestone payment under the licensing agreement with OS Therapies was achieved on April 26, 2021 after OS Therapies completed a financing.

On January 24, 2021, Director David Sidransky introduced Ken Berlin to an executive at another potential transaction counterparty ("Party E") to discuss potential synergies between companies.

At the January 25, 2021 meeting of the Advaxis board of directors, the board received an update from management with respect to the consideration of strategic alternatives, including discussions with Biosight, which had indicated a willingness to consider a post merger ownership structure that would involve Biosight shareholders owning 82.5% of the combined company and Advaxis stockholders owning 17.5%. Specifically, the board was informed that Biosight would consider adjusting the valuation by 0.25% per $1 million raised by Advaxis in a financing transaction, with a valuation of the resulting combined company at $400 million. Director Sidransky reminded the board of his indirect interest in Biosight and recused himself from decisions regarding the Biosight merger.

The Advaxis board discussed various alternatives for how to proceed and respond to Biosight in light of the foregoing discussions. Following discussion, the board agreed to respond to Biosight with a proposal of an 80/20 valuation split, which would include the Party D out license transaction occurring before the Biosight merger. The board also agreed that if Biosight refused this offer, the Biosight merger and the Party D out-license transaction would not proceed.

After this meeting, Advaxis made the proposal to Biosight; Biosight rejected the proposal. On January 29, 2021, Mr. Berlin provided an email update to the Advaxis board members which noted Biosight's rejection of the offer.

On February 8, 2021, a nondisclosure agreement between Party E and Advaxis was executed. Between February 8, 2021 and March 16, 2021, Advaxis and Party E exchanged due diligence information and discussed the terms of a potential transaction.

At the February 11, 2021 meeting of the Advaxis board of directors, the board approved, among other matters, an amendment to Advaxis' Amended and Restated Certificate of Incorporation and a reverse stock split in order to meet the minimum price requirement of Nasdaq. The Board resolved to submit such matters to the stockholders for approval at the 2021 annual meeting of the stockholders.

On March 11, 2021, Advaxis was contacted by a potential transaction counterparty, with whom Advaxis had previously had contact ("Party F"), regarding clinical updates and a recent press release. Over the following two weeks, Advaxis and Party F discussed a potential transaction but Advaxis ultimately determined that the proposed deal terms were not favorable enough to continue to pursue a transaction with Party F.

On March 12, 2021, Advaxis announced with Precision for Medicine, a specialized services company supporting drug development and commercialization, that data would be presented at the American Association for Cancer Research (AACR) Annual Meeting 2021 regarding the development of a novel flow immunophenotyping assay to accurately evaluate total PD-1 expression as a pharmacodynamic biomarker during PD-1 blockade treatment with pembrolizumab and clinical activity observed in the ongoing ADXS-503 clinical trial.

On March 16, 2021, Advaxis announced financial results for the first quarter ended January 31, 2021 and provided a business update regarding continued enrollment in the expanded ADXS-503 HOT program in NSCLC ADXS-503 Phase 1/2 trial, data presented at SITC, demonstrating disease control rate of 67% and overall response rate of 17% in the first six evaluable patients with immediate prior progression on KEYTRUDA®.

On March 17, 2021, Advaxis indicated to Party E that the proposed deal terms would not be acceptable based on recent negative read outs regarding Party E's products.

On April 5, 2021, Advaxis announced an agreement with Columbia University Irving Medical Center to fund a Phase 1 clinical study evaluating ADXS-504 in patients with biochemically recurrent prostate cancer, expected to begin in the second fiscal quarter of 2021, with principal investigator Mark Stein, M.D., Associate Professor of Medicine, Division of Hematology/Oncology at Columbia University Vagelos College of Physicians and Surgeons.

On April 12, 2021, Advaxis announced definitive agreements with two healthcare-focused institutional investors for the purchase of an aggregate of 17,577,400 shares of common stock at an offering price of $0.7921 per share, and 7,671,937 pre-funded warrants, would be sold for a purchase price of $0.7911 per share and will have an exercise price of $0.001 per share. It was contemplated that net proceeds from the offering were planned to fund continued research and development initiatives to expand the product pipeline, including investment in the HOT program and for general corporate purposes. A portion of the net proceeds could also be used to acquire or invest in other businesses, products and technologies.

On April 15, 2021, Director Patton reached out to Director Orbach of Biosight and on April 20, 2021 the two Directors spoke by phone regarding their renewed interest in pursuing a transaction with a 75/25 ownership split of the combined company.

On April 29, 2021, Director Patton had another phone call with Director Orbach regarding certain terms of the proposed transaction, including a 75/25 ownership split of the combined company, with no adjustment based on cash of Advaxis held at closing, board composition and management of the combined company and the applicable break fee. On April 30, 2021, Director Patton updated the Advaxis board regarding the communications with Biosight and the board approved moving ahead with the transaction with Biosight.

On May 10, 2021, Advaxis was contacted by Party D, which expressed renewed interest in resuming deal discussions for the HOT program that had previously terminated in February, 2021. Advaxis management explained to Party D that any such transaction would need to be executed after the potential merger with Biosight and that discussions could resume at that point.

On May 19, 2021, Advaxis announced updated data from the Phase 1/2 study evaluating ADXS 503 in combination with KEYTRUDA® presented as a poster at the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting.

Also on May 19, 2021, Director Patton spoke with Director Orbach and Director Orbach informed Director Patton that Biosight was interested in moving forward with the potential transaction as outlined by Advaxis.

On May 21, 2021, Advaxis indicated to Biosight its interest in proceeding with a transaction.

On May 27, 2021, the Advaxis board met and reviewed ongoing business development discussions and the current opportunities under evaluation by Advaxis management. Mr. Berlin provided an update on the status of management's discussions with Biosight and the board agreed that Advaxis should continue discussions with Biosight and consider whether the opportunity advances further. The board also authorized Advaxis management to consider and move forward with other business development opportunities as they arise, subject to the further review and consideration of the board.

On May 31, 2021, Advaxis sent to Biosight a revised draft of the Merger Agreement. Between May 31, 2021 and July 4, 2021, Advaxis, Biosight and their respective counsel continued to exchange due diligence information and negotiate the Merger Agreement.

On June 3, 2021, Advaxis held a virtual annual meeting of its stockholders. At the meeting, the following matters were submitted to a vote of stockholders: (i) the election of six (6) nominees to serve as directors of Advaxis until the 2022 Annual Meeting of Stockholders and until their respective successors were duly elected and qualified, or until such director's earlier resignation, removal or death; (ii) the approval of an amendment to the Advaxis, Inc. 2015 Incentive Plan (the "2015 Incentive Plan") to increase the existing limitations on awards granted in any calendar year; (iii) the approval of an amendment to Advaxis' Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock, from 170,000,000 shares to 300,000,000 shares; (iv) the approval of an amendment to Advaxis' Amended and Restated Certificate of Incorporation to effect a reverse stock split of the Advaxis common stock at a range to be determined by the Advaxis board of directors between one-for-five and one-for-fifteen, without reducing the authorized number of shares of common stock, to be effected in the sole discretion of the Advaxis board of directors at any time within one year of the date of the annual meeting of stockholders without further approval or authorization of the stockholders; (v) the ratification of the appointment of Marcum LLP to serve as Advaxis' independent registered public accounting firm for the fiscal year ending October 31, 2021; and (vi) the ratification and approval of the amendment to the 2015 Incentive Plan, which was adopted following the 2020 Annual Meeting of Stockholders, to increase the total number of shares of common stock authorized for issuance thereunder from 877,744 shares to 6,000,000 shares. While the other proposals were approved, the amendment to increase the authorized shares of common stock did not receive enough votes to be approved at the annual meeting.

On June 9, 2021, a teleconference call scheduled by Biosight was attended by Biosight and Advaxis management members, respective counsel and certain respective board members to discuss the Merger Agreement and various terms.

In early June, Party A contacted Advaxis and indicated a potential interest in renewed discussion regarding a potential transaction and requested certain information. Advaxis provided the information requested and thereafter had no further contact with Party A regarding a potential transaction.

On June 14, 2021, Advaxis announced financial results for the quarter ended April 30, 2021 and provided a business update, reflecting a cash runway anticipated into the 3rd fiscal quarter of 2023.

On June 16, 2021, a revised draft of the Merger Agreement was sent by White & Case to Morgan Lewis.

On June 17, 2021, Advaxis reconvened a virtual annual meeting of its stockholders. At the annual meeting, among other matters, the approval of an amendment to Advaxis' Amended and Restated Certificate of Incorporation to effect a reverse stock split intended to ensure compliance with the Nasdaq listing requirement was submitted to a vote of stockholders, which proposal did not receive enough votes to be approved at the annual meeting.

On June 21, 2021, a revised draft of the Merger Agreement was sent by Morgan Lewis to White & Case.

On June 25, 2021, a revised draft of the Merger Agreement was sent by White & Case to Morgan Lewis. Thereafter, Advaxis and Biosight directly discussed various open issues with respect to the Merger Agreement and the potential transaction.

On June 28, 2021, a revised draft of the Merger Agreement, and an initial draft of the Support Agreement to be signed by executive officers and directors of Advaxis, were sent by Morgan Lewis to White & Case.

On June 29, 2021, a revised draft of the Support Agreement was sent by White & Case to Morgan Lewis, and on June 30, 2021, a revised draft of the Support Agreement was sent back to White & Case by Morgan Lewis. Later on June 30, 2021, a revised draft of the Support Agreement was sent by White & Case to Morgan Lewis.

On June 30, 2021, a revised draft of the Merger Agreement was sent by White & Case to Morgan Lewis. Later on June 30, 2021, a revised draft of the Merger Agreement was sent by Morgan Lewis to White & Case. Following the exchange of drafts, a teleconference with Ken Berlin and Biosight Director Pini Orbach and Yuval Cabilly, a Co-Founder and Managing Partner of Israel Biotech Fund, was held to discuss open issues in the Merger Agreement.

On July 1, 2021, Advaxis reconvened a virtual annual meeting of its stockholders. At the annual meeting, the approval of an amendment to Advaxis' Amended and Restated Certificate of Incorporation to effect a reverse stock split intended to ensure compliance with the Nasdaq listing requirement was submitted to a vote of stockholders, which proposal did not receive enough votes to be approved at the annual meeting.

Also on July 1, 2021, White & Case sent a revised draft of the Merger Agreement to Morgan Lewis and Morgan Lewis sent a revised draft of the Support Agreement to White &Case, which draft of the Support Agreement was considered to be almost final by the parties. Later on July 1, 2021, an initial draft of the Support Agreement to be signed by executive officers and directors of Biosight, was sent by White & Case to Morgan Lewis. Thereafter, on July 2, 2021, Morgan Lewis sent a revised draft of the Merger Agreement back to White & Case, which Advaxis considered to be almost final. Also on July 2, 2021, White & Case sent to Morgan Lewis a further revised draft of the Support Agreement to be signed by executive officers and directors of Biosight, which draft was considered to be almost final by the parties.

On July 2, 2021, a meeting of the Advaxis board of directors was held to review the status of, and open items relating to, the potential transaction with Biosight. At the meeting, Mr. Berlin led the board in a discussion regarding Biosight's technology and the strategic rationale for the proposed transaction with Biosight, indicating that the proposed transaction would make the combined company a late stage company. The board considered other relevant information, including, without limitation, Advaxis' business, financial condition, results of operations, assets, management, competitive position, operating performance and prospects, both as an independent company and as a potential acquisition target for companies other than Biosight. Mr. Berlin then discussed the financial position of the combined company and the opportunity for a PIPE transaction at or following closing. A representative from LifeSci Capital then reviewed with the Board valuation metrics, Advaxis' capitalization, Biosight's capitalization, the exchange ratio, and the analysis of comparable public company transactions used to prepare the fairness opinion. LifeSci Capital then delivered its oral opinion, confirmed by delivery of a written opinion on July 2, 2021, to the effect that, as of that date and based upon and subject to the various assumptions set forth in LifeSci Capital's opinion, the proposed transaction was fair, from a financial point of view, for the Advaxis stockholders.

In connection with rendering its fairness opinion, LifeSci Capital disclosed to the Advaxis board that it provides certain investor relations consulting services to Biosight and has received retainer or placement fees in connection with executive recruitment services provided to Biosight. Biosight has retained LifeSci Capital since December 2019 to provide such investor relations consulting services and pays LifeSci Capital a retainer fee of approximately $10,000 per month for such services. Biosight paid LifeSci Capital a placement fee of $120,000 in May 2021 in connection with the recruitment of Biosight's current chief medical officer.

A summary of the terms of the Merger Agreement was provided to the Advaxis board by Mr. Berlin and Morgan Lewis. Mr. Berlin further discussed, and each member of the board acknowledged that they were aware of, all material facts regarding the interests that officers and directors of Advaxis may have in connection with the transactions contemplated by the Merger Agreement. Mr. Sidransky recused himself and following such recusal, the then-constituted board determined that the Merger Agreement and the transactions contemplated thereby were in the best interests of Advaxis and its stockholders and unanimously approved the Merger Agreement and the transactions contemplated thereby, including the merger with Biosight.

Between July 2, 2021 and July 4, 2021, negotiations continued on the Merger Agreement with representatives from Advaxis and Biosight, as well as their respective counsel.

On July 4, 2021, the parties finalized and executed the Merger Agreement and the support agreements with certain executive officers and directors of Advaxis and of Biosight.

On the morning of July 6, 2021, prior to the opening of trading on the Nasdaq market, Advaxis and Biosight issued a joint press release announcing their entry into the Merger Agreement and held an investor conference call regarding the proposed transaction.

**Advaxis Reasons for the Merger**

At a meeting held on July 2, 2021, among other things, the Advaxis board of directors unanimously (i) determined that the Merger Agreement, the merger and other transactions contemplated thereby were advisable, fair to and in the best interests of Advaxis and its stockholders, (ii) approved, adopted and declared advisable the Merger Agreement, and (iii) determined to solicit, upon the terms and subject to the conditions set forth in the Merger Agreement, the approval of the Advaxis shareholders of the Merger Agreement.

During the course of its evaluation of the Merger Agreement and the transactions contemplated by the Merger Agreement, the Advaxis board of directors held numerous meetings, consulted with Advaxis' senior management, legal counsel and financial advisor, and reviewed and assessed a significant amount of information. In reaching its decision to approve the Merger Agreement and the transactions contemplated by the Merger Agreement, the Advaxis board of directors considered a number of factors that it viewed as supporting its decision to approve the Merger Agreement, including:

- the financial condition and prospects of Advaxis and the risks associated with continuing to operate Advaxis on a stand-alone basis;
- that the Advaxis board of directors and its financial advisor undertook a comprehensive and thorough process of reviewing and analyzing potential strategic alternatives and merger partner candidates to identify the opportunity that would, in the Advaxis board of directors' view, create the most value for Advaxis stockholders;
- the Advaxis board of directors' belief, after a thorough review of strategic alternatives and discussions with Advaxis' senior management, financial advisors and legal counsel, that the merger is more favorable to Advaxis Stockholders than the potential value that might have resulted from other strategic alternatives available to Advaxis;
- the Advaxis board of directors' belief that, as a result of arm's length negotiations with Biosight, Advaxis and its representatives negotiated the lowest exchange ratio to which Biosight was willing to agree, and that the other terms of the Merger Agreement include the most favorable terms to Advaxis in the aggregate to which Biosight was willing to agree;
- the Advaxis board of directors' view, based on the scientific, regulatory and technical due diligence conducted by Advaxis management, of the regulatory pathway for, and market opportunity of, Biosight's product candidates;
- the Advaxis board of directors' consideration of the expected cash resources of the combined company as of the closing of the merger, with approximately $50 million of cash and cash equivalents on a pro forma basis after giving effect to the merger;
- the Advaxis board of directors' view, following a review with Advaxis' management of Biosight's current development and clinical trial plans, of the likelihood that the combined company would possess sufficient cash resources at the closing of the merger to fund development of the product candidates of the combined company through upcoming value inflection points;
- the prospects of and risks associated with the other strategic candidates that had made proposals for a strategic transaction with Advaxis based on the scientific, technical and other due diligence conducted by Advaxis management;
- the ability of Advaxis stockholders to participate in the growth and value creation of the combined company following the closing of the merger by virtue of their continued ownership of Advaxis common stock;
- the Advaxis board of directors' view that the combined company will be led by an experienced senior management team with representation from each of the current management teams of Advaxis and Biosight and a board of directors with representation from each of the current boards of directors of Advaxis and Biosight;
- the current financial market conditions and historical market prices, volatility and trading information with respect to Advaxis' common stock; and
- the Advaxis board of directors' consideration of the financial analyses of LifeSci Capital LLC, including its opinion to the Advaxis board of directors as to the fairness, from a financial point of view and as of the date of the opinion, to Advaxis of the exchange ratio to be paid by Advaxis pursuant to the terms of the Merger Agreement, as more fully described below under the caption "*The Merger—Opinion of Advaxis' Financial Advisor*," beginning on page 89 in this proxy statement/prospectus/information statement.

The Advaxis board of directors also reviewed the terms of the Merger Agreement and related transaction documents, including those described below, and concluded that the terms of the Merger Agreement and related transaction documents, in the aggregate, were reasonable under the circumstances:

- the calculation of the exchange ratio and the estimated number of shares of Advaxis common stock to be issued in the merger;

- the number and nature of the conditions to Biosight's and Advaxis' respective obligations to complete the merger and the likelihood that the merger will be completed on a timely basis, as more fully described below under the caption "*The Merger Agreement —Conditions to the Completion of the Merger*," beginning on page 110 in this proxy statement/prospectus/information statement;

- the respective rights of, and limitations on, Advaxis and Biosight under the Merger Agreement to consider and engage in discussions regarding unsolicited acquisition proposals under certain circumstances, and the limitations on the board of directors of each party to change its recommendation in favor of the merger, as more fully described below under the caption "*The Merger Agreement —No Solicitation*," beginning on page 114 in this proxy statement/prospectus/information statement;

- the right of each party to terminate the Merger Agreement to accept an unsolicited Acquisition Proposal in certain circumstances, subject to payment of a termination fee, as more fully described below under the caption "*The Merger Agreement —Termination Fee*," beginning on page 121 in this proxy statement/prospectus/information statement;

- the conclusion of the Advaxis board of directors that the potential termination fee of $7,500,000, payable by Advaxis or Biosight, respectively, to the other party, the reimbursement by Advaxis of Biosight's expenses up to a maximum of $2.0 million, and the circumstances when such fees may be payable, were reasonable, as more fully described below under the caption "*The Merger Agreement —Termination Fee*," beginning on page 121 in this proxy statement/prospectus/information statement;

- the support agreements, pursuant to which certain stockholders of Advaxis and Biosight, respectively, have agreed, solely in their capacities as stockholders, to vote all of their shares of Advaxis common stock or Biosight capital stock in favor of the proposals submitted to them in connection with the merger and against any alternative acquisition proposals, as more fully described below under the caption "*Agreements Related to the Merger —Support Agreements*," beginning on page 122 in this proxy statement/prospectus/information statement; and

- the expectation that the merger will qualify as a reorganization within the meaning of Section 368(a) of the Code and the Treasury Regulations promulgated thereunder, with the result that Biosight stockholders will generally not recognize taxable gain or loss for U.S. federal income tax purposes upon the exchange of Biosight share capital for Advaxis common stock pursuant to the merger, as more fully described below under the caption "*The Merger —Tax Characterization of the Merger*," beginning on page 104 in this proxy statement/prospectus/information statement.

In the course of its deliberations, the Advaxis board of directors also considered a variety of risks and other countervailing factors related to entering into the merger, including:

- the potential effect of the $7.5 million termination fee payable by Advaxis and Advaxis' expense reimbursement obligations of up to $2 million upon the occurrence of certain events in deterring other potential acquirors from proposing an alternative acquisition proposal that may be more advantageous to Advaxis stockholders;
- the prohibition on Advaxis to solicit alternative acquisition proposals during the pendency of the merger;
- the substantial expenses to be incurred by Advaxis in connection with the merger;
- the possible volatility of the trading price of the Advaxis common stock resulting from the announcement, pendency or completion of the merger;
- the risk that the merger might not be consummated in a timely manner or at all;
- the fact that the representations and warranties in the Merger Agreement do not survive the closing of the merger and the potential risk of liabilities that may arise post-closing;
- the scientific, technical, regulatory and other risks and uncertainties associated with development and commercialization of Biosight's product candidates;
- the risk that the combined company may not have available sources of financing necessary to fund development of the combined company's product candidates through upcoming value inflection points;
- the lack of availability of appraisal rights under the DGCL to holders of Advaxis common stock which would not allow holders to seek appraisal of the fair value of their shares of Advaxis common stock; and
- the various other risks associated with the combined company and the transaction, including those described in the sections entitled "*Risk Factors*" and "*Cautionary Statement Concerning Forward-Looking Statements*" in this proxy statement/prospectus/information statement.

The foregoing information and factors considered by the Advaxis board of directors are not intended to be exhaustive but are believed to include all of the material factors considered by the Advaxis board of directors. In view of the wide variety of factors considered in connection with its evaluation of the merger and the complexity of these matters, the Advaxis board of directors did not find it useful, and did not attempt, to quantify, rank or otherwise assign relative weights to these factors. In considering the factors described above, individual members of the Advaxis board of directors may have given different weight to different factors. The Advaxis board of directors conducted an overall analysis of the factors described above, including thorough discussions with, and questioning of, the Advaxis management team and the legal and financial advisors of Advaxis, and considered the factors overall to be favorable to, and to support, its determination.

**Biosight Reasons for the Merger**

At a meeting held on July 1, 2021, among other things, the Biosight board unanimously (i) determined that the merger is fair to, advisable for, and in the best interests of, Biosight and its shareholders, (ii) approved and declared advisable the Merger Agreement and (iii) determined to recommend, upon the terms and subject to the conditions set forth in the Merger Agreement, that its shareholders approve the merger.

In the course of reaching its decision to approve the merger, the Biosight board consulted with Biosight's management, financial and tax advisors and legal counsel, reviewed a significant amount of information and considered a number of factors, including, among others:

- the potential increased access to sources of capital and a broader range of investors to support the clinical development of its product candidates following consummation of the transaction compared to if Biosight continued to operate as a privately held company;
- the potential to provide its current shareholders with greater liquidity by owning stock in a public company;
- the board's belief that no alternatives to the merger were reasonably likely to create greater value for Biosight's shareholders, after reviewing the various financing and other strategic options to enhance shareholder value that were considered by the Biosight board;
- the cash resources of the combined organization, with $78.3 million of cash and cash equivalents on a pro forma basis as of April 30, 2021 after giving effect to the merger, which Biosight believes is sufficient to enable Biosight to pursue its near term clinical trials and business plans through the $4^{th}$ quarter of 2022;
- the expectation that the merger with Advaxis would be a more time- and cost-effective means to access capital than other options considered by the Biosight board, including additional private financings or an initial public offering;
- the terms and conditions of the Merger Agreement, including, without limitation, the following:
- the determination that the expected relative percentage ownership of Advaxis stockholders and Biosight's shareholders in the combined organization was appropriate based, in the judgment of the Biosight board, on the Biosight board's assessment of the approximate valuations of Advaxis and Biosight;
- the expectation that the merger will be treated as a reorganization for U.S. federal income tax purposes;
- the limited number and nature of the conditions of the obligation of Advaxis to consummate the merger;
- the rights of Biosight under the Merger Agreement to consider certain unsolicited acquisition proposals under certain circumstances should Biosight receive a superior proposal;
- the conclusion of the Biosight board that the potential termination fee of $7,500,000, payable by Advaxis or Biosight, respectively, to the other party, and the circumstances when such fee may be payable, were reasonable; and
- the belief that the other terms of the Merger Agreement, including the parties' representations, warranties and covenants, and the conditions to their respective obligations, were reasonable in light of the entire transaction;
- the shares of Advaxis common stock issued to Biosight's shareholders will be registered on the registration statement and will become freely tradable for Biosight's shareholders who are not affiliates of Biosight and who are not parties to lock-up agreements;
- the support agreements, pursuant to which certain directors, officers and shareholders of Biosight and Advaxis, respectively, have agreed, solely in their capacity as stockholders of Biosight and Advaxis, respectively, to vote all of their Biosight shares or Advaxis common stock in favor of the adoption or approval, respectively, of the Merger Agreement;
- the Merger may enable certain stockholders of Advaxis and Biosight to increase the value of their current shareholding; and
- the likelihood that the Merger will be consummated on a timely basis.

The Biosight board also considered a number of uncertainties and risks in its deliberations concerning the merger and the other transactions contemplated by the Merger Agreement, including the following:

- the possibility that the merger might not be completed and the potential adverse effect of the public announcement of the Merger on the reputation of Biosight and the ability of Biosight to obtain financing in the future in the event the merger is not completed;
- the exchange ratio used to establish the number of shares of Advaxis common stock to be issued to Biosight's shareholders in the merger is fixed, except for adjustments due to Advaxis' cash balances at closing, and thus the relative percentage ownership of Adavaxis stockholders and Biosight's shareholders in the combined organization immediately following the completion of the merger is similarly fixed;
- the risk that the merger might not be consummated in a timely manner or at all;
- the termination fee of $7,500,000, payable by Biosight to Advaxis upon the occurrence of certain events, and the potential effect of such termination fee in deterring other potential acquirers from proposing an alternative transaction that may be more advantageous to Biosight's stockholders;
- the additional expenses and obligations to which Biosight's business will be subject following the Merger that Biosight has not previously been subject to, and the operational changes to Biosight's business, in each case that may result from being a public company;
- the fact that the representations and warranties in the Merger Agreement do not survive the closing of the Merger and the potential risk of liabilities that may arise post-closing; and
- the lack of availability of appraisal rights under the DGCL to holders of Biosight's share capital which would not allow holders to seek appraisal of the fair value of their shares of Biosight share capital;
- various other risks associated with the combined organization and the merger, including the risks described in the section entitled "Risk Factors" in this proxy statement/prospectus/information statement.

The foregoing information and factors considered by the Biosight board are not intended to be exhaustive but are believed to include all of the material factors considered by the Biosight board. In view of the wide variety of factors considered in connection with its evaluation of the merger and the complexity of these matters, the Biosight board did not find it useful to attempt, and did not attempt, to quantify, rank or otherwise assign relative weights to these factors. In considering the factors described above, individual members of the Biosight board may have given different weight to different factors. The Biosight board conducted an overall analysis of the factors described above, including thorough discussions with, and questioning of, Biosight's management team, the legal and financial advisors of Biosight, and considered the factors overall to be favorable to, and to support, its determination.

**Certain Projected Financial Information**

The information set forth below regarding cash spending projections of Advaxis and Biosight was used by Advaxis and Biosight in connection with their respective reviews of the Business Combination, as described below. Additionally, the information below constitutes all of the projection information provided by the parties to LifeSci Capital in connection with their preparation of their opinion to the Advaxis Board regarding the Business Combination.

The cash spending projections of Biosight were requested by, and disclosed to, Advaxis for use as a component of its overall evaluation of Biosight and are included in this proxy statement/prospectus/information statement because they were provided to the Advaxis Board for its evaluation of the Business Combination. Biosight has not warranted the accuracy, reliability, appropriateness or completeness of the cash spending projections to anyone, including us. Neither the management of Biosight nor any of its representatives, advisors or affiliates has made or makes any representation to any person regarding the ultimate expenses of Biosight compared to the information contained in the cash spending projections, and none of them intends to or undertakes any obligation to update or otherwise revise the cash spending projections to reflect circumstances existing after the date when made or to reflect the occurrence of future events in the event that any or all of the assumptions underlying the cash spending projections are shown to be in error. Accordingly, they should not be looked upon as "guidance" of any sort. You are cautioned not to rely on the cash spending projections in making a decision regarding the transaction, as actual results may be materially different than the cash spending projections.

The cash spending projections of Biosight are forward-looking statements that are based on assumptions that are inherently subject to significant risks, uncertainties and contingencies, many of which are beyond Biosight's control. These include the risks described in the section entitled "*Risk Factors.*" There will be differences between actual and projected spending, and actual cash spending may be materially greater or materially less than those contained in the cash spending projections. The inclusion of the cash spending projections in this proxy statement/prospectus/information statement should not be regarded as an indication that Biosight or its representatives considered or currently consider the cash spending projections to be a reliable prediction of future events, and reliance should not be placed on the cash spending projections.

The projections were prepared by, and are the responsibility of, the management of Biosight. The projections were not prepared with a view towards compliance with GAAP, the published guidelines of the SEC, or the guidelines established by the American Institute of Certified Public Accountants for preparation of prospective financial information. The prospective financial information included in this document has been prepared by, and is the responsibility of, Biosight's management. Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Limited, has not audited, reviewed, examined, compiled nor applied agreed-upon procedures with respect to the accompanying prospective financial information and, accordingly, Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Limited, does not express an opinion or any other form of assurance with respect thereto. The Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Limited, report included in this document relates to Biosight's previously issued financial statements. It does not extend to the prospective financial information and should not be read to do so.

The key elements of the cash spending projections of Biosight provided to Advaxis and LifeSci Capital are summarized in the table below (in thousands of dollars, unaudited).

Biosight's Cash Spending Projections

| Forecast | Q1 2021 Budget | Q2 2021 E Budget | Q3 2021 E Budget | Q4 2021 E Budget | TOTAL 2021 E Budget | Q1 2022 E Budget | Q2 2022 E Budget | Q3 2022 E Budget |
|---|---|---|---|---|---|---|---|---|
| **Total Cash In** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Total Cost in Salaries** | 408 | 555 | 662 | 721 | 2,347 | 1,239 | 784 | 784 |
| **Total Cost in R&D, Clinical, & Regulatory** | 3,835 | 5,368 | 4,191 | 4,628 | 18,022 | 4,515 | 3,555 | 5,335 |
| **Total BD & Market Access** | 142 | 161 | 12 | 12 | 327 | 12 | 12 | 12 |
| **Total G&A** | 542 | 642 | 289 | 289 | 1,763 | 347 | 347 | 347 |
| **Total Expenses** | 5,051 | 6,895 | 5,283 | 5,791 | 23,020 | 6,265 | 4,815 | 6,640 |
| **Ending Cash Balance** | 29,102 | 22,207 | 16,924 | 11,133 | 11,133 | 4,868 | 53 | (6,587) |

In connection with their analyses of the Business Combination, Advaxis provided LifeSci Capital and Biosight with the cash spending projections below.

Advaxis does not warrant the accuracy, reliability, appropriateness or completeness of the cash spending projections to anyone. Neither the management of Advaxis nor any of its representatives, advisors or affiliates has made or makes any representation to any person regarding the ultimate expenses and receipts of Advaxis compared to the information contained in the cash spending projections, and none of them intends to or undertakes any obligation to update or otherwise revise the cash spending projections to reflect circumstances existing after the date when made or to reflect the occurrence of future events in the event that any or all of the assumptions underlying the cash spending projections are shown to be in error. Accordingly, they should not be looked upon as "guidance" of any sort. You are cautioned not to rely on the cash spending projections in making a decision regarding the transaction, as actual results may be materially different than the cash spending projections.

The cash spending projections of Advaxis are forward-looking statements that are based on assumptions that are inherently subject to significant risks, uncertainties and contingencies, many of which are beyond Advaxis's control. These include the risks described in the section entitled "*Risk Factors.*" There will be differences between actual and projected spending, and actual cash spending may be materially greater or materially less than those contained in the cash spending projections. The inclusion of the cash spending projections in this proxy statement/prospectus/information statement should not be regarded as an indication that Advaxis or its representatives considered or currently consider the cash spending projections to be a reliable prediction of future events, and reliance should not be placed on the cash spending projections.

The projections were prepared by, and are the responsibility of, the management of Advaxis. The projections were not prepared with a view towards compliance with GAAP, the published guidelines of the SEC, or the guidelines established by the American Institute of Certified Public Accountants for preparation of prospective financial information. Marcum LLP, Advaxis' independent registered public accounting firm, has not examined, compiled or otherwise applied procedures with respect to the accompanying prospective financial information presented herein and, accordingly, does not express an opinion or any other form of assurance on it. The report of Marcum LLP included in this proxy statement/prospectus relates to historical financial information of Advaxis. It does not extend to the projections and should not be read as if it does.

The key elements of the cash spending projections of Advaxis provided to Biosight and LifeSci Capital are summarized in the table below (in thousands of dollars, unaudited).

| Forecast | 3Q 2021 Budget | 4Q 2021 Budget | 1Q 2022 Budget | 2Q 2022 Budget | 3Q 2022 Budget | 4Q 2022 Budget |
|---|---|---|---|---|---|---|
| **Beginning Cash Balance** | 48,109 | 43,338 | 36,958 | 33,800 | 30,191 | 25,678 |
| **Total Operating Expenses** | 3,311 | 2,122 | 2,114 | 2,114 | 2,199 | 2,199 |
| **BST Merger Closing Costs** | — | 2,000 | — | — | — | — |
| **Total Disbursements** | 6,011 | 6,381 | 3,361 | 3,611 | 4,513 | 3,446 |
| **Total Receipts** | 1,241 | 1 | 203 | 1 | — | — |
| **Ending Cash Balance** | 43,338 | 36,958 | 33,800 | 30,191 | 25,678 | 22,232 |

As noted above, other than the cash spending projections of Advaxis and Biosight, no projection information was provided by the parties to LifeSci Capital in connection with their preparation of their opinion to the Advaxis Board regarding the Business Combination.

**Opinion of Advaxis' Financial Advisor**

LifeSci Capital rendered its opinion to the Advaxis board that, as of July 2, 2021 and based upon and subject to the factors and assumptions set forth therein, the exchange ratio was fair, from a financial point of view, to the holders of shares of Advaxis.

**The full text of the written opinion of LifeSci Capital, dated July 2, 2021, which sets forth assumptions made, procedures followed, matters considered and qualifications and limitations on the review undertaken in connection with the opinion, is attached as *Annex B*. LifeSci Capital provided advisory services and its opinion for the information and assistance of the Advaxis board of directors in connection with its consideration of the merger. The LifeSci Capital opinion is not a recommendation as to how any holder of Advaxis common stock should vote with respect to the merger or any other matter.**

In connection with rendering the opinion described above and performing its related financial analyses, LifeSci Capital:

- Reviewed certain publicly available business and financial information relating to Advaxis and Biosight that LifeSci Capital deemed to be relevant;
- Reviewed and discussed with Advaxis' management certain non-public projected financial and operating data through September 30, 2022 furnished to LifeSci Capital by Advaxis;
- Reviewed and discussed with Advaxis management certain non-public projected financial and operating data through October 31, 2022 furnished to LifeSci Capital by Advaxis;
- Discussed past and current operations, financial projections and current financial conditions of Advaxis and Biosight with the respective managements of Advaxis and Biosight (including their respective views on the risks and uncertainties of achieving such projections);
- Compared Advaxis with certain other selected, similarly situated public companies that LifeSci Capital deemed relevant;
- Compared Biosight with certain other selected, similarly situated public companies that LifeSci Capital deemed relevant;
- Reviewed a draft of the Merger Agreement dated July 1, 2021; and
- Performed such other analyses and examinations and considered such other factors that LifeSci Capital deemed appropriate.

For purposes of rendering the opinion, LifeSci Capital, with Advaxis' consent, (i) relied upon and assumed the accuracy and completeness of the foregoing information without independent verification and (ii) relied on the assurances of the management of Advaxis and Biosight that they are not aware of any facts or circumstances that would make such information inaccurate or misleading. In addition, with Advaxis' consent, LifeSci Capital did not make any independent evaluation or appraisal of any of the assets or liabilities (contingent or otherwise) of Advaxis or Biosight, nor was LifeSci Capital furnished with any such evaluations or appraisals. With respect to the financial projections referred to above and any other forecasts or forward looking information, LifeSci Capital assumed, at the direction of the management of Advaxis, that such projections, forecasts and information were reasonably prepared and reflected the best then available estimates and good faith judgments of the matters covered thereby.

In addition, in arriving at its opinion, LifeSci Capital assumed, with Advaxis' consent, that (i) there had been no material change in any of the assets, liabilities, financial condition, business or prospects of Advaxis or Biosight since the date of the most recent financial statements and other information made available to LifeSci Capital, and there would be no material adjustments to the exchange ratio, (ii) all material information LifeSci Capital requested from Advaxis and Biosight during the scope of LifeSci Capital's engagement had been provided to it fully and in good faith, (iii) the Merger would be consummated in accordance with the terms and conditions set forth in the Merger Agreement (the final terms and conditions of which LifeSci Capital assumed would not differ in any respect material to its analysis from the aforementioned draft LifeSci Capital reviewed), without any waiver, modification or amendment of any materials terms or conditions, (iv) the representations and warranties made by the parties to the Merger Agreement were and would be true and correct in all respects material to LifeSci Capital's analysis, (v) all governmental and third party consents, approvals and agreements necessary for the consummation of the merger would be obtained without any adverse effect on Biosight or the merger, and (vi) the merger would not violate any applicable federal or state statutes, rules or regulations.

The opinion does not constitute legal, regulatory, accounting, insurance, tax or other similar professional advice and does not address (i) the underlying decision of the Advaxis Board to proceed with or effect the merger, (ii) the terms of the merger (other than the exchange ratio to the extent expressly addressed therein) or any arrangements, understandings, agreements or documents related to the merger, (iii) the fairness of the merger (other than with respect to the exchange ratio to the extent expressly addressed therein) or any other transaction to Advaxis or Advaxis' equity holders or creditors or any other person or entity, (iv) the relative merits of the merger as compared to any alternative strategy or transaction that might exist for Advaxis, or the effect of any other transaction which it may consider in the future, (v) the tax, accounting or legal consequences of the Merger, or (vi) the solvency, creditworthiness, fair market value or fair value of any of Advaxis, Biosight or their respective assets under any applicable laws relating to bankruptcy, insolvency, fraudulent conveyance or similar matters. The opinion expresses no opinion as to the fairness or the amount or nature of any compensation to any officers, directors, or employees of any party to the merger, or any class of such persons, relative to the exchange ratio.

LifeSci Capital's opinion was necessarily based on business, economic, monetary, market and other considerations as they existed and could reasonably be evaluated on, and the information made available to LifeSci Capital as of, the date thereof.

In particular, LifeSci Capital noted that there was significant uncertainty in Advaxis' industry and significant volatility in the equity and credit markets. Subsequent developments may have affected the opinion, and LifeSci Capital assumed no responsibility for updating or revising the opinion based on circumstances or events occurring after the date thereof (regardless of the closing date of the merger). LifeSci Capital was not engaged to amend, supplement, or update the opinion at any time. LifeSci Capital expressed no view or opinion as to the prices at which the shares of Advaxis common stock may be sold or exchanged, or otherwise be transferable, at any time.

The following is a summary of the material financial analyses delivered by LifeSci Capital to the Advaxis board in connection with rendering the opinion described above. The following summary, however, does not purport to be a complete description of the financial analyses performed by LifeSci Capital, nor does the order of analyses described represent relative importance or weight given to those analyses by LifeSci Capital. The summaries of the financial analyses include information presented in tabular format. The tables must be read together with the full text of each summary and are alone not a complete description of LifeSci Capital's financial analyses. Except as otherwise noted, the following quantitative information, to the extent that it is based on market data, is based on market data as it existed on or before June 25, 2021 and is not necessarily indicative of current market conditions.

***Advaxis Selected Comparable Company Analysis***

LifeSci Capital reviewed selected financial data of seven early-stage oncology-focused publicly traded biopharmaceutical companies with Phase 1 or Phase 1/2 lead oncology assets. None of the companies is directly comparable to Advaxis. Accordingly, an analysis of the results of such a comparison is not purely mathematical but instead involves complex considerations and judgments concerning differences in historical and projected financial and operating characteristics of the selected companies below. The current fully diluted equity market values are based on closing stock prices as of June 25, 2021. LifeSci Capital reviewed and compared, among other financial and operational metrics, current fully diluted equity market values for the following selected oncology focused companies:

- Onconova Therapeutics
- Celyad Oncology
- Cyclacel Pharmaceuticals
- Plus Therapeutics
- Salarius Pharmaceuticals
- Lixte Biotechnology
- Panbela Therapeutics

These seven companies were chosen because their operations, for the purposes of analysis, may be considered similar to certain operations of Advaxis. The seven selected publicly traded companies had fully diluted equity market values between approximately $39 million and $114 million. LifeSci Capital derived a median equity market value of approximately $62 million and a mean equity market value of approximately $66 million for the selected publicly traded companies. Using the mean and median equity market values, LifeSci Capital determined a range of implied equity values for Advaxis, which was $62 million to $66 million. This compares to Advaxis' approximate fully diluted equity value of $72 million as of June 25, 2021. The results of these analyses are summarized as follows:

Selected Companies

| **Company Name** | | **Current Fully Diluted Equity Market Value** *(Values in US$ millions)* |
|---|---|---|
| Onconova Therapeutics | $ | 114 |
| Celyad Oncology | $ | 83 |
| Cyclacel Pharmaceuticals | $ | 71 |
| Plus Therapeutics | $ | 62 |
| Salarius Pharmaceuticals | $ | 52 |
| Lixte Biotechnology | $ | 42 |
| Panbela Therapeutics | $ | 39 |
| | | |
| All | **Maximum** | **$ 114** |
| | **Mean** | **$ 66** |
| | **Median** | **$ 62** |
| | **Minimum** | **$ 39** |

LifeSci Capital then compared this range to the exchange ratio.

***Advaxis Market Valuation Analysis***

LifeSci Capital reviewed the historical trading price per share of Advaxis Common Stock for the 90 trading days ended June 25, 2021.

Using publicly available information, LifeSci Capital reviewed the closing price per share of Advaxis Common Stock on June 25, 2021, the volume weighted average trading price (which we refer to as VWAP), and 25$^{th}$ and 75$^{th}$ percentile closing prices of Advaxis Common Stock during each of the preceding 30-trading day, 60-trading day and 90-trading day periods and calculated Advaxis' implied fully diluted market capitalization as of June 25, 2021, based on the corresponding share prices. The results of the analysis were as follows:

| | **Share Price** | | **Implied Fully Diluted Market Capitalization Based on Share Price (in millions)** | |
|---|---|---|---|---|
| Closing Price on June 25, 2021 | $ | 0.49 | $ | 72 |
| **30-trading days ended June 25, 2021** | | | | |
| 75$^{th}$ Percentile | $ | 0.51 | $ | 75 |
| VWAP | $ | 0.53 | $ | 78 |
| 25$^{th}$ Percentile | $ | 0.47 | $ | 69 |
| **60-trading days ended June 25, 2021** | | | | |
| 75$^{th}$ Percentile | $ | 0.52 | $ | 77 |
| VWAP | $ | 0.52 | $ | 77 |
| 25$^{th}$ Percentile | $ | 0.46 | $ | 68 |
| **90-trading days ended June 25, 2021** | | | | |
| 75$^{th}$ Percentile | $ | 0.77 | $ | 116 |
| VWAP | $ | 0.61 | $ | 90 |
| 25$^{th}$ Percentile | $ | 0.48 | $ | 71 |

LifeSci Capital noted that Advaxis' closing share price of $0.49 as of June 25, 2021 was within the range of 25th percentile, 75th percentile, and VWAP closing share prices for each of the 30-trading day, 60-trading day, and 90-trading day periods ending June 25, 2021. LifeSci Capital then compared this range to the exchange ratio.

***Biosight Selected Comparable Initial Public Offerings Analysis***

LifeSci Capital reviewed the initial public offerings (referred to as "IPOs") of 43 biopharmaceutical companies with a lead asset in Phase 2 of clinical development which completed an IPO between January 2019 and May 2021. LifeSci Capital analyzed the pre-money fully diluted equity values of IPOs for these companies and identified two specific subsets that LifeSci Capital believed to be most relevant – IPOs by companies that had not completed a crossover financing and IPOs by companies focused on oncology. For the purposes of this analysis, a crossover financing was defined as a private financing led by institutional investors within 12 months of Advaxis' IPO.

*Selected Comparable Phase 2 Initial Public Offerings Without Crossover Financing*

LifeSci Capital identified and analyzed the following IPOs as those done by Phase 2 companies without completing a crossover financing:

- NGM Biopharmaceuticals
- AlloVir
- NLS Pharmaceutics
- Landos Biopharma
- Evaxion Biotech A/S
- Longeveron
- Anebulo Pharmaceuticals

The selected IPOs had pre-money equity values between approximately $29 million and $973 million. LifeSci Capital derived a median pre-money equity value of approximately $187 million and a mean pre-money equity value of approximately $406 million for the selected IPOs.

Using the mean and median of the pre-money equity values, LifeSci Capital then calculated a range of implied equity values for Biosight, which was $187 million to $406 million. This compares to Biosight's implied equity value as per the Merger Agreement of approximately $218 million, based on the exchange ratio of 118.2009. The following table presents the results of this analysis:

IPOs

| Date | Issuer | Pre-Money Fully Diluted Equity Value *(Values in US$ millions)* |
|---|---|---|
| 4/3/2019 | NGM Biopharmaceuticals | $ 973 |
| 7/30/2020 | AlloVir | $ 791 |
| 1/28/2021 | NLS Pharmaceutics | $ 29 |
| 2/3/2021 | Landos Biopharma | $ 550 |
| 2/4/2021 | Evaxion Biotech A/S | $ 187 |
| 2/11/2021 | Longeveron | $ 169 |
| 5/6/2021 | Anebulo Pharmaceuticals | $ 142 |
| **Maximum** | | **$ 973** |
| **Mean** | | **$ 406** |
| **Median** | | **$ 187** |
| **Minimum** | | **$ 29** |

*Selected Comparable Phase 2 Oncology Initial Public Offerings*

LifeSci Capital identified and analyzed the following 12 IPOs as those done by Phase 2 companies with a focus on oncology:

- BioNTech SE
- Ayala Pharmaceuticals, Inc.
- ADC Therapeutics SA
- Poseida Therapeutics, Inc.
- Checkmate Pharmaceuticals, Inc.
- Kronos Bio, Inc.
- BioAtla, Inc.
- Gracell Biotechnologies Inc.
- Sensei Biotherapeutics, Inc.
- Vaccitech plc
- Day One Biopharmaceuticals, Inc.
- Evaxion Biotech A/S

The selected IPOs had pre-money equity values between approximately $138 million and $3,287 million. LifeSci Capital derived a median pre-money equity value of approximately $648 million and a mean pre-money equity value of approximately $819 million for the selected IPOs.

Using the mean and median of the pre-money equity values, LifeSci Capital then calculated a range of implied equity values for Biosight, which was $648 million to $819 million. This compares to Biosight's implied equity value as per the Merger Agreement of approximately $218 million, based on the exchange ratio of 118.2009. The following table presents the results of this analysis:

IPOs

| Date | Issuer | Pre-Money Fully Diluted Equity Value *(Values in US$ millions)* |
|---|---|---|
| 10/9/2019 | BioNTech SE | $ 3,287 |
| 5/8/2020 | Ayala Pharmaceuticals | $ 138 |
| 5/14/2020 | ADC Therapeutics | $ 1,077 |
| 7/10/2020 | Poseida Therapeutics | $ 792 |
| 8/6/2020 | Checkmate Pharmaceuticals | $ 260 |
| 10/8/2020 | Kronos Bio | $ 837 |
| 12/15/2020 | BioAtla | $ 423 |
| 1/8/2021 | Gracell Biotechnologies | $ 1,062 |
| 2/3/2021 | Sensei Biotherapeutics | $ 458 |
| 2/4/2021 | Vaccitech | $ 504 |
| 4/29/2021 | Day One Biopharmaceuticals | $ 807 |
| 5/26/2021 | Evaxion Biotech A/S | $ 187 |
| | | |
| **Maximum** | | **$ 3,287** |
| **Mean** | | **$ 819** |
| **Median** | | **$ 648** |
| **Minimum** | | **$ 138** |

LifeSci Capital then compared this range to the exchange ratio.

***Biosight Selected Comparable Company Analysis***

LifeSci Capital reviewed selected financial data of nine oncology-focused publicly traded biopharmaceutical companies with comparable oncology assets in Phase 1/2 development with interim clinical data available, or Phase 2 development, with an emphasis on companies with assets in potential registration-enabling Phase 2 studies. None of the companies is directly comparable to Biosight. Accordingly, an analysis of the results of such a comparison is not purely mathematical, but instead involves complex considerations and judgments concerning differences in historical and projected financial and operating characteristics of the selected companies below. The current fully diluted equity market values are based on closing stock prices as of June 25, 2021. LifeSci Capital reviewed and compared, among other financial and operational metrics, current fully diluted equity market values for the following selected oncology focused companies:

- Cellectar Biosciences, Inc.
- Kronos Bio, Inc.
- MEI Pharma, Inc.
- Oncternal Therapeutics, Inc.
- Precision Biosciences Inc
- Replimune Group, Inc.
- Syros Pharmaceuticals, Inc.
- Forma Therapeutics Holdings, Inc.
- Elevation Oncology, Inc.

The nine selected publicly traded companies had fully diluted equity market values between approximately $79 million and $2,102 million. LifeSci Capital derived a median equity market value of approximately $381 million and a mean equity market value of approximately $766 million for the selected publicly traded companies. Using the mean and median equity market values, LifeSci Capital determined a range of implied equity values for Biosight, which was $381 million to $766 million. This compares to Biosight's implied equity value as per the Merger Agreement of approximately $218 million, based on the exchange ratio of 118.2009. The following table presents the results of this analysis:

Selected Companies

| **Company Name** | | **Current Fully Diluted Equity Market Value** *(Values in US$ millions)* | |
|---|---|---|---|
| Cellectar Biosciences | | $ | 79 |
| Kronos Bio | | $ | 1,490 |
| MEI Pharma | | $ | 381 |
| Oncternal Therapeutics | | $ | 261 |
| Precision Biosciences | | $ | 685 |
| Replimune Group | | $ | 2,102 |
| Syros Pharmaceuticals | | $ | 350 |
| Forma Therapeutics | | $ | 1,262 |
| Elevation Oncology | | $ | 285 |
| All | **Maximum** | $ | 2,102 |
| | **Mean** | $ | 766 |
| | **Median** | $ | 381 |
| | **Minimum** | $ | 79 |

LifeSci Capital then compared this analysis to the exchange ratio.

The preparation of a fairness opinion is a complex process and does not lend itself to partial analysis or summary description. Selecting portions of the analyses or of the summary set forth above, without considering the analyses as a whole, could create an incomplete view of the processes underlying LifeSci Capital's opinion. In arriving at its fairness determination, LifeSci Capital considered the results of all its analyses and did not attribute any particular weight to any factor or analysis considered by it. Rather, LifeSci Capital made its determination as to fairness based on its experience and professional judgment after considering the results of all of its analyses.

LifeSci Capital prepared these analyses for purposes of LifeSci Capital providing its opinion to the Advaxis Board as to the fairness from a financial point of view of the exchange ratio to the holders of shares of Advaxis. These analyses do not purport to be appraisals, nor do they necessarily reflect the prices at which businesses or securities actually may be sold. Analyses based upon forecasts of future results are not necessarily indicative of actual future results, which may be significantly more or less favorable than suggested by these analyses. Because these analyses are inherently subject to uncertainty, being based upon numerous factors or events beyond the control of the parties or their respective advisors, none of Advaxis, Biosight, LifeSci Capital or any other person assumes responsibility if future results are materially different from those forecasts.

The exchange ratio was determined through arm's-length negotiations between Advaxis and Biosight and was approved by the Advaxis board. LifeSci Capital provided advice to Advaxis during these negotiations. LifeSci Capital did not, however, recommend any specific exchange ratio to Advaxis or the Advaxis Board or that any specific exchange ratio constituted the only appropriate exchange ratio for the merger.

As described in the section entitled "*The Merger—Advaxis Reasons for the Merger*" beginning on page 85 of this proxy statement/prospectus/information statement, LifeSci Capital's opinion to the Advaxis board was one of many factors taken into consideration by the Advaxis board in making its determination to approve the Merger Agreement. The foregoing summary does not purport to be a complete description of the analyses performed by LifeSci Capital in connection with the fairness opinion and is qualified in its entirety by reference to the written opinion of LifeSci Capital attached as *Annex* ____.

LifeSci Capital is a securities firm engaged directly and through affiliates and related persons in a number of investment banking, financial advisory and merchant banking activities. In the past two years, LifeSci Capital or its affiliates have been engaged to provide certain financial advisory or other services to Advaxis from time to time, including ordinary course strategic advisory engagements and investor relations consulting services, and LifeSci Capital has received approximately $695,000 in connection with such engagements. In the past two years, LifeSci Capital or its affiliates have been engaged to provide certain services to Biosight from time to time, including ordinary course investor relations and executive recruitment consulting services, and LifeSci Capital has received approximately $345,000 in connection with such engagements. LifeSci Capital may provide investment banking and other services to or with respect to Advaxis or Biosight or their respective affiliates in the future, for which LifeSci Capital may receive compensation. Certain (i) of LifeSci Capital's and its affiliates' directors, officers, members and employees, or family members of such persons, (ii) of LifeSci Capital's affiliates or related investment funds and (iii) investment funds or other persons in which any of the foregoing may have financial interests or with which they may co-invest, may at any time acquire, hold, sell or trade, in debt, equity and other securities or financial instruments (including derivatives, bank loans or other obligations) of, or investments in, Advaxis or any of its affiliates, or any other party that may be involved in the merger.

The Advaxis board selected LifeSci Capital as its financial advisor because it is an internationally recognized investment banking firm that has substantial experience in transactions similar to the merger and had recently completed a review process which had identified a number of relevant candidates for a potential strategic transaction with Advaxis. Pursuant to an engagement letter agreement dated October 7, 2020, Advaxis engaged LifeSci Capital to act as its financial advisor in connection with the contemplated transaction. The engagement letter between Advaxis and LifeSci Capital provides for a transaction fee that is estimated, based on the information available as of the date of the announcement, at approximately $525,000, $250,000 of which became payable upon the rendering of the fairness opinion, and the remainder of which is contingent upon the completion of the merger. In addition, Advaxis has agreed to reimburse LifeSci Capital for certain of its expenses, including attorneys' fees and disbursements, and to indemnify LifeSci Capital against certain claims and liabilities arising out of LifeSci Capital's engagement.

**Interests of Advaxis Directors and Executive Officers in the Merger**

In considering the recommendation of the Advaxis board of directors with respect to issuing shares of Advaxis common stock in the merger and the other matters to be acted upon by the Advaxis stockholders at the Advaxis special meeting, the Advaxis stockholders should be aware that Advaxis' directors and executive officers have interests in the merger that are different from, or in addition to, the interests of Advaxis' stockholders generally. These interests may present them with actual or potential conflicts of interest, and these interests, to the extent material, are described below.

Advaxis is party to Severance and Change in Control Plan Participation Agreements with each of its executive officers pursuant to the Advaxis Severance Plan that may result in the receipt by such executive officers of cash severance payments and other benefits with a total value of approximately $2.5 million (collectively, and not individually), but not including the value of any accelerated vesting of Advaxis equity awards held by those officers.

Additionally, pursuant to the terms of the Merger Agreement:

- Kenneth A. Berlin and Dr. David Sidransky, members of the Advaxis board of directors, will continue as directors after the effective time of the merger, and, following the closing of the merger, Dr. Sidransky will be eligible to be compensated as a non-employee director of Advaxis pursuant to the Advaxis compensation policy that is expected to remain in place following the effective time of the merger.

- Under the Merger Agreement, Advaxis' directors and executive officers are entitled to continued indemnification, expense advancement and insurance coverage.

- Dr. David Sidransky, a member of the Advaxis board of directors, is a co-founder and owner of Israeli Biotech Fund. Israeli Biotech Fund is an owner of shares of share capital (or options to purchase capital stock) equal to approximately 10% of Biosight on a fully diluted basis.

- The vesting of approximately 73,777 options granted to Kenneth A. Berlin will accelerate in connection with the closing of the merger.

Advaxis' board of directors approved a $1,000,000 retention bonus pool to be provided to certain of its key management personnel in connection with the Merger. As of the date hereof, no decisions have been made or information shared with such personnel as to how such retention bonus pool will be allocated.

As of July 31, 2021, the directors and executive officers of Advaxis owned, in the aggregate, less than 1% of the outstanding voting shares of Advaxis common stock. Each of Advaxis' officers and directors has entered into support agreements in connection with the merger. The support agreements are discussed in greater detail in the section titled "*Agreements Related to the Merger*" in this proxy statement/prospectus/information statement. The Advaxis board of directors was aware of these interests and considered them, among other matters, in the decision to approve the Merger Agreement. For more information, please see the section titled "*The Merger—Interests of the Advaxis Directors and Executive Officers in the Merger*" of this proxy statement/prospectus/information statement.

The Advaxis board of directors was aware of these potential conflicts of interest and considered them, among other matters, in reaching its decision to approve the merger and the Merger Agreement, and to recommend that the Advaxis stockholders approve the proposals to be presented to the Advaxis stockholders for consideration at the Advaxis special meeting as contemplated by this proxy statement/prospectus/information statement.

***Ownership Interests***

As of July 31, 2021, Advaxis' current non-employee directors and executive officers beneficially owned, in the aggregate, less than 1% of the shares of Advaxis common stock, which for purposes of this subsection excludes any Advaxis shares issuable upon exercise of Advaxis stock options held by such individuals. The affirmative vote of the holders of a majority of the shares present in attendance or represented by proxy at the Advaxis special meeting and entitled to vote on the matter, assuming a quorum is present, is required for approval of Proposal Nos. 4 and 5. The affirmative vote of the holders of a majority of the outstanding shares of Advaxis common stock entitled to vote at the Advaxis special meeting is required for approval of Proposals No. 1, 2 and 3. Each of Advaxis' non-employee directors have also entered into a support agreement in connection with the merger. For a more detailed discussion of the support agreements, please see the section titled "*Agreements Related to the Merger—Support Agreements*" beginning on page 122 of this proxy statement/prospectus/information statement.

**Interests of Dr. David Sidransky in Israeli Biotech Fund**

Dr. David Sidransky, a member of the Advaxis board of directors, is a co-founder and owner of Israeli Biotech Fund. Israeli Biotech Fund is an owner of shares of share capital (or options to purchase share capital) of Biosight. Israeli Biotech Fund I, L.P. and Israeli Biotech Fund II, L.P. collectively own an aggregate of 371,608 of Biosight's preferred C shares and warrants to purchase up to 48,774 of Biosight's preferred C shares, which represent, in the aggregate, ownership of approximately 10% of Biosight calculated on a fully diluted basis.

**Treatment of Advaxis Options**

Each option to purchase Advaxis common stock that is issued and outstanding at the effective time of the merger will remain issued and outstanding and such shares will be unaffected by the merger; provided that the number of shares of Advaxis common stock underlying such options, and the exercise prices for such options will be appropriately adjusted to reflect the proposed reverse stock split.

The table below shows the outstanding options for each of the named executive officers as of the date hereof.

| Name | Number of Vested Options Held | Weighted Average Exercise Price of Vested Options | Number of Unvested Options Held | Weighted Average Exercise Price of Unvested Options |
|---|---|---|---|---|
| **Executive Officers** | | | | |
| Kenneth Berlin | 97,556 | $ 13.80 | 73,777(1) | $ 1.22 |
| Andres Gutierrez | 47,221 | $ 9.82 | 52,779 | $ 0.94 |
| Igor Gitelman | | | 50,000 | $ 0.39 |

(1) The vesting of these options will accelerate in connection with the closing of the merger.

**Director Positions Following the Merger**

David Sidransky and Dr. Samir Khleif are currently non-employee directors of Advaxis and will continue as directors of the combined company after the effective time of the merger. Kenneth A. Berlin is currently an officer and director of Advaxis and will continue as an officer and director of the combined company.

**Indemnification and Insurance**

For a discussion of the indemnification and insurance provisions related to the Advaxis directors and officers under the Merger Agreement, please see the section titled "*The Merger Agreement—Indemnification and Insurance for Officers and Directors*" beginning on page 153 below.

**Executive Employment Arrangements**

Advaxis has an employment agreement with its President and Chief Executive Officer, Mr. Berlin, and an employment agreement with its Executive Vice President and Chief Medical Officer, Mr. Gutierrez, both agreements effective April 23, 2018. Pursuant the agreements, in the event the named executive officer's employment is terminated without Just Cause, or if the executive voluntarily resigns with Good Reason, or if the named executive officer's employment is terminated due to disability (all as defined in their respective employment agreements), and so long as the named executive officer executes a confidential separation and release agreement, in addition to the applicable base salary, plus any accrued but unused vacation time and unpaid expenses that have been earned as of the date of such termination, the named executive officer is entitled to the following severance benefits: (i) 12 months of base salary payable in equal monthly installments, (ii) a bonus payment for the year in which the employment is terminated equal to the target bonus percentage, multiplied by the base salary in effect at the time of termination, (iii) continued health and welfare benefits for 12 months, and (iv) full vesting of all stock options and stock awards (with extension of the exercise period for stock options by two years).

In the event Mr. Berlin's employment is terminated without Just Cause during the period beginning three months prior to a Change in Control (as defined in Mr. Berlin's employment agreement) and ending 18 months after the Change in Control (such period, the "CIC Protection Period"), or if Mr. Berlin voluntarily resigns with Good Reason during the CIC Protection Period, and provided that Mr. Berlin continues to comply with certain covenants set forth in his employment agreement, in addition to the applicable base salary and any earned but unpaid bonus for the prior fiscal year, plus any accrued but unused vacation time and unpaid expenses that have been earned as of the date of such termination, Mr. Berlin is entitled to the following severance benefits: (i) an amount equal to 1.75 times the sum of the applicable base salary plus an amount equal to Mr. Berlin's target bonus, payable in a single lump sum within 60 days of the termination, (ii) a bonus payment for the year in which the employment is terminated equal to the target bonus percentage, multiplied by the base salary in effect at the time of termination, multiplied by a fraction, the numerator of which is the number of calendar days Mr. Berlin was employed during such year and the denominator is 365, (iii) continued health and welfare benefits for 21 months, and (iv) full vesting and exercisability of all stock options and stock awards.

**Limitations of Liability and Indemnification**

In addition to the indemnification obligations required by the amended and restated certificate of incorporation and third amended and restated bylaws of Advaxis, Advaxis has offered to enter into indemnification agreements with all directors and has entered into an indemnification agreement with all directors except Samir Khleif. Advaxis has also entered into an indemnification agreement with three of its executive officers, Molly Henderson, Ken Berlin and Andres Gutierrez. These agreements provide for the indemnification of Advaxis' directors and executive officers for all reasonable expenses and liabilities incurred in connection with any action or proceeding brought against them by reason of the fact that they are or were agents of Advaxis. Advaxis believes that these amended and restated certificate of incorporation provisions, third amended and restated bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

**Golden Parachute Compensation**

Advaxis has entered into the employment agreements described above with each of the named executive officers that provide for certain severance payments and benefits in the event the named executive officer's employment with Advaxis is terminated under certain circumstances.

In addition, upon a Change in Control of Advaxis, unvested equity awards held by an executive officer will be accelerated as follows: (i) outstanding stock options and other awards in the nature of rights that may be exercised shall become fully vested and exercisable, (ii) time-based restrictions on restricted stock, restricted stock units and other equity awards shall lapse and the awards shall become fully vested, and (iii) performance-based equity awards, if any, shall become vested and shall be deemed earned based on an assumed achievement of all relevant performance goals at "target" levels, and shall payout pro rata to reflect the portion of the performance period that had elapsed prior to the Change in Control.

The table below shows the estimated value of benefits to each of the named executive officers if their employment had been terminated under various circumstances as of December 31, 2021. The amounts shown in the table exclude accrued but unpaid base salary, unreimbursed employment-related expenses, accrued but unpaid vacation pay, and the value of equity awards that were vested by their terms as of July 31, 2021.

| | **Involuntary Termination without a Change in Control ($)** | **Involuntary Termination in connection with a Change in Control ($)** | **Death ($)** | **Disability ($)** | **Termination for Cause; Voluntary Resignation ($)** |
|---|---|---|---|---|---|
| **Kenneth Berlin** | | | | | |
| *Cash severance* | 576,493(1) | 1,564,737(5) | - | 576,493(1) | - |
| *Bonus* | 317,071(7) | 317,071(2) | 317,071(2) | 317,071(7) | - |
| *Health benefits* | 30,335(3) | 53,087(6) | - | 30,335(3) | - |
| *Value of equity Acceleration* | 2,344(4) | 2,344(4) | 2,344(4) | 2,344(4) | - |
| **Total** | 926,243 | 1,937,239 | 319,415 | 926,243 | - |
| | | | | | |
| **Andres Gutierrez** | | | | | |
| *Cash severance* | 443,456(1) | 443,456(1) | - | 443,456(1) | - |
| *Bonus* | 177,382(7) | 177,382(7) | 177,382(7) | 177,382(7) | - |
| *Health benefits* | 30,335(3) | 30,335(6) | - | 30,335(3) | - |
| *Value of equity Acceleration* | 233(4) | 233(4) | 233(4) | 233(4) | - |
| **Total** | 651,406 | 651,406 | 177,615 | 651,406 | - |

(1) Reflects severance payment equal to one times base salary payable in equal monthly instalments for 12 months.

(2) Reflects pro rata bonus determined by multiplying the target bonus amount for the year in which the termination occurs by a fraction, the numerator of which is the number of calendar days the executive is employed during such year and the denominator of which is 365.

(3) Reflects Advaxis' cost of continued health coverage at active employee rates for 12 months.

(4) Reflects the value of unvested in-the-money stock options and RSUs that vest upon the designated event.

(5) For Mr. Berlin, reflects 1.75 times the sum of his base salary and target bonus, payable in a single lump sum payment. For Mr. Gutierrez, equals one times base salary, payable in equal monthly installments for 12 months.

(6) Reflects the full cost of continued health coverage for 21 months for Mr. Berlin and 12 months for Mr. Gutierrez.

(7) Represents a bonus payment equal to the executive's target bonus.

**Interests of Biosight Directors and Executive Officers in the Merger**

In considering the recommendation of the Biosight board of directors with respect to voting to approve the merger and related transactions at the Biosight shareholder meeting, Biosight shareholders should be aware that certain members of the board of directors and executive officers of Biosight have interests in the merger that may be different from, or in addition to, interests they have as Biosight shareholders. Certain Biosight's directors and executive officers are expected to become directors and executive officers of the combined company upon the closing of the merger, and all of Biosight's directors and executive officers are entitled to certain indemnification and liability insurance coverage pursuant to the terms of the Merger Agreement.

Certain current executive officers and directors of Biosight hold Biosight shares, which will, at the Effective Time, be automatically converted into the right to receive an amount of registered shares of Advaxis common stock equal to the Exchange Ratio. As of June 30, 2021, Biosight's directors and executive officers beneficially owned approximately 20.1% of the outstanding Biosight shares on an as converted, fully diluted basis.

In addition, certain of Biosight's current executive officers and directors hold options to purchase Biosight shares that are outstanding and unexercised immediately prior to the effective time of the merger, which will, at the Effective Time, be automatically converted into fully vested options to purchase such numbers of Advaxis common stock as is determined by multiplying the number of Biosight ordinary shares subject to the option by the Exchange Ratio. As of June 30, 2021, the grant of options to Biosight's directors and executive officers entitled them to purchase 6.9% of the outstanding shares of Biosight shares on an as converted, fully diluted basis.

Certain of Biosight's directors also hold warrants to purchase Biosight shares that are outstanding and unexercised immediately prior to the effective time of the merger, which will, prior to the Effective Time, be exercised, by cash or cashless, and the shares issued as a result of such exercise be automatically converted into an amount of registered shares of Advaxis common stock equal to the Exchange Ratio. As of June 30, 2021, Biosight's directors held warrants to purchase up to 243,296 Preferred C Shares of Biosight.

In addition to the indemnification required by Biosight's Articles of Association, Biosight has entered into indemnification agreements with certain of its directors and officers. With certain exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. Biosight believes that these indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

Pursuant to the Merger Agreement, Advaxis and Biosight agreed that for a period of six years from the effective time of the merger, Advaxis shall cause the combined company's organizational documents to contain provisions no less favorable with respect to indemnification, advancement of expenses and exculpation of present and former directors, managers and officers of Biosight than are presently set forth in the organizational documents of Biosight.

Moreover, at the effective time of the merger, Biosight shall purchase, and for a period of six years following the Effective Time, a directors' and officers' liability "tail" insurance policy or policies covering the all of Biosight's directors and executive officers for events occurring at or prior to the effective time of the merger, that is substantially equivalent to the existing policies of Biosight.

The Biosight board of directors was aware of these interests and considered them, among other matters, in its decision to approve the Merger Agreement.

**Effective Time of the Merger**

The Merger Agreement requires the parties to consummate the merger as promptly as practicable, and in any event within two business days after all of the conditions to the consummation of the Merger contained in the Merger Agreement are satisfied or waived (other than those conditions that by their nature are to be satisfied at the closing of the merger, but subject to the satisfaction or waiver of each of such conditions), including the adoption of the Merger Agreement by the Biosight shareholders and the approval by the Advaxis stockholders of the issuance of Advaxis common stock in the merger, the reverse stock split of Advaxis common stock, and the other transactions proposed under the Merger Agreement, other than those conditions that by their nature are to be satisfied at the closing of the merger (but subject to the satisfaction or waiver of each of such conditions). As soon as practicable after the determination of the date on which the closing of the merger is to take place, each of Biosight and Advaxis shall deliver to the Companies Registrar of the Israeli Corporations Authority (the "Companies Registrar") a notice of the contemplated merger and the proposed date on which the Companies Registrar is requested to issue a certificate evidencing the merger in accordance with Section 323(5) of the Israeli Companies Law—1999, or ICL. The merger will become effective upon the issuance by the Companies Registrar of such certificate evidencing the merger. Neither Advaxis nor Biosight can predict the exact timing of the consummation of the merger.

**Regulatory Approvals**

In the United States, Advaxis must comply with applicable federal and state securities laws and the rules and regulations of Nasdaq in connection with the issuance of shares of Advaxis common stock to Biosight's shareholders in connection with the transactions contemplated by the Merger Agreement and the filing of this proxy statement/prospectus/information statement with the SEC. Advaxis does not require, and consequently, does not intend to seek, any regulatory approval from antitrust authorities to consummate the transactions. Additionally, in connection with the merger, Biosight will be required to file a final written notice with the Israeli National Authority for Technological Innovation (also known as the Israeli Innovation Authority and formerly known as the Office of the Chief Scientist of the Israeli Ministry of Economy and Industry) pursuant to the Israeli Encouragement of Research, Development and Technological Innovation in the Industry Law, 5744 1984, and the rules and regulations related thereto.

**Material U.S. Federal Income Tax Consequences of the Merger**

The following is a discussion of the material U.S. federal income tax consequences of the merger that are applicable to U.S. Holders (as defined below) who exchange shares of Biosight share capital for shares of Advaxis common stock in the merger, assuming that the merger is consummated in the manner described in the Merger Agreement and in this proxy statement/prospectus/information statement. This discussion does not purport to be a complete analysis of all potential tax consequences and is based upon current provisions of the Code, existing Treasury Regulations, judicial decisions and published rulings and administrative pronouncements of the IRS, all in effect as of the date hereof and all of which are subject to differing interpretations or change. Any such change or differing interpretation, which may be retroactive, could alter the tax consequences to Biosight shareholders as described in this summary.

This discussion does not address all U.S. federal income tax consequences relevant to a Biosight shareholder. In addition, it does not address consequences relevant to Biosight shareholders that are subject to particular U.S. or non-U.S. tax rules, including, without limitation to Biosight shareholders that are:

- persons who do not hold their Biosight share capital as a "capital asset" within the meaning of Section 1221 of the Code;
- brokers, dealers or traders in securities, banks, insurance companies, other financial institutions or mutual funds;
- real estate investment trusts; regulated investment companies; tax-exempt organizations or governmental organizations;
- pass-through entities such as partnerships, S corporations, disregarded entities for federal income tax purposes and limited liability companies (and investors therein);
- subject to the alternative minimum tax provisions of the Code;
- persons who hold their shares as part of a hedge, wash sale, synthetic security, conversion transaction or other integrated transaction;
- persons that have a functional currency other than the U.S. dollar;
- traders in securities who elect to apply a mark-to-market method of accounting;
- persons who hold shares of Biosight share capital that may constitute "qualified small business stock" under Section 1202 of the Code or as "Section 1244 stock" for purposes of Section 1244 of the Code;
- persons who acquired their shares of Biosight share capital in a transaction subject to the gain rollover provisions of Section 1045 of the Code;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to Biosight share capital being taken into account in an "applicable financial statement" (as defined in the Code);
- persons deemed to sell Biosight share capital under the constructive sale provisions of the Code;
- persons holding Biosight share capital who exercise dissenters' rights;
- persons who acquired their shares of Biosight share capital pursuant to the exercise of options or otherwise as compensation or through a tax-qualified retirement plan or through the exercise of a warrant or conversion rights under convertible instruments; and
- certain expatriates or former citizens or long-term residents of the United States.

Biosight shareholders subject to particular U.S. or non-U.S. tax rules, including those that are described in this paragraph, are urged to consult their own tax advisors regarding the consequences to them of the merger.

If an entity that is treated as a partnership or other pass-through entity for U.S. federal income tax purposes holds Biosight share capital, the U.S. federal income tax treatment of a partner in the partnership or other pass-through entity will generally depend upon the status of the partner, the activities of the partnership or other pass-through entity and certain determinations made at the partner level. If you are a partner of a partnership or other pass-through entity holding Biosight share capital, you should consult your tax advisors regarding the tax consequences of the Merger.

In addition, the following discussion does not address (a) the tax consequences of transactions effectuated before, after or at the same time as the merger, whether or not they are in connection with the merger, including, without limitation, transactions in which shares of Biosight share capital are acquired or disposed of other than in exchange for shares of Advaxis common stock in the merger; (b) the tax consequences to holders of Biosight convertible notes, or options or warrants issued by Biosight which are assumed in connection with the merger; (c) the tax consequences of the ownership of shares of Advaxis common stock following the merger; (d) any U.S. federal non-income tax consequences of the merger, including U.S. federal estate, gift or other tax consequences; (e) any state, local or non-U.S. tax consequences of the merger; or (f) the Medicare contribution tax on net investment income. No ruling from the Internal Revenue Service, or the IRS, has been or will be requested in connection with the merger. Biosight shareholders should be aware that the IRS could adopt a position which could be sustained by a court contrary to that set forth in this discussion.

**STOCKHOLDERS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS, AS WELL AS ANY TAX CONSEQUENCES OF THE MERGER ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.**

***Definition of "U.S. Holder"***

For purposes of this discussion, a "U.S. Holder" is a beneficial owner of Biosight share capital that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation or any other entity taxable as a corporation created or organized in or under the laws of the United States, any state thereof, or the District of Columbia;
- a trust if either (i) a court within the United States is able to exercise primary supervision over the administration of such trust, and one or more United States persons (within the meaning of Section 7701(a)(30) of the Code) are authorized or have the authority to control all substantial decisions of such trust, or (ii) the trust was in existence on August 20, 1996, and has a valid election in effect under applicable Treasury Regulations to be treated as a United States person for U.S. federal income tax purposes; or
- an estate, the income of which is subject to U.S. federal income tax regardless of its source.

**Tax Characterization of the Merger**

Advaxis and Biosight intend for the merger to qualify as a "reorganization" within the meaning of Section 368(a) of the Code and the Treasury Regulations promulgated thereunder. However, no opinion of counsel or ruling from the IRS has been obtained or will be obtained regarding the treatment of the merger as a tax-free reorganization.

If the merger does not qualify as a "reorganization" within the meaning of Section 368(a) of the Code and the Treasury Regulations promulgated thereunder (including if the IRS successfully challenges the qualification of the merger as such), then each U.S. Holder would recognize gain or loss on the exchange of Biosight share capital for Advaxis common stock in the merger equal to the difference between such Biosight shareholder's adjusted U.S. federal income tax basis in the shares of Biosight share capital surrendered and the fair market value of the shares of Advaxis common stock received in exchange therefor and any cash received in lieu of a fractional share. The remainder of this discussion assumes that the merger will be treated as a tax-free "reorganization" within the meaning of Section 368(a) of the Code and the Treasury Regulations promulgated thereunder.

***Tax Treatment of Biosight shareholders in the Merger***

If the merger qualifies as a "reorganization" within the meaning of Section 368(a) of the Code and the Treasury Regulations promulgated thereunder, except as described below with respect to the receipt of cash in lieu of a fractional share of Advaxis common stock, U.S. Holders generally will not recognize gain or loss upon the exchange of their Biosight share capital for Advaxis common stock. A U.S. Holder generally will obtain an aggregate tax basis in the Advaxis common stock such holder receives in the merger equal to the holder's aggregate adjusted tax basis in the Biosight share capital exchanged therefor reduced by the portion of such holder's aggregate basis allocable to any fractional share of Advaxis common stock for which cash is received. The holding period of the shares of Advaxis common stock received by a U.S. Holder in the merger will include the holding period of the shares of Biosight share capital surrendered in exchange therefor. Treasury Regulations provide detailed rules for allocating the tax basis and holding period of the shares of Biosight share capital surrendered to the shares of Advaxis common stock received. U.S. Holders of shares of Biosight share capital acquired on different dates and at different prices should consult their tax advisors regarding the allocation of the tax basis and holding period of such shares. **Holders of Biosight share capital are urged to consult their tax advisors regarding the U.S. federal income tax consequences of the merger in light of their personal circumstances and the consequences to them under state, local and non-U.S. tax laws and other federal tax laws.**

***Cash in Lieu of Fractional Share***

A U.S. Holder that receives cash in lieu of a fractional share of Advaxis common stock will generally be treated as having received such fractional share and then as having received such cash in redemption of the fractional share. Gain or loss will generally be recognized based on the difference between the amount of cash received in lieu of the fractional share of Advaxis common stock and the portion of the U.S. Holder's aggregate adjusted tax basis in the shares of Biosight share capital exchanged in the merger which is allocable to the fractional share. Such gain or loss will generally be capital gain or loss and will generally be long-term capital gain or loss if the U.S. Holder's holding period for its Biosight share capital surrendered in the merger exceeds one year at the effective time. Long-term capital gains of certain non-corporate U.S. Holders of Biosight share capital, including individuals, are generally taxed at preferential rates. The deductibility of capital losses is subject to limitations.

***Reporting Requirements***

If the merger qualifies as a reorganization within the meaning of Section 368(a) of the Code and the Treasury Regulations promulgated thereunder, each U.S. Holder who receives shares of Advaxis common stock in the merger is required to retain permanent records pertaining to the merger, and make such records available to any authorized IRS officers and employees. Such records should specifically include information regarding the amount, basis, and fair market value of the Biosight share capital exchanged and the amount of Advaxis common stock and cash received in exchange therefor. U.S. Holders who owned immediately before the merger at least one percent (by vote or value) of the total outstanding stock of Biosight are required to attach a statement to their tax returns for the year in which the merger is consummated that contains the information listed in Treasury Regulations Section 1.368-3(b). Such statement must include the U.S. Holder's tax basis in such holder's Biosight share capital surrendered in the merger, the fair market value of such stock, the date of the merger and the name and employer identification number of each of Biosight and Advaxis. U.S. Holders are urged to consult with their tax advisors to comply with these rules.

***Backup Withholding and Information Reporting***

A U.S. Holder may, under certain circumstances, be subject to information reporting and backup withholding (currently, at a rate of 24%) on any payments of cash in lieu of fractional shares, unless such holder properly establishes an exemption or provides its correct tax identification number and otherwise complies with the applicable requirements of the backup withholding rules. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be refunded or credited against a payee's U.S. federal income tax liability, if any, so long as such payee furnishes the required information to the IRS in a timely manner.

**The foregoing summary is of a general nature only and is not intended to be, and should not be construed to be, legal, business or tax advice to any particular Biosight shareholder. This summary does not take into account your particular circumstances and does not address consequences that may be particular to you. Therefore, you should consult your tax advisor regarding the particular consequences of the merger to you.**

**Anticipated Accounting Treatment**

The merger will be accounted for as a reverse recapitalization in accordance with U.S. GAAP. Under this method of accounting, Biosight will be deemed to be the accounting acquirer for financial reporting purposes. This determination was primarily based on the expectations that, immediately following the merger (i) Biosight's shareholders are expected to own approximately 75% of the voting interests of the combined company immediately following the closing of the merger; (ii) directors appointed by Biosight will hold more board seats in the combined company than Advaxis; (iii) Biosight's management will hold key positions in the management of the combined company; and (iv) the combined company will be named "Biosight Therapeutics Inc." Accordingly, for accounting purposes, the merger will be treated as the equivalent of Biosight issuing stock to acquire the net assets of Advaxis. As a result of the merger, the net assets of Advaxis will be recorded at their acquisition-date fair value in the financial statements of Biosight and the reported operating results prior to the merger will be those of Biosight. See the section titled "*Unaudited Pro Forma Condensed Combined Financial Information*" elsewhere in this proxy statement/prospectus/information statement for additional information.

**Nasdaq Stock Market Listing**

Shares of Advaxis common stock are currently listed on The Nasdaq Capital Market under the symbol "ADXS." Advaxis has agreed to use commercially reasonable efforts to cause the shares of Advaxis common stock being issued in the merger to be approved for listing (subject to notice of issuance) on The Nasdaq Capital Market at or prior to the effective time.

In addition, under the Merger Agreement, each of Advaxis' and Biosight's obligation to complete the merger is subject to the satisfaction or waiver by each of the parties, at or prior to the merger, of various conditions, including that the shares of Advaxis common stock to be issued in the merger have been approved for listing (subject to official notice of issuance) on Nasdaq as of the closing of the merger.

If the Nasdaq listing application is accepted, Advaxis anticipates that the common stock of the combined company will be listed on The Nasdaq Capital Market following the closing of the merger under the trading symbol "BSTX." In order for the Nasdaq listing application to be accepted, among other requirements, the combined company must maintain a bid price of $4 or higher for a certain period following the proposed reverse stock split. As of October 12, 2021, the bid price of Advaxis' common stock was $0.51.

**Appraisal Rights and Dissenters' Rights**

Under the DGCL, Advaxis stockholders are not entitled to appraisal rights in connection with the merger.

Under Israeli law, Biosight shareholders are not entitled to appraisal rights in connection with the merger.

## THE MERGER AGREEMENT

*The following is a summary of the material terms of the Merger Agreement. A copy of the Merger Agreement is attached to this proxy statement/prospectus/information statement as Annex A and is incorporated by reference into this proxy statement/prospectus/information statement. The Merger Agreement has been attached to this proxy statement/prospectus/information statement to provide you with information regarding its terms. It is not intended to provide any other factual information about Advaxis, Biosight or Merger Sub. The following description does not purport to be complete and is qualified in its entirety by reference to the Merger Agreement. You should refer to the full text of the Merger Agreement for details of the merger and the terms and conditions of the Merger Agreement.*

*The Merger Agreement contains representations and warranties that Advaxis and Merger Sub, on the one hand, and Biosight, on the other hand, have made to one another as of specific dates. These representations and warranties have been made for the benefit of the other parties to the Merger Agreement and may be intended not as statements of fact but rather as a way of allocating the risk to one of the parties if those statements prove to be incorrect. In addition, the assertions embodied in the representations and warranties are qualified by information in confidential disclosure schedules exchanged by the parties in connection with signing the Merger Agreement. While Advaxis and Biosight do not believe that these disclosure schedules contain information required to be publicly disclosed under the applicable securities laws, other than information that has already been so disclosed, the disclosure schedules do contain information that modifies, qualifies and creates exceptions to the representations and warranties set forth in the attached Merger Agreement. Accordingly, you should not rely on the representations and warranties as current characterizations of factual information about Advaxis or Biosight, because they were made as of specific dates, may be intended merely as a risk allocation mechanism between Advaxis, Merger Sub and Biosight and are modified by the disclosure schedules.*

### General

Under the Merger Agreement, Merger Sub, a wholly owned subsidiary of Advaxis formed by Advaxis in connection with the merger under the laws of Israel, will merge with and into Biosight, with Biosight surviving as a wholly owned subsidiary of Advaxis.

### Merger Consideration

At the effective time of the merger:

- each issued and outstanding share of share capital of Biosight (excluding certain Biosight shares that may be cancelled pursuant to the terms and conditions of the Merger Agreement) shall by virtue of the merger and without any action on the part of the holder thereof, be deemed to have been transferred to Biosight in exchange for the right to receive 118.2009 shares of Advaxis common stock and, with respect to 102 Biosight Shares (as defined in the Merger Agreement), in exchange for the right to receive 102 Advaxis Shares (as defined in the Merger Agreement) (the “Exchange Ratio”), with the Exchange Ratio subject to adjustment to account for the proposed Advaxis reverse stock split;

- each ordinary share, par value one Israeli Agora (NIS 0.01) per share, of Merger Sub issued and outstanding immediately prior to the effective time of the merger shall be automatically and without further action converted into and become one validly issued, fully paid and non-assessable ordinary share, par value one Israeli Agora (NIS 0.01) per share, of the surviving company of the merger; and

- each option to purchase Biosight shares of share capital outstanding and unexercised immediately prior to the effective time of the merger will be assumed by Advaxis and will become an option to purchase (A) that number of shares of Advaxis common stock (rounded down to the nearest whole share) equal to the product obtained by multiplying (i) the total number of Biosight shares subject to such option immediately prior to the effective time of the merger by (ii) the Exchange Ratio, (B) at a per share exercise price (rounded up to the nearest whole cent) equal to the quotient obtained by dividing (i) the exercise price per Biosight share at which such option was exercisable immediately prior to the effective time of the merger by (ii) the Exchange Ratio (rounding the resulting exercise price up to the nearest whole cent), with the Exchange Ratio, in each case, subject to adjustment to account for the proposed Advaxis reverse stock split.

No fractional shares of Advaxis common stock will be issuable pursuant to the merger, and no certificates or scrip for any such fractional shares shall be issued, with no cash being paid for any fractional share eliminated by such rounding. Any fractional shares of Advaxis common stock that a shareholder of Biosight would otherwise be entitled to receive shall be aggregated together prior to eliminating any remaining fractional share.

The Merger Agreement provides that, at the effective time of the merger, Advaxis will deposit with an exchange agent that is mutually acceptable to Advaxis and Biosight certificates or book entry shares representing the shares of Advaxis common stock issuable in connection with the merger.

The Merger Agreement provides that, promptly (and in any event within two Business Days) after the effective time of the merger, Advaxis and Biosight shall cause the exchange agent to mail to each record holder of Biosight Share Certificates (as defined in the Merger Agreement) immediately prior to the effective time of the merger a letter of transmittal and instructions for surrendering and exchanging the record holder's Biosight Share Certificates for shares of Advaxis common stock. Upon surrender of a Biosight Share Certificate for exchange to the exchange agent, together with a duly signed letter of transmittal and duly executed copies of any applicable tax forms as instructed in such letter of transmittal, the Biosight Share Certificate surrendered will be canceled and the holder will be entitled to receive in exchange:

- a certificate (or non-certificated book entry) representing the number of whole shares of Advaxis common stock that such holder has the right to receive pursuant to the provisions of the Merger Agreement; and

- dividends or other distributions, if any, declared or made with respect to Advaxis common stock with a record date after the effective time of the merger.

At the effective time of the merger, all holders of certificates representing shares of share capital of Biosight that were issued and outstanding immediately prior to the effective time of the merger will cease to have any rights as shareholders of Biosight. In addition, no transfer of shares of share capital of Biosight after the effective time of the merger will be registered on the stock transfer books of Biosight.

If any Biosight Share Certificate has been lost, stolen or destroyed, Advaxis may, in its discretion, and as a condition to the delivery of any certificate or book entry representing shares of Advaxis common stock, require the owner of such lost, stolen or destroyed certificate to deliver an affidavit claiming such certificate has been lost, stolen or destroyed.

From and after the effective time of the merger, until it is surrendered, each Biosight Share Certificate will be deemed to represent only the right to receive shares of Advaxis common stock. Advaxis will not pay dividends or other distributions on any shares of Advaxis common stock to be issued in exchange for any unsurrendered Biosight Share Certificate until such Biosight Share Certificate is surrendered as provided in the Merger Agreement.

**Treatment of Biosight Options**

At the effective time of the merger, each option to purchase Biosight shares that is outstanding and unexercised immediately prior to the effective time of the merger will, automatically and without any action on the part of the holder thereof, be assumed by Advaxis and be converted into an option to purchase Advaxis common stock. Advaxis will assume the Biosight Ltd. 2009 Israeli Share Option Plan as necessary to assume the 102 Biosight Options and 3(i) Biosight Options and issuance of 102 Advaxis Shares to the 102 Trustee in connection with the merger (each capitalized term as defined in the Merger Agreement). All rights with respect to Biosight shares subject to Biosight options assumed by Advaxis will be converted into rights with respect to Advaxis common stock. Accordingly, from and after the effective time of the merger, each Biosight option assumed by Advaxis may be exercised for such number of shares of Advaxis common stock as is determined by multiplying the number of Biosight ordinary shares subject to the option by the Exchange Ratio (which is subject to adjustments to account for the effect of the proposed Advaxis reverse stock split prior to the consummation of the Merger) and rounding that result down to the nearest whole number of shares of Advaxis common stock. The per share exercise price of the converted option will be determined by dividing the existing exercise price of the Biosight option by the Exchange Ratio (which is subject to adjustments to account for the effect of the proposed Advaxis reverse stock split prior to the consummation of the Merger) and rounding that result up to the nearest whole cent. Any restrictions on the exercise of any Biosight option assumed by Advaxis will continue following the conversion and the term, exercisability and other provisions of assumed Biosight options will generally remain unchanged (for the avoidance of doubt, any Biosight option assumed by Advaxis may be subject to adjustment to reflect changes in Advaxis capitalization after the effective time of the merger and the Advaxis board of directors or a committee thereof will succeed to the authority of the board of directors of Biosight with respect to each assumed Biosight option), provided, however, that unvested options held by service providers shall become fully vested at the effective time of the merger.

In the case of options to purchase Advaxis common stock issued in connection with the assumption of Biosight options, which are subject to tax pursuant to Sections 102(b)(2) or 102(b)(3) of the Israeli Income Tax Ordinance New Version, 1961, as amended, and the rules and regulations promulgated thereunder (the "Ordinance"), such Advaxis options shall be deposited with the IBI Capital Compensation and Trusts (2004) Ltd. subject to the provisions of Section 102 of the Ordinance and any tax ruling received from the ITA regarding such Biosight options (including the Option Tax Ruling (as defined in the Merger Agreement) and Interim Option Tax Ruling (as defined in the Merger Agreement)).

**Treatment of Advaxis Options and Warrants**

Each share of Advaxis common stock issued and outstanding at the time of the merger will remain issued and outstanding and such shares will be appropriately adjusted to reflect the proposed reverse stock split of Advaxis common stock. In addition, each option and warrant to purchase shares of Advaxis common stock that is outstanding immediately prior to the effective time of the merger, whether vested or unvested, will survive the closing and remain outstanding in accordance with its terms. The number of shares of Advaxis common stock underlying such options and warrants, and the exercise prices for such stock options will be appropriately adjusted to reflect the proposed reverse stock split of Advaxis common stock. If any holder of a warrant to purchase Advaxis common stock issued in connection with Advaxis' September 2018 offering properly exercises such holder's right to receive a cash payment in connection with the merger pursuant to the terms and conditions of the underlying agreement governing such warrant, Advaxis shall promptly pay such cash payment to such holder, in each case in such amount as determined in accordance with, and pursuant to the procedures set forth in, such agreement governing such warrant.

**Directors and Officers of Advaxis Following the Merger**

Pursuant to the Merger Agreement, certain of the directors and executive officers of Advaxis will resign at or prior to the effective time of the merger; provided, however, that three directors of Advaxis will remain on the Advaxis board of directors and certain executive officers of Advaxis will remain as executive officers of Advaxis following the effective time of the merger. Prior to the effective time of the merger but to be effective at the effective time of the merger, the Advaxis board of directors will elect six designees selected by Biosight and three designees selected by Advaxis to serve as members of the Advaxis board of directors effective upon consummation of the merger. The composition of the Advaxis board of directors following the effective time of the merger in the aggregate is expected to satisfy the requisite independence requirements, as well as the sophistication and independence requirements for the required committees, pursuant to Nasdaq listing requirements. It is anticipated that after the effective time of the merger, the Advaxis board of directors will be the following:

- Pini Orbach
- Aaron Sasson
- Briggs Morrison
- Gary Gordon
- Gary Titus
- Yuval Cabilly
- Kenneth A. Berlin
- Dr. David Sidransky

It is anticipated that the executive officers of Advaxis upon the consummation of the merger will be:

| Name | Title |
|---|---|
| Kenneth Berlin | President and Chief Executive Officer |
| Roy Golan | Chief Financial Officer |
| Andres Gutierrez, M.D., Ph.D. | Chief Medical Officer |

**Amendment to Certificate of Incorporation of Advaxis**

Stockholders of record of Advaxis common stock on the record date for the special meeting will also be asked to approve the amendment to the certificate of incorporation of Advaxis to effect (i) an increase to the number of authorized shares of Advaxis common stock, if necessary, (ii) a change of the name of Advaxis to "Biosight Therapeutics Inc." and (iii) the proposed Advaxis reverse stock split, which requires the affirmative vote of holders of a majority of the outstanding Advaxis common stock on the record date for the special meeting.

**Conditions to the Completion of the Merger**

Each party's obligation to complete the merger is subject to the satisfaction or waiver (to the extent permitted by applicable legal requirements) by each of the parties, at or prior to the merger, of various conditions, which include the following:

- the registration statement, of which this proxy statement/prospectus/information statement is a part, must have become effective in accordance with the provisions of the Securities Act and must not be subject to any stop order or proceeding, or any proceeding threatened by the SEC, seeking a stop order with respect to the registration statement that has not been withdrawn;

- there must not have been any adoption or promulgation after the date of the Merger Agreement of any law, statute, rule, regulation, ruling or decree, and there must not have been any issuance of any temporary restraining order, preliminary or permanent injunction or other order which remains in effect, in each case, by any court of competent jurisdiction or other governmental entity of competent jurisdiction and having the effect of making the merger illegal or otherwise prohibiting the consummation of the merger or transactions contemplated by the Merger Agreement;

- the holders of at least sixty percent (60%) of the shares of outstanding Biosight ordinary shares and preferred voting together as one class (on an as converted basis), the holders of at least seventy-five percent (75%) of the shares of outstanding Biosight ordinary shares and preferred shares who participate in such vote (excluding abstentions), voting together as one class, the holders of more than fifty percent (50%) of Biosight Series B Preferred Shares (on an as covered basis) and at least sixty percent (60%) of Biosight Series C Preferred Shares (on an as converted basis), must have adopted and approved the Merger Agreement and the transactions contemplated by the Merger Agreement, and approved the merger, in addition to class votes of other classes of preferred shares that may be required as well in accordance with the ICL;

- the affirmative vote at the Advaxis special meeting or any adjournment or postponement thereof of the holders of a majority of Advaxis common stock represented and entitled to vote thereat must have voted in favor of the Advaxis reverse stock split, the Advaxis Certificate of Incorporation Amendment and the issuance of Advaxis common stock in the merger in accordance with the terms of the Merger Agreement; and

- any waiting period (and any extension thereof) applicable to the merger under the Hart-Scott-Rodino Antitrust Improvements Act shall have been terminated or shall have expired or the necessary approval or clearance shall have been obtained and any other applicable waiting periods (or any extension thereof), consents, waivers, filings or approvals under any applicable law, statutes, rule, regulation, ruling or decree required to consummate the transactions contemplated by the Merger Agreement shall have expired, been terminated, been made or been obtained.

In addition, each party's obligation to complete the merger is further subject to the satisfaction or waiver by that party of the following additional conditions:

- each of the fundamental representations of the other party shall be true and correct as of the date of the Merger Agreement and as of the date of the closing of the merger as though made on and as of the closing date (except to the extent in either case that such representations and warranties speak as of another date), and all other representations and warranties of the other party in the Merger Agreement shall be true and correct on the date of the Merger Agreement and as of the date of the closing of the merger as though made on and as of the closing date (except to the extent in either case that such representations and warranties speak as of another date) as if none of such representations and warranties contained any qualifications or limitations as to "materiality" or "material adverse effect", except where the failure of these representations and warranties to be true and correct as so made does not constitute a material adverse effect on such other party;

- the other party to the Merger Agreement must have performed or complied in all material respects with all covenants and obligations in the Merger Agreement required to be performed or complied with by it on or before the consummation of the merger;

- the other party must have delivered certain certificates and other documents as specified and required under the Merger Agreement for the consummation of the merger; and

In addition, the obligation of Advaxis and Merger Sub to complete the merger is further subject to the satisfaction or waiver by Advaxis of the following condition:

- there shall not have occurred any material adverse effect on Biosight that is continuing.

In addition, the obligation of Biosight to complete the merger is further subject to the satisfaction or waiver by Biosight of the following conditions:

- there shall not have occurred any material adverse effect on Advaxis that is continuing;

- Biosight shall have obtained the Option Tax Ruling (as defined in the Merger Agreement) and the Israeli Income Tax Ruling (as defined in the Merger Agreement) or the Israeli Interim Income Tax Ruling (as defined in the Merger Agreement) and, if necessary, the parties to the Merger Agreement shall have entered into a customary paying agent agreement for the implementation of the Option Tax Ruling and the Israeli Income Tax Ruling and/or the Israeli Interim Income Tax Ruling; and

- Nasdaq shall not have rejected Advaxis' appeal to its determination by the Listing Qualifications Department of The Nasdaq Stock Market LLC that Advaxis is not in compliance with Nasdaq Listing Rule 5550(a)(2), and the shares of Advaxis common stock to be issued in the merger shall be approved for listing (subject to official notice of issuance) on the Nasdaq Capital Market as of the effective time of the merger.

The Merger Agreement provides that the following events shall not be considered a material adverse effect to Biosight:

- effects in general economic or political conditions or the securities market in general, or changes in or affecting the industries in which Biosight and its subsidiaries operate;
- any failure by Biosight to meet internal projections;
- the execution, delivery, announcement or performance of the obligations under this Agreement or the announcement, pendency or anticipated consummation of the merger;
- the resignation or termination of any officer or director;
- any natural disaster, any epidemic, pandemic or disease outbreak (including the COVID-19 virus) or other public health emergencies (as declared by the World Health Organization or the Health and Human Services Secretary of the United States) or any acts of terrorism, sabotage, military action or war or any escalation or worsening thereof, but solely to the extent Biosight can prove that such effect was caused directly as a result of such natural disaster, epidemic, pandemic, disease outbreak or other health emergency; or
- any changes (after the date of the Merger Agreement) in U.S. GAAP or applicable laws, statutes, rules, regulations, rulings or decrees;

provided, that any effect referred to in the first, fifth and sixth bullets above may be taken into account in determining whether there has been, or would reasonably be expected to be, a material adverse effect to Biosight to the extent such effect has a disproportionate effect on Biosight and its subsidiaries, taken as a whole, relative to other similarly sized participants in the businesses, industries and geographic locations in which Biosight and its subsidiaries operate.

The Merger Agreement provides that the following events shall not be considered a material adverse effect to Advaxis:

- effects in general economic or political conditions or the securities market in general, or changes in or affecting the industries in which Advaxis and its subsidiaries operate;
- any failure by Advaxis to meet internal projections or forecasts or third-party revenue or earnings predictions for any period ending (or for which revenues or earnings are released) on or after the date of the Merger Agreement or any change in the price or trading volume of Advaxis common stock (it being understood, however, that any effect causing or contributing to any such failure to meet projections or predictions or any change in stock price or trading volume may cause a material adverse effect to Advaxis and may be taken into account in determining whether material adverse effect to Advaxis has occurred);
- the execution, delivery, announcement or performance of the obligations under this Agreement or the announcement, pendency or anticipated consummation of the merger;
- the resignation or termination of any officer or director;
- any natural disaster, any epidemic, pandemic or disease outbreak (including the COVID-19 virus) or other public health emergencies (as declared by the World Health Organization or the Health and Human Services Secretary of the United States) or any acts of terrorism, sabotage, military action or war or any escalation or worsening thereof, but solely to the extent Advaxis can prove that such effect was caused directly as a result of such natural disaster, epidemic, pandemic, disease outbreak or other health emergency; or
- any changes (after the date of the Merger Agreement) in U.S. GAAP or applicable laws, statutes, rules, regulations, rulings or decrees;

provided, that any effect referred to in the first, fifth and sixth bullets above may be taken into account in determining whether there has been, or would reasonably be expected to be, a material adverse effect to Advaxis to the extent such effect has a disproportionate effect on Advaxis and its subsidiaries, taken as a whole, relative to other similarly sized participants in the businesses, industries and geographic locations in which Advaxis and its subsidiaries operate.

**Representations and Warranties**

The Merger Agreement contains customary, reciprocal (other than to the extent inapplicable to Advaxis, Merger Sub or Biosight) representations and warranties of Advaxis, Merger Sub and Biosight for a transaction of this type relating to, among other things:

- subsidiaries;
- due organization;
- organizational documents;
- capitalization;
- financial statements;
- Advaxis SEC reports;
- the absence of material changes or events;
- title to assets;
- real property and leaseholds;
- intellectual property;
- material contracts to which the parties or their subsidiaries are a party and any violation, default or breach to such contracts;
- liabilities;
- compliance with laws and regulations;
- permits and restrictions;
- tax matters;
- employee benefit plans;
- labor and employment matters;
- environmental matters;
- insurance;
- legal proceedings and orders;
- authority to enter into the Merger Agreement and the related agreements;
- takeover statutes;
- except as otherwise specifically identified in the Merger Agreement, the fact that the consummation of the merger would not contravene or require the consent of any third party;
- bank accounts receivables;
- any brokerage or finder’s fee or other fee or commission payable in connection with the merger;
- privacy matters relating to personally identifiable health information collected by each party;
- CARES Act matters;
- disclosures to be included in this proxy statement/prospectus/information statement;
- an assertion that no other representations and warranties, except as set forth in the Merger Agreement, are being given to the other party; and
- an acknowledgement that the other party is not providing any other representations or warranties except as set forth in the Merger Agreement.

The representations and warranties are, in many respects, qualified by materiality and knowledge, and will not survive the merger, but their accuracy forms the basis of one of the conditions to the obligations of Advaxis and Biosight to complete the merger.

**No Solicitation**

Each of Advaxis and Biosight agreed that, except as described below, neither it nor any of its subsidiaries will, and neither it nor its subsidiaries will authorize or permit any of their officers, directors, employees, investment bankers, attorneys, accountants, representatives, consultants or other agents retained by it or any of its subsidiaries to, directly or indirectly:

- solicit, initiate, encourage, induce or knowingly facilitate the communication, making, submission or announcement of any Acquisition Proposal (as defined below) or take any action that could reasonably be expected to lead to an Acquisition Proposal;
- furnish to any person any information or data with respect to, or cooperate in any way that would otherwise reasonably be expected to lead to, any proposal or inquiry that constitutes, or would reasonably be expected to lead to, any Acquisition Proposal;
- enter into, continue or otherwise engage in any discussions or negotiations with any person with respect to any Acquisition Proposal or any proposal or inquiry that would reasonably be expected to lead to any Acquisition Proposal;
- submit to such party's stockholders or shareholders, as applicable, for their approval or adoption, any Acquisition Proposal;
- approve, declare advisable, adopt or recommend, or publicly propose to approve, declare advisable, adopt or recommend, or allow such party or any of its subsidiaries to execute or enter into, any binding or non-binding letter of intent, agreement in principle, memorandum of understanding, merger agreement, acquisition agreement, option agreement, joint venture agreement, partnership agreement or other agreement contemplating or otherwise in connection with, or that is intended to or would reasonably be expected to lead to, any Acquisition Proposal;
- grant any waiver or release under any confidentiality, standstill or similar agreement (other than to the other party); or
- agree or publicly announce an intention to take any of the foregoing actions.

An “Acquisition Proposal” means with respect to Advaxis or Biosight, any inquiry, proposal or offer from any person, other than from the other party to the Merger Agreement, relating to any:

- direct or indirect acquisition (whether in a single transaction or a series of related transactions) of assets of such party equal to 15% or more of the consolidated assets of such party and its subsidiaries, or to which 15% or more of the revenues or earnings of such party and its subsidiaries on a consolidated basis are attributable for the most recent fiscal year in which audited financial statements are then available,

- direct or indirect acquisition or issuance (whether in a single transaction or a series of related transactions) of 15% or more of any class of equity or voting securities of such party,

- tender offer or exchange offer that, if consummated, would result in such person beneficially owning 15% or more of any class of equity or voting securities of such party, or

- merger, consolidation, share exchange, business combination, joint venture, reorganization, recapitalization, liquidation, dissolution or similar transaction or series of related transactions involving such party or any of its subsidiaries, under which (A) such person would, directly or indirectly, acquire assets equal to 15% or more of the consolidated assets of such party and its subsidiaries, or to which 15% or more of the revenues or earnings of such party and its subsidiaries on a consolidated basis are attributable for the most recent fiscal year in which audited financial statements are then available, or (B) the stockholders or equityholders of such third-party person immediately after giving effect to such transaction(s) would beneficially own 15% or more of any class of equity or voting securities of such party or the surviving or resulting entity in such transaction(s), except in each case, with respect to Advaxis, as set forth in a specific section of the disclosure schedule delivered by Advaxis in connection with the Merger Agreement.

However, before obtaining the applicable Advaxis or Biosight shareholder approvals required to consummate the merger, each party may furnish nonpublic information regarding such party to, and may enter into discussions or negotiations with, any third party in response to a bona fide Acquisition Proposal first received after the date of the Merger Agreement, if:

- neither such party nor any representative of such party has breached the non solicitation provisions of the Merger Agreement described above with respect to such Acquisition Proposal;

- such party’s board of directors determines in good faith, after consultation with its outside legal counsel and a reputable financial advisors, that such Acquisition Proposal is reasonably likely to result in a “superior offer,” as defined below

- such party’s board of directors determines in good faith, after consultation with its outside legal counsel and a reputable financial advisor, that the failure to furnish such information or enter into such discussions or negotiations with respect to such Acquisition Proposal would constitute a breach of the fiduciary duties of such board of directors under applicable legal requirements;

- at least three business days prior to furnishing any such information to, or entering into discussions or negotiations with, such third party, such party gives the other party prior notice of the identity of the third party and of such party’s intention to furnish any such information to, or enter into any such discussions with, such third party;

- the furnishing of any nonpublic information is pursuant to and in accordance with an Acceptable Confidentiality Agreement (as defined in the Merger Agreement); and

- at least three business days prior to the furnishing of any non-public information to a third party, such party furnishes the same non-public information to the other party to the extent such non-public information has not been previously furnished to such other party.

A “superior offer” means an unsolicited bona fide Acquisition Proposal (i) with all references to “15%” in the definition of Acquisition Proposal, as described above, being treated as references to 50% for these purposes; and (ii) and in the case of Biosight, the term “Acquisition Proposal” including any other transaction that results in the shareholders of Biosight being the majority holders of a publicly traded company) made by a third party after the date of the Merger Agreement that (A) did not result from, and is not otherwise attributable to, a direct or indirect breach of (or in violation of) the no solicitation covenants described above and (B) the board of directors of Advaxis or Biosight, as applicable, receiving the offer determines in good faith, after consultation with its outside legal counsel and financial advisor:

- is reasonably likely to be consummated in accordance with its terms (if accepted) without unreasonable delay, taking into account all legal, regulatory and financing aspects (including certainty of closing, any termination or break-up fees and, to the extent third-party financing is required, that such financing is then fully committed on customary terms and conditions) of such Acquisition Proposal, the person making the proposal, as well as any written offer by the other party to amend the terms of the Merger Agreement, and other aspects of the Acquisition Proposal that the board of directors of such party (Advaxis or Biosight, as applicable) deems relevant; and

- if consummated, would result in a transaction more favorable from a financial point of view to the stockholders of Advaxis or the shareholders Biosight, as applicable, than the terms of the Merger Agreement.

The Merger Agreement also provides that each of Advaxis or Biosight, as applicable, will promptly (and in no event later than 24 hours after becoming aware of such Acquisition Proposal) advise the other party of any Acquisition Proposal it receives before the closing of the merger. Further, the Merger Agreement also provides that each of Advaxis or Biosight, as applicable, shall keep the other party informed in all material respects on the status and terms of any such Acquisition Proposal and any modification or proposed modification thereto. Additionally, the Merger Agreement also provides that Advaxis or Biosight, as applicable, will provide the other party with at least three (3) business days’ written notice of a meeting of such party’s board of directors (or any committee thereof) at which its board of directors (or any committee thereof) is reasonably expected to consider an Acquisition Proposal it has received.

**Meetings of Stockholders**

Unless the Merger Agreement is terminated in accordance with the terms of the Merger Agreement, Advaxis is obligated under the Merger Agreement to establish a record date for, call, give notice of and hold a special meeting of its stockholders for the purposes of adopting and approving the Advaxis stockholder proposals. The special meeting will be held (on a date selected by Advaxis in consultation with Biosight) as promptly as practicable after the registration statement, of which this proxy statement/prospectus/information statement is a part, being declared effective by the SEC.

Unless the Merger Agreement is terminated in accordance with the terms of the Merger Agreement, Biosight is obligated under the Merger Agreement to call, give notice of, convene and hold a special meeting of Biosight shareholders to approve the merger and all other transactions contemplated thereby. The special meeting will be held as promptly as practicable after the registration statement, of which this proxy statement/prospectus/information statement is a part, being declared effective by the SEC. Alternatively, in accordance with the provisions of Sections 314-327 of the Companies Law 5759-1999 of the State of Israel and Biosight’s constituent documents, Biosight may seek such approval by written consent.

**Covenants; Conduct of Business Pending the Merger**

Biosight agreed that during the period from the date of the Merger Agreement to the earlier of the termination of the Merger Agreement in accordance with its terms and the effective time of the merger (the "Interim Period"), it will, and cause each of its subsidiaries to, conduct its business in the ordinary course of its normal operations and in accordance with past practices and in compliance with all applicable laws and regulations and the requirements of certain material contracts, and not take any action that would reasonably be expected to adversely affect its ability to consummate the merger or the other transactions contemplated by the Merger Agreement. Biosight also agreed that, subject to certain limited exceptions, without the consent of Advaxis, it will not, and will not cause or permit any of its subsidiaries to, during the Interim Period (except as expressly contemplated or permitted by the Merger Agreement):

- declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of share capital; or repurchase, redeem or otherwise reacquire any shares of share capital or other securities (except for Biosight shares from terminated employees of Biosight);

- amend the certificate of incorporation, bylaws or other charter or organizational documents of Biosight, except as related to the transactions contemplated by the Merger Agreement;

- effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except as related to the transactions contemplated by the Merger Agreement, acquire the assets or securities of any other person, or adopt or implement a plan of complete or partial liquidation or resolution providing for or authorizing such liquidation or a dissolution, restructuring or other reorganization of Biosight or any of its subsidiaries;

- sell, issue (other than any share capital issued as part of an exercise of an option) or grant, or authorize the issuance of, or make any commitments to do any of the foregoing, (A) any share capital or other security, (B) any option, warrant or right to acquire any share capital or any other security, or (C) any instrument convertible into or exchangeable for any share capital or other security;

- form any subsidiary or enter into any joint venture, partnership or similar arrangement or acquire any equity interest or other interest in any other entity;

- make any loans, advances or capital contributions to, or investments in, any other person, (B) create, incur, guarantee, assume or otherwise become liable for any indebtedness, issuances of debt securities, guarantees, indemnities, loans or advances not in existence as of the date of the Merger Agreement, or (C) make or commit to make any capital expenditure, other than in the ordinary course of business;

- sell, lease, license, subject to an encumbrance, encumber or otherwise surrender, relinquish or dispose of any assets, property or rights owned or held by Biosight or any of its subsidiaries;

- except as required under applicable legal requirements or the terms of any Biosight benefit plan existing as of the date of the Merger Agreement (A) increase in any manner the compensation, bonus, pension, welfare, fringe or other benefits, severance or termination pay of any of the current or former directors, officers, employees or independent contractors of Biosight or its subsidiaries, (B) become a party to, establish, amend, commence participation in, terminate or commit itself to the adoption of any stock option plan or other stock-based compensation plan, or any compensation, severance, pension, retirement, profit-sharing, welfare benefit, or other employee benefit plan or agreement with or for the benefit of any current or former directors, officers, employees or independent contractors of Biosight or its subsidiaries (or newly hired employees), including under the applicable Biosight benefit plans, (C) accelerate the vesting of or lapsing of restrictions with respect to any stock-based compensation or other long-term incentive compensation under any Biosight benefit plan, (D) grant any new awards under any Biosight benefit plan, (E) amend or modify any outstanding award under any Biosight benefit plan, (F) enter into, amend or terminate any collective bargaining agreement or other agreement with a labor union, works council or similar organization, (G) forgive any loans, or issue any loans (other than routine travel advances issued in the ordinary course of business) to any of its or its subsidiaries' directors, officers, independent contractors or employees, or (H) hire or engage any new employee or independent contractor;

- enter into any material transaction outside the ordinary course of business;

- except as required by applicable legal requirements, make, change or revoke any material tax election; file any material amendment to any tax return; adopt or change any accounting method in respect of taxes; change any annual tax accounting period; enter into any tax allocation agreement, tax sharing agreement or tax indemnity agreement (other than commercial contracts entered into in the ordinary course of business with vendors, customers or landlords); enter into any closing agreement with respect to any tax; settle or compromise any claim, notice, audit report or assessment in respect of material taxes; apply for or enter into any ruling from any governmental authority with respect to taxes; surrender any right to claim a material tax refund; or consent to any extension or waiver of the statute of limitations period applicable to any material tax claim or assessment;

- change any method of accounting or accounting principles or practices by Biosight or any of its subsidiaries, except for any such change required by a change in legal requirement or by a governmental authority;

- enter into, amend in any material respect, terminate or waive any rights under any material contract or enter into any successor agreement to an expiring material contract that changes the terms of the expiring material contract in a way that is materially adverse to Biosight or any of its subsidiaries;

- sell, assign, transfer, license, sublicense or otherwise dispose of any material intellectual property rights (other than non-exclusive licenses in the ordinary course of business);

- initiate or settle any material legal proceeding; or

- agree, resolve or commit to do any of the foregoing.

Advaxis agreed that during the Interim Period, it will, and cause each of its subsidiaries to, conduct its business in the ordinary course of its normal operations and consistent with past practices and in compliance with all applicable laws, regulations and the requirements of certain material contracts, and not take any action which would reasonably be expected to adversely affect its ability to consummate the merger or the other transactions contemplated by the Merger Agreement. Advaxis also agreed that, subject to certain limited exceptions, without the consent of Biosight, it will not, and will not cause or permit any of its subsidiaries to, during the Interim Period (except as expressly contemplated or permitted by the Merger Agreement):

- declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of capital stock; or repurchase, redeem or otherwise reacquire any shares of capital stock or other securities (except for shares of Advaxis common stock from terminated employees of Advaxis);

- except as required to effect the reverse split, amend the certificate of incorporation, bylaws or other charter or organizational documents of Advaxis;

- effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except as related to the transactions contemplated by the Merger Agreement, acquire the assets or securities of any other person, or adopt or implement a plan of complete or partial liquidation or resolution providing for or authorizing such liquidation or a dissolution, restructuring or other reorganization of Advaxis or any of its subsidiaries;

- sell, issue (other than any capital stock issued as part of an exercise of an option or with respect to 14,005,202 private placement warrants issued on April 14, 2021 for shares of capital stock not yet authorized) or grant, or authorize the issuance of (or make any commitments to do any of the foregoing) any capital stock or other security (except for shares of common stock issued upon the valid exercise of options or warrants outstanding on the date of the Merger Agreement); any option, warrant or right to acquire any capital stock or any other security; or any instrument convertible into or exchangeable for any capital stock or other security;

- form any subsidiary or enter into any joint venture, partnership or similar arrangement or acquire any equity interest or other interest in any other entity;

- make any loans, advances or capital contributions to, or investments in, any other person, (B) create, incur, guarantee, assume or otherwise become liable for any indebtedness, issuances of debt securities, guarantees, indemnities, loans or advances not in existence as of the date of the Merger Agreement, or (C) make or commit to make any capital expenditure, other than in the ordinary course of business;

- sell, lease, license, subject to an encumbrance, encumber or otherwise surrender, relinquish or dispose of any assets, property or rights owned or held by Advaxis or any of its subsidiaries;

- except as required under applicable legal requirements or the terms of any Advaxis benefit plan existing as of the date of the Merger Agreement (A) increase in any manner the compensation, bonus, pension, welfare, fringe or other benefits, severance or termination pay of any of the current or former directors, officers, employees or independent contractors of Advaxis or its subsidiaries, (B) become a party to, establish, amend, commence participation in, terminate or commit itself to the adoption of any stock option plan or other stock-based compensation plan, or any compensation, severance, pension, retirement, profit-sharing, welfare benefit, or other employee benefit plan or agreement with or for the benefit of any current or former directors, officers, employees or independent contractors of Advaxis or its subsidiaries (or newly hired employees), including under the applicable Advaxis benefit plans, (C) accelerate the vesting of or lapsing of restrictions with respect to any stock-based compensation or other long-term incentive compensation under any Advaxis benefit plan, (D) grant any new awards under any Advaxis benefit plan, (E) amend or modify any outstanding award under any Advaxis benefit plan, (F) enter into, amend or terminate any collective bargaining agreement or other agreement with a labor union, works council or similar organization, (G) forgive any loans, or issue any loans (other than routine travel advances issued in the ordinary course of business) to any of its or its subsidiaries' directors, officers, independent contractors or employees, or (H) hire or engage any new employee or independent contractor;

- enter into any material transaction outside the ordinary course of business;

- except as required by applicable legal requirements, make, change or revoke any material tax election; file any material amendment to any tax return; adopt or change any accounting method in respect of taxes; change any annual tax accounting period; enter into any tax allocation agreement, tax sharing agreement or tax indemnity agreement (other than commercial contracts entered into in the ordinary course of business with vendors, customers or landlords); enter into any closing agreement with respect to any tax; settle or compromise any claim, notice, audit report or assessment in respect of material taxes; apply for or enter into any ruling from any governmental authority with respect to taxes; surrender any right to claim a material tax refund; or consent to any extension or waiver of the statute of limitations period applicable to any material tax claim or assessment;

- change any method of accounting or accounting principles or practices by Biosight or any of its subsidiaries, except for any such change required by a change in legal requirement or by a governmental authority;

- enter into, amend in any material respect, terminate or waive any rights under any material contract or enter into any successor agreement to an expiring material contract that changes the terms of the expiring material contract in a way that is materially adverse to Advaxis or any of its subsidiaries;

- sell, assign, transfer, license, sublicense or otherwise dispose of any material intellectual property rights (other than non-exclusive licenses in the ordinary course of business);

- initiate or settle any material legal proceeding; or

- agree, resolve or commit to do any of the foregoing.

**Regulatory Approvals**

Each of Advaxis and Biosight has agreed:

- that each party would use reasonable best efforts to file or otherwise submit, as soon as practicable after the date of the Merger Agreement, all filings, submissions and declarations with any governmental entity or other third party as mutually agreed and as necessary in connection with the consummation of the transactions contemplated by the Merger Agreement;

- to comply at the earliest practicable date with any request for additional information, documents or other materials received from the U.S. Federal Trade Commission, the Antitrust Division of the Department of Justice or any other governmental entity in connection with antitrust or competition matters; and

- to act in good faith and reasonably cooperate with the other party in connection with any such filings, submissions and declarations.

**Other Agreements**

Each of Advaxis and Biosight has agreed to use its commercially reasonable efforts to:

- take all actions necessary, proper or advisable to consummate the merger and the transactions contemplated by the Merger Agreement;

- obtain all consents, approvals or waivers reasonably required to be obtained in connection with the transactions contemplated by the Merger Agreement;

- lift any injunction prohibiting, or any other legal bar to, the merger or the transactions contemplated by the Merger Agreement; and

- satisfy the conditions precedent to the consummation of the merger set forth in the Merger Agreement.

Each of Advaxis and Biosight has also agreed that:

- Advaxis, Merger Sub and Biosight shall use commercially reasonable efforts to make all filings and other submissions and give all notices required to be made and given by such party in connection with the merger and the transactions contemplated by the Merger Agreement;

- neither party will make any public statement concerning the merger during the Interim Period, subject to certain exceptions;

- Advaxis and Biosight will each purchase prior to the effective time of the merger and, for a period of six years following the effective time of the merger, continue in effect, a directors' and officers' liability "tail" insurance policy or policies covering the directors, managers or officers of such party;

- for a period of six years after the consummation of the merger, the surviving company of the merger will indemnify each of the current and former directors, managers and officers of Biosight to the fullest extent required under such surviving company's constituent documents;

- for a period of six years after the consummation of the merger, Advaxis will indemnify each of the current and former directors, managers and officers of Advaxis to the fullest extent required under Advaxis' constituent documents; and

- Advaxis, Merger Sub and Biosight shall cooperate reasonably with each other and shall provide the other party with such assistance as may be reasonably requested for the purpose of facilitating the performance by each party of its respective obligations under the Merger Agreement and to enable the combined company to continue to meet its obligations following the consummation of the merger.

**Termination**

The Merger Agreement may be terminated at any time before the completion of the merger, whether before or after the required stockholder approvals to complete the merger have been obtained (except as otherwise set forth in the Merger Agreement), as set forth below:

- by mutual written consent of Advaxis and Biosight;
- by either Advaxis or Biosight, if (a) the merger shall not have been consummated by December 31, 2021, which date may be extended by an additional 60 days by Advaxis or Biosight if the registration statement is not declared effective by November 1, 2021; (b) if there exists any restraint (other than a temporary restraining order, preliminary injunction or similar non-permanent order) which has the effect of making the merger illegal or otherwise prohibiting consummation of the transactions contemplated by the Merger Agreement and such restraint shall have become final and non-appealable; and (c) the Advaxis Stockholder Approval (as defined in the Merger Agreement) or Biosight Shareholder Approval (as defined in the Merger Agreement) has not been obtained at the applicable stockholders meetings (or any adjournments or postponements thereof), in each of (a), (b) and (c) where the terminating party's failure to fulfill any obligation under the Merger Agreement is not the primary cause of, or has directly resulted in, the failure of such condition;
- by Biosight if
    - Advaxis breaches or fails to perform any of its representations, warranties or covenants contained in the Merger Agreement and such breach or failure is incapable of being cured or is not cured in accordance with the Merger Agreement and results in the failure of the related closing conditions in the Merger Agreement,
    - Advaxis or any of its subsidiaries or their respective representatives has willfully breached any applicable non-solicitation covenants,
    - Advaxis' board of directors fails to take certain actions required of it pursuant to the Merger Agreement or takes certain actions which would have the effect of impeding completion of the merger, in each case as further described in the Merger Agreement; or
    - Advaxis has willfully breached the Merger Agreement.
- by Advaxis, if:
    - Biosight breaches or fails to perform any of its representations, warranties or covenants contained in the Merger Agreement and such breach or failure is incapable of being cured or is not cured in accordance with the Merger Agreement and results in the failure of the related closing conditions in the Merger Agreement,
    - Biosight or its representatives has willfully breached its non-solicitation covenant;
    - the Biosight board of directors changes its recommendation to its stockholders to approve the merger and related transactions; or
    - Biosight has willfully breached the Merger Agreement.

**Termination Fee**

As further detailed in the Merger Agreement, Advaxis or Biosight, as applicable, will be required to pay a termination fee in the amount of $7,500,000 to the other party if the Merger Agreement is terminated under certain circumstances. In addition, upon termination of the Merger Agreement under certain circumstances, and provided that Advaxis has not paid the $7,500,000 termination fee, Advaxis will be required to pay up to $2,000,000 to Biosight for reimbursement of transaction-related expenses.

**Amendment**

The Merger Agreement may be amended by the parties at any time, with the approval of their respective boards, except that after the Merger Agreement has been adopted and approved by the stockholders of a party, no amendment which by law requires further approval by the stockholders of such party shall be made without such further approval.

## AGREEMENTS RELATED TO THE MERGER

**Support Agreements**

In order to induce Advaxis to enter into the Merger Agreement, certain current directors and executive officers of Biosight are parties to support agreements with Advaxis pursuant to which, among other things, each such person has agreed, solely in his or her capacity as a Biosight shareholder (to the extent applicable), to vote all of his or her shares of Biosight's share capital in favor of the adoption and approval of the Merger Agreement and the transactions contemplated thereunder. These Biosight shareholders also agreed to vote against any Acquisition Proposal with respect to Biosight that competes with the transactions contemplated by the Merger Agreement.

As of August 1, 2021, the Biosight current directors and executive officers that are party to a support agreement with Advaxis owned an aggregate of (a) 778,392 shares of Biosight that were issued in connection with financing transactions, (b) 243,296 shares of Biosight underlying outstanding warrants, (c) 61,674 shares of Biosight that were issued in connection with the exercise of options under Biosight's share option plan and (d) 199,090 options that were granted under Biosight's share option plan, which in aggregate represent approximately a 30.62% ownership interest in Biosight's share capital on a fully diluted, as converted to ordinary shares basis (provided, however, that options granted and shares issued pursuant to Biosight's share option plan do not entitle their holders to voting rights with respect to such options and shares).

Under these support agreements, subject to certain exceptions, such stockholders have also agreed not to sell or transfer their shares of Biosight's share capital and equity securities of Biosight held by them, or any voting rights with respect thereto, until the earlier of the termination of the Merger Agreement, the termination of the applicable support agreement upon mutual agreement of the parties thereto and the completion of the merger, subject to certain exceptions. To the extent that any such sale or transfer is permitted pursuant to the exceptions included in the support agreements, each person to which any shares of Biosight's share capital or equity securities of Biosight are so sold or transferred (other than if such buyer or transferee is Advaxis or Biosight) must agree in writing to be bound by the terms and provisions of the support agreement.

In addition, in order to induce Biosight to enter into the Merger Agreement, certain current directors and executive officers of Advaxis stockholders have entered into support agreements with Biosight pursuant to which, among other things, each such person has agreed, solely in his or her capacity as an Advaxis stockholder (to the extent applicable), to vote all of his or her shares of Advaxis capital stock in favor of the adoption and approval of the Merger Agreement and the transactions contemplated thereunder, including the issuance of Advaxis common stock in connection with the Merger and the reverse stock split of Advaxis shares. These Advaxis stockholders also agreed to vote against any Acquisition Proposal with respect to Advaxis that competes with the transactions contemplated by the Merger Agreement.

As of July 31, 2021, the Advaxis stockholders that are party to a support agreement owned an aggregate of 70,715 shares of Advaxis common stock (or options or other rights to acquire Advaxis common stock) representing approximately less than 1% of the outstanding shares of Advaxis common stock (or options or other rights to acquire shares of capital stock of Biosight) on an as converted to common stock basis.

Under these support agreements, subject to certain exceptions, such stockholders have also agreed not to sell or transfer their shares of Advaxis common stock and equity securities of Advaxis held by them until the earlier of the termination of the Merger Agreement, the termination of the applicable support agreement upon mutual agreement of the parties thereto and the completion of the merger, subject to certain exceptions. To the extent that any such sale or transfer is permitted pursuant to the exceptions included in the support agreements, each person to which any shares of Advaxis common stock or equity securities of Advaxis are so sold or transferred (other than if such buyer or transferee is Advaxis or Biosight) must agree in writing to be bound by the terms and provisions of the support agreement.

The foregoing description of the support agreements does not purport to be complete and is qualified in its entirety by the full text of the forms of support agreements, which are attached hereto as *Annex C* and *Annex D*, respectively.

## ADVAXIS DIRECTORS, OFFICERS AND CORPORATE GOVERNANCE

**Independence of Advaxis' Board of Directors**

Each of our incumbent non-employee directors is independent in accordance with the definition set forth in the Nasdaq rules. Each nominated member of each of our board committees is an independent director under the Nasdaq standards applicable to such committees. Our board of directors considered all information it considered relevant when considering the independence of each director.

**Leadership Structure of Advaxis' Board of Directors**

On May 27, 2015, David Sidransky was appointed Chairman and continues to serve as Chairman. Dr. Sidransky's experience in life science companies, as well as his scientific knowledge, his history with our Company and his own history of innovation and strategic thinking, qualify him to serve as our Chairman. Additionally, on April 23, 2018, Kenneth Berlin was appointed President and Chief Executive Officer and named a member of our board of directors. He also currently serves as Interim Chief Financial Officer. Mr. Berlin's knowledge of industry standards and his experience in industry operations and his leadership experience complements Dr. Sidransky's scientific knowledge.

While we do not have a formal policy regarding the separation of our principal executive officer and chairman of our board of directors, we believe the current structure is in the best interest of the Company at this time. Further, this structure demonstrates to our employees, customers and stockholders that we are under strong leadership, with multiple skills and sets the tone for managing our operations. This leadership structure promotes strategic development and execution, timely decision-making and effective management of our resources. We believe that we are well served by this structure.

**Role of Advaxis' Board of Directors in Risk Oversight**

Advaxis' board of directors has an active role in overseeing our risk management and is responsible for discussing with management and the independent auditors our major financial risk exposures, the guidelines and policies by which risk assessment and management is undertaken, and the steps management has taken to monitor and control risk exposure. The board of directors regularly engages in discussions of the most significant risks that we are facing and how those risks are being managed. Advaxis' board of directors believes that its work, and the work of the Chairman and the principal executive officer, enables the board of directors to effectively oversee our risk management function.

**Meetings of Advaxis' Board of Directors**

All directors who served as directors at the time attended our 2020 and 2021 Annual Meetings of Stockholders. Directors are expected, but not required, to attend the Annual Meeting of Stockholders. We will encourage, but will not require, our directors to attend our next Annual Meeting of Stockholders. Each director attended at least 75% of the aggregate of (1) the total number of board of directors' meetings and (2) the total number of meetings of the committee(s) of which he was a member, if any. Our board of directors holds meetings at least quarterly. Our board of directors held 15 meetings during fiscal year 2020, four of which were regularly scheduled and 11 were special meetings.

## ADVAXIS EXECUTIVE COMPENSATION

The following table sets forth the compensation of our chief executive officer and chief financial officer, and our "named executive officers," or NEOs, for the fiscal years ended October 31, 2020 and 2019:

**Summary Compensation Table**

| Name and Principal Position | Fiscal Year | Salary | Bonus[1] | Stock Award(s) | Option Award(s)[2] | All Other Compensation[3] | Total |
|---|---|---|---|---|---|---|---|
| Kenneth Berlin[4] | 2020 | $554,320 | $554,320 | - | $ 26,000 | $ 53,809 | $1,188,449 |
| President, Chief Executive Officer, Interim Chief Financial Officer | 2019 | $551,750 | $240,000 | - | $ 146,398 | $ 45,588 | $ 983,736 |
| Molly Henderson[4] | 2020 | $369,163 | $ - | - | $ 26,000 | $ 18,593 | $ 413,756 |
| Executive VP, Chief Financial Officer | 2019 | $397,896 | $120,000 | - | $ 58,498 | $ 20,052 | $ 596,446 |
| Andres Gutierrez[4] | 2020 | $426,130 | $170,560 | - | $ 26,000 | $ 27,575 | $ 650,265 |
| Executive VP, Chief Medical Officer | 2019 | $424,423 | $120,000 | - | $ 58,498 | $ 24,346 | $ 627,267 |

[1] Represents annual incentive bonuses for services performed during fiscal 2020 and fiscal 2019, which in each case were paid in the following fiscal year. In fiscal 2020, the NEOs received bonuses approximating 100% for Mr. Berlin and 0% for Ms. Henderson and 40% for Dr. Gutierrez. In fiscal 2019, the NEOs received bonuses approximating 43% for Mr. Berlin and 30% for Ms. Henderson and 28% for Dr. Gutierrez. These bonuses reflect achievement of corporate goals and objectives for fiscal 2020 and fiscal 2019, respectively.

[2] Reflects the aggregate grant date fair value of stock options determined in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 718. The assumptions used in determining the grant date fair values of the stock options are set forth in Note 7 to the Company's audited financial statements contained herein.

[3] All Other Compensation is more fully described in the table under *"All Other Compensation—Supplemental" below*.

[4] Mr. Berlin and Mr. Gutierrez began their employment with the Company as the CEO and the CMO, respectively, in April 2018. Ms. Henderson began her employment as the Company's CFO in June 2018 and resigned effective September 25, 2020. Mr. Berlin was appointed as Interim Chief Financial Officer following Ms. Henderson's resignation.

*All Other Compensation – Supplemental*

| Name and Principal Position | Fiscal Year | Health Insurance Premiums $ | Life and AD&D Insurance $ | Matching Contributions to 401(k) Plan $ | Other $ | Total $ |
|---|---|---|---|---|---|---|
| Kenneth Berlin | 2020 | 26,402 | 5,568 | 21,239 | 600 | 53,809 |
| President, Chief Executive Officer | 2019 | 23,348 | 998 | 21,242 | - | 45,588 |
| Molly Henderson | 2020 | 2,769 | 510 | 14,760 | 554 | 18,593 |
| Executive VP, Chief Financial Officer | 2019 | 3,115 | 998 | 15,939 | - | 20,052 |
| Andres Gutierrez | 2020 | 26,399 | 576 | - | 600 | 27,575 |
| Executive VP, Chief Medical Officer | 2019 | 23,348 | 998 | - | - | 24,346 |

**Employment Agreements with Named Executive Officers**

The Company appointed Mr. Berlin as President and Chief Executive Officer effective April 23, 2018. The Company and Mr. Berlin entered into an employment agreement, effective April 23, 2018, which provides for an initial three-year term, after which it will be automatically renewed for one-year periods, unless otherwise terminated by either party upon 90 days' written notice. The employment agreement provides that Mr. Berlin will receive a base salary of $554,320 per year, as adjusted for annual increases by the Compensation Committee since entry of the agreement, and he is eligible for an annual bonus targeted at 55% of his base salary based on achievement of performance goals in the discretion of the Compensation Committee. Mr. Berlin also received a one-time lump-sum bonus equal to $150,000 that was paid within 15 days following the effective date of the agreement. Mr. Berlin also received 50,000 stock options and 16,667 restricted stock units (both as adjusted to account for the Company's 1 for 15 reverse stock split effective March 29, 2019), which vest in equal installments over the first three years of his employment. In May 2020, Mr. Berlin received an additional 50,000 stock options, which vest in equal instalments of 16,667 options on the first three anniversary dates of the grant.

The Company appointed Ms. Henderson as Executive Vice President and Chief Financial Officer, effective June 6, 2018 and she resigned effective September 25, 2020. The Company and Ms. Henderson entered into an employment agreement, effective June 6, 2018, which provided for an initial three-year term, after which it automatically renewed for one year periods, unless otherwise terminated by either party upon ninety (90) days' written notice. The employment agreement provided that Ms. Henderson would receive a base salary of $399,750 per year, as adjusted for annual increases by the Compensation Committee since entry of the agreement, and be eligible for an annual bonus based on achievement of performance goals in the discretion of the Compensation Committee. On June 6, 2018, Ms. Henderson also received 16,667 stock options (as adjusted to account for the Company's 1 for 15 reverse stock split effective March 29, 2019), which vest annually on the first three anniversaries of her employment. In November 2018 and in October 2019, Ms. Henderson received 8,333 and 25,000 stock options respectively, which vest in three equal annual instalments each. In May 2020, Ms. Henderson received an additional 50,000 stock options, which vest in equal annual instalments of 16,667 options on the first three anniversary dates of the grant. Following Ms. Henderson's resignation from the Company, which was effective September 25, 2020, all of Ms. Henderson's options, expired unexercised.

The Company appointed Mr. Gutierrez as Executive Vice President and Chief Medical Officer, effective April 23, 2018. The Company and Mr. Gutierrez entered into an employment agreement, effective April 23, 2018, which provides for an initial three-year term, after which it will be automatically renewed for one-year periods, unless otherwise terminated by either party upon 90 days' written notice. The employment agreement provides that Mr. Gutierrez will receive a base salary of $426,400 per year, as adjusted for annual increases by the Compensation Committee since entry of the agreement, and he is eligible for an annual bonus based on achievement of performance goals at the discretion of the Compensation Committee. Mr. Gutierrez also received a one-time lump-sum bonus equal to $40,000 that was paid within the first 90 days following the effective date of the agreement. Mr. Gutierrez also received 16,667 stock options (as adjusted to account for the Company's 1 for 15 reverse stock split effective March 29, 2019), which vest annually on the first three anniversaries of his employment as an equity incentive award. In May 2020, Mr. Gutierrez received an additional 50,000 stock options, which vest in equal installments of 16,667 options on the first three anniversary dates of the grant.

In the event the named executive officer's employment is terminated without Just Cause, or if the executive voluntarily resigns with Good Reason, or if the named executive officer's employment is terminated due to disability (all as defined in their respective employment agreements), and so long as the named executive officer executes a confidential separation and release agreement, in addition to the applicable base salary, plus any accrued but unused vacation time and unpaid expenses that have been earned as of the date of such termination, the named executive officer is entitled to the following severance benefits: (i) 12 months of base salary payable in equal monthly installments, (ii) a bonus payment for the year in which the employment is terminated equal to the target bonus percentage, multiplied by the base salary in effect at the time of termination, (iii) continued health and welfare benefits for 12 months, and (iv) full vesting of all stock options and stock awards (with extension of the exercise period for stock options by two years).

In the event Mr. Berlin's employment is terminated without Just Cause during the period beginning three months prior to a Change in Control (as defined in Mr. Berlin's employment agreement) and ending 18 months after the Change in Control (such period, the "CIC Protection Period"), or if Mr. Berlin voluntarily resigns with Good Reason during the CIC Protection Period, and provided that Mr. Berlin continues to comply with certain covenants set forth in his employment agreement, in addition to the applicable base salary and any earned but unpaid bonus for the prior fiscal year, plus any accrued but unused vacation time and unpaid expenses that have been earned as of the date of such termination, Mr. Berlin is entitled to the following severance benefits: (i) an amount equal to 1.75 times the sum of the applicable base salary plus an amount equal to Mr. Berlin's target bonus, payable in a single lump sum within 60 days of the termination, (ii) a bonus payment for the year in which the employment is terminated equal to the target bonus percentage, multiplied by the base salary in effect at the time of termination, multiplied by a fraction, the numerator of which is the number of calendar days Mr. Berlin was employed during such year and the denominator is 365, (iii) continued health and welfare benefits for 21 months, and (iv) full vesting and exercisability of all stock options and stock awards.

The named executive officer employment agreements contain customary covenants regarding non-solicitation, non-compete, confidentiality and works for hire.

**Potential Payments Upon Termination or Change in Control**

*Termination of Employment*

As described above under "*Employment Agreements with Named Executive Officers*," the Company has entered into employment agreements with each of the named executive officers that provide for certain severance payments and benefits in the event the named executive officer's employment with the Company is terminated under certain circumstances.

In addition, upon a Change in Control of the Company, unvested equity awards held by an executive officer will be accelerated as follows: (i) outstanding stock options and other awards in the nature of rights that may be exercised shall become fully vested and exercisable, (ii) time-based restrictions on restricted stock, restricted stock units and other equity awards shall lapse and the awards shall become fully vested, and (iii) performance-based equity awards, if any, shall become vested and shall be deemed earned based on an assumed achievement of all relevant performance goals at "target" levels, and shall payout pro rata to reflect the portion of the performance period that had elapsed prior to the Change in Control.

The table below shows the estimated value of benefits to each of the named executive officers if their employment had been terminated under various circumstances as of October 31, 2020. The amounts shown in the table exclude accrued but unpaid base salary, unreimbursed employment-related expenses, accrued but unpaid vacation pay, and the value of equity awards that were vested by their terms as of October 31, 2020.

| | Involuntary Termination Without a Change in Control ($) | Involuntary Termination in Connection with a Change in Control ($) | Death ($) | Disability ($) | Termination for Cause; Voluntary Resignation ($) |
|---|---|---|---|---|---|
| **Kenneth Berlin** | | | | | |
| *Cash severance* | 554,320(1) | 1,503,593(5) | - | 554,320(1) | - |
| *Bonus* | 304,876(7) | 304,876(2) | 304,876(2) | 304,876(7) | - |
| *Health benefits* | 30,335(3) | 53,087(6) | - | 30,335(3) | - |
| *Value of equity acceleration* | 2,344(4) | 2,344(4) | 2,344(4) | 2,344(4) | - |
| **Total** | 891,875 | 1,863,900 | 307,220 | 891,875 | - |
| | | | | | |
| **Andres Gutierrez** | | | | | |
| *Cash severance* | 426,130(1) | 426,130(1) | - | 426,130(1) | - |
| *Bonus* | 170,452(7) | 170,452(7) | 170,452(7) | 170,452(7) | - |
| *Health benefits* | 30,318(3) | 30,318(6) | - | 30,318(3) | - |
| *Value of equity acceleration* | 233(4) | 233(4) | 233(4) | 233(4) | - |
| **Total** | 627,133 | 627,133 | 170,685 | 627,133 | - |

(1) Reflects severance payment equal to one times base salary payable in equal monthly installments for 12 months.

(2) Reflects pro rata bonus determined by multiplying the target bonus amount for the year in which the termination occurs by a fraction, the numerator of which is the number of calendar days the executive is employed during such year and the denominator of which is 365. Because the amounts reflected in the table assume the named executive officer's employment was terminated on October 31, 2020 (the last day of the 2020 fiscal year), the amounts reflected are not prorated.

(3) Reflects the Company's cost of continued health coverage at active employee rates for 12 months.

(4) Reflects the value of unvested in-the-money stock options and restricted stock units, or RSUs, that vest upon the designated event.

(5) For Mr. Berlin, reflects 1.75 times the sum of his base salary and target bonus, payable in a single lump sum payment. For Dr. Gutierrez, equals one times base salary, payable in equal monthly installments for 12 months.

(6) Reflects the full cost of continued health coverage for 21 months for Mr. Berlin and 12 months for the other named executive officers.

(7) Represents a bonus payment equal to the executive's target bonus.

**Outstanding Equity Awards at 2020 Fiscal Year-End**

The following table summarizes all outstanding equity awards held by our named executive officers at fiscal year-end. The market or payout value of unearned shares, units or rights that have not vested equals $0.338, which was the closing price of Advaxis' common shares on Nasdaq on October 31, 2020, and for performance-based restricted stock units presumes that the target performance goals are met.

| Name | Number of Securities Underlying Unexercised Options (#) Exercisable | Number of Securities Underlying Unexercised Options (#) Unexercisable | Option Exercise Price ($) | Option Expiration Date | Number of Shares or Units of Stock That Have Not Vested (#) | Value of Shares or Units of Stock That Have Not Vested ($) |
|---|---|---|---|---|---|---|
| **Kenneth Berlin** | 33,334 | 16,666(1) | 24.30 | 4/23/2028 | 5,555(6) | 1,878 |
| | 7,111 | 14,222(2) | 8.10 | 11/5/2028 | - | - |
| | 16,667 | 33,333(3) | 0.31 | 10/24/2029 | - | - |
| | - | 50,000(4) | 0.66 | 5/04/2030 | - | - |
| **Molly Henderson** | 11,112 | - | 25.65 | 12/25/2020 | - | - |
| | 2,778 | - | 8.10 | 12/25/2020 | - | - |
| **Andres Gutierrez** | 11,112 | 5,555(5) | 24.30 | 4/23/2028 | - | - |
| | 2,778 | 5,555(2) | 8.10 | 11/5/2028 | - | - |
| | 8,333 | 16,667(3) | 0.31 | 10/24/2029 | - | |
| | - | 50,000(4) | 0.66 | 5/04/2030 | - | - |

(1) Of these options, one-third vested on December 31, 2018, one-third vested on April 23, 2020, and the award will be fully vested on April 23, 2021.

(2) Of these options, one-third vested on November 5, 2019, one-third will vest on November 5, 2020, and the award will be fully vested on November 5, 2021.

(3) Of these options, one-third vested on October 24, 2020, one-third will vest on October 24, 2021, and the award will be fully vested on October 24, 2022.

(4) Of these options, one-third will vest on May 4, 2021, one-third will vest on May 4, 2022, and the award will be fully vested on May 4, 2023.

(5) Of these options, one-third vested on April 23, 2019, one-third vested on April 23, 2020, and the award will be fully vested on April 23, 2021.

(6) Represents restricted stock units granted to Mr. Berlin as an inducement award on April 23, 2018. The award vests over three years with one-third vested on December 31, 2018, one-third vesting on April 23, 2020, and the award will be fully vested on April 23, 2021.

## ADVAXIS DIRECTOR COMPENSATION

For fiscal year 2020, non-employee directors received an annual cash retainer of $50,000 for board of directors services, and the Chairman of the board of directors and the Vice Chairman of the board of directors received larger annual cash retainers of $80,000 and $65,000, respectively. Non-employee directors received additional annual retainers for serving on board of directors committees, as follows: $15,000 for Audit Committee Chair; $15,000 for Compensation Committee Chair; $7,500 for Audit Committee member; $7,500 for Compensation Committee member; $10,000 for Nominating and Corporate Governance Chair; $10,000 for Research and Development Chair; $5,000 for Nominating and Corporate Governance member; and $5,000 for Research and Development member. On May 4, 2020, each non-employee director was granted 13,000 stock options. Of these options, one-third vest on May 4, 2021, one-third vest on May 4, 2022, and the final third will vest on May 4, 2023. The Compensation Committee annually reviews and makes recommendations to the board of directors regarding compensation and benefits for non-employee directors. As part of its annual review, the Compensation Committee regularly engages an independent compensation consultant to provide competitive market data and advice regarding non-employee director compensation.

The following table sets forth information regarding the compensation earned for service on Advaxis' board of directors for fiscal year 2020 by Advaxis' directors who were not also its employees. Kenneth A. Berlin, Advaxis' President and Chief Executive Officer and Interim Chief Financial Officer, is also a member of Advaxis' board of directors, but did not receive any additional compensation for service as a director in fiscal year 2020. The compensation for Mr. Berlin as an executive officer is set forth above under "*Advaxis Executive Compensation—Summary Compensation Table*."

| Name | Fees Earned or Paid in Cash ($) [1] | Option Awards ($) [2] | Total ($) |
|---|---|---|---|
| Dr. David Sidransky | 105,000 | 6,760 | 111,760 |
| Dr. James Patton | 87,500 | 6,760 | 94,260 |
| Roni A. Appel | 62,500 | 6,760 | 69,260 |
| Richard J. Berman | 72,500 | 6,760 | 79,260 |
| Dr. Samir N. Khleif | 67,500 | 6,760 | 74,260 |

(1) Represents the annual retainers paid in cash for director services in fiscal year 2020.

(2) Reflects the aggregate grant date fair value of stock options determined in accordance with FASB ASC Topic 718. The assumptions used in determining the grant date fair values of the stock options are set forth in Note 7 to the Company's audited financial statements contained herein.

**Compensation of Officers and Directors**

The aggregate compensation paid and equity-based compensation and other payments expensed by us to our directors and executive officers with respect to the year ended December 31, 2020 was $1.5 million. This amount includes approximately $136,000 set aside or accrued to provide pension, severance, retirement or similar benefits or expenses, but does not include business travel, relocation, professional and business association dues and expenses reimbursed to office holders, and other benefits commonly reimbursed or paid by companies in our industry.

As of December 31, 2020, options to purchase 293,607 ordinary shares granted to our directors and executive officers were outstanding under our share option plan at a weighted average exercise price of $5.64 per share. We do not have any written agreements with any director providing for benefits upon the termination of such director’s relationship with our company. Unvested options held by service providers shall become fully vested at the effective time of the merger.

## MATTERS BEING SUBMITTED TO A VOTE OF ADVAXIS STOCKHOLDERS

## PROPOSAL NO. 1:

## APPROVAL OF THE ISSUANCE OF COMMON STOCK IN THE MERGER AND THE CHANGE OF CONTROL RESULTING FROM THE MERGER

At the Advaxis special meeting, Advaxis stockholders will be asked to approve the issuance of Advaxis common stock in the merger. Immediately following the merger, it is expected that the former Biosight shareholders, including shares issued in the Biosight pre-closing financing, will own approximately 75% of the common stock of Advaxis and the Advaxis stockholders as of immediately prior to the merger will own approximately 25% of the common stock of Advaxis.

The terms of, reasons for and other aspects of the Merger Agreement, the merger and the issuance of Advaxis common stock in the merger are described in detail in the other sections in this proxy statement/prospectus/information statement. A copy of the Merger Agreement is attached as *Annex A* to this proxy statement/prospectus/information statement.

Under Nasdaq Listing Rule 5635(a)(1), a company listed on Nasdaq is required to obtain stockholder approval prior to the issuance of common stock, among other things, in connection with the acquisition of another company's stock, if the number of shares of common stock to be issued is in excess of 20% of the number of shares of common stock then outstanding. The potential issuance of the shares of Advaxis common stock in the merger exceeds the 20% threshold under the Nasdaq Listing Rules and is expected to represent approximately 75% of Advaxis' common stock following the merger. Accordingly, in order to ensure compliance with Nasdaq Listing Rule 5635(a)(1), Advaxis must obtain the approval of Advaxis stockholders for the issuance of these shares of common stock in the merger.

Under Nasdaq Listing Rule 5635(b), a company listed on Nasdaq is required to obtain stockholder approval prior to an issuance of stock that will result in a "change of control" of the listed company. Nasdaq has determined that the merger constitutes a "change of control" of the listed company. Accordingly, in order to ensure compliance with Nasdaq Listing Rule 5635(b), Advaxis must obtain the approval of Advaxis stockholders of the change of control resulting from the merger.

***Required Vote***

The affirmative vote of the holders of a majority of the outstanding shares of Advaxis common stock entitled to vote at the Advaxis special meeting is required to approve the issuance of Advaxis common stock in the merger and the change of control of Advaxis resulting from the merger.

**ADVAXIS' BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS A VOTE "FOR" THIS PROPOSAL NO. 1 TO APPROVE THE ISSUANCE OF ADVAXIS COMMON STOCK IN THE MERGER AND THE CHANGE OF CONTROL OF ADVAXIS RESULTING FROM THE MERGER.**

Unless otherwise instructed, it is the intention of the persons named in the accompanying proxy card to vote shares represented by properly executed proxy cards "FOR" the approval of the issuance of Advaxis common stock in the merger and the change of control of Advaxis resulting from the merger.

**PROPOSAL NO. 2:**

**APPROVAL OF THE AMENDMENT TO AMENDED AND RESTATED CERTIFICATE OF INCORPORATION AS AMENDED OF ADVAXIS TO EFFECT THE REVERSE STOCK SPLIT**

***General***

At the Advaxis special meeting, Advaxis stockholders will be asked to approve a series of amendments to the restated certificate of incorporation of Advaxis as amended that will implement a reverse stock split of the issued and outstanding shares of Advaxis common stock, at a reverse stock ratio in the range of between one new share for every 10 shares and one new share for every 30 shares outstanding (or any number in between). The effectiveness of any one of these amendments and the abandonment of the other amendments, or the abandonment of all of these amendments, will be determined by the Advaxis board of directors in its discretion and subject to agreement by Biosight in connection with the merger. Upon the effectiveness of such amendment to the restated certificate of incorporation of Advaxis as amended to effect the reverse stock split, or the reverse stock split effective time, the issued and outstanding shares of Advaxis common stock immediately prior to the reverse stock split effective time will be reclassified into a smaller number of shares such that an Advaxis stockholder will own one new share of Advaxis common stock for each 10 to 30 (or any number in between) shares of issued common stock held by such stockholder immediately prior to the reverse stock split effective time, as specified.

The Advaxis board of directors may determine to effect the reverse stock split, if it is approved by the stockholders, even if the other proposals to be acted upon at the meeting are not approved, including the issuance of Advaxis common stock pursuant to the Merger Agreement.

By approving this Proposal No. 2, Advaxis stockholders will: (a) approve a series of alternate amendments to the restated certificate of incorporation of Advaxis as amended pursuant to which any whole number of issued and outstanding shares of common stock between and including 10 to 30 and could be combined and reclassified into one share of common stock; and (b) authorize the Advaxis board of directors to file only one such amendment, as determined by the Advaxis board of directors in its sole discretion, and to abandon each amendment not selected by the Advaxis board of directors. Should Advaxis receive the required stockholder approval for this Proposal No. 2, and following such stockholder approval, the Advaxis board of directors, subject to agreement by Biosight, determines that effecting the reverse stock split is in the best interests of Advaxis and its stockholders, the reverse stock split will become effective as specified in the amendment filed with the Secretary of State of the State of Delaware. The amendment filed thereby will contain the number of shares selected by the Advaxis board of directors within the limits set forth in this Proposal No. 2 to be combined and reclassified into one share of Advaxis common stock. Accordingly, upon the effectiveness of the amendment to the restated certificate of incorporation of Advaxis as amended to effect the reverse stock split, or the split effective time, every 10 to 15 shares (or any number in between) of Advaxis common stock outstanding immediately prior to the split effective time will be combined and reclassified into one share of Advaxis common stock.

The proposed form of certificate of amendment to the restated certificate of incorporation of Advaxis as amended to effect the reverse stock split, as more fully described below, will affect the reverse stock split but ***will not*** change the number of authorized shares of Advaxis common stock or preferred stock, or the par value of Advaxis common stock or preferred stock.

A copy of the proposed form of certificate of amendment to the restated certificate of incorporation of Advaxis as amended to effect the reverse stock split is attached as *Annex F* to this proxy statement/prospectus/information statement.

Notwithstanding approval of this Proposal No. 2 by Advaxis stockholders, the Advaxis board of directors may, in its sole discretion, abandon the proposed amendments and determine prior to the effectiveness of any filing with the Secretary of State of the State of Delaware not to effect the reverse stock split, as permitted under Section 242(c) of the DGCL.

***Purpose***

The Advaxis board of directors approved the proposal approving the amendment to the Advaxis restated certificate of incorporation as amended effecting the reverse stock split for the following reasons:

- the Advaxis board of directors believes effecting the reverse stock split will result in an increase in the minimum bid price of Advaxis' common stock and reduce the risk of a delisting of Advaxis common stock from Nasdaq in the future; and

- the Advaxis board of directors believes a higher stock price may help generate investor interest in Advaxis and ultimately the combined company and help Advaxis attract and retain employees.

If the reverse stock split successfully increases the per share price of Advaxis common stock, Advaxis' board of directors also believes this increase may increase trading volume in Advaxis common stock and facilitate future financings by Advaxis.

***Nasdaq Requirements for Listing on Nasdaq***

Advaxis common stock is listed on The Nasdaq Capital Market under the symbol "ADXS." Advaxis will file an initial listing application pursuant to the terms of the Merger Agreement for the combined company with Nasdaq.

According to the Nasdaq rules, an issuer must, in a case such as this, apply for initial inclusion following a transaction whereby the issuer combines with a non-Nasdaq entity, resulting in a change of control of the issuer and potentially allowing the non-Nasdaq entity to obtain a Nasdaq listing. Accordingly, the listing standards of Nasdaq will require Advaxis to have, among other things, a $4.00 per share minimum bid price for a certain number of trading days preceding the closing of the merger. Therefore, the reverse stock split may be necessary in order to consummate the merger.

In addition, it is a condition to the closing of the merger that the shares of Advaxis common stock to be issued in the merger pursuant to the Merger Agreement have been approved for listing on Nasdaq.

One of the effects of the reverse stock split will be to effectively increase the proportion of authorized shares which are unissued relative to those which are issued. This could result in Advaxis' management being able to issue more shares without further stockholder approval. The reverse stock split will not affect the number of authorized shares of Advaxis capital stock that will continue to be authorized pursuant to the restated certificate of incorporation of Advaxis, as amended.

***Potential Increased Investor Interest***

On October 12, 2021, Advaxis common stock closed at $0.51 per share. An investment in Advaxis common stock may not appeal to brokerage firms that are reluctant to recommend lower-priced securities to their clients. Investors may also be dissuaded from purchasing lower-priced stocks because the brokerage commissions, as a percentage of the total transaction, tend to be higher for such stocks. Moreover, the analysts at many brokerage firms do not monitor the trading activity or otherwise provide research coverage of lower-priced stocks. Also, the Advaxis board of directors believes that most investment funds are reluctant to invest in lower-priced stocks.

There are risks associated with the reverse stock split, including that the reverse stock split may not result in an increase in the per share price of Advaxis common stock.

Advaxis cannot predict whether the reverse stock split will increase the market price for Advaxis common stock. The history of similar stock split combinations for companies in like circumstances is varied. There is no assurance that:

- the market price per share of Advaxis common stock after the reverse stock split will rise in proportion to the reduction in the number of shares of Advaxis common stock outstanding before the reverse stock split;
- the reverse stock split will result in a per share price that will attract brokers and investors who do not trade in lower-priced stocks;
- the reverse stock split will result in a per share price that will increase the ability of Advaxis to attract and retain employees;
- the market price per share will either exceed or remain in excess of the $1.00 minimum bid price as required by Nasdaq for continued listing; or
- the market price per share will achieve and maintain the $4.00 minimum bid price requirement for a sufficient period for the combined company's common stock to be approved for listing by Nasdaq.

The market price of Advaxis common stock will also be based on the performance of Advaxis, and after the merger, on the performance of the combined company, and other factors, some of which are unrelated to the number of shares outstanding. If the reverse stock split is effected and the market price of Advaxis common stock declines, the percentage decline as an absolute number and as a percentage of the overall market capitalization of Advaxis may be greater than would occur in the absence of a reverse stock split. Furthermore, the liquidity of Advaxis common stock could be adversely affected by the reduced number of shares that would be outstanding after the reverse stock split.

***Principal Effects of the Reverse Stock Split***

The reverse stock split will be realized simultaneously for all shares of Advaxis common stock and options to purchase shares of Advaxis common stock outstanding immediately prior to the effective time of the reverse stock split. The reverse stock split will affect all holders of shares of Advaxis common stock outstanding immediately prior to the effective time of the reverse stock split uniformly and each such stockholder will hold the same percentage of Advaxis common stock outstanding immediately following the reverse stock split as that stockholder held immediately prior to the reverse stock split, except for immaterial adjustments that may result from the treatment of fractional shares as described below. The reverse stock split will not change the par value of Advaxis common stock or preferred stock and will not reduce the number of authorized shares of Advaxis common stock or preferred stock. Advaxis common stock issued pursuant to the reverse stock split will remain fully paid and non-assessable. The reverse stock split will not affect Advaxis continuing to be subject to the periodic reporting requirements of the Exchange Act.

***Procedure for Effecting Reverse Stock Split and Exchange of Stock Certificates***

If the Advaxis stockholders approve the amendment to the Advaxis amended and restated certificate of incorporation as amended effecting the reverse stock split, and if the Advaxis board of directors still believes that a reverse stock split is in the best interests of Advaxis and its stockholders, Advaxis will file the amendment to the restated certificate of incorporation as amended with the Secretary of State of the State of Delaware at such time as the Advaxis board of directors has determined to be the appropriate split effective time. The Advaxis board of directors may delay effecting the reverse stock split without resoliciting stockholder approval. Beginning at the split effective time, each stock certificate representing pre-split shares will be deemed for all corporate purposes to evidence ownership of post-split shares.

As soon as practicable after the split effective time, stockholders will be notified that the reverse stock split has been effected. Advaxis expects that the Advaxis transfer agent will act as exchange agent for purposes of implementing the exchange of stock certificates. Holders of pre-split shares will be asked to surrender to the exchange agent stock certificates representing pre-split shares in exchange for stock certificates (or book-entry positions) representing post-split shares in accordance with the procedures to be set forth in a letter of transmittal to be sent by Advaxis. No new certificates (or book-entry positions) will be issued to a stockholder until such stockholder has surrendered such stockholder's outstanding certificate(s) together with the properly completed and executed letter of transmittal to the exchange agent. Shares held in book-entry form will be automatically exchanged. Any pre-split shares submitted for transfer, whether pursuant to a sale or other disposition, or otherwise, will automatically be exchanged for post-split shares. **Stockholders should not destroy any stock certificate(s) and should not submit any certificate(s) unless and until requested to do so.**

***Fractional Shares***

No fractional shares will be issued in connection with the reverse stock split. Stockholders of record who otherwise would be entitled to receive fractional shares because they hold a number of pre-split shares not evenly divisible by the number of pre-split shares for which each post-split share is to be reclassified, will be entitled, upon surrender to the exchange agent of certificates representing such shares, to a cash payment in lieu thereof at a price equal to the fraction to which the stockholder would otherwise be entitled multiplied by the closing price of the common stock on Nasdaq on the date of the filing of the amendment to the restated certificate of incorporation as amended effecting the reverse stock split. For the foregoing purposes, all shares of common stock held by a holder will be aggregated (thus resulting in no more than one fractional share per holder). The ownership of a fractional interest will not give the holder thereof any voting, dividend or other rights except to receive payment therefor as described herein.

Stockholders should be aware that, under the escheat laws of the various jurisdictions where stockholders reside, where Advaxis is domiciled and where the funds will be deposited, sums due for fractional interests that are not timely claimed after the effective date of the split may be required to be paid to the designated agent for each such jurisdiction, unless correspondence has been received by Advaxis or the exchange agent concerning ownership of such funds within the time permitted in such jurisdiction. Thereafter, stockholders otherwise entitled to receive such funds will have to seek to obtain them directly from the state to which they were paid.

***Potential Anti-Takeover Effect***

Although the increased proportion of unissued authorized shares to issued shares could, under certain circumstances, have an anti-takeover effect, for example, by permitting issuances that would dilute the stock ownership of a person seeking to effect a change in the composition of the Advaxis board of directors or contemplating a tender offer or other transaction for the combination of Advaxis with another company, the reverse stock split proposal is not being proposed in response to any effort of which Advaxis is aware to accumulate shares of Advaxis common stock or obtain control of Advaxis, other than in connection with the merger, nor is it part of a plan by management to recommend a series of similar amendments to the Advaxis board of directors and stockholders. Other than the proposals being submitted to the Advaxis stockholders for their consideration at the Advaxis special meeting, the Advaxis board of directors does not currently contemplate recommending the adoption of any other actions that could be construed to affect the ability of third parties to take over or change control of Advaxis. For more information, please see the section titled "*Risk Factors—Risks Related to the Combined Company*" beginning on page 19.

***Material U.S. Federal Income Tax Consequences of the Reverse Stock Split***

The following is a discussion of certain material U.S. federal income tax consequences of the reverse stock split that are applicable to U.S. Holders (as defined below) of Advaxis common stock. This discussion does not purport to be a complete analysis of all potential tax consequences and is based upon current provisions of the Code, existing Treasury Regulations, judicial decisions and published rulings and administrative pronouncements of the IRS, all in effect as of the date hereof and all of which are subject to differing interpretations or change. Any such change or differing interpretation, which may be retroactive, could alter the tax consequences to holders of Advaxis common stock as described in this summary.

This discussion does not address all U.S. federal income tax consequences relevant to holders of Advaxis common stock. In addition, it does not address consequences relevant to holders of Advaxis common stock that are subject to particular U.S. or non-U.S. tax rules, including, without limitation, to holders of Advaxis common stock that are:

- persons who do not hold their Advaxis common stock as a "capital asset" within the meaning of Section 1221 of the Code;
- brokers, dealers or traders in securities, banks, insurance companies, other financial institutions or mutual funds;

- real estate investment trusts; regulated investment companies; tax-exempt organizations or governmental organizations;
- pass-through entities such as partnerships, S corporations, disregarded entities for federal income tax purposes and limited liability companies (and investors therein);
- subject to the alternative minimum tax provisions of the Code;
- persons who hold their shares as part of a hedge, wash sale, synthetic security, conversion transaction or other integrated transaction;
- persons that have a functional currency other than the U.S. dollar;
- traders in securities who elect to apply a mark-to-market method of accounting;
- persons who hold shares of Advaxis common stock that may constitute "qualified small business stock" under Section 1202 of the Code or as "Section 1244 stock" for purposes of Section 1244 of the Code;
- persons who acquired their shares of Advaxis stock in a transaction subject to the gain rollover provisions of Section 1045 of the Code;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to Advaxis stock being taken into account in an "applicable financial statement" (as defined in the Code);
- persons deemed to sell Advaxis common stock under the constructive sale provisions of the Code;
- persons who acquired their shares of Advaxis common stock pursuant to the exercise of options or otherwise as compensation or through a tax-qualified retirement plan or through the exercise of a warrant or conversion rights under convertible instruments; and
- certain expatriates or former citizens or long-term residents of the United States.

Holders of Advaxis common stock subject to particular U.S. or non-U.S. tax rules, including those that are described in this paragraph, are urged to consult their own tax advisors regarding the consequences to them of the reverse stock split.

If an entity that is treated as a partnership for U.S. federal income tax purposes holds Advaxis stock, the U.S. federal income tax treatment of a partner in the partnership or other pass-through entity will generally depend upon the status of the partner, the activities of the partnership or other pass-through entity and certain determinations made at the partner level. If you are a partner of a partnership or other pass-through entity holding Advaxis common stock, you should consult your tax advisors regarding the tax consequences of the merger.

In addition, the following discussion does not address the tax consequences of the reverse stock split under state, local and foreign tax laws. Furthermore, the following discussion does not address any tax consequences of transactions effectuated before, after or at the same time as the reverse stock split, whether or not they are in connection with the reverse stock split.

**STOCKHOLDERS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS, AS WELL AS ANY TAX CONSEQUENCES OF THE REVERSE STOCK SPLIT ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.**

This discussion is limited to holders of Advaxis common stock that are U.S. Holders. For purposes of this discussion, a "U.S. Holder" is a beneficial owner of Advaxis common stock that, for U.S. federal income tax purposes, is or is treated as:

- an individual who is a citizen or resident of the United States;
- a corporation or any other entity taxable as a corporation created or organized in or under the laws of the United States, any state thereof, or the District of Columbia;

- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or

- a trust if either (i) a court within the United States is able to exercise primary supervision over the administration of such trust, and one or more United States persons (within the meaning of Section 7701(a)(30) of the Code) is authorized or has the authority to control all substantial decisions of such trust, or (ii) the trust was in existence on August 20, 1996, and has a valid election in effect under applicable Treasury Regulations to be treated as a United States person for U.S. federal income tax purposes.

***Tax Consequences of the Reverse Stock Split***

The proposed reverse stock split should constitute a "recapitalization" for U.S. federal income tax purposes pursuant to Section 368(a)(1)(E) of the Code. As a result, a U.S. Holder generally should not recognize gain or loss upon the proposed reverse stock split, except with respect to cash received in lieu of a fractional share of Advaxis common stock, as discussed below. A U.S. Holder's aggregate adjusted tax basis in the shares of Advaxis common stock received pursuant to the proposed reverse stock split should equal the aggregate adjusted tax basis of the shares of the Advaxis common stock surrendered (excluding any portion of such basis that is allocated to any fractional share of Advaxis common stock), and such U.S. Holder's holding period in the shares of Advaxis common stock received should include the holding period in the shares of Advaxis common stock surrendered. U.S. Treasury Regulations provide detailed rules for allocating the tax basis and holding period of the shares of Advaxis common stock surrendered to the shares of Advaxis common stock received in a recapitalization pursuant to the proposed reverse stock split. U.S. Holders of shares of Advaxis common stock acquired on different dates and at different prices should consult their tax advisors regarding the allocation of the tax basis and holding period of such shares.

***Cash in Lieu of Fractional Shares***

A U.S. Holder that receives cash in lieu of a fractional share of Advaxis common stock pursuant to the proposed reverse stock split should recognize capital gain or loss in an amount equal to the difference between the amount of cash received and the U.S. Holder's tax basis in the shares of Advaxis common stock surrendered that is allocated to such fractional share of Advaxis common stock. Such capital gain or loss should be long-term capital gain or loss if the U.S. Holder's holding period for Advaxis common stock surrendered exceeded one year at the effective time of the reverse stock split.

***Information Reporting and Backup Withholding***

Payments of cash made in lieu of a fractional share of Advaxis common stock may, under certain circumstances, be subject to information reporting and backup withholding. To avoid backup withholding, each holder of Advaxis common stock that does not otherwise establish an exemption should furnish its taxpayer identification number and comply with the applicable certification procedures.

Backup withholding is not an additional tax. Any amounts withheld will be allowed as a credit against the holder's U.S. federal income tax liability and may entitle such holder to a refund, provided the required information is timely furnished to the IRS. Holders of Advaxis common stock should consult their tax advisors regarding their qualification for an exemption from backup withholding and the procedures for obtaining such an exemption.

***Required Vote***

The affirmative vote of the holders of a majority of the outstanding shares of Advaxis common stock entitled to vote at the Advaxis special meeting is required to approve the amendment to the amended and restated certificate of incorporation of Advaxis as amended to effect a reverse stock split of Advaxis common stock.

**ADVAXIS' BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS A VOTE "FOR" THIS PROPOSAL NO. 2 TO APPROVE THE AMENDMENT TO THE RESTATED CERTIFICATE OF INCORPORATION OF ADVAXIS AS AMENDED TO EFFECT THE REVERSE STOCK SPLIT.**

Unless otherwise instructed, it is the intention of the persons named in the accompanying proxy card to vote shares represented by properly executed proxy cards "FOR" the approval of the amendment to the amended and restated certificate of incorporation of Advaxis as amended to effect the reverse stock split.

## PROPOSAL NO. 3

## APPROVAL OF THE AMENDMENT TO AMENDED AND RESTATED CERTIFICATE OF INCORPORATION AS AMENDED OF ADVAXIS TO CHANGE THE CORPORATE NAME FROM ADVAXIS, INC. TO "BIOSIGHT THERAPEUTICS INC." IN THE FORM ATTACHED AS *ANNEX F* TO THIS PROXY STATEMENT/PROSPECTUS/INFORMATION STATEMENT.

At the Advaxis special meeting, Advaxis stockholders will be asked to approve an amendment to the amended and restated certificate of incorporation, as amended, of Advaxis to change the corporate name of Advaxis to "Biosight Therapeutics Inc." in the form attached as *Annex F* to this proxy statement/prospectus/information statement, each pursuant to the Merger Agreement.

***Corporate Name Change***

The certificate of incorporation amendment also amends the amended and restated certificate of incorporation as amended to change the corporate name of Advaxis to "Biosight Therapeutics Inc." Approval by Advaxis' stockholders of the corporate name change is a condition to completion of the merger.

Advaxis believes the current name of Advaxis, Inc. will not accurately reflect the operations of the combined company if the merger is consummated, and believes the proposed name change better conveys the clinical products and clinical programs of the combined company. The corporate name change, if approved by Advaxis' stockholders, would have the effect of changing Advaxis' legal name.

***Procedure for Effecting the Certificate of Incorporation Amendment***

If the Advaxis stockholders approve the amendment to the Advaxis amended and restated certificate of incorporation as amended effecting the corporate name change, and if the Advaxis board of directors still believes that a corporate name change is in the best interests of Advaxis and its stockholders, Advaxis will file the amendment to the amended and restated certificate of incorporation as amended with the Secretary of State of the State of Delaware at such time as the Advaxis board of directors has determined to be the appropriate time. The Advaxis board of directors may delay effecting the certificate of incorporation amendment proposal without resoliciting stockholder approval.

As soon as practicable after the certificate of incorporation amendment effective time, stockholders will be notified that the certificate of incorporation amendment has been effected.

***Required Vote***

The affirmative vote of the holders of a majority of the outstanding shares of Advaxis common stock entitled to vote at the Advaxis special meeting is required to approve the amendment to the amended and restated certificate of incorporation of Advaxis as amended to change the corporate name of Advaxis to "Biosight Therapeutics Inc."

**ADVAXIS' BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS A VOTE "FOR" THIS PROPOSAL NO. 3 TO CHANGE THE CORPORATE NAME FROM ADVAXIS, INC. TO "BIOSIGHT THERAPEUTICS INC." IN THE FORM ATTACHED AS *ANNEX F* TO THIS PROXY STATEMENT/PROSPECTUS/INFORMATION STATEMENT.**

Unless otherwise instructed, it is the intention of the persons named in the accompanying proxy card to vote shares represented by properly executed proxy cards "FOR" the approval of the amendment to the amended and restated certificate of incorporation of Advaxis as amended to change the corporate name of Advaxis to "Biosight Therapeutics Inc."

## PROPOSAL NO. 4

## ADVISORY, NON-BINDING VOTE ON MERGER-RELATED EXECUTIVE COMPENSATION ARRANGEMENTS

Section 14A of the Exchange Act, which was enacted as part of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, requires that Advaxis provide stockholders with the opportunity to vote to approve, on non-binding, advisory basis, the payment of certain compensation that will or may become payable by Advaxis to its named executive officers in connection with the merger, as disclosed in the section titled "*The Merger—Interests of the Advaxis Directors and Executive Officers in the Merger—Golden Parachute Compensation.*"

Upon the consummation of the merger, each of the Advaxis named executive officers will resign with good reason. Therefore, Advaxis is asking stockholders to indicate their approval of the compensation that will or may become payable by Advaxis to its named executive officers in connection with the merger and the associated termination by the named executive officers for good reason upon the consummation of the merger. These payments are set forth in the section titled "*The Merger—Interests of the Advaxis Directors and Executive Officers in the Merger—Golden Parachute Compensation*," and the accompanying footnotes. In general, the employment agreements, equity awards and other arrangements pursuant to which these compensation payments may be made have previously formed a part of Advaxis' overall compensation program for its named executive officers and previously have been disclosed to stockholders as part of Advaxis' annual proxy statements or its other reports filed with the SEC. These historical employment agreements, equity awards and other arrangements were adopted and approved by the compensation committee of the Advaxis board of directors, which is composed solely of non-management directors, and are believed to be reasonable and in line with marketplace norms.

Accordingly, Advaxis is seeking approval of the following resolution at the Advaxis special meeting:

"RESOLVED, that the stockholders of Advaxis, Inc. approve, on a non-binding, advisory basis, the compensation that will or may become payable by Advaxis to its named executive officers that is based on or otherwise relates to the merger as disclosed pursuant to Item 402(t) of Regulation S-K in the section titled '*The Merger—Interests of the Advaxis Directors and Executive Officers in the Merger—Golden Parachute Compensation.*'"

Stockholders of Advaxis should note that this proposal is not a condition to the closing of the merger, and as an advisory vote, the result will not be binding on Advaxis, its board of directors or the named executive officers. Further, the underlying employment agreements, equity awards and other arrangements are contractual in nature and not, by their terms, subject to stockholder approval. Accordingly, regardless of the outcome of the advisory vote, if the merger is consummated and Advaxis' named executive officers are terminated in connection with the merger, the named executive officers will be eligible to receive the compensation that is based on or otherwise relates to the merger in accordance with the terms and conditions applicable to the underlying employment agreements, equity awards and other arrangements Advaxis entered into with these named executive officers.

***Required Vote***

The affirmative vote of the holders of a majority of the shares present in attendance or represented by proxy at the Advaxis special meeting and entitled to vote on the matter, assuming a quorum is present, is required to approve the non-binding advisory vote on compensation that will or may become payable by Advaxis to its named executive officers in connection with the merger.

**ADVAXIS' BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS A VOTE "FOR" THIS PROPOSAL NO. 4 TO APPROVE, ON A NON-BINDING ADVISORY VOTE BASIS, COMPENSATION THAT WILL OR MAY BECOME PAYABLE BY ADVAXIS TO ITS NAMED EXECUTIVE OFFICERS IN CONNECTION WITH THE MERGER**.

## PROPOSAL NO. 5

## APPROVAL OF POSSIBLE ADJOURNMENT OF THE SPECIAL MEETING

If Advaxis fails to receive a sufficient number of votes to approve Proposal Nos. 1, 2 and 3, Advaxis may propose to adjourn the Advaxis special meeting, for a period of not more than 60 days, for the purpose of soliciting additional proxies to approve Proposal Nos. 1, 2 and 3. Advaxis currently does not intend to propose adjournment at the Advaxis special meeting if there are sufficient votes to approve Proposal Nos. 1, 2 and 3.

***Required Vote***

The affirmative vote of the holders of a majority of the shares present in attendance or represented by proxy at the Advaxis special meeting and entitled to vote on the matter, assuming a quorum is present, is required to approve the adjournment of the Advaxis special meeting for the purpose of soliciting additional proxies to approve Proposal Nos. 1, 2 and 3.

**ADVAXIS' BOARD OF DIRECTORS RECOMMENDS A VOTE "FOR" THIS PROPOSAL NO. 6 TO ADJOURN THE ADVAXIS SPECIAL MEETING, IF NECESSARY, TO SOLICIT ADDITIONAL PROXIES IF THERE ARE NOT SUFFICIENT VOTES IN FAVOR OF PROPOSAL NOS. 1, 2 AND 3.**

Unless otherwise instructed, it is the intention of the persons named in the accompanying proxy to vote shares "FOR" the ratification to adjourn the Advaxis special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposal Nos. 1, 2 and 3.

## ADVAXIS' BUSINESS

### General

Advaxis is a clinical-stage biotechnology company focused on the development and commercialization of proprietary *Listeria monocytogenes*, or *Lm*, Technology antigen delivery products based on a platform technology that utilizes live attenuated *Lm* bioengineered to secrete antigen/adjuvant fusion proteins. We believe *Lm*-based strains are a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy and are designed to access and direct antigen-presenting cells, or APCs, to stimulate anti-tumor T cell immunity, activate the immune system with the equivalent of multiple adjuvants, and simultaneously reduce tumor protection in the tumor micro-environment, or TME, to enable T cells to eliminate tumors. The Company believes that *Lm* Technology immunotherapies can complement and address significant unmet needs in the current oncology treatment landscape. Specifically, the Company's product candidates have the potential to optimize checkpoint inhibitor performance, while having a generally well-tolerated safety profile, and most of its product candidates have an expected low cost of goods. On July 15, 2021, Advaxis announced the initiation of a Phase 1 clinical study evaluating ADXS-504 in patients with biochemically recurrent prostate cancer. The study, being conducted at Columbia University Irving Medical Center, is the first clinical evaluation of ADXS-504, Advaxis' off-the-shelf neoantigen immunotherapy drug candidate for early prostate cancer. The Company's passion for the clinical potential of *Lm* Technology is balanced by focus and fiscal discipline which is directed toward improving treatment options for cancer patients and increasing shareholder value.

Advaxis is focused on multiple antigen delivery products and is in various stages of clinical development. All of the Company's products are anchored in the Company's *Lm* Technology™, a unique platform designed for its ability to target various cancers in multiple ways. As an intracellular bacterium, *Lm* is an effective vector for the presentation of multiple neoantigens through both the Major Histocompatibility Complex, or MHC, I and II pathways, due to its active phagocytosis by APCs. Within the APCs, *Lm* produces virulence factors that allow survival in the host cytosol and potently stimulate the immune system.

Through a license from the University of Pennsylvania and through its own development efforts, Advaxis has exclusive access to a proprietary formulation of attenuated *Lm* that it calls *Lm* Technology. *Lm* Technology is designed to optimize this natural system, and one of the keys to the enhanced immunogenicity of *Lm* Technology is the *tLLO*-fusion protein, which is made up of tumor associated antigen, or TAA, fused to a highly immunogenic bacterial protein that triggers potent cellular immunity. The *tLLO*-fusion protein is also designed to help reduce immune tolerance in the TME and to promote antigen spreading, thereby improving activity in the TME. Multiple copies of the *tLLO*-fusion protein within each construct may increase antigen presentation and TME impact.

As the field of immunotherapy continues to evolve, the flexibility of the *Lm* Technology platform has allowed Advaxis to develop highly innovative products utilizing a single vector targeting a wide array of neoantigens relevant to the tumor type treated. To date, *Lm* Technology has demonstrated preclinical synergy with multiple checkpoint inhibitors, co-stimulatory agents and radiation therapy. The safety profile of all *Lm* Technology constructs seen to date across over 470 patients has been generally predictable and manageable, consisting mostly of mild to moderate flu-like symptoms that have been transient and associated with infusion.

### The Advaxis Corporate Strategy

Our strategy is to advance the *Lm* Technology platform and leverage its unique capabilities to design and develop an array of cancer treatments. We are currently conducting or have conducted clinical studies of *Lm* Technology immunotherapies in non-small cell lung cancer and other solid tumor types, prostate cancer and HPV-associated cancers. We are working with, or are in the process of identifying, collaborators and potential licensees for these programs.

Advaxis is currently mainly concentrating on its disease-focused, hotspot/"off-the-shelf" neoantigen-directed therapies called ADXS-HOT. ADXS-HOT is a program that leverages the Company's proprietary *Lm* Technology to target hotspot mutations that commonly occur in specific cancer types. ADXS-HOT drug candidates are designed to target acquired shared or "public" mutations in tumor driver genes along with other cancer-associated antigens that also commonly occur in specific cancer types.

We expect that we will continue to invest in our core clinical program areas and will also remain opportunistic in evaluating Investigator Sponsored Trials, or ISTs, as well as licensing opportunities as we are actively looking for partners and/or licensees for these programs. The *Lm* Technology platform is protected by a range of patents, covering both product and process, some of which we believe can be maintained into 2039.

***Lm* Technology and the Immunotherapy Landscape**

The challenge of cancer immunotherapy has been to find the best overall balance between efficacy and side effects when mobilizing the body's immune system to fight against cancer. The development of immune checkpoint inhibitors was a significant step forward, particularly with anti-PD-1 therapies, and brought with it impressive clinical activity in many different types of cancers, including melanoma, lung, head and neck and urothelial cancers. However, a literature review published in *Science* in 2018 noted that anti-PD-1 monotherapy response rates are only in the 15%-25% range, and rise to ≥50% only in selected groups of patients with desmoplastic melanoma, Merkel carcinoma or tumors with mismatch-repair deficiency. Development of secondary resistance with disease progression is yet another common limitation of these therapies. Therefore, for most cancer patients, there is room for improvement. Checkpoint inhibitors can expand existing cancer-fighting cells that may already be present in low numbers and support their activity against cancer cells, but if the right cancer-fighting cells are not present, checkpoint inhibitors may not provide clinical benefit. Similarly, there are many mechanisms of immune tolerance that are distinct from the checkpoints which may also be blocking the immune system from fighting cancer. Based on both preclinical and early clinical data, Advaxis believes that checkpoint inhibitors, when combined with treatments such as *Lm* Technology, can have an amplified anti-tumor effect. *Lm* Technology incorporates several complementary elements that include innate immune stimulation, potent generation of cancer-targeted T cells, ability to boost immunity through multiple treatments, enhancing lymphocyte infiltration into tumors, reduction of non-checkpoint mediated immune tolerance within the TME, and promotion of antigen spreading, which may amplify the effects of treatment. These results provide rationale for further testing of *Lm* Technology agents alone and in combination with checkpoint inhibitors.

Traditional cancer vaccines were another development within immunotherapy and have a history beginning over 30 years ago. Unfortunately, these vaccines have largely been unsuccessful for a variety of potential reasons. These include poor selection of targets, imbalanced antigen presentation by inclusion of certain immune enhancing agents (adjuvants), failure to consider the blocking actions of immune tolerance, and choice of vaccine vectors. In some cases, patients may develop neutralizing antibodies, preventing further treatments. In contrast to traditional cancer vaccines, *Lm* Technology takes advantage of a natural pathway in the immune system that evolved to protect us against *Listeria* infections, which also happens to generate the same type of immunity that is required when fighting cancer. The live but weakened (attenuated) bacteria stimulate a balanced concert of innate immune triggers and present the tumor antigen target precisely where it needs to be in order to generate potent cancer-fighting cells from within the immune system itself. The multitude of accompanying signals serves to broadly mobilize most of the immune system in support of fighting what seems to be a *Listeria* infection and is then "re-directed" against cancer cell targets. Additionally, the unique intracellular lifecycle of *Listeria* avoids the creation of neutralizing antibodies, thereby allowing for repeat administration as a chronic therapy with a sustained enhancing of tumor antigen-specific T cell immunity.

Looking back on the last two decades, there have been promising technology advancements to harness and activate killer T cells against cancers and every day more is learned about the interplay between immunity and cancer that can lead to improved treatments. However, there are still significant unmet needs in the immunotherapy landscape that Advaxis believes *Lm* Technology may be able to address and complement. Specifically, *Lm* Technology has the potential to optimize and expand checkpoint inhibitor activity in combination. It also avoids many of the limitations of previous cancer vaccine attempts by tapping into the pathway reserved for defense against *Listeria* infection while incorporating the best cancer targets science can identify, including neoantigens that result from mutations in the cancer. To date, *Lm* Technology products have a manageable safety profile, do not generate neutralizing antibodies lending themselves to retreatments, and most of the products are designed to be immediately available for treatment without the complication and expense of modifying a patient's own cells in a laboratory.

***Lm* Technology: An optimized *Listeria*-based antigen delivery system**

Advaxis' *Listeria*-based immunotherapies are designed for antigen delivery through a process of insertion of multiple copies of the proprietary *tLLO*-fusion protein into each extrachromosomal protein expression and secretion plasmid that makes and secretes the target protein right inside the patient's APCs to initiate and/or boost their immune response. The *tLLO*-fusion protein approach was developed at the University of Pennsylvania as an improvement over insertion of a single copy of the target gene, as an ACT-A (or other *Lm* peptide) fusion, within the bacterial genome for four key reasons:

1. Multiple copies of the DNA in the plasmids per bacteria can result in larger amounts of *tLLO*-fusion protein being expressed simultaneously, versus a single copy. This is designed to improve antigen presentation and immunologic priming and increases the number of T cells generated for a particular treatment.
2. *tLLO* expressed on plasmids (with or without a tumor target protein attached) has been shown preclinically to reduce numbers and immune suppressive function of Tregs and myeloid-derived suppressor cells, or MDSCs, in the TME. Presented preclinical data demonstrates that Tregs are destroyed as soon as five days after the first *Lm* Technology treatment and that suppressive M2 tumor-associated macrophages, or TAMs, are replaced by M1 macrophages which support antigen presentation and adoptive immunity.
3. The extrachromosal DNA plasmids themselves also contain CpG sequence patterns that trigger TLR-9, which confers additional innate immune stimulation beyond a *listeria* without the plasmids.
4. The multiple copies of bacterial DNA plasmids (up to 80-100 per bacteria) confers additional stimulation of the STING receptor within APC's, which has been associated with enhancing anti-cancer immunity in patients.

**Clinical Pipeline**

Advaxis is focused on the development and commercialization of proprietary *Lm* Technology antigen delivery products. Advaxis has completed and closed out clinical studies of *Lm* Technology immunotherapies in three program areas:

- HPV associated cancers
- Personalized neoantigen-directed therapies
- PSA directed therapy

All these clinical program areas are anchored in the Company's *Lm* Technology™, a unique platform designed for its ability to safely and effectively target various cancers in multiple ways. The Phase 1/2 study with ADXS-PSA ± pembrolizumab in metastatic castration-resistant prostate cancer patients was closed on January 25, 2021. The MEDI Phase 2 combo study (AZ) with AXAL ± durvalumab in Cervical and Head and Neck Cancer and the AIM2CERV Phase 3 clinical trial with ADXS-HPV (AXAL) in cervical cancer were closed on August 22, 2019 and June 11, 2021, respectively. The study with personalized neoantigen-directed therapies (ADXS-NEO) was closed on May 22, 2020 and the NEO program-IND inactivation request was submitted to the FDA on May 10, 2021

While we are currently winding down clinical studies of *Lm* Technology immunotherapies in these program areas, our license agreements continue with OS Therapies, LLC, for ADXS-HER2, and with GBP for the exclusive license for the development and commercialization of ADXS-HPV or AXAL in Asia, Africa, and the former USSR territory, exclusive of India and certain other countries.

**Advaxis Pipeline of Product Candidates**


*Disease-focused hotspot/"off-the-shelf" neoantigen therapies (ADXS-HOT)*

Advaxis is creating a new group of immunotherapy constructs for major solid tumor cancers that combines our optimized *Lm* Technology vector with promising targets designed to generate potent anti-cancer immunity. The ADXS-HOT program is a series of novel cancer immunotherapies that will target somatic mutations, or hotspots; cancer testis antigens, or CTAs; and oncofetal antigens, or OFAs. These three types of targets form the basis of the ADXS-HOT program because they are designed to be more capable of generating potent, tumor-specific, and high-strength killer T cells, versus more traditional over-expressed native sequence tumor associated antigens. Most hotspot mutations and OFA/CTA proteins play critical roles in oncogenesis; targeting both at once could significantly impair cancer proliferation. The ADXS-HOT products will combine many of the potential high avidity targets that are expressed in all patients with the target disease into one "off-the-shelf," ready-to-administer treatment. The ADXS-HOT technology has a strong intellectual property, or IP, position, with potential protection into 2037, and an IP filing strategy providing for broad coverage opportunities across multiple disease platforms and combination therapies. In July 2018, the Company announced that the U.S. Food and Drug Administration, or FDA, allowed the Company's investigational new drug, or IND, application for its ADXS-HOT drug candidate (ADXS-503) for non-small cell lung cancer, or NSCLC.

The Phase 1/2 clinical trial of ADXS-503 is seeking to establish the recommended dose, safety, tolerability and clinical activity of ADXS-503 administered alone and in combination with a KEYTRUDA® in approximately 50 patients with NSCLC, in at least five sites across the U.S. The two dose levels with monotherapy in Part A, (1 x$10^8$ CFU and 5 x$10^8$ CFU) have been completed. Part B with ADXS-503 (1 x$10^8$ CFU) in combination with KEYTRUDA® is currently enrolling its efficacy expansion for up to 18 patients at dose level 1 (1 x$10^8$ CFU + KEYTRUDA®) with the potential to proceed to dose level 2 (5 x$10^8$ CFU + KEYTRUDA®) at a later date. Part C, which is evaluating ADXS-503 in combination with KEYTRUDA® (1 x$10^8$ CFU + KEYTRUDA®) as a first-line treatment for patients with NSCLC with PD-L1 expression ≥ 1% or who are unfit for chemotherapy, is currently enrolling patients.

Initial results from Part A and Part B were presented in a poster titled, "*Phase 1/2 Study of an Off-the-Shelf, Multi-Neoantigen Vector (ADXS-503) Alone and in Combination with Pembrolizumab in Subjects with Metastatic Non-Small Cell Lung Cancer (NSCLC*)" at the 2020 Society for Immunotherapy of Cancer (SITC) Annual Meeting. ADXS-503 alone (Part A) and in combination with pembrolizumab (Part B-DL1 and Part C) appeared safe and tolerable. There were no added toxicities from combining ADXS-503 with pembrolizumab.

In Part A, ADXS-503 alone achieved stable disease in 50% (n=6) of heavily pre-treated patients including prior treatment with checkpoint inhibitors in all but one patient. In Part B, the overall response rate (17%) and disease control rate (67%) (n=6) suggest that adding on ADXS-503 after immediate prior progression on pembrolizumab may re-sensitize or enhance response to pembrolizumab. The first two patients treated in the Part B achieved SD and PR for more than 10 months. Another patient with squamous histology in Part B also achieved stable disease, suggesting this regimen may be broadly applicable across NSCLC. Patients with known KRAS mutations in tumor samples have achieved stable disease in the study, including KRAS G12D in two out of six patients in Part A and KRAS G12V in one out of three in Part B DL1. Mutational analysis is ongoing across all patients. Biomarker data from nine patients to date, six from Part A and three from Part B, showed (a) activation of cytotoxic- and/or memory-CD8+ T cells in patients treated with monotherapy and in combination therapy and (b) 100% efficient priming by ADXS-503 with generation of CD8+ T cells against neoantigens in the vector as well as antigen spreading observed.

The Company presented updated clinical data from Part B of the ADXS-503 clinical study at the ASCO Annual Meeting 2021. The poster presentation titled "*A phase 1 study of an off-the-shelf, multi-neoantigen vector (ADXS-503) in patients with metastatic non-small-cell lung cancer (NSCLC) progressing on pembrolizumab as last therapy*" presented data on 10 patients who have been treated with ADXS-503 as an add-on therapy to patients failing pembrolizumab as last therapy with 10 patients evaluable for safety and nine patients evaluable for efficacy. Combination therapy was well tolerated with no dose limiting toxicity or added toxicity of the two drugs. Grades 1 and 2, transient and reversible events included chills, fever, and fatigue, in approximately half of the patients. The Overall Response Rate ("ORR") was 11% (1/9) and Disease Control Rate ("DCR") was 44% (4/9). Clinical benefit was durable, with an observed partial response ("PR") and stable disease ("SD") sustained for over a year, and another observed SD lasting over six months. An additional PR was maintained for approximately four months. Biomarker data demonstrate that patients who seem to achieve clinical benefit include those with PD-L1 expression ≥50%, secondary resistance disease to pembrolizumab and those who show proliferation and/or activation of NK and CD8+ T cells within the first weeks of therapy. Translational studies showed (a) antitumoral T cell responses elicited against hot-spot mutation antigens and/or tumor-associated antigens ("TAAs"); (b) emergence of naive CD8+ T cell clones, suggesting reactivity against novel antigens; and (c) induction of proliferation and/or activation of pre-existing CD8+ T cell clones, including PD-1 upregulation.

Enrollment in Part B of the ongoing study will continue to further evaluate the clinical benefit and immune effects of adding on ADXS-503 to patients progressing on pembrolizumab.

Advaxis also entered into an agreement with Columbia University Irving Medical Center in April 2021 to fund a phase 1 clinical study evaluating ADXS-504 in patients with biochemically recurrent prostate cancer. The study started early in 3Q 2021 and it will be the first clinical evaluation of ADXS-504, Advaxis' off-the-shelf neoantigen immunotherapy drug candidate for early prostate cancer.

Nearly 248,530 men in the United States will be diagnosed with prostate cancer in 2021. It has been estimated that ~135,000 new cases undergo radical prostatectomy (RP) or radiotherapy (RT). Of these cases, 20–40% of pts with RP and 30–50% with RT will experience rising prostate specific antigen (PSA) levels following local therapy (BCR) within 10 years, a condition known as biochemical recurrence (BCR). BCR is not typically associated with imminent death, and biochemical progression may occur over a prolonged period. Clinicians treating men with BCR thus face a difficult set of decisions in attempting to delay the onset of metastatic disease and death while avoiding over-treating patients whose disease may never affect their overall survival or quality of life.

The phase 1 open-label study will evaluate the safety and tolerability of ADXS-504 monotherapy, administered via infusion, in 9-18 patients with biochemically recurrent prostate cancer, i.e., those with elevation of prostate-specific antigen (PSA) in the blood after radical prostatectomy or radical radiotherapy (external beam or brachytherapy) and who are not currently receiving androgen ablation therapy. The study will also evaluate if the body's immune system can control the prostate cancer following treatment with ADXS-504 monotherapy.

***HPV-Related Cancers***

The Company conducted several studies evaluating axalimogene filolisbac, or AXAL, for HPV-related cancers. AXAL is an *Lm*-based antigen delivery product directed against HPV and designed to target cells expressing HPV.

In June 2019, the Company announced the closing of its AIM2CERV Phase 3 clinical trial with axalimogene filolisbac (AXAL) in high-risk, locally advanced cervical cancer. Company estimates showed that the remaining cost to complete the AIM2CERV trial ranged from $80 million to $90 million, and initial efficacy data was not anticipated for at least three years. Therefore, results from the clinical trial were not the basis for the decision to close the study, nor was safety, as the trial recently underwent its third Independent Data Monitoring Committee ("IDMC") review with no safety issues noted. The Company has unblinded the AIM2CERV clinical data generated to date.

In 2014, Advaxis granted GBP an exclusive license for the development and commercialization of AXAL in Asia, Africa, and the former USSR territory, exclusive of India and certain other countries. GBP is responsible for all development and commercial costs and activities associated with the development in their territories.

*Other HPV Program Licensing Agreements*

Biocon Limited, or Biocon, our co-development and commercialization partner for AXAL in India and key emerging markets, filed an MAA for licensure of this immunotherapy in India. The companies will evaluate next steps regarding potential registration in India.

Específicos Stendhal SA de CV, or Stendhal, the Company's co-development and commercialization partner for AXAL in Mexico, Brazil, Colombia and other Latin American countries, agreed to pay $10 million in support payment toward the expense of AIM2CERV over the duration of the trial, contingent upon Advaxis achieving annual project milestones, pursuant to a Co-Development and Commercialization Agreement, or the Stendhal Agreement. The Company was in arbitration proceedings with Stendhal. For more information, see Note 9, "Commitments and Contingencies – Legal Proceedings" of the "Notes to the Financial Statements" to our audited financial statements included herein.

Knight Therapeutics Inc., or Knight, holds an exclusive license to commercialize AXAL in Canada, as well as other product candidates.

*Personalized Neoantigen-directed Therapies (ADXS-NEO)*

ADXS-NEO is an individualized *Lm* Technology antigen delivery product developed using whole-exome sequencing of a patient's tumor to identify neoantigens. ADXS-NEO is designed to work by presenting a large payload of neoantigens directly into dendritic cells within the patient's immune system and stimulating a T cell response against cancerous cells. In October 2019, the Company announced that it has dosed its last patient in Part A, in monotherapy, and does not intend to continue into Part B, in combination with a checkpoint inhibitor. As a result, The Company has closed the study, and the NEO program-IND inactivation request has been submitted to FDA.

*Prostate Cancer (ADXS-PSA)*

According to the American Cancer Society, prostate cancer is the second most common type of cancer found in American men and is the second leading cause of cancer death in men, behind only lung cancer. More than 160,000 men were estimated to be diagnosed with prostate cancer in 2018, with approximately 30,000 deaths each year. Unfortunately, in about 10%-20% of cases, men with prostate cancer will go on to develop castration-resistant prostate cancer, or CRPC, which refers to prostate cancer that progresses despite androgen deprivation therapy. Metastatic CRPC, or mCRPC, occurs when the cancer spreads to other parts of the body and there is a rising prostate-specific antigen ("PSA") level. This stage of prostate cancer has an average survival of nine to 13 months, is associated with deterioration in quality of life, and has few therapeutic options available.

Recent data regarding checkpoint inhibitor monotherapy has shown some antitumor activity that provides disease control in a subset of patients with bone-predominant mCRPC previously treated with next-generation hormonal agents and docetaxel. Data from the KEYNOTE-199 trial in bone-predominant mCRPC patients treated with KEYTRUDA®, or pembrolizumab, was updated at the ASCO meeting in 2019. In this trial, the total stable disease/disease stabilization rate was 39% with no responses reported so far, and only one patient with ≥50% decrease in the post-baseline PSA value. It is hypothesized that the limited activity in mCRPC may be due to (1) the inability of the checkpoint inhibitor to infiltrate the TME and (2) the presence of an immunosuppressive TME. The combination therapy with agents—such as *Lm* constructs—that induce T cell infiltration within the tumor and decrease negative regulators in the TME may improve performance of checkpoints in prostate cancer.

*Lm* Technology constructs demonstrated the ability to induce anti-tumor T cell responses and T cell infiltration in the TME and to reduce the number and suppressive function of Tregs and MDSCs in the TME. For example, destruction of Tregs in the TME has been documented as soon as five days after dosing *Lm* constructs in models. This reduction of immune suppression in the tumors has been attributed to our proprietary *tLLO*-fusion peptides expressed by multiple copies of the plasmids in each bacteria. Because of all these effects, it is hypothesized that *Lm* constructs can turn "cold prostate tumors" into "hot tumors" that better respond to checkpoint inhibitors. Advaxis believes that the combination of ADXS-PSA, its immunotherapy designed to target the PSA antigen, with a checkpoint inhibitor may provide an alternative treatment option for patients with mCRPC.

Advaxis has entered into a clinical trial collaboration and supply agreement with Merck to evaluate the safety and efficacy of ADXS-PSA as monotherapy and in combination with KEYTRUDA®, Merck's anti PD-1 antibody, in a Phase 1/2, open-label, multicenter, dose determination and expansion trial in patients with previously treated metastatic, castration-resistant prostate cancer (KEYNOTE-046). ADXS-PSA was tested alone or in combination with KEYTRUDA in an advanced and heavily pretreated patient population who had progressed on androgen deprivation therapy. A total of 13 and 37 patients were evaluated on monotherapy and combination therapy, respectively. For the ADXS-PSA monotherapy dose escalation and determination portion of the trial, cohorts were started at a dose of 1 x $10^9$ cfu (n=7) and successfully escalated to higher-dose levels of 5x$10^9$ cfu (n=3) and 1x$10^{10}$ cfu (n=3) without achieving a maximum-tolerated dose. TEAEs noted at these higher-dose levels were generally consistent with those observed at the lower-dose level (1 x $10^9$ cfu) other than a higher occurrence rate of Grade 2/3 hypotension. The recommended Phase II dose of ADXS-PSA monotherapy was determined to be 1x $10^9$ cfu based on a review of the totality of the clinical data. This dose was used in combination with 200 mg of pembrolizumab in a cohort of six patients to evaluate the safety of the combination before moving into an expanded cohort of patients. The safety of the combination was confirmed and enrollment in the expansion cohort phase was initiated. Enrollment in the study was completed in January 2017.

At the final data cutoff of September 16, 2019, median overall survival for 37 patients in the combination arm was 33.6 months (95% CI, range 15.4 months-33.6 months). This updated median overall survival is an increase from the previous data presented at the American Association for Cancer Research Annual Meeting in April 2019, where median overall survival was 21.1 months in the combination arm. The combination of ADXS-PSA with KEYTRUDA® might be associated with prolonged OS in this population, particularly in patients with unmet medical needs like visceral metastasis (16.4 months, range 4.0 - not reached) and those with prior docetaxel (16 months, range 6.4-34.6). The majority of TEAEs consisted of transient and reversible Grade 1-2 chills/rigors, fever, hypotension, nausea and fatigue. The combination of ADXS-PSA and KEYTRUDA® has appeared to be well tolerated to date, with no additive toxicity observed. The Company presented these new data at the ASCO Genitourinary Cancers Symposium in San Francisco, California on February 13, 2020. The Company is currently seeking potential partners regarding opportunities to expand or advance this mCRPC program.

***Other Lm Technology Products***

*HER2 Expressing Solid Tumors*

HER2 is overexpressed in a percentage of solid tumors including osteosarcoma. According to published literature, up to 60% of osteosarcomas are HER2 positive, and this overexpression is associated with poor outcomes for patients. ADXS-HER2 is an *Lm* Technology antigen delivery product candidate designed to target HER2 expressing solid tumors, including human and canine osteosarcoma. ADXS-HER2 has received FDA and EMA orphan drug designation for osteosarcoma and has received Fast Track designation from the FDA for patients with newly diagnosed, non-metastatic, surgically resectable osteosarcoma.

In September 2018, the Company announced that it had granted a license to OS Therapies, LLC, or OS Therapies, for the use of ADXS31-164, also known as ADXS-HER2, for evaluation in the treatment of osteosarcoma in humans. Under the terms of the license agreement, OS Therapies, in collaboration with the Children's Oncology Group, will be responsible for the conduct and funding of a clinical study evaluating ADXS-HER2 in recurrent, completely resected osteosarcoma. In December 2020 and January 2021, we received an aggregate of $1,345,000 from OS Therapies upon achievement of the $1,550,000 funding milestone set forth in the license agreement. The Company therefore transferred, and OS Therapies took full ownership of, the IND application for ADXS31-164 in its entirety along with agreements and promises contained therein, as well as all obligations associated with this IND or any HER2 product/program development.

On April 26, 2021, the Company achieved the second milestone set forth in the license agreement for evaluation in the treatment of osteosarcoma in humans. The Company had a receivable due from OS Therapies of $1.375 million at April 30, 2021.

*Canine Osteosarcoma*

On March 19, 2014, we entered into a definitive Exclusive License Agreement, or Aratana Agreement, with Aratana Therapeutics, Inc., or Aratana, where we granted Aratana an exclusive, worldwide, royalty-bearing license, with the right to sublicense, certain of our proprietary technology that enables Aratana to develop and commercialize animal health products that will be targeted for treatment of osteosarcoma and other cancer indications in animals. A product license request was filed by Aratana for ADXS-HER2 (also known as AT-014 by Aratana) for the treatment of canine osteosarcoma with the United States Department of Agriculture, or USDA. Aratana received communication in December 2017 that the USDA granted Aratana conditional licensure for AT-014 for the treatment of dogs diagnosed with osteosarcoma, one year of age or older. Initially, Aratana plans to make the therapeutic available for purchase at approximately two dozen veterinary oncology practice groups across the United States who participate in the study. Aratana received communication in December 2017 that the USDA granted Aratana conditional licensure for AT-014 for the treatment of dogs diagnosed with osteosarcoma, one year of age or older. Aratana is currently conducting an extended field study, which is a requirement for full USDA licensure. Initially, Aratana plans to make the therapeutic available for purchase at approximately two dozen veterinary oncology practice groups across the United States who participate in the study.

Under the terms of the Aratana Agreement, Aratana paid an upfront payment to Advaxis in the amount of $1,000,000 upon signing of the Aratana Agreement. Aratana will also pay Advaxis (a) up to $36.5 million based on the achievement of a milestone relating to the advancement of products through the approval process with the USDA in the United States and the relevant regulatory authorities in the European Union, or E.U., in all four therapeutic areas and up to an additional $15 million in cumulative sales milestones based on achievement of gross sales revenue targets for sales of any and all products for use in non-human animal health applications, or the Aratana Field (regardless of therapeutic area), and (b) tiered royalties starting at 5% and going up to 10%, which will be paid based on net sales of any and all products (regardless of therapeutic area) in the Aratana Field in the United States. Royalties for sales of products outside of the United States will be paid at a rate equal to half of the royalty rate payable by Aratana on net sales of products in the United States (starting at 2.5% and going up to 5%). Royalties will be payable on a product-by-product and country-by-country basis from first commercial sale of a product in a country until the later of (a) the 10th anniversary of first commercial sale of such product by Aratana, its affiliates or sub licensees in such country or (b) the expiration of the last-to-expire valid claim of our patents or joint patents claiming or covering the composition of matter, formulation or method of use of such product in such country. Aratana will also pay us 50% of all sublicense royalties received by Aratana and its affiliates. In fiscal year 2019, the Company received approximately $8,000 in royalty revenue from Aratana. Additionally, in July 2019, Aratana announced that their shareholders approved a merger agreement with Elanco Animal Health, or Elanco, whereby Elanco is now the majority shareholder of Aratana. On October 6, 2020, the Company received a notice from Aratana, dated September 17, 2020, indicating that Aratana was terminating the Exclusive License Agreement effective December 21, 2020. The Company did not incur any early termination penalties as a result of the termination. Aratana was required to make all payments to the Company that were otherwise payable under the Exclusive License Agreement through the effective date of termination.

**Corporate Information**

We were originally incorporated in the State of Colorado on June 5, 1987, under the name Great Expectations, Inc. We were a publicly traded “shell” company without any business until November 12, 2004, when we acquired Advaxis, Inc., a Delaware corporation, through a Share Exchange and Reorganization Agreement, dated as of August 25, 2004, which we refer to as the Share Exchange, by and among Advaxis, the stockholders of Advaxis and us. As a result of the Share Exchange, Advaxis became our wholly owned subsidiary and our sole operating company. On December 23, 2004, we amended and restated our articles of incorporation and changed our name to Advaxis, Inc. On June 6, 2006, our stockholders approved the reincorporation of our company from Colorado to Delaware by merging the Colorado entity into our wholly owned Delaware subsidiary. Our date of inception, for financial statement purposes, is March 1, 2002, and the Company was uplisted to Nasdaq in 2014.

Our principal executive offices are located at 9 Deer Park Drive, Suite K-1, Monmouth Junction, New Jersey 08852, and our telephone number is (609) 452-9813. We maintain a corporate website at www.advaxis.com which contains descriptions of our technology, our product candidates and the development status of each drug. We make available free of charge through our Internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to these reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the SEC. The information on Advaxis' website is not included as a part of, nor incorporated by reference into, this proxy statement/prospectus/information statement. The SEC maintains a website that contains annual, quarterly, and current reports, proxy statements, and other information that issuers (including us) file electronically with the SEC. The SEC's website address is http://www.sec.gov.

**Intellectual Property**

Protection of our intellectual property is important to our business. We have a robust patent portfolio that protects our product candidates and *Lm*-based immunotherapy technology. Currently, we own or have rights to several hundred patents and applications, which are owned, licensed from, or co-owned with the University of Pennsylvania, or Penn; Merck; the National Institutes of Health, or NIH; and/or Augusta University. We aggressively prosecute and defend our patents and proprietary technology. Our patents and applications are directed to the compositions of matter, use, and methods thereof, of our *Lm*-LLO immunotherapies for our product candidates, including AXAL, ADXS-PSA, ADXS-HOT (such as ADXS-503 and ADXS-504) and ADXS-HER2. We have and may continue to abandon prosecuting certain patents that are not strategically aligned with the direction of the Company.

Our approach to the intellectual property portfolio is to create, maintain, protect, enforce and defend our proprietary rights for the products we develop from our immunotherapy technology platform. We endeavor to maintain a coherent and aggressive strategic approach to building our patent portfolio with an emphasis in the field of cancer vaccines. Issued patents which are directed to AXAL, ADXS-PSA, and ADXS-HER2, in the United States, will expire between 2020 and 2032. Issued patents directed to our product candidates AXAL, ADXS-PSA, and ADXS-HER2 outside of the United States, will expire in 2032. Issued patents directed to our *Lm*-based immunotherapy platform in the United States, will expire between 2020 and 2031. Issued patents directed to our *Lm*-based immunotherapy platform outside of the United States, will expire between 2020 and 2033.

We have pending patent applications directed to our product candidates AXAL, ADXS-PSA, ADXS-HER2, and ADXS-HOT that, if issued, would expire in the United States and in countries outside of the United States between now and 2037. We have pending patent applications directed to methods of using of our product candidates AXAL, ADXS-PSA, ADXS-HOT, ADXS-HER2 directed to the following indications and others: prostate cancer and HER2/neu-expressing cancer, that, if issued, would expire in the United States and in countries outside of the United States between now and 2037, depending on the specific indications.

We will be able to protect our technology from unauthorized use by third parties only to the extent it is covered by valid and enforceable patents or is effectively maintained as trade secrets. Patents and other proprietary rights are an essential element of our business.

Our success will depend in part on our ability to obtain and maintain proprietary protection for our product candidates, technology, and know-how, to operate without infringing on the proprietary rights of others, and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions, and improvements that are important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation, and in-licensing opportunities to develop and maintain our proprietary position.

Any patent applications that we have filed or will file or to which we have or will have license rights may not issue, and patents that do issue may not contain commercially valuable claims. In addition, any patents issued to us or our licensors may not afford meaningful protection for our products or technology, or may be subsequently circumvented, invalidated, narrowed, or found unenforceable. Our processes and potential products may also conflict with patents that have been or may be granted to competitors, academic institutions or others. As the pharmaceutical industry expands and more patents are issued, the risk increases that our processes and potential products may give rise to interferences filed by others in the USPTO, or to claims of patent infringement by other companies, institutions or individuals. These entities or persons could bring legal actions against us claiming damages and seeking to enjoin clinical testing, manufacturing and marketing of the related product or process. In recent years, several companies have been extremely aggressive in challenging patents covering pharmaceutical products, and the challenges have often been successful. If any of these actions are successful, in addition to any potential liability for damages, we could be required to cease the infringing activity or obtain a license in order to continue to manufacture or market the relevant product or process. We may not prevail in any such action, and any license required under any such patent may not be made available on acceptable terms, if at all. Our failure to successfully defend a patent challenge or to obtain a license to any technology that we may require to commercialize our technologies or potential products could have a materially adverse effect on our business. In addition, changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

We also rely upon unpatented proprietary technology, and in the future may determine in some cases that our interests would be better served by reliance on trade secrets or confidentiality agreements rather than patents or licenses. We may not be able to protect our rights to such unpatented proprietary technology, and others may independently develop substantially equivalent technologies. If we are unable to obtain strong proprietary rights to our processes or products after obtaining regulatory clearance, competitors may be able to market competing processes and products.

Others may obtain patents having claims that cover aspects of our products or processes that are necessary for, or useful to, the development, use or manufacture of our services or products. Should any other group obtain patent protection with respect to our discoveries, our commercialization of potential therapeutic products and methods could be limited or prohibited.

**The Drug Development Process**

The product candidates in our pipeline are at various stages of clinical development. The path to regulatory approval includes multiple phases of clinical trials in which we collect data that will ultimately support an application to regulatory authorities to allow us to market a product for the treatment, of a specific type of cancer. There are many difficulties and uncertainties inherent in research and development of new products, resulting in high costs and variable success rates. Bringing a drug from discovery to regulatory approval, and ultimately to market, takes many years and significant costs.

The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies, and formulation studies in compliance with the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an Investigational New Drug Application, or IND, which must become effective before human clinical trials may begin at United States clinical trial sites;
- approval by an Institutional Review Board, or IRB, for each clinical site, or centrally, before each trial may be initiated;
- adequate and well-controlled human clinical trials to establish the product candidate's safety, purity, and potency for its intended use, performed in accordance with GCPs;
- development of manufacturing processes to ensure the product candidate's identity, strength, quality, purity, and potency;
- submission to the FDA of a Biologics License Application, or BLA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the products are produced to assess compliance with cGMPs and to ensure that the facilities, methods, and controls are adequate to preserve the therapeutics' identity, strength, quality, purity, and potency as well as satisfactory completion of an FDA inspection of selected clinical sites and selected clinical investigators to determine GCP compliance; and
- FDA review and approval of the BLA to permit commercial marketing for particular indications for use.

Preclinical studies include laboratory evaluation of chemistry, pharmacology, toxicity, and product formulation, as well as animal studies to assess potential safety and efficacy. Such studies must generally be conducted in accordance with the FDA's GLPs. Prior to commencing the first clinical trial at a U.S. investigational site with a product candidate, an IND sponsor must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data, any available clinical data or literature, and proposed clinical study protocols among other things, to the FDA as part of an IND. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA notifies the applicant of safety concerns or questions related to one or more proposed clinical trials and places the trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during trials due to safety concerns or non-compliance. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

Clinical testing, known as clinical trials or clinical studies, is either conducted internally by pharmaceutical or biotechnology companies or managed on behalf of these companies by CROs. The process of conducting clinical studies is highly regulated by the FDA, as well as by other governmental and professional bodies. In a clinical trial, participants receive specific interventions according to the research plan or protocol created by the study sponsor and implemented by study investigators. Clinical trials must be conducted in accordance with federal regulations and GCP requirements, which include the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial, as well as review and approval of the study by an IRB. Additionally, some clinical trials are overseen by an independent data safety monitoring board, which reviews data and advises the study sponsor on study continuation. A protocol for each clinical trial, and any subsequent protocol amendments, must be submitted to the FDA as part of the IND.

Clinical trials may compare a new medical approach to a standard one that is already available or to a placebo that contains no active ingredients or to no intervention. Some clinical trials compare interventions that are already available to each other. When a new product or approach is being studied, it is not usually known whether it will be helpful, harmful, or no different than available alternatives. The investigators try to determine the safety and efficacy of the intervention by measuring certain clinical outcomes in the participants.

*Phase 1*. Phase 1 clinical trials begin when regulatory agencies allow initiation of clinical investigation of a new drug or product candidate. They typically involve testing an investigational new drug on a limited number of patients. Phase 1 studies determine a drug's basic safety, maximum-tolerated dose, mechanism of action and how the drug is absorbed by, and eliminated from, the body. Typically, cancer therapies are initially tested on late-stage cancer patients.

*Phase 2.* Phase 2 clinical trials involve larger numbers of patients that have been diagnosed with the targeted disease or condition. Phase 2 clinical trials gather preliminary data on effectiveness (where the drug works in people who have a certain disease or condition) and to determine the common short-term side effects and risks associated with the drug. If Phase 2 clinical trials show that an investigational new drug has an acceptable range of safety risks and probable effectiveness, a company will continue to evaluate the investigational new drug in Phase 3 studies.

*Phase 3.* Phase 3 clinical trials are typically controlled multicenter trials that involve a larger number of patients to ensure the study results are statistically significant. The purpose is to confirm effectiveness and safety on a large scale and to provide an adequate basis for physician labeling. These trials are generally global in nature and are designed to generate clinical data necessary to submit an application for marketing approval to regulatory agencies. Typically, two Phase 3 trials are required for product approval. Under limited circumstances, however, approval may be based upon a single adequate and well-controlled clinical trial plus confirmatory evidence or a single large multicenter trial without confirmatory evidence.

FDA may also consider additional kinds of data in support of a BLA, such as patient experience data and real world evidence. For genetically targeted populations and variant protein targeted products intended to address an unmet medical need in one or more patient subgroups with a serious or life-threatening rare disease or condition, the FDA may allow a sponsor to rely upon data and information previously developed by the sponsor or for which the sponsor has a right of reference, that was submitted previously to support an approved application for a product that incorporates or utilizes the same or similar genetically targeted technology or a product that is the same or utilizes the same variant protein targeted drug as the product that is the subject of the application.

Reports regarding clinical study progress must be submitted to the FDA and IRB on an annual basis. Additional reports are required if serious adverse events or other significant safety information is found. Certain reports may also be required to be submitted to the IBC. Investigational biologics must additionally be manufactured in accordance with cGMPs, imported in accordance with FDA requirements, and exported in accordance with the requirements of the receiving country as well as FDA.

Additionally, under the Pediatric Research Equity Act, or PREA, BLAs or BLA supplements for a new active ingredient, dosage form, dosage regimen, or route of administration, unless subject to the below requirement for molecularly targeted cancer products, must contain data to assess the safety and effectiveness of the product in all relevant pediatric subpopulations. The FDA may, however, grant deferrals or full or partial waivers of this requirement. PREA does not apply to orphan designated products approved solely for the orphan indication.

If a product is intended for the treatment of adult cancer and is directed at molecular targets that the FDA determines to be substantially relevant to the growth or progression of pediatric cancer, even if the product has orphan designation, the application sponsors must submit reports from molecularly targeted pediatric cancer investigations designed to yield clinically meaningful pediatric study data, gathered using appropriate formulations for each applicable age group, to inform potential pediatric labeling. Like PREA, FDA may grant deferrals or waivers of some or all of this data requirement.

Certain gene therapy studies are also subject to the NIH's Guidelines for Research Involving Recombinant DNA Molecules, or NIH Guidelines. The NIH Guidelines include the review of the study by a local institutional committee called an institutional biosafety committee, or IBC. The IBC assesses the compliance of the research with the NIH Guidelines, assesses the safety of the research and identifies any potential risk to public health or the environment.

In addition to the regulations discussed above, there are a number of additional standards that apply to clinical trials involving the use of gene therapy. The FDA has issued various guidance documents regarding gene therapies, which outline additional factors that the FDA will consider during product development. These include guidance regarding preclinical studies; chemistry, manufacturing, and controls; the measurement of product potency; how FDA will determine whether a gene therapy product is the same as another product for the purpose of the agency's orphan drug regulations; and long term patient and clinical study subject follow up and regulatory reporting.

*Biologic License Application (BLA)*. During clinical trials, companies usually also complete additional preclinical studies. Companies further develop additional information about the product candidate's physical characteristics and finalize the cGMP manufacturing process. The results of the clinical trials using biologics are submitted to the FDA as part of a BLA. Following the completion of Phase 3 studies, if the sponsor of a potential product in the United States believes it has sufficient information to support the safety and effectiveness of the investigational biologic, the sponsor submits a BLA to the FDA requesting marketing approval. The application is a comprehensive filing that includes the results of all preclinical and clinical studies, information about the product's composition, and the sponsor's plans for manufacturing, packaging, labeling and testing the investigational new product.

Subject to certain exceptions, the BLA must be accompanied by a substantial user fee at the time of the first submission. FDA has 60 days from its receipt of a BLA to determine whether the application is sufficiently complete for filing and for a substantive review. If the FDA determines that the NDA is incomplete, the FDA may refuse to file the application, in which case the applicant must address the FDA identified deficiencies before refiling. After the BLA is accepted for filing, the FDA reviews the application to determine whether the product meets FDA's approval standards. The FDA aims to complete its review within ten months of the 60-day filing date. For products that present significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions FDA aims to complete its review within six months of the 60-day filing date. The FDA, however, does not always meet its review goal. The review goal date may also be extended if FDA requests or the sponsor provides additional information regarding the application. As part of the approval process, FDA will typically inspect one or more clinical sites, as well as the facility or the facilities at which the product is manufactured to ensure GCP and cGMP compliance.

FDA may also refer an application for review by an independent advisory committee. Specifically, for a product candidate for which no active ingredient (including any ester or salt of active ingredients) has previously been approved by the FDA, the FDA must either refer that product candidate to an advisory committee or provide in an action letter, a summary of the reasons why the FDA did not refer the product candidate to an advisory committee. While FDA is not bound by the recommendation of an advisory committee, it does carefully consider the committee's recommendations.

After evaluating the application, FDA may issue an approval letter, authorizing product marketing, or a Complete Response Letter, or CRL, indicating that the application is not ready for approval. The CRL describes the application's deficiencies and conditions that must be met for product approval. If a CRL is issued, the applicant may resubmit the application, addressing the deficiencies, withdraw the application, or request a hearing. Even with submission of additional information, the FDA ultimately may decide that the application is not approvable.

If approval is granted, the FDA may limit the indications for use, including the indicated population, require contraindications, warnings or precautions be included in the product labeling, including black box warnings, or may not approve label statements necessary for successful commercialization. FDA may also require, or companies may conduct, additional clinical trials following approval, called Phase 4 studies, which can confirm or refute the effectiveness of a product candidate, and can provide important safety information. FDA may also require the implementation of a risk evaluation and mitigation strategy, or REMS, which may include requirements for a medication guide or patient package insert, a communication plan on product risks, or other elements to assure safe use.

After approval, some types of changes to the approved product, such as adding new indications or label claims, which may themselves require further clinical testing, or changing the manufacturing process are subject to further FDA review and approval. FDA can also require the implementation REMS or the conduct of Phase 4 studies after product approval.

**Government Regulations**

*General*

Government authorities in the United States and other countries extensively regulate, among other things, the preclinical and clinical testing, manufacturing, labeling, storage, recordkeeping, advertising, promotion, import, export, marketing and distribution of biopharmaceutical and drug products. In the United States, the FDA subjects drugs to rigorous review under the Federal Food, Drug and Cosmetic Act, or FDCA; the Public Health Service Act, or PHSA; and implementing regulations.

*Orphan Drug Designation*

Under the Orphan Drug Act, the FDA may grant Orphan Drug Designation, or ODD, to a drug or biological product intended to treat a rare disease or condition, which means a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States, but for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States will be recovered from domestic sales of the product. Additionally, sponsors must present a plausible hypothesis for clinical superiority to obtain ODD if there is a product already approved by the FDA that that is considered by the FDA to be the same as the already approved product and is intended for the same indication. This hypothesis must be demonstrated to obtain orphan exclusivity.

The benefits of ODD can be substantial, including research and development tax credits, grants and exemption from user fees. The tax advantages, however, were limited in the 2017 Tax Cuts and Jobs Act. Moreover, if there is no other product that the FDA considers to be the same product that is approved for the orphan indication, the orphan designated product is eligible for seven years of orphan market exclusivity once the product is approved. During that period, the FDA generally may not approve any other application for the same product for the same indication, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity. Other applicants, however, may receive approval of different products for the orphan indication or the same product for a different indication during the orphan exclusivity period. In order to qualify for these incentives, a company must apply for designation of its product as an "Orphan Drug" and obtain approval from the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

We currently have ODD with the FDA for AXAL for treatment of anal cancer (granted August 2013), HPV-associated head and neck cancer (granted November 2013); and treatment of Stage II-IV invasive cervical cancer (granted May 2014). We also have ODD with the FDA for ADXS-HER2 for the treatment of osteosarcoma (granted May 2014).

In Europe, the Committee for Orphan Medicinal Products has issued a positive opinion on the application for ODD of AXAL for the treatment of anal cancer (December 2015) and on the application for ODD of ADXS-HER2 for osteosarcoma (November 2015).

*Expedited Review and Approval Programs for Serious Conditions*

Four core FDA programs are intended to facilitate and expedite development and review of new biologics to address unmet medical need in the treatment of serious or life-threatening conditions: fast track designation, breakthrough therapy designation, accelerated approval, and priority review. We intend to avail ourselves of any and all of these programs as applicable to our products.

FDA is required to facilitate the development, and expedite the review, of products that are intended for the treatment of a serious or life-threatening disease or condition, and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new biologic product candidate may request that FDA designate the drug candidate for a specific indication as a fast track drug concurrent with, or after, the filing of the IND for the product candidate. FDA must determine if the product candidate qualifies for Fast Track Designation within 60 days of receipt of the sponsor's request. If Fast Track Designation is obtained, sponsors may be eligible for more frequent development meetings and correspondence with the FDA. FDA may also initiate review of sections of a fast track product's BLA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, FDA's period goal for reviewing an application does not begin until the last section of the BLA is submitted.

Under FDA's accelerated approval programs, FDA may approve a product for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by FDA.

Under the provisions of the Food and Drug Administration Safety and Innovation Act enacted in 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Products designated as breakthrough therapies are eligible for intensive guidance on an efficient development program beginning as early as Phase 1 trials, a commitment from the FDA to involve senior managers and experienced review staff in a proactive collaborative and cross-disciplinary review, rolling review, and the facilitation of cross-disciplinary review.

Another expedited pathway is the Regenerative Medicine Advanced Therapy, or RMAT, designation. Qualifying products must be a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or a combination of such products, and not a product solely regulated as a human cell and tissue product. The product must be intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, and preliminary clinical evidence must indicate that the product has the potential to address an unmet need for such disease or condition. Advantages of the RMAT designation include all the benefits of the Fast Track and breakthrough therapy designation programs, including early interactions with the FDA. These early interactions may be used to discuss potential surrogate or intermediate endpoints to support accelerated approval.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the period for FDA review or approval will not be shortened.

*Disclosure of Clinical Trial Information*

Sponsors of clinical trials of FDA regulated products, including biologics, are required to register and submit certain clinical trial information within specific timeframes to the NIH, for public dissemination on their clinicaltrials.gov website. Information related to the product, patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years, depending on the circumstances, after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

*Coverage, Pricing and Reimbursement*

Successful commercialization of new drug products depends in part on the extent to which reimbursement for those drug products will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drug products they will pay for and establish reimbursement levels. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford a drug product. Sales of drug products depend substantially, both domestically and abroad, on the extent to which the costs of drugs products are paid for by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular drug products. In many countries, the prices of drug products are subject to varying price control mechanisms as part of national health systems. In general, the prices of drug products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for drug products, but monitor and control company profits. Accordingly, in markets outside the United States, the reimbursement for drug products may be reduced compared with the United States. In the United States, the principal decisions about reimbursement for new drug products are typically made by the CMS, an agency within the Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new drug product will be covered and reimbursed under certain federal governmental healthcare programs, such as Medicare, and private payors tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists among third-party payors and coverage and reimbursement levels for drug products can differ significantly from payor to payor. In the United States, the process for determining whether a third-party payor will provide coverage for a biological product typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. With respect to biologics, third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication, or place products at certain formulary levels that result in lower reimbursement levels and higher cost sharing obligation imposed on patients. A decision by a third-party payor not to cover our product candidates could reduce physician utilization of a product. Moreover, a third-party payor’s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable a manufacturer to maintain price levels sufficient to realize an appropriate return on its investment in product development. Additionally, coverage and reimbursement for products can differ significantly from payor to payor. One third-party payor’s decision to cover a particular medical product does not ensure that other payors will also provide coverage for the medical product, or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process usually requires manufacturers to provide scientific and clinical support for the use of their products to each payor separately and is a time-consuming process.

Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness of pharmaceutical products, in addition to questioning safety and efficacy. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover that product after FDA approval or, if they do, the level of payment may not be sufficient to allow a manufacturer to sell its product at a profit.

In addition, in many foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. In the European Union, governments influence the price of products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed to by the government. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. The downward pressure on healthcare costs in general, particularly prescription products, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross border imports from low-priced markets exert a commercial pressure on pricing within a country (particularly in the EEA where it is illegal to impede such imports from elsewhere within the EEA).

*Other Healthcare Laws*

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including CMS, the HHS Office of Inspector General and HHS Office for Civil Rights, other divisions of the HHS and the Department of Justice.

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our current and future arrangements with third-party payors, healthcare providers and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any drugs for which we obtain marketing approval. In the United States, these laws include, without limitation, state and federal anti-kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, including but not limited to those described below.

The U.S. federal Anti-Kickback Statute, or AKS, prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. The AKS has been interpreted to apply to arrangements between pharmaceutical and medical device manufacturers on the one hand and prescribers, purchasers, formulary managers and beneficiaries on the other hand. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Although we would not submit claims directly to payors, drug manufacturers can be held liable under the federal False Claims Act, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Several biopharmaceutical, medical device and other healthcare companies have been prosecuted under federal false claims and civil monetary penalty laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved (e.g., or off-label), and thus non-covered, uses. In addition, the civil monetary penalties statute imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Claims which include items or services resulting from a violation of the federal AKS are false or fraudulent claims for purposes of the False Claims Act.

Our future marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products, if approved, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our product candidates, are subject to scrutiny under these laws.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibits, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and certain other healthcare providers. The ACA imposed, among other things, new annual reporting requirements through the Physician Payments Sunshine Act for covered manufacturers for certain payments and "transfers of value" provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties. Covered manufacturers must submit reports by the 90th day of each subsequent calendar year and the reported information is made available publicly on a searchable website.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, including the Final HIPAA Omnibus Rule published on January 25, 2013, impose specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates. Among other things, HITECH made HIPAA's security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity, although it is unclear that we would be considered a "business associate" in the normal course of our business. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same requirements, thus complicating compliance efforts.

Similar state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services. Such laws are generally broad and are enforced by various state agencies and private actions. Also, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant federal government compliance guidance, and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

*Current and Future Legislation*

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

*Non-U.S. Regulation*

Before our products can be marketed outside the United States, they are subject to regulatory approval of the respective authorities in the country in which the product should be marketed. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate application has been approved by the regulatory authorities in that country. The time spent in gaining approval varies from that required for FDA approval, and in certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices might not be approved for such product.

**Collaborations, Partnerships and Agreements**

Collaborations, partnerships and agreements are a key component of Advaxis' corporate strategy. As a clinical-stage biotechnology company without sales revenue, partnerships are an essential part of the ongoing strategy. Additionally, the evolution of the field of immunotherapy has resulted in combination treatments becoming ubiquitous; ongoing clinical studies and agreements with many of the leading, large oncology pharmaceutical companies helps validate that *Lm* Technology may play a key role in the cancer treatment protocols of the future.

Our collaborators and partners include Merck, Aratana, OS Therapies, Biocon, Global BioPharma, Knight, and others. For more information, see Note 8, "Collaboration and Licensing Agreements," to the audited financial statements contained herein.

We entered into an exclusive worldwide license agreement with Penn, on July 1, 2002, with respect to the innovative work of Yvonne Paterson, Ph.D., Associate Dean for Research at the School of Nursing at Penn, and former Professor of Microbiology at Penn, in the area of innate immunity, or the immune response attributed to immune cells, including dendritic cells, macrophages and natural killer cells, that respond to pathogens non-specifically (subject to certain U.S. government rights). This agreement was amended and restated as of February 13, 2007, and, thereafter, has been amended from time to time.

This license, unless sooner terminated in accordance with its terms, terminates upon the latter of (a) the expiration of the last to expire of the Penn patent rights; or (b) 20 years after the effective date of the license. Penn may terminate the license agreement early upon the occurrence of certain defaults by us, including, but not limited to, a material breach by us of the Penn license agreement that is not cured within 60 days after notice of the breach is provided to us.

The license provides us with the exclusive commercial rights to the patent portfolio developed by Penn as of the effective date of the license, in connection with Dr. Paterson, and requires us to pay various milestone, legal, filing and licensing payments to commercialize the technology. In exchange for the license, Penn received shares of Advaxis common stock. In addition, Penn is entitled to receive a non-refundable initial license fee, royalty payments and milestone payments based on net sales and percentages of sublicense fees and certain commercial milestones. Under the amended licensing agreement, Penn is entitled to receive 2.5% of net sales in the territory. Should annual net sales exceed $250 million, the royalty rate will increase to 2.75%, but only with respect to those annual net sales in excess of $250 million. Additionally, Penn will receive tiered sales milestone payments upon the achievement of cumulative global sales ranging between $250 million and $2 billion, with the maximum aggregate amounts payable to Penn in the event that maximum sales milestones are achieved being $40 million. Notwithstanding these royalty rates, upon first in-human commercial sale (U.S. & EU), we have agreed to pay Penn a total of $775,000 over a four-year period as an advance minimum royalty, which shall serve as an advance royalty in conjunction with the above terms. In addition, under the license, we are obligated to pay an annual maintenance fee of $100,000 commencing on December 31, 2010, and each December 31 thereafter, for the remainder of the term of the agreement until the first commercial sale of a Penn licensed product. We are responsible for filing new patents and maintaining and defending the existing patents licensed to us, and we are obligated to reimburse Penn for all attorney's fees, expenses, official fees and other charges incurred in the preparation, prosecution and maintenance of the patents licensed from Penn.

Upon first regulatory approval in humans (U.S. or EU), Penn will be entitled to a milestone payment of $600,000. Furthermore, upon the achievement of the first sale of a product in certain fields, Penn will be entitled to certain milestone payments, as follows: $2.5 million will be due upon the first in-human commercial sale (U.S. or EU) of the first product in the cancer field and $1.0 million will be due upon the date of first in-human commercial sale (U.S. or EU) of a product in each of the secondary strategic fields sold.

**Manufacturing**

cGMPs are the standards identified to conform to requirements by governmental agencies that control authorization and licensure for manufacture and distribution of biologic products for either clinical investigations or commercial sale. GMPs identify the requirements for procurement, manufacturing, testing, storage, distribution and the supporting quality systems to ensure that a drug product is safe for its intended application. cGMPs are enforced in the United States by the FDA, under the authorities of the FDCA and its implementing regulations and use the phrase “current good manufacturing practices” to describe these standards.

Each of Advaxis’ wholly owned product candidates is manufactured using a platform process, with uniform methods and testing procedures. This allows for an expedited pathway from construct discovery to clinical product delivery, while helping to keep cost of goods low.

Advaxis has entered into agreements with multiple third-party organizations, or CMOs, to handle the manufacturing, testing, and distribution of product candidates. These organizations have extensive experience within the biologics space and with the production of clinical and commercial GMP supplies.

The Company’s long-term manufacturing strategy is to leverage its partners’ capabilities in order to build a supply chain that is reliable, flexible, and cost competitive.

**Competition**

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, our actual or proposed immunotherapies could become obsolete before we recoup any portion of our related research and development expenses. While we believe that our product candidates, technology, knowledge and experience provide us with competitive advantages, we face competition from established and emerging pharmaceutical and biotechnology companies, among others. The biotechnology and biopharmaceutical industries are highly competitive, and this competition comes from both biotechnology firms and from major pharmaceutical companies, including BioNtech, Moderna, Gritstone, BMS, AstraZeneca, Merck, Neon Therapeutics et al., each of which is pursuing cancer vaccines and/or immunotherapies.

Many of these companies have substantially greater financial, marketing, and human resources than we do (including, in some cases, substantially greater experience in clinical testing, manufacturing, and marketing of pharmaceutical products). We also experience competition in the development of our immunotherapies from universities and other research institutions and compete with others in acquiring technology from such universities and institutions. In addition, certain of our immunotherapies may be subject to competition from investigational new drugs and/or products developed using other technologies, some of which have completed numerous clinical trials.

Our competition will be determined in part by the potential indications for which drugs are developed and ultimately approved by regulatory authorities. Additionally, the timing of market introduction of some of our potential immunotherapies or of competitors’ products may be an important competitive factor. Accordingly, the speed with which we can develop immunotherapies, complete preclinical testing, clinical trials and approval processes and supply commercial quantities to market are expected to be important competitive factors. We expect that competition among products approved for sale will be based on various factors, including product efficacy, safety, administration, reliability, acceptance, availability, price and patent position.

**Experience and Expertise**

Our management team has extensive experience in oncology development, including contract research, development, manufacturing and commercialization across a board range of science, technologies, and process operations. We have built internal capabilities supporting research, clinical, medical, manufacturing and compliance operations and have extended our expertise with collaborations.

**Employees**

As of October 31, 2020, we had 18 employees, 17 of whom were full time employees. Of our full-time employees, one holds a Ph.D. None of our employees are represented by a labor union, and we consider our relationship with our employees to be good.

We will continue to rent necessary offices and laboratories to support our business.

## BIOSIGHT'S BUSINESS

### Overview

Biosight is a private Phase 2 clinical-stage biotechnology company developing an innovative therapeutic for hematological malignancies and disorders. Our investigational product, BST-236, is an innovative, proprietary anti-metabolite that seeks to address unmet medical needs by enabling high-dose chemotherapy with reduced systemic toxicity. BST-236 is currently being evaluated as a single agent in a Phase 2b clinical trial, which recently completed enrollment, for the first-line treatment of AML. Interim results demonstrate tolerability with promising efficacy among the challenging population of AML patients who are unfit for intensive standard-of-care chemotherapy. An additional Phase 2 study in patients with relapsed/refractory AML and MDS in collaboration with the European Myelodysplastic Syndrome Cooperative Group was recently launched. A similar Phase 2 study is to be initiated in the US in 2021.

*BST-236*

Our pipeline targets the development of treatments for hematological malignancies and related disorders for which there is a high unmet need. We are currently developing one product candidate, BST-236, an innovative proprietary anti-metabolite that is designed to enable high-dose therapy in the treatment of AML but with reduced systemic toxicity. BST-236 is composed of cytarabine covalently bound to asparagine, which acts as a pro-drug of cytarabine. Cytarabine is the backbone of existing treatments for AML, but its highly toxic qualities, especially at high doses, can cause side effects that reduce both the quality of life and the effectiveness of the treatment among older patients and those who are medically unfit for standard chemotherapy. Upon administration, cytarabine is gradually released from BST-236 via non-enzymatic hydrolyzation over approximately 8 hours. Due to its unique pharmacokinetics and metabolism, BST-236 seeks to enable high-dose therapy with lower systemic exposure to free cytarabine and relative sparing of normal tissues, and as such, may serve as a new therapy for AML and other hematological malignancies and disorders, including for older adults who are unfit for intensive therapy.

AML is a heterogeneous hematological malignancy characterized by abnormal proliferation of immature hematopoietic progenitor cells of the myeloid lineage. AML is a serious, life-threatening but uncommon disease that accounts for less than 1.2% of all cancers. AML is recognized as a disease of older adults, with a median age at presentation of 68 years and advanced age being an adverse prognostic factor. Intensified treatment improves remission rate, leukemia-free survival, and overall survival ("OS"), but it is also associated with increased treatment-related mortality due to its serious toxicity. Therefore, many AML patients are deemed unfit for intensive chemotherapy, either due to advanced age or comorbidities.

Recently, several drugs have been approved for AML patients unfit for intensive chemotherapy, with the most promising outcomes reported from venetoclax therapy in combination with either hypomethylating agent ("HMA") or low-dose cytarabine ("LDAC"). However, partially due to the heterogeneous nature of the disease, certain patient subgroups continue to have suboptimal outcomes resulting in an unmet medical need. Patients can therefore benefit from the availability of a variety of agents with different mechanisms of action.

There are limited published data on the outcomes of newly approved therapies for certain patient subgroups who are unfit for intensive chemotherapy, including patients with secondary AML and patients with prior HMA therapy, as well as patients with adverse European LeukemiaNet ("ELN") score, and patients of 75 years of age or older. According to the data published on venetoclax therapy in combination with LDAC, there was no significant improvement in OS compared to LDAC alone. There are limited published data regarding OS and complete remission ("CR") with hematological recovery data by subgroup for venetoclax therapy in combination with HMA. In addition, venetoclax-based treatment in AML requires multiple cycles until disease progression or unacceptable toxicity. This long-term treatment may result in accumulated toxicities, which may require dose reductions, dose interruptions, and risk of disease relapse. There is no available therapy for most relapsed/refractory AML patients.

MDS is a diverse group of clonal hematopoietic disorders characterized by ineffective hematopoiesis, progressive bone marrow failure, cytogenetic and molecular abnormalities, and variable risk of progression to AML. While many patients with MDS have lower-risk disease and are managed by existing treatments, there currently is no clear standard of care for many patients. For patients with higher-risk disease (of whom 40-50% are at a risk of transforming to AML), the treatment priority is changing the natural history of the disease by delaying disease progression to AML and improving overall survival. However, existing treatments for MDS are generally not curative and many patients experience relapse or resistance to first-line treatment. Patients with intermediate to higher-risk MDS are assessed to evaluate if they are candidates for allogeneic hematopoietic stem cell transplantation, and appropriate candidates are transplanted. Patients who are not candidates for allo-HSCT are usually treated with HMA. MDS treatment with HMA without allo-HSCT results in low complete remission rates, ranging between 5.4-21%, and responses are often not durable. The group of patients that fails HMA therapy has particularly poor prognosis with an estimated survival of 4 to 6 months. Thus, there remains an unmet need for new, more effective but tolerable strategies to manage MDS, especially for relapsed or refractory patients, where there is no available therapy for most patients.

According to the currently available clinical data, BST-236 appears to be an effective regimen for AML with a considerable reduction of the attendant toxicities that are typically associated with standard intensive cytotoxic therapies. The results suggest that BST-236, given as monotherapy, is generally safe and effective as a first-line therapy for AML patients who are unfit for intensive chemotherapy. These data support BST-236 as a new treatment option for older patients with AML, including patients with secondary AML that has transformed from higher-risk MDS or prior therapy. Furthermore, BST-236 may serve as a backbone for combination therapy with targeted or other chemotherapy agents, as well as for younger patients with AML.

**Regulatory Approvals**

In May, 2019, we received orphan drug designation from the U.S. Food and Drug Administration (the "FDA") for BST-236. This designation entitles BST-236 to 7 years of market exclusivity for the use of AML, if approved, as well as significant development initiatives such as tax credits relating to clinical trial expenses, an exemption from the FDA-user fee and assistance from the FDA in designing clinical trials.

In November, 2020, we also received orphan medicinal product designation from the European Medicines Agency (the "EMA") for BST-236. This designation will provide us with up to 10 years of market exclusivity in Europe, in addition to the 7-year exclusivity in the U.S. as a result of the FDA's orphan drug designation in 2019. EMA designation will also provide us with other benefits and incentives such as clinical protocol assistance, access to a centralized marketing authorization procedure that is valid in all European Union ("EU") member states and reduced regulatory fees.

Additionally, in August 2020, the FDA granted BST-236 fast track designation for patients who are 75 or older or those who are medically unfit to receive intensive induction chemotherapy. The FDA fast track designation is designed to facilitate the development and expedite the review of drugs to treat serious conditions to fulfill an unmet medical need, ultimately enabling drugs to reach patients more rapidly. As a result of its fast track designation, BST-236 may be eligible for more frequent interactions and communications with the FDA on matters related to its clinical development plan, as well as eligibility for accelerated approval and priority review. For more information, please see the sections entitled "Biosight's Business—Orphan Drug Pathway" and "Biosight's Business—Expedited Review and Approval."

To date, we have conducted preclinical studies for BST-236, as well as a Phase 1/2a clinical study (the "Phase 1/2a") and a phase 2 clinical study, which we believe produced promising results, particularly for our target population of newly-diagnosed adult AML patients who are medically unfit for standard chemotherapy. BST-236 is currently being investigated as a single-agent in a Phase 2b clinical study (the "Phase 2b") for first-line treatment of AML. Enrollment of 65 newly-diagnosed AML patients unfit for standard chemotherapy into the Phase 2b clinical study was completed in May of 2021.

*Completed Phase 1/2a*

Results from the Phase 1/2a clinical study, conducted between April 2014 and August 2017, suggested that BST-236 was a safe and well-tolerated treatment for older patients at all evaluated doses (up to 36 g/m2). The Phase 1/2a clinical study was designed as an open-label, dose-escalating, first-in-human study aimed to assess the safety, tolerability, pharmacokinetics ("PK") and efficacy of BST-236 as a single-agent in relapsed or newly-diagnosed patients with AML and ALL who were unfit for standard therapy. To conduct the study, 26 patients with a median age of 76.5 years were enrolled at two Israeli sites with at least one BST-236 dose. The study population included newly-diagnosable AML patients (*de novo* or secondary), newly-diagnosed ALL patients who were not eligible for standard chemotherapy, and relapsed or refractory AML or ALL patients. Patients were administered doses in the range of 0.3 to 6 $g/m^2/d$ intraveniously, in 1 to 2 6-day induction courses. The study produced the following results:

- ***Doses of BST-236 are well-tolerated in older patients with AML.*** The patients participating in the Phase 1/2a clinical study reported no cerebral or cerebellar toxicity, no grade≥3 oral mucositis, no alopecia and no renal failure. The most frequent treatment emergent adverse events were cytopenia and infections, which were congruent with the drug's mode of action. In addition, the patients did not report having other adverse events known to be associated with high-dose cytarabine, such as corneal disorder, necrotizing colitis and skin exfoliation.

- ***The observed reduced toxicity of BST-236 is assumed to emerge from its prodrug construct design***. A PK analysis of BST-236 confirmed a prodrug profile with an approximately 20:1 ratio of BST-236 to free cytarabine detected in the plasma at any dose. The maximum concentration (Cmax) of cytarabine in patients receiving a 1 hour infusion of 4.5 $g/m^2$ BST-236 (containing the molar equivalent of high-dose cytarabine, 3 $g/m^2$ of cytarabine) was 40 µM, similar to the Cmax of high-dose cytarabine with 3 $g/m^2$ of free cytarabine administrated over 3 hours, but with much shorter exposure to peak levels. The area under the curve observed for cytarabine following exposure to BST-236, 91.7 µM/h, was twofold to threefold lower than the area under the curve reported in the literature for high-dose cytarabine treatment, confirming reduced systemic exposure to free cytarabine.

- ***Although BST-236 treatment was associated with reduced toxicity, it retained high anti-leukemic potency, particularly for a newly-diagnosed subgroup.*** The Phase 1/2a clinical study suggested the greatest clinical benefit for one particular subgroup studied: newly diagnosed patients with AML who are unfit for standard induction. BST-236 proved beneficial as a first-line therapy for this population of AML patients, as they demonstrated tolerability with promising efficacy through the following results:
    - Complete remission rate of 36%;
    - Overall response rate of 45%;
    - Median overall survival of 6.5 months; and
    - Median overall survival of responders (*i.e.*, patients achieving complete remission) was not reached at 2 years.

The Phase 1/2a clinical study demonstrates that BST-236 has a promising efficacy-safety profile, particularly for older and medically-unfit patients who currently cannot benefit from intensive cytarabine therapy.

*Ongoing Phase 2b Study (Study BST002)*

In light of the findings from the Phase 1/2a clinical study, we are currently investigating BST-236 as a single-agent, first-line treatment in a Phase 2b clinical study. We initiated this multi-center, open label, single arm clinical study in August 2018. The purpose of the clinical study is to evaluate the safety and efficacy of BST-236 in a baseline population of 65 adult, newly-diagnosed AML patients who are not eligible for standard chemotherapy due to their advanced age (75 years or older) or the existence of comorbidities, which preclude the use of intensive cytarabine therapy.

BST-236 is administrated at 4.5 g/m$^2$/d (containing 3 g/m$^2$/d cytarabine) in 1-2 induction and 1-3 consolidation courses, each consisting of 6 daily 1-hour infusions. Patients with secondary AML, prior HMA therapy, and therapy-related AML, are eligible.

We have completed enrollment of 65 patients (including 54 patients enrolled May 2020 – May 2021, during COVID-19 pandemic) in the study, which is being conducted at 16 sites, 12 in the US and 4 in Israel. The Phase 2b clinical study is currently ongoing and, to date, has indicated that repeated courses of BST-236 were generally well-tolerated in older patients and those deemed unfit for chemotherapy. As of September 2021, the 65 AML patients enrolled in the study were evaluable for safety and efficacy analysis. The median age of the 65 patients was 75 years (range 54-88 years), 38% had Eastern Cooperative Oncology Group ("ECOG") Performance Status ≥2, 40% had secondary AML, either to MDS or chronic myelomonocytic leukemia ("CMML") (29%) or therapy-related AML (11%), and 17% received prior HMA therapy to a prior condition. Fifty-two percent of patients had adverse ELN score (Table x).

Table x. BST002 Study Patient Baseline Characteristics

| | | |
|---|---|---|
| N | | 65 |
| Age, median, y (range) | | 75 (54-88) |
| ≥75 years, n (%) | | 34 (52) |
| ECOG, n (%) | 0-1 | 40 (62) |
| | 2-3 | 25 (38) |
| Secondary AML, n (%) | | 26 (40) |
| Secondary to MDS/CMML, n (%) | | 19 (29) |
| Secondary to therapy, n (%) | | 7 (11) |
| Prior HMA, n (%) | | 11 (17) |
| Bone marrow blast percentage, n (%) | <30 | 22 (34) |
| | 30-50 | 16 (25) |
| | >50 | 27 (41) |
| ELN risk score, n (%) | Favorable | 9 (14) |
| | Intermediate | 16 (25) |
| | Adverse | 34 (52) |
| | Unavailable | 6 (9) |

BST-236 was well-tolerated in repeated-course administration. Grade ≥3 drug-related adverse events included mainly hematological events and infections. The 30-day all-cause mortality rate was 12.3%. In addition, the study primary endpoint, complete remission rate, was 37% across all AML patients, with complete hematological recovery and a median time of recovery of 26 days (and a range of 11 – 40 days). The CR rate of patients with *de novo* and patients with secondary AML was 44% and 27%, respectively. The CR rate of patients with adverse ELN score or ECOG ≥2 was 32%, and 35% for patients at the age of 75 years or higher. Importantly, the CR rate of patients who were previously treated with HMA was 27% (Figure 1). The CRs were achieved following 1-2 courses, and there were no cases of prolonged neutropenia (Figure 2). 50% of the CRs were found to be negative in a Minimal Residual Disease analysis using flow cytometry.

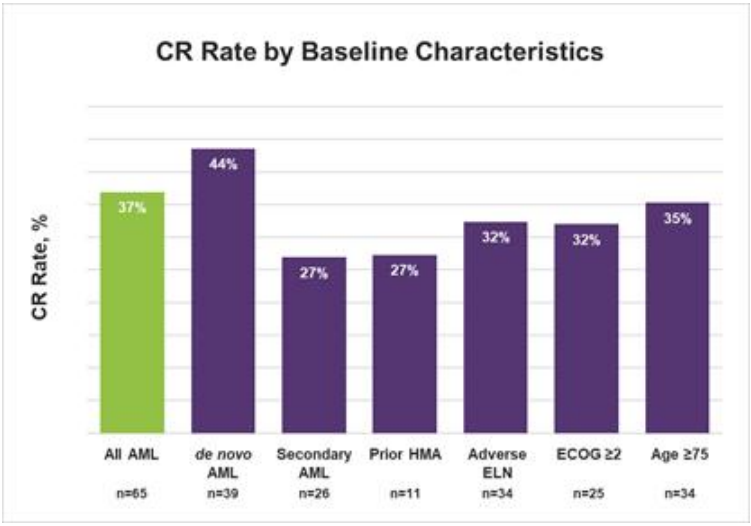


Figure 1. BST002 Study Final CR Rates by Patient Subgroup

| | N* | Days from Cycle Day 1 Median (Range) |
|---|---|---|
| Neu ≥500/µl | 65 | 24.0 (11-39) |
| Neu ≥1,000/µl | 64 | 25.0 (11-39) |
| PLT ≥50,000/µl | 65 | 24.0 (11-40) |
| PLT ≥100,000/µl | 61 | 26.0 (18-40) |

*N = number of total courses, all responding patients

Figure 2. Time to Hematological Recovery Following BST-236 Treatment (Induction/Consolidation)

While follow up is ongoing, as of September 2021 the median OS of the entire intend-to-treat population was 8.9 months ((95% CI, 5.1-not reached (NR)), the median OS of responders was not reached in two years (95% CI, 8.9-NR), and the median OS of non-responders was 2.7 months (95% CI, 2.0-6.0).

The findings support the goal of expanding our research to additional Phase 2 trials with a focus on patient populations with relapsed/refractory AML or MDS. While mechanisms of disease progression and transformation from a chronic MDS phase to a more aggressive AML phase are still poorly understood, on average, approximately 30% of patients with MDS develop overt AML during the course of the disease. We expect to have final primary endpoint data of 65 points with 6 month follow up in the fourth quarter of 2021 and expect to initiate registrational study in the second half of 2022. We tentatively plan to submit NDA in 2025.

Our contract research organization (“CRO”) for the Phase 2b clinical study is ICON plc (formerly Pharmaceutical Research Associates, Inc., or “PRA”) (“ICON”), with which we have entered into a Master Agreement For Clinical Trials Management Services, effective as of November 20, 2017, and additional related agreements (collectively, as amended, “CRO Agreement”). In accordance with the CRO Agreement, ICON had entered into clinical trial agreements and other related agreements with the sites in which the Phase 2b clinical study is being conducted (the “Sites”) on our behalf. We also entered into agreements directly with other Sites. Along with the agreements between us, ICON and the Sites, we offer indemnification letters to the vast majority of the Sites.

For additional information regarding the CRO Agreement, please refer to the section entitled “Biosight’s Business—Agreements”.

*Clinical Trial Collaboration with the European Cooperative Group (Study BST003-GFM)*

In July 2020, we entered into an independent research funding agreement (the "GFM Agreement") with the French Study Group of the European Myelodysplastic Syndrome Cooperative Group, led by Dr. Pierre Fenaux of the GFM. GFM is a non-profit organization comprised of French hematology centers which conducts and sponsors clinical trials, as well as translational research, and assists in coordinating diagnostic and therapeutic guidelines for MDS.

Pursuant to the GFM Agreement, GFM has agreed to sponsor, and we have agreed to provide certain funding and support for, GFM and Dr. Fenaux to conduct a Phase 2 clinical study to evaluate our investigational product candidate, BST-236. GFM and Dr. Fenaux will conduct this open-label, single arm, multi-center Phase 2 study to assess the safety and efficacy of BST-236 as a single-agent, second-line treatment for patients with relapsed or refractory MDS or AML (i.e., those who failed or relapsed following a first-line therapy treatment), and are medically unfit for standard, intensive chemotherapy treatments. Through our collaborative efforts with GFM, we have launched the clinical study and will seek to enroll approximately 40 eligible patients in similar sites in Europe. The study is open for enrollment, and the first patient was enrolled in August 2021. As of September 2021, 3 patients were enrolled in the study. We expect preliminary data read outs in the second half of 2022. We tentatively plan to submit NDA in 2024 and could potentially be eligible for accelerated approval.

For additional information regarding the GFM Agreement, please refer to Section the section entitled "Biosight's Business—Agreements".

*Clinical Trial in the US. Lead investigator Dr. Eytan M. Stein (Study BST004)*

In parallel with the clinical trial collaboration with the GFM, we are in the process of launching a similar open-label, single arm, multi-center Phase 2 study in the United States to assess the safety and efficacy of BST-236 as a single-agent, second-line treatment for patients with relapsed or refractory MDS or AML. The study is planned to enroll 40 patients, and the lead investigator in this study is Dr. Eytan M. Stein from Memorial Sloan Kettering Cancer Center (MSKCC). The study is sponsored by Biosight. The protocol has been cleared by the FDA, and start-up activities are ongoing. We expect enrollment to start in the fourth quarter of 2021 and preliminary data read outs in the second half of 2022. We tentatively plan to submit NDA in 2024 and could potentially be eligible for accelerated approval.

**Strategy**

Our goal is to develop and commercialize innovative therapeutic products for a variety of oncology and hematological malignancies and related disorders. We intend to focus on addressing significant, unmet needs for treatment, particularly for certain patient populations whose medical vulnerabilities make standard, existing treatments unsuccessful. In addressing unmet medical needs, we hope to improve both the quality and the outcome of the lives of patients who suffer from cancer and other life-threatening diseases. To executive this strategy, we plan to:

- **Advance our investigational product, BST-236, through the completion of clinical trials and commercialization.** By the end of 2022, we aim to complete the Phase 2b for BST-236 as a single-agent, first-line therapy for the treatment of AML for patients who are medically unfit for standard chemotherapy and launch a confirmatory Phase 3 study in a similar population.

- **Expand our research on the efficacy of BST-236 through additional clinical trials.** We aim to expand our research of the effects of BST-236 through additional clinical trials in patient populations with relapsed/refractory MDS and AML.

- **Demonstrate the potential of BST-236 as a backbone for combination therapy in AML and other hematological indications.** We intend to launch clinical studies of BST-236 in combination with targeted agents and other chemotherapy agents. The first phase 1/2 study, to evaluate the safety and efficacy of BST-236 in combination with venetoclax as a first-line therapy for AML patients unfit for standard chemotherapy, is expected to be launched in the first quarter of 2022. We tentatively plan to submit NDA in 2026.

- **Identify and develop new opportunities.** We intend to identify, develop and commercialize new product candidates for oncology, hematological malignancies and other related disorders, while in parallel, considering avenues to expand our market presence through new clinical or commercial partnership opportunities.

**Competition**

The pharmaceutical and biotechnology industries face rapidly advancing technologies, intense competition and place a strong emphasis on obtaining and maintaining proprietary rights. We compete in segments of these industries and other, related markets that are focused on developing anti-cancer and chemotherapy products, particularly for hematological malignancies and disorders. While we believe that our development experience, scientific resources and proprietary rights provide us with a competitive advantage, we face competition from several different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Any product candidates that we develop and commercialize, particularly our current product candidate, BST-236, will compete with existing drugs at least in some of the indications, as well as new drugs that could become available in the future. Our competitors include companies such as, but not limited to, AbbVie, Aprea, Astellas, BMS, Gilead, Jazz Pharmaceuticals, Novartis and Pfizer.

Many of the organizations against which we compete or could compete in the future have significantly greater financial resources, as well as expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory or other requisite approvals and marketing approved products. These organizations also compete with us in recruiting and retaining qualified scientific and management consultants and personnel, establishing clinical trial sites, recruiting and enrolling patients for clinical trials and obtaining the technologies complementary to, or necessary for, our programs, including the development, formulation or testing of our product candidates.

Additionally, mergers and acquisitions in the pharmaceutical and biotechnology industries could occur and result in the concentration of resources among a smaller number of our competitors. Smaller or early-stage companies could also prove to compete with us, particularly if they collaborate with large and established companies.

Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects or are less expensive than the products that we are developing or could develop in the future. Our competitors could also obtain FDA or other regulatory approval for their products more quickly than we are able, which could impact the success of marketing or commercializing our products. In addition, insurers and other third-party payers could impact our ability to compete if they seek to encourage the use of more cost-effective products.

**Certain Projected Revenue Information**

Set forth below are projected peak revenues for use of BST-236 in the treatment of AML and MDL prepared by Cello Health BioConsulting and certain information upon which the projections are based. The full text of the Opportunity Assessment for BST-236, dated September 23, 2021 (the “Report”), which sets forth, among other things, the various qualifications, assumptions and limitations on the scope of the review undertaken, is attached as Exhibit 99.1 to this Registration Statement. Any summaries of the Report set forth herein are qualified in their entirety by reference to the full text of the Report. Holders of Biosight shares and Advaxis common stock are urged to read the Report in its entirety. The Report speaks only as of its date and does not reflect any developments that may occur or may have occurred after the date of the Report and prior to the completion of the Business Combination. The preparation of revenue projections is a complex process and is not susceptible to a partial analysis or summary description. Cello Health BioConsulting believes that its Report must be considered as a whole and that selecting portions of its Report, without considering the Report taken as a whole, may create an incomplete view of the revenue projections.

The revenue projections were not available to the boards of Biosight or Advaxis in connection with their respective reviews of the Business Combination because the first draft of the revenue projections had not been provided by Cello Health BioConsulting to Biosight until July 7, 2021 which was after Biosight and Advaxis entered into the Merger Agreement. In addition, because they had not yet been prepared, the revenue projections were not available the LifeSci Capital in connection with their preparation of their opinion to the Advaxis Board regarding the Business Combination.

Biosight has not warranted the accuracy, reliability, appropriateness or completeness of the cash spending projections to anyone, including us. Neither the management of Biosight nor any of its representatives, advisors or affiliates has made or makes any representation to any person regarding the ultimate revenue of Biosight compared to the information contained in the revenue projections, and none of them intends to or undertakes any obligation to update or otherwise revise the revenue projections to reflect circumstances existing after the date when made or to reflect the occurrence of future events in the event that any or all of the assumptions underlying the cash spending projections are shown to be in error. The revenue projections are subjective in many respects. As a result, there can be no assurance that the revenue projections will be realized or that actual results will not be significantly higher or lower than estimated. Since the revenue projections cover multiple years, that information by its nature becomes less predictive with each successive year. Accordingly, they should not be looked upon as “guidance” of any sort. You are cautioned not to rely on the revenue projections in making a decision regarding the transaction, as actual results may be materially different from the revenue projections.

While presented in this proxy statement/prospectus/information statement with numeric specificity, the revenue projections of Biosight are forward-looking statements that are based on assumptions that are inherently subject to significant risks, uncertainties and contingencies, many of which are beyond Biosight’s control. These include the risks described in the section entitled “Forward-Looking Statements” and “Risk Factors.” The revenue projections also reflect assumptions as to certain business decisions that are subject to change. There may be differences between actual and projected revenue, and actual revenue may be materially less or materially greater than those contained in the revenue projections. The inclusion of the revenue projections in this proxy statement/prospectus/information statement should not be regarded as an indication that Biosight or its representatives considered or currently consider the revenue projections to be a reliable prediction of future events, and reliance should not be placed on the revenue projections.

The projections were prepared by Cello Health BioConsulting. The projections were not prepared with a view towards compliance with GAAP, the published guidelines of the SEC, or the guidelines established by the American Institute of Certified Public Accountants for preparation of prospective financial information. The prospective financial information included in this document has been prepared by, and is the responsibility of, Biosight's management. Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Limited, has not audited, reviewed, examined, compiled nor applied agreed-upon procedures with respect to the accompanying prospective financial information and, accordingly, Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Limited, does not express an opinion or any other form of assurance with respect thereto. The Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Limited, report included in this document relates to Biosight's previously issued financial statements. It does not extend to the prospective financial information and should not be read to do so.

The key elements of the revenue projections of Biosight are as follows (in millions of dollars, unaudited):

The revenue projections was prepared using a number of assumptions, including the following assumptions that are believed to be material:

● The revenue projections assume that (i) FDA approval for use of BST-236 for relapsed/refractory AML is received on an accelerated basis in 2024, (2) FDA approval for use of BST-236 in high-risk relapsed/refractory MDS is received on an accelerated basis in 2024, (3) FDA approval for use of BST-236 as a first-line, venetoclax combination treatment for AML is received in 2025 and (4) FDA approval for use of BST-236 as a first-line, single-agent treatment for AML for adults unfit for intensive chemotherapy is received in 2025. While Biosight and Cello Health are inherently unable to predict the behavior of the FDA as an independent agency, and what the FDA, in its sole discretion may decide, the assumed timing of these approvals represents Biosight's and Cello Health's best estimate of when these approvals might occur. These estimates are based on Biosight's and Cello Health's own estimates of the remaining time and activities necessary to complete clinical trials that might be required by the FDA in the future, and Biosight's ability to meet these requirements. Biosight and Cello Health based these assumptions on the current status of ongoing and planned clinical trials, their general knowledge of other oncology companies past submissions and the requirements imposed on new drug applications for similar pharmaceuticals. Actual results may vary significantly from these estimates. Further, there is no guarantee Biosight will successfully receive timely FDA approval for BST-236 any of these applications according to its projected timelines, or at all, and if Biosight fails to achieve approval or incurs significant delays in its approval for any of these applications, this could have a material adverse impact on its ability to achieve the projected revenues set forth above.

● Assuming FDA approval is obtained, projected revenues assume that BST-236 continues to demonstrate tolerability and efficacy similar to that demonstrated in completed and ongoing clinical trials. The outcome of preclinical studies and early clinical trials are not always predictive of the success of later clinical trials, and interim results of clinical trials do not necessarily predict success in the results of completed clinical trials. For example, even though Biosight's Phase 1/2a and Phase 2 clinical trials provided promising data that BST-236, has safe and effective qualities in the treatment of AML, these results may not be indicative of any results Biosight achieves in future randomized Phase 3 clinical trials that may be conducted with a different patient pool.

● Projected revenues assume that (i) total value of U.S. sales for all AML pharmaceutical treatments rise rapidly from approximately $1 billion now to approximately $6 billion by 2026 and (ii) total value of U.S. sales for all MDS pharmaceutical treatments rise rapidly from approximately $500 million now to approximately $2.4 billion by 2026. Projected revenues also assume a projected target patient population penetration of 35% for each application.

● Assuming FDA approval is obtained, projected revenues assume a price for BST-236 in the treatment of AML as a first-line treatment of $125,000 annually, $75,000 annually for treatment of relapsed/recurring AML and $125,000 annually for treatment of high-risk relapsed/recurring MDS. Biosight's ability to commercialize BST-236, or any other product candidates, will depend substantially on the extent to which the costs of its product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities (such as, in the United States, Medicare and Medicaid), private health coverage insurers and other third-party payors. The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, and could view our products as not being cost-effective.

● Assuming FDA approval is obtained, projected revenues assume that no competing product is safer, more effective, has fewer or less severe side effects or is less expensive than BST-236. Biosight's commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects or are less expensive than BST-236. Biosight's competitors could also obtain FDA or other regulatory approval for their products more quickly than Biosight is able, which could impact the success of marketing or commercializing BST-236. In addition, insurers and other third-party payers could impact Biosight's ability to compete if they seek to encourage the use of more cost-effective products.

**Government Regulation and Product Approval**

Government authorities in the U.S. at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biopharmaceutical and other drug products, such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The processes for obtaining regulatory approvals in the U.S. and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require us to expend substantial time and financial resources.

*United States Government Regulations*

In the U.S., the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires us to expend substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the drug development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process that the FDA requires before biopharmaceutical or drug product candidates may be marketed in the U.S. generally involves the following:

- Completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice ("**GLP**") regulations;
- Submission to the FDA of an Investigational New Drug ("**IND**"), which must become effective before human clinical trials may begin;
- Approval by an IRB, at each clinical site before each trial may be initiated;
- Performance of adequate and well-controlled clinical trials in accordance with good clinical practice ("**GCP**") requirements to establish the safety and efficacy of the proposed drug for each indication;
- Submission to the FDA of an NDA;
- Satisfactory completion of an FDA advisory committee review, if applicable;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with the FDA's cGMP requirements, and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- Satisfactory completion of an FDA inspection of selected clinical sites to assure compliance with GCPs and the integrity of the clinical data;
- Payment of user fees; and
- FDA review and approval of the NDA.

*Preclinical Studies*

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND sponsor must submit the results of the nonclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some nonclinical testing may continue even after the IND is submitted. An IND automatically becomes effective and a human subject clinical trial proposed in the IND may begin 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

*Clinical Trials*

Clinical trials involve the administration of the investigational new product candidate to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must continue to oversee the clinical trial while it is being conducted. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their ClinicalTrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined. In Phase 1, the drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an initial indication of its effectiveness. In Phase 2, the drug typically is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. In Phase 3, the drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the safety and efficacy of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

In some cases, the FDA may condition approval of an NDA for a product candidate on the sponsor's agreement to conduct additional clinical trials after NDA approval. In other cases, a sponsor may voluntarily conduct additional clinical trials post approval to gain more information about the drug. Such post approval trials are typically referred to as Phase 4 clinical trials.

Progress reports detailing the results of the clinical trials must be submitted, at least annually, to the FDA, and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements, or if the drug has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

*Orphan Drug Pathway*

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making the product available in the U.S. for this type of disease or condition will be recovered from sales of the product in the U.S. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety, by providing a major contribution to patient care or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication that could be used "off-label" by physicians in the orphan indication, even though the competitor's product is not approved in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do of the same product, as defined by the FDA, for the same indication we are seeking, or if our product candidate is determined to be contained within the scope of the competitor's product for the same indication or disease. If one of our products designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity. Orphan drug status in the EU has similar, but not identical, requirements and benefits.

*Expedited Review and Approval*

The FDA has various programs, including fast track designation, breakthrough therapy designation, accelerated approval and priority review, which are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides opportunities for more frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the approval application for a fast track product on a rolling basis before the complete application is submitted, if the sponsor and the FDA agree on a schedule for the submission of the application sections, and the sponsor pays any required user fees upon submission of the first section of the approval application.

In addition, under the provisions of the Food and Drug Administration Safety and Innovation Act (the "FDASIA"), passed in July 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs or biologics designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions with respect to breakthrough therapies, such as holding timely meetings with, and providing advice to, the product sponsor, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than an irreversible effect on morbidity or mortality ("IMM"), that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a product receiving accelerated approval to perform post-marketing trials to verify and describe the predicted effect on IMM or other clinical endpoint, and the product may be subject to expedited withdrawal procedures.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, breakthrough therapy designation, accelerated approval and priority review do not change the standards for approval and may not ultimately expedite the development or approval process.

*Post-Approval Requirements*

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved NDA. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- Restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- Fines, warning letters or holds on post-approval clinical studies;
- Refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- Product seizure or detention, or refusal of the FDA to permit the import or export of products; or
- Injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics and drugs. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

*Marketing Approval*

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act (the "PDUFA"), guidelines that are currently in effect, the FDA has a goal of 10 months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes 12 months from the date the NDA is submitted to the FDA because the FDA has 60 days from receipt to make a decision as to whether the application has been accepted for filing.

In addition, under the Pediatric Research Equity Act of 2003 as amended and reauthored, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

The FDA also may require submission of a REMS, plan to ensure that the benefits of the drug outweigh its risks. A REMS plan could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical trial sites to assure compliance with GCP requirements.

The testing and approval process for an NDA requires substantial time, effort and financial resources, and each may take several years to complete. Data obtained from preclinical and clinical testing are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval of an NDA on a timely basis, or at all.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

*European Drug Development and Government Regulations*

In Europe, our product candidates, as well as any future candidates we may develop, may also be subject to extensive regulatory requirements. As in the U.S., medicinal products can only be marketed if a marketing authorization from the competent regulatory agencies has been obtained.

Similar to the U.S., the various phases of preclinical and clinical research in Europe are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU member states have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority ("NCA") and one or more Ethics Committees ("ECs"). Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

In 2014, a new Clinical Trials Regulation 536/2014, replacing the current Directive, was adopted. The new Regulation will become directly applicable in all EU member states (without national implementation) once the EU Portal and Database are fully functional. The Regulation is expected to become fully applicable in 2022, and seeks to simplify and streamline the approval of clinical trials in the EU. For example, the sponsor shall submit a single application for approval of a clinical trial via the EU Portal. As part of the application process, the sponsor shall propose a reporting member state, who will coordinate the validation and evaluation of the application. The reporting member state shall consult and coordinate with the other concerned member states. If an application is rejected, it can be amended and resubmitted through the EU Portal. If an approval is issued, the sponsor can start the clinical trial in all concerned member states. However, a concerned member state can in limited circumstances declare an "opt-out" from an approval. In such a case, the clinical trial cannot be conducted in that member state. The Regulation also aims to streamline and simplify the rules on safety reporting, and introduces enhanced transparency requirements such as mandatory submission of a summary of the clinical trial results to the EU Database.

*European Drug Review and Approval*

In the European Economic Area (the "EEA") which is comprised of the 28 member states of the EU plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations:

The Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use of the EMA and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of drugs, such as biotechnology medicinal drugs, orphan medicinal drugs, and medicinal drugs containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for drugs containing a new active substance not yet authorized in the EEA, or for drugs that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

National MAs, which are issued by the competent authorities of the member states of the EEA and only cover their respective territories, are available for drugs not falling within the mandatory scope of the Centralized Procedure. Where a drug has already been authorized for marketing in a member state of the EEA, this National MA can be recognized in other member states through the Mutual Recognition Procedure. If the drug has not received a National MA in any member state at the time of application, it can be approved simultaneously in various member states through the Decentralized Procedure. Under the Decentralized Procedure, an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the Reference Member State. The competent authority of the Reference Member State prepares a draft assessment report, a draft summary of the drug characteristics ("SPC"), and a draft of the labeling and package leaflet, which are sent to the other member states (referred to as the Member States Concerned) for their approval. If the member states Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the drug is subsequently granted a national MA in all the member states (i.e., in the Reference Member State and the Member States Concerned).

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the member states of the EEA make an assessment of the risk-benefit balance of the drug on the basis of scientific criteria concerning its quality, safety and efficacy.

*European Chemical Entity Exclusivity*

In Europe, new chemical entities, sometimes referred to as new active substances, qualify for 8 years of data exclusivity upon marketing authorization and an additional 2 years of market exclusivity. This data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application for eight years, after which generic marketing authorization can be submitted, and the innovator's data may be referenced, but not approved for two years. The overall 10-year period will be extended to a maximum of 11 years if, during the first 8 years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

*European Union General Data Protection Regulation*

In addition to EU regulations related to the approval and commercialization of our products, we may be subject to the EU's General Data Protection Regulation (the "GDPR"). The GDPR went into effect on May 25, 2018. The GDPR introduced new data protection requirements in the European Union, as well as potential fines for noncompliant companies of up to the greater of € 20 million, or 4% of annual global revenue. The regulation imposes numerous new requirements for the collection, use and disclosure of personal information, including more stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulators and affected individuals of personal data breaches, extensive new internal privacy governance obligations and obligations to honor expanded rights of individuals in relation to their personal information (e.g., the right to access, correct and delete their data). In addition, the GDPR includes restrictions on cross-border data transfer. The GDPR will increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules. Further, the United Kingdom's vote in favor of exiting the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear whether the United Kingdom will enact data protection legislation equivalent to the GDPR and how data transfers to and from the United Kingdom will be regulated.

*Other Global Government Regulations*

For other countries outside of the U.S. and the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, drug licensing, pricing and reimbursement vary from country to country. In all cases the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

**Manufacturing**

The manufacturing, processing and packing of our product candidates are subject to extensive government and other regulatory bodies that impose various procedural, documentation and certification requirements. These requirements, such as those under cGMP requirements include, but are not limited to, standards with respect to the methods, facilities and controls used in the manufacturing process, personnel, quality control and quality assurance.

We do not intend to manufacture in-house and rely on third-party contract manufacturing organizations ("CMOs") for the production and supply of our current product candidate, BST-236, and plan to use them for any product candidates we may develop in the future. The CMOs upon which we rely are cGMP-compliant, and we expect that they, and any other manufacturers whose services we use, will manufacture all of our current and future product candidates under cGMP conditions. To meet our projected needs for clinical supplies to support our activities through regulatory approval and commercial manufacturing, the CMOs with whom we currently work will need to increase the scale of production, or we will need to secure alternate suppliers. We are also in the process of replacing one of our CMOs and believe that there are several potential sources for our contract manufacturing, but we have not engaged alternate suppliers in the event that our current CMOs are unable to scale production. Our relationships with CMOs are managed by internal personnel with extensive experience in pharmaceutical development and manufacturing.

If we are unable to obtain sufficient quantities of our product candidates or receive raw materials from our CMOs in a timely manner, we could be required to delay our ongoing clinical trials and seek alternative third-party contract manufacturers. Any delay could be costly, time-consuming and impact the competitive capabilities of our products.

**Sales and Marketing**

Our leadership team is working to commercialize our investigational product candidate, BST-236, as well as develop, seek approval for, and complete a commercial launch of new therapies for hematological cancers and other related diseases. If we receive approval, we intend to commercialize BST-236 by partnering with third parties to maximize the global potential of our portfolio.

**Agreements**

Biosight has entered into various agreements which Biosight deems material.

*CRO Agreement*

On May 3, 2018, Biosight entered into the CRO Agreement with ICON (formerly PRA), pursuant to which PRA provides services related to the design, implementation and management of clinical development programs for pharmaceutical products under development by or under control of Biosight. The CRO Agreement has been amended and extended from time to time throughout its term. The CRO Agreement expires on November 20, 2021, unless terminated earlier in accordance with the provisions of the CRO Agreement. In the event of an expiration or termination of the CRO Agreement, any outstanding task order placed thereunder will continue until completion of the services described in such task order or appropriate termination of such task order.

*AMRI Agreement*

On June 16, 2017, Biosight entered into a Master Services Agreement with Albany Molecular Research Inc. (as amended, the "AMRI Agreement" and "AMRI") pursuant to which AMRI will provide Biosight services related to manufacturing of Biosight's drug product. The AMRI Agreement entered into effect on June 16, 2017 and will continue to be in effect until June 15, 2022, unless further extended or terminated early in accordance with the provisions of the AMRI Agreement. Pursuant to the AMRI Agreement, AMRI is entitled to various labor fees and reimbursement expenses.

*GFM Agreement*

On July 15, 2020, the Company entered into the GFM Agreement with GFM in connection with a clinical trial of Biosight's drug product. The GFM Agreement entered into effect on June 16, 2017 and will end upon Biosight's receipt of a final study report and written notification that the study data have been accepted for publication in a peer-reviewed journal or until completion of all obligations under the GFM Agreement, unless terminated early by Biosight pursuant to the terms of the GFM Agreement. Biosight may terminate the GFM Agreement in the exercise of its sole discretion upon fifteen days written notice to the other parties.

*Sterling Agreement*

In August, 2021, Biosight entered into a Master Agreement with Sterling Wisconsin, LLC (the "Sterling Agreement" and "Sterling"), pursuant to which Sterling will provide Biosight services related to manufacture of Biosight's drug product. The Sterling Agreement entered into effect in August, 2021 and shall continue until its fifth anniversary, unless further extended or terminated early in accordance with the terms of the Sterling Agreement. The Sterling Agreement provides, among other things, that Sterling will manufacture and supply Biosight's drug product in accordance with Biosight's written instructions as set forth in separate product orders that will be executed from time to time by Sterling and Biosight pursuant to the commercial and legal terms specified in the Sterling Agreement. The Sterling Agreement includes customary representations, warranties and additional undertakings of each of Sterling and Biosight.

*Separation Agreement*

Dr. Ben Yakar serves as Biosight's chief executive officer pursuant to a consultancy agreement, dated December 21, 2014, by and between Biosight and RAM Technologies (RBY 2012) Ltd. ("RAM"). On or about October 7, 2021, Biosight, RAM and Dr. Ben Yakar entered into a separation agreement pursuant to which, RAM and Dr. Ben Yakar, as applicable, shall, immediately following and contingent upon the closing of the merger resign from her position as a director of Biosight and cease to serve as an officer of Biosight and support Biosight in the handover of responsibilities and perform all tasks assigned to it/her by the board of directors for a proper transition of her position to the new Biosight chief executive officer (including without limitation, fully support the merger) for a period of 12 months following the Closing (as such term is defined in the Merger Agreement) as a consultant of Biosight (the "Consultancy Period").

In consideration for Dr. Ben Yakar's services to Biosight during the Consultancy Period, RAM shall receive; (i) at the end of each month during the first three months of the Consultancy Period, an amount of NIS 92,400 + VAT; and (ii) at the end of each month during the remaining nine months of the Consultancy Period, an amount of NIS 5,000 + VAT. The provision of such services by Dr. Ben Yakar (through the CEO) shall not be deemed a "Termination of Employment" for purposes of Biosight's option plan. Contingent upon the closing of the merger, RAM will receive a one-time bonus payment in the amount of NIS 550,000 + VAT to be paid within 14 days of closing. Immediately following and contingent upon the closing the merger, all outstanding unvested options granted to Dr. Ben Yakar for her services as a member of Biosight's board of directors under Biosight's option plan will become fully vested. RAM and Dr. Ben Yakar are subject to non-competition and confidentiality obligations pursuant to the consultancy agreement, and RAM, Dr. Ben Yakar and Biosight are subject to mutual non-disparagement obligations pursuant to the separation agreement. In consideration of the foregoing, RAM and Dr. Ben Yakar have provided a release of claims in favor of Biosight in connection with the consultancy agreement and the separation agreement.

**Intellectual Property**

Our commercial success depends, in part, on our ability to obtain and maintain proprietary protection for our product candidate, BST-236, as well any future product candidates, novel discoveries, product development technologies and know-how. We own all of our intellectual property and have a patent portfolio that includes several patent families that cover composition, methods and use. We protect these intellectual property rights, which are critical to the development, formulation and marketing of our product candidate, by filing patents or patent applications with the USPTO and the comparable patent offices of Israel, Europe and other countries. In addition, we rely on know-how, continuing technological innovation, orphan drug exclusivity and potential in-licensing opportunities to develop and maintain our proprietary position. As of July 30, 2021, we have filed patent applications in multiple jurisdictions, including Australia, Brazil, Canada, China, Europe, India, Japan, Israel, Russia and the United States, as well as under the Patent Cooperation Treaty. We have been issued five patents in United States, two in Europe and one in each of Australia, India, Israel and Russia. Issued patents and currently pending patent applications are summarized below:

- *BIOST/001 patent family*. We have three issued US patents (US 7,638,127, US 7,135,547, US 8,314,060), one Israeli patent and two European patents (validated in France, Germany, Italy, Netherlands, Switzerland and the United Kingdom) to cover API, composition and use.

- *BIOST/002 patent family*. We have two issued US patents (US 8,993,278, US 7,989,188) and one European patent application under examination to cover BST-236, composition and use. The patent is expected to expire in 2025-26, not including potential patent term extension ("PTE"), including patent term adjustment ("PTA").

- *BIOST/004*. We have one granted in the US, one granted in each of Australia, Russia and India and one under examination in each of EP, Brazil, Canada, China, Japan, Israel to cover BST-236 pharmaceutically acceptable salts and use. The patent is expected to expire in 2036, not including potential PTE and PTA.

- *BIOST/005 patent family*. We have two US patent applications submitted, one granted in each of Russia and the US and one under examination in each of EP, Australia, Brazil, Canada, China, Japan and Israel to cover use. The patent is expected to expire in 2036, not including potential PTE and PTA.

- *BIOST/007*. We have one patent under the Patent Cooperation Treaty ("PCT") (national phase) to cover combination therapy. The patent is expected to expire in 2038, not including potential PTE and PTA.

- *BIOST/008*. We have one patent under the PCT to cover use. The patent is expected to expire in 2041, not including potential PTE and PTA.

- *BIOST/009*. We have one patent under the PCT to cover formulation. The patent is expected to expire in 2041, not including potential PTE and PTA.

- *BIOST/010*. We have one patent under the PCT to cover polymorph. The patent is expected to expire in 2041, not including potential PTE and PTA.

**Employees**

As of June 30, 2021, Biosight had nine full-time employees or service providers in Israel and one full-time employee in the United States. No Biosight employee is represented by a labor union or covered by a collective bargaining agreement. Additionally, we utilize independent contractors and other third parties to assist with various aspects of our business.

**Properties and Facilities**

Our principal location is at Airport City, Israel. Biosight leases the facility pursuant to a sub-lease agreement with Strauss Ice Cream Ltd. Under the sub-lease agreement, the initial lease period commenced on March 10, 2019 and ended on March 9, 2020 and provided Biosight with the option to extend for three additional consecutive lease periods of 12 months each. To date, Biosight has exercised the options to extend for two additional periods and intends to exercise the third option in March 2022.

**Legal Proceedings**

From time to time, we may become a party to various legal proceedings arising in the ordinary course of our business. We are not currently a party to any other legal proceeding that we believe would have a material adverse effect on our business, financial condition, or operating results.

On or about October 5, 2021, Biosight received a letter from counsel to Foodronix Ltd., an Israeli company ("Foodronix"), claiming that Foodronix is entitled to an amount equal to 4.8% of the share capital to be allocated and/or issued to Biosight shareholders in connection with the merger. The asserted entitlement is alleged to arise pursuant to a purported agreement between Biosight and Foodronix, which Foodronix claims was entered into in 2011. Foodronix did not provide a copy of the purported agreement or any other evidence of an agreement or commitment to this effect.

Based on a discussion with Biosight's former chief executive officer, and an Israeli court ruling dated July 14, 2015 from a lawsuit in which Foodronix was sued by an affiliate of one of Biosight's current shareholders (the "Ruling"), Biosight believes that during March 2011, meetings were held by Biosight's former chief executive officer with several companies in an effort to identify a shell company listed on the Tel Aviv Stock Exchange to merge with Biosight in order for Biosight to become public. Biosight believes that the meetings were held in the presence of Foodronix and that there was some arrangement under which Foodronix would have been entitled to compensation for its role in facilitating a transaction with a Tel Aviv Stock Exchange listed shell company. However, while a proposal was ultimately presented to Biosight's board of directors, in or around March 2011, for a proposed merger with such a shell company. Biosight's board of directors rejected this proposal, Biosight notified Foodronix that it did not intend to proceed and discussions with all such shell companies were discontinued. There is no further indication that Foodronix continued its efforts to identify such a company or to facilitate any transaction involving Biosight.

Biosight has responded to Foodronix and rejected all claims asserted in the October 5 letter, including the entitlement of Foodronix to any equity as a result of the currently contemplated merger or any transaction involving Biosight other than a potential transaction with a shell company listed on the Tel Aviv Stock Exchange. The response notes that Foodronix's assertion of this entitlement comes 10 years after the last interaction between the parties and relates to a transaction as to which Foodronix has had no involvement.

Biosight believes that the claim by Foodronix lacks merit, and if Foodronix files a claim against Biosight, Biosight intends to mount a vigorous defense to such claim.

The Company believes that it has meritorious defenses to any potential claim and would defend any such claim vigorously; however, given the inherent uncertainty involved in litigation, we cannot predict the outcome of any potential legal proceedings.

## ADVAXIS MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of Advaxis' financial condition and results of operations in conjunction with the audited and interim financial statements and the related notes, each included elsewhere in this proxy statement/prospectus/information statement. In addition to historical financial information, the following discussion contains forward-looking statements that reflect Advaxis' plans, estimates, beliefs and expectations that involve risks and uncertainties. Advaxis' actual results and the timing of events could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this proxy statement/prospectus/information statement, particularly in the sections titled "Risk Factors" and "Cautionary Statement Concerning Forward-Looking Statement."*

**Overview**

Advaxis, Inc. ("Advaxis" or the "Company") is a clinical-stage biotechnology company focused on the development and commercialization of proprietary *Lm* Technology antigen delivery products based on a platform technology that utilizes live attenuated *Listeria monocytogenes*, or *Lm*, bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm*-based strains are believed to be a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy by accessing and directing antigen presenting cells to stimulate anti-tumor T cell immunity, stimulate and activate the innate immune system with the equivalent of multiple adjuvants, and simultaneously reduce tumor protection in the Tumor Microenvironment, or TME, to enable the T cells to attack tumor cells.

The Company believes that *Lm* Technology immunotherapies can complement and address significant unmet needs in the current oncology treatment landscape. Specifically, our product candidates (i.e., ADXS-PSA and ADXS-503) have the potential to optimize checkpoint performance, while having a generally well-tolerated safety profile, and most of our product candidates have an expected low cost of goods. A new Investigator-Sponsored-Study with our FDA-approved IND is expected to start with ADXS-504-HOT construct in biochemically recurrent prostate cancer patients at a leading US Medical Institution in the first half of 2021.

Advaxis is currently winding down or has wound down clinical studies of *Lm* Technology immunotherapies in three program areas:

- Human Papilloma Virus ("HPV")-associated cancers
- Personalized neoantigen-directed therapies
- Human epidermal growth factor receptor-2 (HER-2) associated cancers

All these clinical program areas are anchored in the Company's *Lm* Technology™, a unique platform designed for its ability to safely and effectively target various cancers in multiple ways. While we are currently winding down clinical studies of *Lm* Technology immunotherapies in these three program areas, our license agreements continue with OS Therapies, LLC for ADXS-HER2 and with Global BioPharma, or GBP, for the exclusive license for the development and commercialization of AXAL in Asia, Africa, and the former USSR territory, exclusive of India and certain other countries.

**Recent Developments**

The global health crisis caused by the novel coronavirus ("COVID-19") pandemic and its resurgences has and may continue to negatively impact global economic activity, which, despite progress in vaccination efforts, remains uncertain and cannot be predicted with confidence. In addition, a new Delta variant of COVID-19, which appears to be the most transmissible variant to date, has begun to spread globally. The impact of the Delta variant cannot be predicted at this time, and could depend on numerous factors, including vaccination rates among the population, the effectiveness of COVID-19 vaccines against the Delta variant and the response by governmental bodies and regulators.

In response to COVID-19, the Company implemented remote working and thus far, has not experienced a significant disruption or delay in its operations as it relates to the clinical development or drug production of our drug candidates by third parties. We continue to monitor the COVID-19 pandemic and take steps intended to mitigate the potential risks to our workforce and our operations. The COVID-19 pandemic has, and may continue to, directly or indirectly affect the pace of enrollment in our clinical trials as patients may avoid or may not be able to travel to healthcare facilities and physicians' offices unless due to a health emergency and clinical trial staff can no longer get to the clinic. Nonetheless, thus far, the COVID-19 pandemic has not had a significant impact on our business or results of operations. However, we remain in contact with the clinical sites in our study and are in discussion with additional sites to combat any potential impact in enrollment. We are unable to determine or predict the extent, duration or scope of the overall impact of the COVID-19 pandemic on our business, operations, financial condition or liquidity.

**Merger with Biosight**

On July 4, 2021, the Company entered into a Merger Agreement (the "Merger Agreement"), subject to shareholder approval, with Biosight Ltd. ("Biosight") and Advaxis Ltd. ("Merger Sub"), a direct, wholly-owned subsidiary of Advaxis. Under the terms of the agreement, Biosight will merge with and into Merger Sub, with Biosight continuing as the surviving company and a wholly-owned subsidiary of Advaxis (the "Merger"). Immediately after the merger, Advaxis stockholders as of immediately prior to the merger are expected to own approximately 25% of the outstanding shares of the combined company and former Biosight shareholders are expected to own approximately 75% of the outstanding shares of the combined company. The merger will be accounted for a reverse acquisition pursuant to ASC 805-40.

At the effective time of the Merger (the "Effective Time"), each share of share capital of Biosight (excluding certain Biosight shares that may be cancelled pursuant to the terms of the Merger Agreement) issued and outstanding immediately prior to the Effective Time will be converted into the right to receive a number of shares of Advaxis common stock, par value $0.001 per share, equal to the exchange ratio, 118.2009 shares of Advaxis common stock per Biosight share (subject to adjustment to account for the proposed Advaxis reverse stock split).

If the Merger Agreement is terminated under certain circumstances, Advaxis or Biosight, as applicable, will be required to pay the other party a termination fee up to $7,500,000.

**Results of Operations for the Three Months Ended July 31, 2021 and 2020**

*Revenue*

Revenue was $0.3 million for the three months ended July 31, 2021 compared to $0 for the three months ended July 31, 2020. In the current period, we received the annual licensing fee from GBP.

*Research and Development Expenses*

We invest in research and development to advance our Lm technology through our pre-clinical and clinical development programs. Research and development expenses for the three months ended July 31, 2021 and July 31, 2020 were categorized as follows (in thousands):

| | Three Months Ended July 31, | | Increase (Decrease) | |
|---|---|---|---|---|
| | 2021 | 2020 | $ | % |
| Hotspot/Off-the-Shelf therapies | $ 546 | $ 768 | $ (222) | (29)% |
| Prostate cancer | 113 | 338 | (225) | (67)% |
| HPV-associated cancers | 420 | 786 | (366) | (47)% |
| Personalized neoantigen-directed therapies | 7 | 103 | (96) | (93)% |
| Other expenses | 617 | 1,463 | (846) | (58)% |
| Total research & development expense | $ 1,703 | $ 3,458 | $ (1,755) | (51)% |
| Stock-based compensation expense included in research and development expense | $ 29 | $ 79 | $ (50) | (63)% |

Research and development expenses for the three months ended July 31, 2021 decreased approximately $1.8 million, or 51%, compared to the same period in 2020. The decrease was primarily attributable to the substantial reduction in costs associated with the winding down of clinical studies that have been discontinued.

*General and Administrative Expenses*

General and administrative expenses primarily include salary and benefit costs and stock-based compensation expense for employees included in our finance, legal and administrative organizations, outside legal and professional services, and facilities costs. General and administrative expenses for the three months ended July 31, 2021 and July 31, 2020 were as follows (in thousands):

| | Three Months Ended July 31, | | Increase (Decrease) | |
|---|---|---|---|---|
| | 2021 | 2020 | $ | % |
| General and administrative expense | $ 2,678 | $ 2,384 | $ 294 | 12% |
| Stock-based compensation expense included in general and administrative expense | $ 31 | $ 176 | $ (145) | 82% |

General and administrative expenses for the three months ended July 31, 2021 increased approximately $0.3 million, or 12%, compared to the same period in 2020. This increase primarily relates to (1) an increase of $0.6 million in legal and consulting fees related to the merger with Biosight and (2) the annual meeting proxy solicitation fees. These increases were partially offset by decreases in: (1) rent and utilities due to the termination of our office lease at our former location, (2) personnel costs and (3) charges related to the abandonment of non-strategic intellectual property.

*Changes in Fair Values*

For the three months ended July 31, 2021, we recorded non-cash income from changes in the fair value of the warrant liability of approximately $0.8 million. The decrease in the fair value of liability warrants resulted from resulted from a decrease in our share price from $0.49 at April 30, 2021 to $0.41 at July 31, 2021.

For the three months ended July 31, 2020, we recorded non-cash income from changes in the fair value of the warrant liability of approximately $7,000. The decrease in the fair value of liability warrants resulted from a decrease in our share price from $0.67 at April 30, 2020 to $0.58 at July 31, 2020.

**Results of Operations for the Nine Months Ended July 31, 2021 and 2020**

*Revenue*

Revenue increased approximately $3.0 million for the nine months ended July 31, 2021 compared to $0.3 million for the nine months ended July 31, 2020. In the current period, we recognized royalty payments from OST.

*Research and Development Expenses*

We invest in research and development to advance our Lm technology through our pre-clinical and clinical development programs. Research and development expenses for the nine months ended July 31, 2021 and July 31, 2020 were categorized as follows (in thousands):

| | Nine Months Ended July 31, | | Increase (Decrease) | |
|---|---|---|---|---|
| | 2021 | 2020 | $ | % |
| Hotspot/Off-the-Shelf therapies | $ 2,531 | $ 2,230 | $ 301 | 13% |
| Prostate cancer | 207 | 872 | (665) | (76)% |
| HPV-associated cancers | 1,865 | 3,310 | (1,445) | (44)% |
| Personalized neoantigen-directed therapies | 400 | 1,011 | (611) | (60)% |
| Other expenses | 3,613 | 4,816 | (1,203) | (25)% |
| Total research & development expense | $ 8,616 | $ 12,239 | $ (3,623) | (30)% |
| Stock-based compensation expense included in research and development expense | $ 142 | $ 233 | $ (91) | (39)% |

Research and development expenses for the nine months ended July 31, 2021 decreased approximately $3.6 million, or 30%, compared to the same period in 2020. The decrease was primarily attributable to the substantial reduction in costs associated with the winding down of clinical studies that have been discontinued.

*General and Administrative Expenses*

General and administrative expenses primarily include salary and benefit costs and stock-based compensation expense for employees included in our finance, legal and administrative organizations, outside legal and professional services, and facilities costs. General and administrative expenses for the nine months ended July 31, 2021 and July 31, 2020 were as follows (in thousands):

| | Nine Months Ended July 31, | | Increase (Decrease) | |
|---|---|---|---|---|
| | 2021 | 2020 | $ | % |
| General and administrative expense | $ 9,038 | $ 8,063 | $ 975 | 12% |
| Stock-based compensation expense included in general and administrative expense | $ 369 | $ 475 | $ (106) | (22)% |

General and administrative expenses for the nine months ended July 31, 2021 increased approximately $1.0 million, or 12%, compared to the same period in 2020. This increase primarily relates to increases in (1) an increase of $0.8 million in legal and consulting fees related to the merger with Biosight (2) the annual meeting proxy solicitation fees (3) sublicense fees, (4) amounts paid in settlement of a shareholder demand letter and (5) losses on disposal of property and equipment in connection with the termination of our office lease at our former location. These increases were partially offset by decreases in (1) rent and utilities due to the termination of our office lease at our former location, (2) personnel costs and (3) charges related to the abandonment of non-strategic intellectual property.

*Changes in Fair Values*

For the nine months ended July 31, 2021, we recorded non-cash income from changes in the fair value of the warrant liability of approximately $1.8 million. The decrease in the fair value of liability warrants resulted primarily from the issuance of warrants in the April 2021 Private Placement. The warrants issued in the April 2021 Private Placement had a decrease in fair value of approximately $1.8 million from date of issuance to July 31, 2021, which resulted from a decrease in our share price from $0.57 at April 14, 2021 to $0.41 at July 31, 2021.

For the nine months ended July 31, 2020, we recorded non-cash expense from changes in the fair value of the warrant liability of approximately $16,000. The increase in the fair value of liability warrants resulted from an increase in our share price from $0.32 at October 31, 2019 to $0.58 at July 31, 2020.

**Results of Operations for the Fiscal Year Ended October 31, 2020 Compared to the Fiscal Year Ended October 31, 2019**

*Revenue*

Revenue decreased from $20.6 million to $0.3 million for the fiscal year ended October 31, 2020 compared to $20.9 million for the fiscal year ended October 31, 2019. The decrease was due to the fact that the Company did not have another large collaboration in the current year after the Amgen Agreement (as defined below) was terminated. On December 10, 2018, we received a written notice of termination from Amgen with respect to the global agreement with Amgen (the “Amgen Agreement”). The termination was effective as of February 8, 2019. As of the notification date, we adjusted revenue on a cumulative catch-up basis considering the revised measure of progress for the combined performance obligation based on the modified service period up to and through the contract termination date of February 8, 2019 resulting in total revenue of $18.7 million in the prior period. In addition, the reimbursement of research and development costs of approximately $2.0 million by Amgen was included in revenue in the prior period.

*Research and Development Expenses*

We invest in research and development to advance our *Lm* Technology through our preclinical and clinical development programs. Research and development expenses for the years ended October 31, 2020 and 2019 were categorized as follows (in thousands):

| | Fiscal Years Ended October 31, | | Increase (Decrease) | |
|---|---|---|---|---|
| | 2021 | 2020 | $ | % |
| Hotspot/Off-the-Shelf therapies | $ 3,515 | $ 3,221 | $ 294 | 9% |
| Prostate cancer | 948 | 863 | 85 | 10% |
| HPV-associated cancers | 3,667 | 8,139 | (4,472) | (55)% |
| Personalized neoantigen-directed therapies | 1,266 | 2,932 | (1,666) | (57)% |
| Other expenses | 6,216 | 11,522 | (5,306) | (46)% |
| Total research & development expense | $ 15,612 | $ 26,677 | $ (11,065) | (41)% |
| | | | | |
| Stock-based compensation expense included in research and development expense | $ 308 | $ 1,036 | $ (728) | (70)% |

*Hotspot/Off-the-Shelf Therapies (ADXS-HOT)*

Research and development costs associated with our hotspot mutation-based therapy for the fiscal year ended October 31, 2020 increased by approximately 9% to $3.5 million compared to the same period in 2019. The increase is attributable to the costs associated with the Part B and Part C expansion of the study.

*Prostate Cancer Therapy (ADXS-PSA)*

Research and development costs associated with our prostate cancer therapy for the fiscal year ended October 31, 2020 increased by approximately $0.1 million, or 10%, compared to the same period in 2019. The increase is attributable to a change order from the contract research organization during the current period. The Phase 1/2 study of our ADXS-PSA compound is in combination with KEYTRUDA® (pembrolizumab), Merck's humanized monoclonal antibody. During 2020, we presented updated data from this study that demonstrated an increase in the median overall survival, or mOS, to 33.7 months for patients in the combination arm of this study and mOS of 16.4 for patients with visceral metasteses (n=11). We are in currently seeking potential partners on next steps for this therapy.

*HPV-Associated Cancers (AXAL)*

The majority of the HPV-associated research and development costs include clinical trial and other related costs associated with our AXAL programs in cervical and head and neck cancers. HPV-associated costs for the fiscal year ended October 31, 2020 decreased by approximately $4.5 million, or 55%, compared to the same period in 2019. The decrease resulted from the announcement made in June 2019 regarding the closing of our Phase 3 AIM2CERV study in high-risk locally advanced cervical cancer. AIM2CERV was completed and closed on June 11, 2021. We anticipate that we will continue to incur costs associated with the writing of the clinical study report and regulatory submissions. Additionally, a winding down of several studies, including our Fawcett study in anal cancer and our MEDI4736 study in combination with MedImmune's investigational anti-PD-L1 immune checkpoint inhibitor, (durvalumab) drove further reduction in costs as compared to the prior period. We anticipate that our costs surrounding HPV-associated studies will continue to decline as both the Fawcett study and the MEDI Phase 2 combo study (AZ) with AXAL ± durvalumab in Cervical + HNSCC have already been finalized and closed. We just need to wrap up the drafting of the study report for MEDI and the regulatory obligations of the AXAL program. We currently do not anticipate funding any new AXAL studies.

*Personalized Neoantigen-Directed Therapies (ADXS-NEO)*

Research and development costs associated with personalized neoantigen-directed therapies for the fiscal year ended October 31, 2020 decreased by approximately $1.7 million, or 57%, compared to the same period in 2019. In October 2019, we announced that we enrolled our last patient in the ADXS-NEO program in monotherapy and will not continue into Part B of this study. As a result, the costs incurred for ADXS-NEO during the fiscal year ended October 31, 2020 consisted of wind-down costs associated with terminating the study. We do not anticipate that we will incur additional costs for this study with personalized neoantigen-directed therapies (ADXS-NEO) as it was closed on May 22, 2020 and the NEO program IND inactivation request was submitted to the FDA on May 10, 2021.

*Other Expenses*

Other expenses include salary and benefit costs, stock-based compensation expense, professional fees, laboratory costs and other internal and external costs associated with our research and development activities. Other expenses for the fiscal year ended October 31, 2020 decreased by approximately $5.3 million, or 46%, compared to the same period in 2019. The decrease was primarily attributable to a decrease in salary-related expenses, including stock compensation, and travel expenses resulting from cost-control measures put in place beginning in June 2018. In addition, there were decreases in laboratory and manufacturing costs, as we are focused on the clinical development of our HOT program and less on early research programs. Additionally, we announced in October 2019 that we are winding down ADXS-NEO and therefore no longer incurring costs to manufacture ADXS-NEO.

*General and Administrative Expenses*

General and administrative expenses primarily include salary and benefit costs and stock-based compensation expense for employees included in our finance, legal and administrative organizations; outside legal and professional services; and facilities costs. General and administrative expenses for the years ended October 31, 2020 and 2019 were as follows (in thousands):

| | Years Ended October 31, | | Increase (Decrease) | |
|---|---|---|---|---|
| | 2021 | 2020 | $ | % |
| General and administrative expense | $ 11,090 | $ 12,179 | $ (1,089) | (9)% |
| Stock-based compensation expense included in research and development expense | $ 583 | $ 966 | $ (383) | (40)% |

General and administrative expenses for the fiscal year ended October 31, 2020 decreased by approximately $1.1 million, or 9%, compared to the same period in 2019. The decrease is attributable to lower legal fees and business development costs partially offset by increased abandonment of certain non-strategic intellectual property.

*Changes in Fair Values*

For the fiscal year ended October 31, 2020, we recorded non-cash expense from changes in the fair value of the warrant liability of $0.

For the fiscal year ended October 31, 2019, we recorded non-cash income from changes in the fair value of the warrant liability of approximately $2.6 million. The decrease in the fair value of liability warrants resulted from a decrease in our share price from $0.56 at October 31, 2018 to $0.32 at October 31, 2019, as well as a decrease in the number of liability warrants as a result of the warrant exchange (see "*Loss on shares issued in settlement of warrants*" below*).*

*Loss on shares issued in settlement of warrants*

On October 16, 2020, the Company entered into private exchange agreements with certain holders of warrants issued in connection with the Company's January 2020 public offering of common stock and warrants. The warrants being exchanged provide for the purchase of up to an aggregate of 5 million shares of our common stock at an exercise price of $1.25 per share. The warrants became exercisable on July 21, 2020 and have an expiration date of July 21, 2025. Pursuant to such exchange agreements, the Company agreed to issue 3 million shares of common stock to the investors in exchange for the warrants. In connection with the exchange of warrants for common stock, the Company recorded a loss of approximately $77,000 as the fair value of the shares issued exceeded the fair value of warrants exchanged.

On March 14, 2019, we entered into private exchange agreements with certain holders of warrants issued in connection with our September 2018 public offering of common stock and warrants. Pursuant to the exchange agreements, we issued 856,865 shares of common stock to the investors in exchange for warrants on a 1:1 basis. In connection with the warrant exchange, we recorded a loss of approximately $1.6 million for the fiscal year ended October 31, 2019.

**Liquidity and Capital Resources**

*Management's Plans*

Similar to other development stage biotechnology companies, our products that are being developed have not generated significant revenue. As a result, we have historically suffered recurring losses and we have required significant cash resources to execute our business plans. These losses are expected to continue for the foreseeable future.

Historically, the Company's major sources of cash have comprised proceeds from various public and private offerings of its securities (including common stock), debt financings, clinical collaborations, option and warrant exercises, income earned on investments and grants, and interest income. From October 2013 through July 31, 2021, the Company raised approximately $339.4 million in gross proceeds ($30.0 million during the nine months ended July 31, 2021) from various public and private offerings of our common stock. The Company has sustained losses from operations in each fiscal year since our inception, and we expect losses to continue for the indefinite future. As of July 31, 2021 and October 31, 2020, the Company had an accumulated deficit of approximately $423.2 million and $410.7 million, respectively, and stockholders' equity of approximately $44.3 million and $30.2 million, respectively.

The COVID-19 pandemic has negatively affected the global economy and created significant volatility and disruption of financial markets. An extended period of economic disruption could negatively affect the Company's business, financial condition, and access to sources of liquidity. As of July 31, 2021, the Company had approximately $45.3 million in cash and cash equivalents. The actual amount of cash that the Company will need to continue operating is subject to many factors. The Company based this estimate on assumptions that may prove to be wrong, and we could use available capital resources sooner than currently expected.

The Company recognizes that it will need to raise additional capital in order to continue to execute its business plan in the future. There is no assurance that additional financing will be available when needed or that the Company will be able to obtain financing on terms acceptable to it or whether the Company will become profitable and generate positive operating cash flow. If the Company is unable to raise sufficient additional funds, it will have to further scale back its operations.

In conjunction with the Merger described above, the Company may seek a private investment in public equity ("PIPE") capital raise to provide capital for the combined company. The Company expects any such fundraising efforts to begin in September 2021 and seeks to raise a least an aggregate of $25 million in capital to close concurrently with the Merger.

Outside of the PIPE capital raise, the Company does not have any current plans to raise capital in the near term, absent an extraordinary change in circumstances, such as unforeseen liabilities or if we acquire new assets that require additional investment. The Company believes it has sufficient capital to fund its obligations, as they become due, in the ordinary course of business into the 3rd fiscal quarter of 2023.

**Cash Flows for the Nine Months Ended July 31, 2021 and 2020**

*Operating Activities*

Net cash used in operating activities includes reduced spending associated with our clinical trial programs and general and administrative activities. Net cash used in operating activities was approximately $11.7 million for the nine months ended July 31, 2021 compared to $18.7 million for the nine months ended July 31, 2020. The decrease was due to measures to control costs for non-essential items in areas that did not support our strategic direction, and as a result, we have continued to reduce non-strategic operating expenditures over the past several quarters.

*Investing Activities*

Net cash used in investing activities was approximately $0.1 million for the nine months ended July 31, 2021 compared to $0.4 million for the nine months ended July 31, 2020. The decrease is a result of proceeds on disposal of property and equipment and the abandonment of certain non-strategic intellectual property in the prior period.

*Financing Activities*

Net cash provided by financing activities was approximately $31.9 million for the nine months ended July 31, 2021, as compared to $10.6 million for the nine months ended July 31, 2020. In April 2021, the Company completed an offering of (i) 17,577,400 shares of common stock, (ii) 7,671,937 pre-funded warrants to purchase 7,671,937 shares of common stock and (iii) registered common share purchase warrants to purchase 11,244,135 shares of common stock (the "Registered Direct Offering") with two healthcare focused, institutional investors. The Company also issued to the investors, in a concurrent private placement, unregistered common share purchase warrants to purchase 14,005,202 shares of the Company's common stock (the "Private Placement" and together with the Registered Direct Offering, the "April 2021 Offering"). We received gross proceeds of approximately $20 million, before deducting the fees and expenses payable by us in connection with the April 2021 Offering. On November 27, 2020, the Company completed an underwritten public offering of 26,666,666 shares of common stock and common stock warrants to purchase up to 13,333,333 shares of common stock (the "November 2020 Offering").

On November 24, 2020, the underwriters notified us that they had exercised their option to purchase an additional 3,999,999 shares of common stock and 1,999,999 warrants in full. After giving effect to the full exercise of the underwriters' option, we issued and sold an aggregate 30,666,665 shares of common stock and warrants to purchase up to 15,333,332 shares of common stock. We received gross proceeds of approximately $9.2 million, before deducting the underwriting discounts and commissions and fees and expenses payable by us in connection with the November 2020 Offering. In January 2020, we completed a public offering of 10,000,000 shares of our common stock, which resulted in net proceeds of approximately $9.7 million. Additionally, during the nine months ended July 31, 2020, we sold 1,375,337 shares under the ATM program for net proceeds of approximately $1.0 million.

**Cash Flows for the Fiscal Years Ended October 31, 2020 and 2019**

*Operating Activities*

Net cash used in operating activities was approximately $21.9 million for the fiscal year ended October 31, 2020 compared to $36.1 million for the fiscal year ended October 31, 2019. Net cash used in operating activities includes reduced spending associated with our clinical trial programs and general and administrative activities. The decrease was due to measures to control costs for non-essential items in areas that did not support our strategic direction and, as a result, we have continued to reduce non-strategic operating expenditures over the past several quarters.

*Investing Activities*

Net cash used in investing activities was approximately $0.7 million for the fiscal year ended October 31, 2020 compared to $1.2 million for the nine months ended July 31, 2019. The reduction is a result of the abandonment of certain non-strategic intellectual property.

*Financing Activities*

Net cash provided by financing activities was approximately $15.5 million for the fiscal year ended October 31, 2020 as compared to $24.6 million for the fiscal year ended October 31, 2019. In January 2020, we completed a public offering of 10,000,000 shares of our common stock, which resulted in net proceeds of approximately $9.7 million. Additionally, during the year-end October 31, 2020, we sold 2,489,104 shares under the ATM program for net proceeds of $1.531 million, and we sold 11,242,048 shares of common stock under the Lincoln Park Purchase Agreement for net proceeds of approximately $5.1 million. In fiscal year 2019, we received net proceeds of approximately $24.5 million from the sales of 13,150,000 shares of our common stock and 13,656,000 pre-funded warrants in public offerings.

On November 27, 2020, the Company completed the November 2020 Offering. On November 24, 2020, the underwriters notified us that they had exercised their option to purchase an additional 3,999,999 shares of common stock and 1,999,999 warrants in full. After giving effect to the full exercise of the underwriters' option, we issued and sold an aggregate 30,666,665 shares of common stock and warrants to purchase up to 15,333,332 shares of common stock pursuant to our existing shelf registration statement on Form S-3 (File No. 333-226988). We received gross proceeds of approximately $9.2 million, before deducting the underwriting discounts and commissions and fees and expenses payable by us in connection with the November 2020 Offering.

**Off-Balance Sheet Arrangements**

As of July 31, 2021, we had no off-balance sheet arrangements.

**Critical Accounting Estimates**

The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts and related disclosures in the financial statements. Management considers an accounting estimate to be critical if:

- it requires assumptions to be made that were uncertain at the time the estimate was made, and
- changes in the estimate or different estimates that could have been selected could have material impact in our results of operations or financial condition.

While we base our estimates and judgments on our experience and on various other factors that we believe to be reasonable under the circumstances, actual results could differ from those estimates and the differences could be material. The most significant estimates impact the following transactions or account balances: stock compensation, warrant liability valuation and impairment of intangibles.

See Note 2 to our condensed consolidated financial statements for a discussion of our significant accounting policies.

**Critical Accounting Policies**

*Revenue Recognition*

Effective November 1, 2018, the Company adopted ASC Topic 606, *Revenue form Contracts with Customers* ("ASC 606"), using the modified retrospective transition method. Under this method, results for reporting periods beginning on November 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with ASC Topic 605, *Revenue Recognition* ("ASC 605"). The Company only applied the modified retrospective transition method to contracts that were not completed as of November 1, 2018, the effective date of adoption for ASC 606. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company enters into licensing agreements that are within the scope of ASC 606, under which it may exclusively license rights to research, develop, manufacture and commercialize its product candidates to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, upfront license fees; reimbursement of certain costs; customer option exercise fees; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for these arrangements, the Company must use significant judgment to determine (a) the number of performance obligations based on the determination under step (ii) above; (b) the transaction price under step (iii) above; and (c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above. The Company uses judgment to determine whether milestones or other variable consideration, except for royalties, should be included in the transaction price as described further below. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied.

Amounts received prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

*Exclusive Licenses.* If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. In assessing whether a performance obligation is distinct from the other performance obligations, the Company considers factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the collaboration partner can benefit from a performance obligation for its intended purpose without the receipt of the remaining performance obligation, whether the value of the performance obligation is dependent on the unsatisfied performance obligation, whether there are other vendors that could provide the remaining performance obligation, and whether it is separately identifiable from the remaining performance obligation. For licenses that are combined with other performance obligations, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the research and development and licensing agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

*Research and Development Services.* The performance obligations under the Company's collaboration agreements may include research and development services to be performed by the Company on behalf of the partner. Payments or reimbursements resulting from the Company's research and development efforts are recognized as the services are performed and presented on a gross basis because the Company is the principal for such efforts.

*Milestone Payments.* At the inception of each arrangement that includes research or development milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. An output method is generally used to measure progress toward complete satisfaction of a milestone. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and earnings in the period of adjustment.

*Royalties.* For arrangements that include sales-based royalties, including milestone payments based on a level of sales, which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied.

*Stock-Based Compensation*

The Company has an equity plan that allows for the granting of stock options to its employees, directors and consultants for a fixed number of shares with an exercise price equal to the fair value of the shares at date of grant. The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. The fair value of the award is measured on the grant date and is then recognized over the requisite service period, usually the vesting period, in both research and development expenses and general and administrative expenses on the statement of operations, depending on the nature of the services provided by the employees or consultants.

The process of estimating the fair value of stock-based compensation awards and recognizing stock-based compensation cost over their requisite service period involves significant assumptions and judgments. The Company estimates the fair value of stock option awards on the date of grant using the BSM for the remaining awards, which requires that the Company makes certain assumptions regarding (i) the expected volatility in the market price of its common stock; (ii) dividend yield; (iii) risk-free interest rates; and (iv) the period employees are expected to hold the award prior to exercise (referred to as the expected holding period). As a result, if the Company revises its assumptions and estimates, stock-based compensation expense could change materially for future grants.

The Company accounts for stock-based compensation using fair value recognition and records forfeitures as they occur. As such, the Company recognizes stock-based compensation cost only for those stock-based awards that vest over their requisite service period, based on the vesting provisions of the individual grants.

*Derivative Financial Instruments*

The Company does not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. The Company evaluates all of its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then revalued at each reporting date, with changes in the fair value reported in the statements of operations. For stock-based derivative financial instruments, the Company used the Monte Carlo simulation model to value the derivative instruments at inception and on subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative liabilities are classified in the balance sheet as current or non-current based on whether net-cash settlement of the instrument could be required within 12 months of the balance sheet date.

*Intangible Assets*

Intangible assets primarily consist of legal and filing costs associated with obtaining patents and licenses and are amortized on a straight-line basis over their remaining useful lives which are estimated to be 20 years from the effective dates of the University of Pennsylvania (Penn) License Agreements, beginning in July 1, 2002. These legal and filing costs are invoiced to the Company through Penn and its patent attorneys.

Management has reviewed its long-lived assets for impairment whenever events and circumstances indicate that the carrying value of an asset might not be recoverable and its carrying amount exceeds its fair value, which is based upon estimated undiscounted future cash flows. Net assets are recorded on the balance sheet for patents and licenses related to AXAL, ADXS-NEO, ADXS-HOT, ADXS-PSA and ADXS-HER2 and other products that are in development. However, if a competitor were to gain FDA approval for a treatment before us or if future clinical trials fail to meet the targeted endpoints, the Company would likely record an impairment related to these assets. In addition, if an application is rejected or fails to be issued, the Company would record an impairment of its estimated book value.

*Income Taxes*

The Company uses the asset and liability method of accounting for income taxes in accordance with ASC Topic 740, Income Taxes. Under this method, income tax expense is recognized for the amount of (i) taxes payable or refundable for the current year and (ii) deferred tax consequences of temporary differences resulting from matters that have been recognized in an entity's financial statements or tax returns. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the results of operations in the period that includes the enactment date. A valuation allowance is provided to reduce the deferred tax assets reported if, based on the weight of the available positive and negative evidence, it is more likely than not some portion or all of the deferred tax assets will not be realized.

ASC Topic 740-10-30 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. ASC Topic 740-10-40 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. The Company will classify as income tax expense any interest and penalties. The Company has no material uncertain tax positions for any of the reporting periods presented. The Company files tax returns in U.S. federal and state jurisdictions, including New Jersey, and is subject to audit by tax authorities beginning with the fiscal year ended October 31, 2017.

*Leases*

Effective November 1, 2019, the Company adopted ASC Topic 842, *Leases* ("ASC 842"), using the modified retrospective transition approach by applying the new standard to all leases existing as of the date of initial application. Results and disclosure requirements for reporting periods beginning after November 1, 2019 are presented under ASC 842, while prior period amounts have not been adjusted and continue to be reported in accordance with the previous guidance in ASC 840, *Leases*.

At the inception of an arrangement, the Company determines whether an arrangement is or contains a lease based on the facts and circumstances present in the arrangement. An arrangement is or contains a lease if the arrangement conveys the right to control the use of an identified asset for a period in exchange for consideration. Most leases with a term greater than one year are recognized on the balance sheet as operating lease right-of-use assets and current and long-term operating lease liabilities, as applicable. The Company has elected not to recognize on the balance sheet leases with terms of 12 months or less. The Company typically only includes the initial lease term in its assessment of a lease arrangement. Options to extend a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew.

Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as prepaid or accrued rent. The interest rate implicit in the Company's leases is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. In transition to ASC 842, the Company utilized the remaining lease term of its leases in determining the appropriate incremental borrowing rates.

**Recently Issued Accounting Standards Not Yet Effective or Adopted**

Management does not believe that any recently issued, but not yet effective accounting pronouncements, if adopted, would have a material impact on the accompanying condensed consolidated financial statements.

## BIOSIGHT MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis of financial condition and results of operations should be read together with the consolidated financial statements of Biosight and accompanying notes and related financial information, each appearing elsewhere in this proxy statement/prospectus/information statement. This discussion of Biosight's financial condition and results of operations contains certain statements that are not strictly historical and are "forward-looking" statements and involve a high degree of risk and uncertainty. Actual results may differ materially from those projected in the forward-looking statements due to other risks and uncertainties that exist in Biosight's operations, development efforts and business environment, including those set forth in the section titled "Risk Factors" in this proxy statement/prospectus/information statement and the other risks and uncertainties described elsewhere in this proxy statement/prospectus/information statement. All forward-looking statements included in this proxy statement/prospectus/information statement are based on information available to Biosight as of the date hereof, and Biosight assumes no obligation to update any such forward-looking statement. All references in this section to "Biosight," the "Company," "we," "us," or "our" mean Biosight Ltd., unless we state otherwise or the context otherwise indicates.*

**Business Overview**

Biosight is a private Phase 2 clinical-stage biotechnology company developing an innovative therapeutic for hematological malignancies and disorders. Our investigational product, BST-236, is an innovative, proprietary anti-metabolite that seeks to address unmet medical needs by enabling high-dose chemotherapy with reduced systemic toxicity. BST-236 is currently being evaluated as a single agent in a Phase 2b clinical trial, which recently completed enrollment, for the first-line treatment of AML. Interim results demonstrate tolerability with promising efficacy among the challenging population of AML patients who are unfit for intensive standard-of-care chemotherapy. An additional Phase 2 study in patients with relapsed/refractory AML and MDS in collaboration with the European Myelodysplastic Syndrome Cooperative Group was recently launched. A similar Phase 2 study is to be initiated in the US in 2021.

We are dedicated to developing treatments for patients suffering from oncology and hematological malignancies who cannot tolerate the side effects and toxicity levels typically associated with standard chemotherapy treatments. To effectively meet this highly unmet need, we are continuing our efforts to develop BST-236 and additional product candidates by securing a strong patent portfolio partnering with leading scientific personnel and organizations with experience in clinical trials, treatments and diagnostics.

We were formed on November 10, 1999 and since inception, we have devoted substantially all of our efforts and financial resources to organizing and staffing the company, business planning, raising capital, discovering product candidates and securing related intellectual property rights and conducting discovery, research and development activities for our product candidates. We do not have any products approved for sale and have not generated any revenue from product sales. Since inception, we have funded our operations primarily with proceeds from sales of preferred stock and proceeds from the issuance of convertible debt. Through June 30, 2021, we had received net proceeds of $62.6 million from sales of our preferred stock and a convertible security.

Since inception, we have incurred recurring operating losses. For the years ended on December 31, 2019 and 2020 and for the six months ended June 30, 2021, Biosight's net losses were $8.0 million, $10.6 million and $6.3 million, respectively. As of June 30, 2021, we had an accumulated deficit of $45.0 million. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates, notably BST-236. Management believes that Biosight's cash as of June 30, 2021 will be sufficient to fund its projected operations only through mid-2022 and, as a result, there is substantial doubt regarding Biosight's ability to continue as a going concern. Substantial additional financing will be needed to fund Biosight's operations because we expect to continue to incur signficant expenses and operating losses for the forseeable future, and our expenses will likely increase as a result of our ongoing acitivities, particularly if and as we:

- conduct additional clinical trials for BST-236, including but not limited to a Phase 3 clinical study, and other product candidates we may develop in the future;
- continue to discover and develop additional product candidates;

- maintain, expand and protect our intellectual property and patent portfolio;
- seek regulatory approvals for BST-236 and any other product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval;
- hire additional clinical, scientific and commercial personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts, as well as to support our transition to a public reporting company; and
- experience delays in development, manufacture, preclinical and clinical evaluation of any product candidate, including our investigational product candidate, BST-236.

These factors raise substantial doubt about Biosight's ability to continue as a going concern. Since the Company's management is of the opinion that its available funds as of June 30, 2021 are not sufficient to meet its liquidity requirements for the following 12 months. We will not generate revenue from product sales, if any, unless and until we successfully complete clinical development and obtain regulatory approval for BST-236 and any other product candidates we may develop in the future. If we obtain regulatory approval for BST-236 or any of our product candidates and do not enter into a commercialization partnership, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing and distribution. Further, in the event the merger with Advaxis, as described below, occurs, we expect to incur additional costs associated with operating as a public company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions. We may not be able to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we would have to significantly delay, reduce or eliminate the development and commercialization of one or more of our product candidates.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we would be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

***Proposed Merger with Advaxis***

On July 4, 2021, Biosight and Advaxis entered into the Merger Agreement, pursuant to which Merger Sub, a wholly-owned subsidiary of Advaxis, will merge with and into Biosight, with Biosight surviving as a wholly-owned subsidiary of Advaxis. Biosight and Advaxis believe that the merger will result in a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics for the treatment of rare diseases.

The business combination will be accounted for as a reverse acquisition in accordance with U.S. generally accepted accounting principles ("GAAP"). Under GAAP, Biosight will be deemed to be the accounting acquirer for financial reporting purposes. This determination was primarily based on the expectations that, immediately following the Merger: (1) Biosight shareholders will own a substantial majority of the voting rights of the combined company; (2) Biosight will designate a substantial majority of the initial members of the board of directors of the combined company; and (3) Biosight is the larger entity based on enterprise value. Accordingly, for accounting purposes, the business combination will be treated as the equivalent of Biosight issuing common stock to acquire the net assets of Advaxis. As a result of the Merger, the net assets of Advaxis will be recorded at their acquisition-date fair values in the financial statements of Biosight and the reported operating results prior to the business combination will be those of Biosight.

The accompanying financials have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Management believes that, after completion of the merger, with the receipt of the cash available to Advaxis, the combined company's cash will be sufficient to fund its project operations through the 4$^{th}$ quarter of 2022.

**COVID-19 Business Update**

Our management team continues to closely monitor the impact of the COVID-19 pandemic on our business, financial position and results of operations. We are taking proactive measures to protect the health and safety of our employees, patients, and collaborators while ensuring, to the extent possible, business continuity and, in particular, the development of BST-236. While we believe that the measures we are implementing are appropriate and adequately reflect regulatory and public health guidance, we aim to adjust our activities as appropriate in order to comply with additional guidance that may be issued, if any. We follow governmental regulations and guidance issued by the jurisdictions of our principal place of business and where we conduct our clinical studies, including in Israel and the United States, as they have been updated from time to time.

In addition, we have also implemented measures to protect the health and safety of the patients, healthcare workers and employees participating in our ongoing clinical trials. For patients already enrolled in our clinical trials, we are working closely with clinical trial investigators and site staff to continue treatment in compliance with trial protocols and to uphold trial integrity, while working to observe government and institutional guidelines designed to safeguard the health and safety of patients, clinical trial investigators and site staff. We are continuing to evaluate clinical trial site initiations and patient enrollment on a case-by-case and patient-by-patient basis in coordination with clinical trial investigators and site staff. Some clinical trial sites, both within the United States and Israel, continue to screen patients in our clinical trials, and new patients are being enrolled when appropriate. Our clinical trial progression, dosing, patient enrollment and related activities may be delayed, and reporting of some clinical data may be incomplete or delayed if patients enrolled in our clinical trials are unable to fully participate in all necessary measurement protocols, due to prioritization of hospital resources toward the COVID-19 pandemic or concerns among patients about participating in clinical trials during a pandemic, or restrictions imposed by institutions or local, state or national governments, among other factors. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. For example, patients in our clinical trials for BST-236 can involve elderly adults, often with advanced disease, who may not be able to safely participate in clinical trials for these product candidates during the COVID-19 pandemic. We are working with sites and investigators to ensure safe and ethical data collection at future time points through the pandemic in accordance with regulatory guidance. While the COVID-19 pandemic has not resulted in a significant delay to our clinical development timelines to-date, the global pandemic of COVID-19 continues to evolve rapidly, and could materially impact our clinical development and any future commercialization timelines.

Our business could also be harmed by health epidemics wherever we have business operations, including operations of third-party manufacturers, contract research organizations and other third parties upon whom we rely. Biosight is based in Israel, and we have business operations in the United States and certain of our contract manufacturers are located therein. We are also dependent on an international supply chain for products to be used in our clinical trials and, if approved by the regulatory authorities, for commercialization. While the COVID-19 pandemic has not adversely impacted our business operations, international supply chain, productivity or clinical development timelines to-date, executive orders issued by the Israeli government and others have imposed continuing aggressive orders, health directives and recommendations to reduce the spread of the disease, including shelter-in-place directives and executive orders directing that all non-essential businesses close their physical operations, as well as our work-from home policies, may negatively impact productivity, disrupt our business or international supply chain and delay our clinical programs and timelines in the future, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.

The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, these effects could harm our operations, and we will continue to monitor the COVID-19 situation closely. For additional information about risks and uncertainties related to the COVID-19 pandemic that may impact our business, financial condition and results of operations, see “Risk Factors.”

**Components of Results of Operations**

***Operating Expenses***

*Research and Development Expenses*

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect research and development costs to increase for the foreseeable future as our product candidates progress in clinical trials. See “Biosight’s Business — Overview—BST-236.” During the six months ended June 30, 2021 and the year ended December 31, 2020, we have incurred a total of $5.9 million and $9.9 million, respectively, in expenses for research and development.

Research and development expenses consist primarily of costs incurred in connection with the discovery and development of Biosight’s product candidates. Research and development costs are expensed as incurred and include the following:

- costs directly attributable to the conduct of research and development programs, including the cost of clinical trials and clinical trial supplies,
- employee-related expenses, including salaries, share-based compensation expenses, payroll taxes and other employee benefits,
- expenses incurred to acquire, develop and manufacture clinical trial materials and facilities, including lab expenses and consumable equipment; and
- consulting fees.

All costs associated with research and developments are expensed as incurred. Grants received from the Israeli Innovation Authority (“IIA”) for approved research and development projects are recognized at the time Biosight is entitled to such grants, on the basis of the costs incurred and included as a deduction from research and development expenses.

We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense when the goods have been delivered or the services have been performed.

Our direct research and development expenses consist primarily of external costs, such as fees paid to outside consultants, CROs, contract manufacturing organizations and research laboratories in connection with our preclinical development, process development, manufacturing and clinical development activities. We do not allocate employee costs and costs associated with our discovery efforts, laboratory supplies and facilities, including depreciation or other indirect costs, to specific product candidates because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to conduct our research and discovery as well as for managing our preclinical development, process development, manufacturing and clinical development activities. These employees work across multiple programs and, therefore, we do not track our costs by product candidate.

We expect our research and development expenses will increase for the foreseeable future as we expect to advance development of BST-236 and our other product candidates. The successful development of BST-236 and any other product candidates we may develop in the future is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of our current pipeline or any future product candidates we may develop due to the numerous risks and uncertainties associated with clinical development, including those related to:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs that we decide to pursue;
- our ability to maintain our current research and development programs and to establish new ones;
- establishment of appropriate safety profiles with investigational new drug-enabling studies;
- the successful enrollment of patients in our clinical trials;
- the successful initiation and completion of such trials with safety, tolerability and efficacy profiles that are satisfactory to the relevant governmental or regulatory authorities;
- receiving regulatory approvals from the relevant governmental or regulatory authorities;
- the timing, receipt and terms of marketing approvals from relevant governmental or regulatory authorities;
- our ability to establish collaboration agreements for clinical development of product candidates;
- the maintenance of current, and ability to enter into future, agreements with third-party contract manufacturing organizations for the supply of our clinical trials and commercial manufacturing of BST-236 or any product candidates that receive approval, if any;
- obtaining, maintaining, defending and enforcing intellectual property and patent rights;
- our ability to launch commercial sales of BST-236 and any other product candidates, if approved, whether alone or in collaboration with third parties; and
- maintaining a continued safety profile for BST-236 and any other product candidates, if approved.

Any changes to the outcomes of the above variables as they relate to the development of our product candidates, particularly BST-236, could significantly change the costs and timing associated with such development. Further, we could fail to obtain regulatory approval for any of our product candidates, which could result in further costs and an inability to generate product revenue.

*General and Administrative Expenses*

General and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance and administrative functions. General and administrative expenses also include direct and allocated facility-related costs as well as professional fees for legal, patent, consulting, accounting, and audit services.

Our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates. We will incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with being a public company.

***Interest Expense***

On June 16, 2019, Biosight entered a convertible securities agreement with its shareholders, pursuant to which several shareholders agreed to provide Biosight with a convertible security in an amount of $3.6 million. As of March 29, 2020, the date on which the loan was converted into shares of Biosight, the fair value of the convertible security was $4.5 million. We recognized $678,000 and $222,000 for the year ended December 31, 2020 and the year ended December 31, 2019, respectively, as a financial expense due to the change in the fair value of the convertible security.

***Income Taxes***

The standard corporate tax rate in Israel was 23% for the 2020 and 2021 tax years. To date, we have not generated taxable income due to our operating losses. As of December 31, 2020, Biosight had $32.5 million of net carry forward tax losses in Israel, which are available to reduce future taxable income with no limited period of use. We do not expect to pay taxes in Israel until we have taxable income after the full utilization of our carry forward tax losses. Biosight has recorded a full valuation allowance against its deferred tax assets due to the uncertainty of realizing a benefit from those items in the future.

**Results of Operations**

***Comparison of the Six Months Ended June 30, 2021 and June 30, 2020.***

The following table sets forth Biosight's results of operations for the six months ended June 30, 2020 and June 30, 2021:

| | Six Months Ended June 30, | | |
|---|---|---|---|
| | **2020** | **2021** | **Change** |
| | ($ in thousands) | | |
| Operating expenses: | | | |
| Research and development | $ 3,953 | $ 5,859 | $ 1,906 |
| General and administrative | 678 | 981 | 303 |
| Loss from operations | (4,631) | (6,840) | (2,209) |
| Finance Income (expenses), net | 1,026 | 492 | (534) |
| Net loss | $ (3,605) | $ (6,348) | $ (2,743) |

*Research and Development Expenses*

Research and development expenses were $5.8 million for the six months ended on June 30, 2021, compared to $3.9 million for the six months ended on June 30, 2020. The increase of $1.9 million was primarily related to clinical trial, phase II expenses.

*General and Administrative Expenses*

General and administrative expenses were $981,000 for the six months ended on June 30, 2021, compared to $678,000 for the six months ended on June 30, 2020. The increase of $0.3 million was primarily due to a $0.2 million increase in salaries and related costs and a $0.05 million increase in legal and professional fees. Professional fees increased due to higher legal costs and other costs incurred in connection with the proposed merger transaction and costs associated with our ongoing business operations. Salaries and related costs increased due to approx. $150,000 share-based compensation distribution and a 5% increase in salary in January 2021.

*Finance Income, net*

Net finance income was $492,000 during six months ended on June 30, 2021, compared to $1,026,000 net for the six months ended on June 30, 2020. The decrease in finance income of $0.5 million was primarily due to gain from changes in the fair value of warrants and convertible securities of $0.4 million and a currency exchange decrease of $0.1 million.

***Comparison of the Years Ended December 31, 2020 and December 31, 2019.***

The following table sets forth Biosight's results of operations for the years ended December 31, 2020 and December 31, 2019:

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2020** | **2019** | **Change** |
| | ($ in thousands) | | |
| Operating expenses: | | | |
| Research and development | $ 9,920 | $ 6,841 | $ 3,079 |
| General and administrative | 1,657 | 884 | 773 |
| Loss from operations | (11,577) | (7,725) | (3,852) |
| Finance Income (expenses), net | 942 | (322) | 1,264 |
| Net loss | $ (10,635) | $ (8,047) | $ (2,588) |

*Research and Development Expenses*

Research and development expenses were $9.9 million for the year ended December 31, 2020, compared to $6.8 million for the year ended December 31, 2019. The increase of $3.1 million was primarily due to expenses of $2.8 million related to our clinical trials and an increase of $0.3 million in other expenses.

*General and Administrative Expenses*

General and administrative expenses were $1.7 million for the year ended December 31, 2020 compared to $884,000 for the year ended December 31, 2019. The increase of $0.8 million was primarily due to a $0.7 million increase in legal and professional fees and a $0.1 million increase in salary expenses related costs.

*Finance Income, net*

Net finance income was $942,000 during the year ended December 31, 2020, compared to net finance expenses of $322,000 for the year ended December 31, 2019. The increase in finance income of $1.2 million was primarily due to an increase in gain from changes in the fair value of warrants and convertible securities of $1.1 million.

**Liquidity and Capital Resources**

***Sources of Liquidity***

Since inception, we have not generated any revenue and have incurred net losses and negative cash flows from our operations. From inception, we funded our operations primarily with proceeds from sales of preferred stock and proceeds from the issuance of convertible securities. The following table summarizes our sources and uses of cash for each of the periods presented:

| | Year Ended December 31, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | ($ in thousands) | | | |
| | 2019 | 2020 | 2020 | 2021 |
| Net cash used in operating activities | $ (6,676) | $ (10,543) | $ (3,122) | $ (7,834) |
| Net cash used by investing activities | (102) | (3) | (2) | (6) |
| Net cash provided by financing activities | 3,600 | 41,952 | 15,000 | - |
| Net increase (decrease) in cash | $ (3,178) | $ 31,406 | $ 11,876 | $ (7,840) |

***Sources of Funds***

Through June 30, 2021, we received net proceeds of $62.6 million from sales of our preferred stock and the issuance of convertible securities.

The sales of our shares were made, during the past 3 years, pursuant to the following financing transactions:

- *Preferred B-1 Round. On August 9, 2018, Biosight issued 128,076 B-1 Preferred Shares for a total consideration of $6.5 million, and 128,076 Preferred B-1 Warrants for no additional consideration.*

- *2019 convertible security.* On June 16, 2019, Biosight received a $3.6 million investment pursuant to convertible securities from certain shareholders. The security subsequently converted into preferred shares and warrants of Biosight in connection with the Preferred C Round described below.

- *Preferred C Round.* During 2020, Biosight issued 1,726,215 Preferred C Shares and 181,184 Preferred C Warrants for a purchase price of $26.91 per share for total consideration of $42.0 million.

***Uses of Funds***

*Operating Activities*

During the six months ended June 30, 2021, we used $7.8 million of cash in operating activities. Cash used in operating activities reflected our net loss of $6.3 million offset by adjustments required to reconcile net loss to net cash used in operating activities of $1.5 million. The adjustments required to reconcile net loss to net cash used in operating activities were primarily attributable to the changes of $0.9 million in accounts payable and a $0.4 million change in the fair value of warrants partially offset by $0.2 million in shared-based compensation. The changes in accounts payable are primarily due to the higher amount paid to our main suppliers, AMRI and ICON during the six months ended June 30, 2021, as we increased our operational activity and budget during the period.

During the year ended December 31, 2020, we used $10.5 million of cash in operating activities. Cash used in operating activities reflected our net loss of $10.5 million. The adjustments required to reconcile net loss to net cash used in operating activities were primarily attributable to an increase of $0.8 million in accounts payable, a revaluation of convertible securities in an amount of $0.7 million and $0.2 million of share-based compensation expense partially offset by a $1.4 million change in the fair value of warrants and $0.2 million of accrued expenses and other payables. The increase in accounts payable is primarily due to the higher amount paid to our main suppliers, AMRI and ICON during the year ended December 30, 2020, as we increased our operational activity and budget.

During the year ended December 31, 2019, we used $6.7 million of cash in operating activities. Cash used in operating activities reflected our net loss of $8.0 million offset by adjustments required to reconcile net loss to net cash used in operating activities of $1.3 million.

*Investing Activities*

During the six month ended June 30, 2021, we used $6,000 net cash in investing activities primarily attributable to our purchase of fixed assets. During the year ended December 31, 2020, we used $3,000 net cash in investing activities primarily attributable to our purchase of fixed assets.

During the year ended December 31, 2019, net cash used by investing activities was $102,000, primarily attributable to our purchase of fixed assets.

*Financing Activities*

During the six month ended June 30, 2021, we had no financing activities.

During the year ended December 31, 2020, net cash provided by financing activities was $42.0 million, consisting of net proceeds of $42.0 million from our issuance of Preferred C Shares and warrants.

During the year ended December 31, 2019, net cash provided by financing activities was $3.6 million, consisting of proceeds of $3.6 million from our issuance of convertible securities.

***Funding Requirements***

We are currently in the clinical stage of operations and have not yet achieved profitability. We expect to continue to incur significant operating and net losses, as well as negative cash flows from operations, for the foreseeable future as we continue to develop BST-236 and any future product candidates, as well as prepare for potential future regulatory approvals and commercialization of our products. We have not generated any revenue to date and do not expect to generate product revenue unless and until we successfully complete development and obtain regulatory approval for BST-236 or at least one of our product candidates. Management believes that Biosight's cash as of June 30, 2021 will be sufficient to fund its projected operations through mid-2022. Substantial additional financing will be needed to fund Biosight's operations. These factors raise substantial doubt about Biosight's ability to continue as a going concern. In addition, upon the closing of the merger, we expect to incur additional costs associated with operating as a public company. The timing and amount of our operating expenditures will depend largely on:

- progress, timing, costs and results of our clinical trials, including but not limited to a Phase 3 clinical study of BST-236 and any other future product candidates that we may develop;
- the clinical development plans we establish for our product candidates;
- the effects of the COVID-19 pandemic on our business and operations, the medical community and the global economy;
- outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA and other comparable foreign regulatory authorities;
- cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- cost of obtaining necessary intellectual property and defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or our current and future product candidates;
- impacts of competing technological and market developments;
- cost and timing for completing commercial-scale manufacturing activities;

- initiation, progress, timing and results of our commercialization of product candidates, if approved for commercial sale;
- our ability to obtain marketing approval for BST-236 and other product candidates;
- the costs to operate as a public company in the United States, including the need to implement additional financial and reporting systems and other internal systems and infrastructure for our business; and
- delays, if there are any, in development, manufacture, preclinical and clinical evaluation of any product candidate, including our investigational product candidate, BST-236.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution or licensing arrangements with third parties. Management believes that, after completion of the merger, with the receipt of the cash available to Advaxis, the combined company's cash will be sufficient to fund its project operations through the 4$^{th}$ quarter of 2022. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of Biosight may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect the rights of the Biosight shareholders and the rights of the shareholders of the combined organization following the closing of the merger. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our patent portfolio and technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, reduce or eliminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

**Off-Balance Sheet Arrangements**

We do not have any relationships with unconsolidated entities or financial partnerships, including entities sometimes referred to as structured finance or special purpose entities that were established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. We do not engage in off-balance sheet financing arrangements. In addition, we do not engage in trading activities involving non-exchange traded contracts. Therefore, we believe that we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

**Quantitative and Qualitative Disclosure about Market Risk**

We are exposed to a variety of financial risks, including market risk (including foreign exchange risk and price risk), credit and interest risks and liquidity risk. Our overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on our financial performance.

***Foreign currency exchange risk***

The U.S. dollar is the currency of the primary economic environment in which the operations of Biosight are conducted. Almost all of the Company's operating expenses are denominated in dollars or are dollar-linked. The Company's financing has been provided to date in dollars. Accordingly, the Company has virtually no foreign currency exchange risk.

***Credit and rate risks***

Our liquid instruments are held as cash and cash equivalents in highly-rated banks. We estimate that since the liquid instruments are held in this form and with highly-rated institutions, the credit and cash flow interest rate risks associated with these balances are immaterial.

***Inflation-related risks***

We do not believe that the rate of inflation in Israel has had a material impact on our business to date, however, our costs in Israel will increase if inflation in Israel exceeds the devaluation of the shekel against the U.S. dollar or if the timing of such devaluation lags behind inflation in Israel.

**Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these consolidated financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the dates of the balance sheets and the reported amounts of expenses during the reporting periods. In accordance with GAAP, we evaluate our estimates and judgments on an ongoing basis. The most significant estimates and assumptions relate to the fair value of share based compensation, warrants, and clinical trial accruals. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We define our critical accounting policies as those under GAAP that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles.

Our significant accounting policies are more fully described in Note 2 to Biosight's financial statements included elsewhere in this proxy statement/prospectus/information statement. Not all of these significant accounting policies, however, require that we make estimates and assumptions that we believe are "critical accounting estimates." We believe that our estimates relating to significant accounting policies described below have the greatest potential impact on our consolidated financial statements and consider these to be our critical accounting policies and estimates and our "critical accounting estimates."

*Research and Development Expenses*

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of clinical trials, clinical trial supplies, salaries, share-based compensation expenses, payroll taxes and other employee benefits, lab expenses, consumable equipment and consulting fees. All costs associated with research and development are expensed as incurred.

Grants received from the IIA for approved research and development projects are recognized at the time Biosight is entitled to such grants, on the basis of the costs incurred and included as a deduction from research and development expenses.

*Clinical trial accruals*

Clinical trial expenses are charged to research and development expense as incurred. Biosight accrues for expenses resulting from obligations under contracts with clinical research organizations (CROs). The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided. Our objective is to reflect the appropriate trial expense in the financial statements by matching the appropriate expenses with the period in which services and efforts are expended. In the event advance payments are made to a CRO, the payments are recorded as other assets, which will be recognized as expenses as services are rendered.

*Warrants*

Biosight's warrants were issued alongside several series of preferred shares. The warrants are within the scope of ASC 480 and are measured at fair value. Subsequently, the warrants are measured at fair value, with changes recognized in earnings. The fair value of the warrants was determined according to the option-price method (OPM).

*Convertible security*

The convertible security that was converted in 2020 was accounted for using the guidance set forth in the Financial Accounting Standards Board ("FASB") Accounting Standards Codification (ASC) 480, requiring that Biosight first and foremost determine whether the convertible security should be classified as liability. Since the convertible security was convertible into a variable number of shares based predominantly on a fixed monetary amount, the instrument was accounted for as a liability in accordance with ASC 480. The instrument is measured at fair value upon inception, and measured subsequently at fair value with changes in fair value recognized in earnings. The primary assumptions as to the fair value of the convertible security were that the security will be converted at a 20% discount and the expected timing of a qualified financing that would trigger conversion.

*Share-based compensation*

Biosight accounts for stock options and other share-based awards granted to its directors, employees and consultants based on their fair value on the date of the grant and recognizes compensation expense associated with those awards, over the requisite service period, which is generally the vesting period of the respective award. The fair value of each option granted is estimated using the Black-Scholes option pricing method with key inputs determined as follows:

- Volatility is based on a combination of historical volatilities of companies in comparable stages as well as companies in the industry, by statistical analysis of daily share pricing model.
- The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of the options granted in dollar terms.
- The Company's management uses the expected term of each option as its expected life.
- The expected term of the options granted represents the period of time that the granted options are expected to remain outstanding.

As a private company with no active public market for its ordinary shares, Biosight's management periodically determined the estimated per share fair value of its ordinary shares at various dates. Biosight engaged a third-party valuation firm to assist in its estimation of the value of its ordinary shares as of certain prior dates. Biosight's determinations of the fair value of its ordinary shares were made using methodologies, approaches and assumptions consistent with the Accounting and Valuation Guide: Valuation of Privately-Held-Company Equity Securities Issued as Compensation, issued by the American Institute of Certified Public Accountants.

*Income Taxes*

We record income taxes in accordance with ASC Topic 740, Income Taxes ("ASC 740"), which provides for deferred taxes using an asset and liability approach. We recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the differences between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

We account for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, we recognize the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of June 30, 2021, we did not have any uncertain tax positions.

We have incurred substantial losses since our inception and have not yet generated any revenue. We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and we may never achieve profitability. As of December 31, 2020, Biosight had $32.5 million of net carry forward tax losses in Israel, which are available to reduce future taxable income with no limited period of use. We do not expect to pay taxes in Israel until we have taxable income after the full utilization of our carry forward tax losses. Biosight has recorded a full valuation allowance against its deferred tax assets due to the uncertainty of realizing a benefit from those items in the future

*Going Concern*

We assess and determine our ability to continue as a going concern under the provisions of ASC Topic 205-40, "Presentation of Financial Statements—Going Concern," which requires us to evaluate whether there are conditions or events that raise substantial doubt about our ability to continue as a going concern within one year after the date that our annual and interim consolidated financial statements are available for issuance. Certain additional financial statement disclosures are required if such conditions or events are identified. If and when an entity's liquidation becomes imminent, financial statements should be prepared under the liquidation basis of accounting.

Determining the extent, if any, to which conditions or events raise substantial doubt about our ability to continue as a going concern, or the extent to which mitigating plans sufficiently alleviate any such substantial doubt, as well as whether or not liquidation is imminent, requires significant judgment by us. Since we are engaged in research and development activities, we have not derived income from our activities and have incurred accumulated losses in the amount of $38.6 million through December 31, 2020 and negative cash flows from operating activities. Our independent registered public accounting firm audit opinion with respect to our year ended December 31, 2020 contains an explanatory paragraph relating to Biosight's ability to continue as a going concern. Management is of the opinion that our available funds as of June 30, 2021 will be sufficient to fund our projected operations into mid-2022. Substantial additional financing will be needed to fund Biosight's operations because we expect to continue to incur signficant expenses and operating losses for the forseeable future. These factors raise substantial doubt as to our ability to continue as a going concern. The accompanying consolidated financial statements for the year ended on December 31, 2020 has been prepared on a going concern basis, which assumes we will continue to realize our assets and discharge our liabilities in the normal course of business. Management believes that, after completion of the merger, with the receipt of the cash available to Advaxis, the combined company's cash will be sufficient to fund its project operations through the 4$^{th}$ quarter of 2022. If we do not raise the requisite funds, we will need to curtail or cease operations. These financial statements do not include any adjustments that may be necessary should we be unable to continue as a going concern.

**Recent Accounting Pronouncements**

A description of recently issued accounting pronouncements that may potentially impact Biosight's financial position and results of operations is disclosed in Note 2.t. to Biosight's Financial Statements as of December 31, 2020 included elsewhere in this proxy statement/prospectus/information statement.

## MANAGEMENT FOLLOWING THE MERGER

### Executive Officers and Directors

***Executive Officers and Directors of the Combined Company Following the Merger***

Advaxis' Chief Executive Officer, Kenneth A. Berlin, will lead the combined company, with Andres Gutierrez, M.D., Ph.D. (of Advaxis) serving as Chief Medical Officer and Roy Golan (of Biosight) serving as Chief Financial Officer. The board of directors will consist of nine directors: six designated by Biosight and three by Advaxis, with David Sidransky to be nominated as Chairman of the board of directors.

The following table lists the names, ages and positions of the individuals who are expected to serve as executive officers and directors of the combined company upon completion of the merger:

| Name | Age | Position |
|---|---|---|
| ***Executive Officers:*** | | |
| Kenneth A. Berlin | 57 | Chief Executive Officer and Director |
| Roy Golan | 48 | Chief Financial Officer |
| Andres Gutierrez, M.D., Ph.D. | 60 | Chief Medical Officer |
| | | |
| ***Non-Employee Directors:*** | | |
| David Sidransky, M.D. | 60 | Chairman of the Board of Directors Independent Director |
| Pini Orbach, Ph.D. | 57 | Independent Director |
| Aaron Sasson | 62 | Independent Director |
| Briggs Morrison, M.D. | 62 | Independent Director |
| Gary Gordon, M.D., Ph.D. | 69 | Independent Director |
| Gary Titus | 61 | Independent Director |
| Yuval Cabilly, Ph.D. | 41 | Independent Director |
| Dr. Samir Khleif | 58 | Independent Director |

***Executive Officers***

***Kenneth Berlin.*** Mr. Berlin has served as Advaxis' President and Chief Executive Officer and a member of its board of directors since April 2018. Mr. Berlin has served as Advaxis' Interim Chief Financial Officer since September 2020. Prior to joining Advaxis, Mr. Berlin served as President and Chief Executive Officer of Rosetta Genomics from November 2009 until April 2018. Prior to Rosetta Genomics, Mr. Berlin was Worldwide General Manager at cellular and molecular cancer diagnostics developer Veridex, LLC, a Johnson & Johnson company. At Veridex he grew the organization to over 100 employees, launched three cancer diagnostic products, led the acquisition of its cellular diagnostics partner, and delivered significant growth in sales as Veridex transitioned from an R&D entity to a commercial provider of oncology diagnostic products and services. Mr. Berlin joined Johnson & Johnson in 1994 and served as corporate counsel for six years. From 2001 until 2004 he served as Vice President, Licensing and New Business Development, in the pharmaceuticals group, and from 2004 until 2007 served as Worldwide Vice President, Franchise Development, Ortho-Clinical Diagnostics. Mr. Berlin holds an A.B. degree from Princeton University and a J.D. from the University of California Los Angeles School of Law. Mr. Berlin's experience in life science companies, as well as his business experience in general, qualify him to service as our director.

***Roy Golan.*** Mr. Golan is a registered CPA with broad experience in various aspects of public company listings, initial public offerings, and mergers and acquisitions. Prior to joining Biosight, Mr. Golan served in several financial management positions in the biotech industry, including as the Chief Financial Officer of Neuroderm, where he had a pivotal role in their successful initial public offering on Nasdaq, two follow-on offerings, and Neuroderm's acquisition by Mitsubishi Tanabe Pharmaceutical Corporation for a total of $1.1 billion. Mr. Golan started his career at PricewaterhouseCoopers. Mr. Golan holds a B.A. in accounting and business from the Israeli College of Management School of Business and an LL.M. in Law from Bar-Ilan University.

***Andres Gutierrez.*** Dr. Gutierrez has served as Advaxis' Executive Vice President and Chief Medical Officer since April 2018. Prior to joining Advaxis, Dr. Gutierrez served as Chief Medical Officer for Oncolytics Biotech, Inc. from November 2016 to April 2018. Prior to Oncolytics, Dr. Gutierrez was Chief Medical Officer at SELLAS Life Sciences Group from November 2015 to September 2016 and was Medical Director, Early Development Immuno-Oncology, at Bristol-Myers Squibb from October 2012 to November 2015 where he oversaw the development of translational and clinical development of immunooncology programs in solid tumors and hematological malignancies. Earlier, Dr. Gutierrez was medical director for several biotechnology companies, including Sunesis Pharmaceuticals, BioMarin Pharmaceutical, Proteolix and Oculus Innovative Sciences, leading key programs with talazoparib, carfilzomib, nivolumab, relatlimab and anti-CXCR4, among others. Prior to Oculus, he served as Director of the Gene & Cell Therapy Unit at the National Institutes of Health in Mexico City and as a consultant physician at the Hospital Angeles del Pedregal.

***Non-Employee Directors***

***Dr. David Sidransky*.** Dr. Sidransky currently serves as the Chairman of Advaxis' board of directors and has served as a member of our board of directors since July 2013. He is a renowned oncologist and research scientist named and profiled by *Time* magazine in 2001 as one of the top physicians and scientists in America, recognized for his work with early detection of cancer. Since 1994, Dr. Sidransky has been the Director of the Head and Neck Cancer Research Division and Professor of Oncology, Otolaryngology, Genetics, and Pathology at Johns Hopkins University School of Medicine. He has served as Chairman or Lead of the board of directors of Champions Oncology since October 2007 and was a director and Vice-Chairman of ImClone Systems until its merger with Eli Lilly Inc. He is the Chairman of Tamir Biotechnology and Ayala and serves on the board of directors of Galmed and Orgenesis. He has served on scientific advisory boards of MedImmune, Roche, Amgen, and Veridex, LLC (a Johnson & Johnson diagnostic company), among others. Dr. Sidransky served as Director (2005-2008) of the American Association for Cancer Research. He earned his B.S. from Brandeis University and his M.D. from Baylor College of Medicine. Dr. Sidransky's experience in life science companies, as well as his scientific knowledge, qualify him to service as our director and non-executive chairman.

***Pini Orbach, Ph.D.*** Dr. Orbach has been the Head of the Pharma Division of Arkin Holdings since 2010 and a member of the Board at several of its pharmaceutical companies, including UroGen Pharma and Quiet Therapeutics, from which he shares his extensive hands-on drug development and business experience. He originally gained his foundation in US based companies such as, Arisaph Pharmaceuticals and Epix Pharmaceuticals (NASDAQ, EPIX), as well as Israeli-based companies such as, cCAM BioTherapeutics – a cancer immunotherapy company, which was sold to Merck in 2015 for $605M. He holds a PhD from the University of Florida, and was a postdoctoral fellow at Harvard Medical School – Massachusetts General Hospital. Dr. Orbach's experience as an investor in and director of pharmaceutical companies, as well as his scientific knowledge and education, qualify him to serve as one of our directors.

***Briggs Morrison, MD***. Dr. Morrison has, since June 2015, served as an Executive Partner at MPM Capital and CEO at Syndax. Dr. Morrison served as Chief Medical Officer and Executive Vice President for Global Medicines Development at AstraZeneca and Head of Global Medicines Development at AstraZeneca from January 2012 to June 2015, where he oversaw all clinical development functions and late-stage clinical development projects. Prior to that, Dr. Morrison served as Head of Clinical Development at Pfizer, where he oversaw Phase 1-3 development and operations for all therapeutic areas before being appointed the Head of Development, Medical Affairs, Safety and Regulatory Affairs for all Pfizer human health businesses. Dr. Morrison earned his M.D. from the University of Connecticut and completed his training in Internal Medicine at Massachusetts General Hospital and in Medical Oncology at the Dana-Farber Cancer Institute. He also completed a post-doctoral research fellowship in the Department of Genetics at Harvard Medical School and additional post-doctoral work at the Dana-Farber Cancer Institute. He received his B.S. in Biology from Georgetown University. Dr. Morrison's experience as an executive officer and department head of a public pharmaceutical company, and as an investor in healthcare companies, as well as his scientific knowledge and education, qualifies him to serve as one of our directors.

***Gary Gordon, MD, Ph.D.*** Dr. Gordon is an accomplished pharmaceutical executive with an extensive experience in Oncology across all phases of clinical development. Dr. Gordon, currently serving as Venture Advisor at Israel Biotech Fund since June 2019, served as Vice President, Oncology Development at AbbVie from January 2013 to April 2018, where he oversaw the development of AbbVie's oncology projects and helped expand the oncology pipeline. He played a critical role in the oncology business expansion which included the approval of venetoclax, several major acquisitions, multiple Break Through and Orphan Drug Designations, and a development portfolio of nearly 200 studies in approximately 50 countries. Prior to AbbVie, Dr. Gordon served as senior oncology roles including Divisional Vice President, Global Oncology Development at Abbot from September 2003 to December 2012 and as Chief Scientific Officer at Ovation Pharmaceuticals from June 2001 to September 2003, and other roles at Pharmacia and G.D. Searle Company from January 1995 to June 2001. Prior to his career in the pharmaceutical industry, Dr. Gordon was an Associate Professor of Medical oncology at the Johns Hopkins University School of Medicine from 1988 to December 1995. He holds an M.D. and Ph.D. from the Johns Hopkins University School of Medicine where he also completed his residency, fellowship and postdoctoral training. Dr. Gordon's experience as a pharmaceutical executive and in Biotech investment, as well as his scientific knowledge and education, qualifies him to serve as one of our directors.

***Aaron Sasson***. Mr. Sasson has been a member of the Board of Directors of CancerLinQ$^{TM}$ LLC, a subsidiary of the American Society of Clinical Oncology (ASCO) established for the development and operations of the CancerLinQ$^{TM}$ initiative, which seeks dramatic advances in the prevention, diagnosis, treatment, and cure of all types of cancer since November 2014. Mr. Sasson has been a director of Biosight since April 2016. Mr. Sasson is also the founder of several technology companies, lead by Mr. Sasson to technological and commercial success. Mr. Sasson's experience as a successful entrepreneur and as a member of the Board of Directors of CancerLinQ$^{TM}$ LLC qualifies him to serve as one of our directors.

***Gary Titus, CPA*.** Mr. Titus is currently Chief Financial Officer of Blue Lake Biotechnology, a private startup company which is working on several novel vaccine candidates including for Covid-19. Mr. Titus has more than 25 years of business experience in the healthcare and biopharmaceutical industries, primarily in senior management roles. Mr. Titus was Chief Financial Officer of UroGen Pharma LTD, where he led the successful 2017 IPO, from 2015 to 2018. Prior to his appointment as our Chief Financial Officer at UroGen from 2014 to 2015, Mr. Titus held the position of Chief Financial Officer of BioCardia, Inc. Prior to that, from 2008 to 2013, Mr. Titus was Senior Vice President and Chief Financial Officer at SciClone Pharmaceuticals, Inc. From 2006 to 2008, Mr. Titus was Senior Vice President of Finance and Chief Financial Officer at Kosan Biosciences, Inc. From 2003 to 2006, he was Chief Financial Officer and Vice President at Nuvelo, Inc. Earlier in his career, Mr. Titus held a variety of positions at other companies, including Metabolex, Inc., Intrabiotics Pharmaceuticals, Inc. and Johnson & Johnson. He has held Board of Director positions as Audit Committee Chair and Chairman of the Board. Mr. Titus holds a B.Sc. in Accounting from the University of South Florida and a B.Sc. in Finance from the University of Florida. Mr. Titus also completed the Global BioExecutive Program at the University of California Berkeley's Haas School of Business. Mr. Titus' experience as an officer, director and audit committee member qualify him to serve as one of our directors.

***Yuval Cabilly. Ph.D.*** Dr. Cabilly has been Co-Founder and Managing Partner of Israel Biotech Fund since April 2014. Dr. Cabilly has vast experience in identifying, funding and engaging in business development activities of Israeli biotech companies. Dr. Cabilly received his Ph.D. in molecular cell biology

from Tel Aviv University, where he focused his research on a neurodegenerative disease, and several of his articles have been published in well-known scientific journals. Dr. Cabilly's experience as an investor in biotech companies, as well as his scientific knowledge and education, qualify him to serve as one of our directors.

***Dr. Samir Khleif.*** Dr. Khleif is currently a Biomedical Scholar and a professor in Medicine and Oncology at Georgetown University Medical School and the Director of the Cancer for Immunology and Immunotherapy and the Loop Immuno-Oncology Laboratory. Dr. Khleif has served as a member of our Board of Directors since October 2014. He served as the Director of the State of Georgia Cancer Center, Georgia Regents University Cancer Center and the Cancer Service Line. Dr. Khleif was formerly Chief of the Cancer Vaccine Section at the NCI, and also served as a Special Assistant to the Commissioner of the FDA leading the Critical Path Initiative for oncology. Dr. Khleif is a Georgia Research Alliance Distinguished Cancer Scientist and Clinician and holds a professorship in Medicine, Biochemistry and Molecular Biology, and Graduate Studies at Georgia Regents University. Dr. Khleif's research program at Georgia Regents University Cancer Center focuses on understanding the mechanisms of cancer-induced immune suppression, and utilizing this knowledge for the development of novel immune therapeutics and vaccines against cancer. His research group designed and performed some of the first cancer vaccine clinical trials targeting specific genetic changes in cancer cells. He led many national efforts and committees on the development of biomarkers and integration of biomarkers in clinical trials, including the AACR-NCI-FDA Cancer Biomarker Collaborative and the ASCO Alternative Clinical Trial Design. Dr. Khleif was detailed by the US government to serve as the founder and CEO/Director General of the King Hussein Cancer Center (KHCC) in Jordan, the premier cancer center in the Middle East, and also developed the King Hussein Institute of Biotechnology and Cancer (KHIBC), which reformed Jordan's health care system and higher education. Dr. Khleif is the author of many book chapters and scientific articles on tumor immunology and biomarkers process development, and he is the editor for two textbooks on cancer therapeutics, tumor immunology, and cancer vaccines. Dr. Khleif was inducted into the American Society for Clinical Investigation, received the National Cancer Institute's Director Golden Star Award, the National Institutes of Health Award for Merit, the Commendation Medal of the US Public Health Service, and he was recently appointed to the Institute of Medicine National Cancer Policy Forum. Dr. Khleif's distinguished career as well as his extensive expertise in vaccines and immunotherapies qualify him to serve as our director.

**Election of Officers**

The combined company's executive officers will be appointed by, and serve at the discretion of, the combined company's board of directors. There are no family relationships among any of the combined company's proposed directors or executive officers.

**Board of Directors of the Combined Company Following the Merger**

Advaxis' board of directors currently consists of eight directors divided into three staggered classes, with one class to be elected at each annual meeting to serve for a three-year term. The staggered structure of the board of directors will remain in place for the combined company following the completion of the merger. It is anticipated that the incoming directors will be appointed to applicable vacant director seats of the combined company board of directors.

Following the closing of the merger, the combined company expects to identify and appoint, through its nominating and corporate governance committee, an individual to replace Dr. Cabilly on the board of directors within 6 months.

There are no family relationships among any of the proposed combined company directors and officers.

***Director Independence***

Nasdaq's listing standards require that the combined company's board of directors consist of a majority of independent directors, as determined under the applicable rules and regulations of Nasdaq. Each of David Sidransky, Pini Orbach, Aaron Sasson, Briggs Morrison, Gary Gordon, Gary Titus, Yuval Cabilly, and Samir Khleif are expected to qualify as independent directors following the completion of the merger.

***Committees of the Board of Directors***

Presently, Advaxis' board of directors has the following standing committees: Audit Committee, Compensation Committee, Nominating and Corporate Governance Committee, and the Research and Development Committee. Each of the standing committees is composed solely of independent directors. Following the completion of the merger the combined company will continue to have the following standing committees: Audit Committee, Compensation Committee, Nominating and Corporate Governance Committee, and Research and Development Committee.

*Audit Committee*

Advaxis' audit committee oversees its corporate accounting and financial reporting process. Among other matters, the audit committee is responsible for recommending the engagement of auditors to the full board of directors; reviewing the results of the audit engagement with the independent registered public accounting firm; reviewing the quality and integrity of our financial statements in consultation with our independent accountants and suggesting an appropriate course of action for any irregularities; reviewing the adequacy, scope, and results of the internal accounting controls and procedures; reviewing the degree of independence of the auditors, as well as the nature and scope of our relationship with our independent registered public accounting firm; and reviewing the auditors' fees.

The audit committee of the combined company is expected to retain these duties and responsibilities following the completion of the merger.

In connection with the closing of the merger, the combined company's board of directors is expected to select members of the audit committee. To qualify as independent to serve on the combined company's audit committee, listing standards of Nasdaq and the applicable SEC rules require that a director not accept any consulting, advisory or other compensatory fee from the combined company, other than for service as a director, or be an affiliated person of the combined company. Advaxis and Biosight believe that, following the completion of the merger, the composition of the audit committee will comply with the applicable requirements of the rules and regulations of Nasdaq and the SEC.

*Compensation Committee*

Advaxis' compensation committee determines the salaries, bonuses, and incentive and equity compensation of our officers subject to applicable employment agreements, provides recommendations for the salaries and incentive compensation of our other employees and consultants, and reviews and oversees our compensation programs and policies generally. For executives other than the Chief Executive Officer, the compensation committee receives and considers performance evaluations and compensation recommendations submitted to the compensation committee by the Chief Executive Officer. In the case of the Chief Executive Officer, the evaluation of his performance is conducted by the compensation committee, which determines any adjustments to his compensation as well as awards to be granted.

The compensation committee of the combined company is expected to retain these duties and responsibilities following completion of the merger.

In connection with the closing of the merger, the combined company's board of directors is expected to select members of the compensation committee. Each member of the combined company's compensation committee is expected to be a "non-employee" director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange Act and independent within the meaning of the independent director guidelines of Nasdaq. Advaxis and Biosight believe that, following the completion of the merger, the composition of the compensation committee will comply with the applicable requirements of the rules and regulations of Nasdaq.

*Nominating and Corporate Governance Committee*

The functions of Advaxis' nominating and corporate governance committee include identifying and recommending to the board of directors individuals qualified to serve as members of the board of directors and on the committees of the board of directors; advising the board of directors with respect to matters of board composition, procedures and committees; developing and recommending to the board of directors a set of corporate governance principles applicable to us and overseeing corporate governance matters generally including review of possible conflicts and transactions with persons affiliated with directors or members of management; and overseeing the annual evaluation of the board of directors and our management.

The nominating and corporate governance committee of the combined company is expected to retain these duties and responsibilities following completion of the merger.

In connection with the closing of the merger, the combined company's board of directors is expected to select members of the nominating and corporate governance committee. Advaxis and Biosight believe that, after the completion of the merger, the composition of the nominating and corporate governance committee will meet the requirements for independence under, and the functioning of such nominating and corporate governance committee will comply with, any applicable requirements of the rules and regulations of Nasdaq.

***Research and Development Committee***

Advaxis' research and development committee was established in August 2013 with the purpose of providing advice and guidance to the board of directors on scientific and medical matters and development. The functions of the research and development committee include providing advice and guidance to the board of directors on scientific matters and providing advice and guidance to the board of directors on medical matters. The combined company will also have a research and development committee.

***Compensation Committee Interlocks and Insider Participation***

In connection with the closing of the merger, the combined company's board of directors is expected to select members of the compensation committee. Each member of the compensation committee is expected to be a "non-employee" director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange Act and independent within the meaning of the independent director guidelines of Nasdaq. None of the proposed combined company's executive officers serves as a member of the board of directors or compensation committee of any entity that has one or more executive officers who is proposed to serve on the combined company's board of directors or compensation committee following the completion of the merger.

**Non-Employee Director Compensation**

Please refer to "*Advaxis Director Compensation*" above for a discussion of Advaxis' current policies with regard to the compensation of its non-employee directors. In connection with closing of the merger, it is expected that the combined company will provide compensation to non-employee directors that is consistent with Advaxis' current practices; however, these director compensation policies may be re-evaluated by the combined company and the compensation committee following the completion of the merger and may be subject to change. Non-employee directors are expected to receive an annual retainer fee and equity compensation in the form of a stock option grant.

## CERTAIN RELATIONSHIPS AND RELATED-PARTY TRANSACTIONS OF THE COMBINED COMPANY

In addition to the compensation arrangements, including employment, termination-of-employment and change-in-control arrangements, with Biosight's and Advaxis' directors and executive officers, including those discussed in the sections titled "*Management Following the Merger*," "*Biosight Executive Compensation*" and "*Advaxis Executive Compensation*," the following is a description of each transaction involving Advaxis since November 1, 2018, each transaction involving Biosight since January 1, 2019 and each currently proposed transaction in which:

- either Biosight or Advaxis has been or are to be a participant;
- the amounts involved exceeded or will exceed the lesser of $120,000 and 1% of the average of Biosight's or Advaxis' total assets at year end for the last two completed fiscal years, as applicable; and
- any of Biosight's or Advaxis' directors, executive officers or holders of more than 5% of Biosight's or Advaxis' capital stock, or an affiliate or immediate family member of the foregoing persons, had or will have a direct or indirect material interest.

**Dr. Sidransky's Interests in the Merger**

Dr. Sidransky, a member of the Advaxis board of directors, is a co-founder and owner of Israeli Biotech Fund. Israeli Biotech Fund is an owner of shares (or options to purchase shares) of Biosight. Israeli Biotech Fund I, L.P. and Israeli Biotech Fund II, L.P. collectively own an aggregate of 371,608 of Biosight's preferred C shares and warrants to purchase up to 48,774 of Biosight's preferred C shares, which represent, in the aggregate, ownership of approximately 10% of Biosight calculated on a fully diluted basis.

**Biosight Transactions**

Described below are any transactions occurring since January 1, 2019 to which Biosight was a party and in which a director, executive officer, or a principal owner according to ASC 850-10-20 of Biosight had or will have a direct or indirect material interest.

*Options Granted to Directors and Executive Officers*

In the years ended December 31, 2019 and 2020, Biosight awarded options to purchase 34,408 and 139,031 shares, respectively, to executive officers and directors. Unvested options held by service providers shall become fully vested at the effective time of the merger.

*Convertible Security*

On June 16, 2019, Biosight entered into a convertible security agreement (the "CSA"), pursuant to which, the following existing shareholders each owning more than 5% of the Company's issued and outstanding share capital agreed to provide the Company with an amount of $3.6 million in several installments in exchange for a convertible security: (i) Arkin Bio Ventures, Limited Partnership, (ii) Marstrand Partners, Limited Partnership, (iii) Odesey I, Limited Partnership, (iv) Ilan Holdings (M&I) Ltd. and (v) Tech Pe Investments Corp.

On March 29, 2020, in connection with the Preferred C Shares Share Purchase Agreement (the "PC SPA"), the convertible security converted into 154,393 Preferred C Shares and 38,599 Preferred C Warrants. On December 1, 2020, such number of Preferred C Shares was increased to 167,223 and such number of Preferred C Warrants was increased to 41,807 as a result of a reduction in the price per share of the Preferred C Shares as set forth in the PC SPA.

*Issuance of Preferred Shares to Existing Shareholders in Private Placement*

During 2020, the Company issued 1,726,215 Preferred C Shares (including Preferred C Shares that were issued to lenders under the CSA) and 495,730 Preferred C Warrants (including Preferred C Warrants that were issued in connection with restructuring of previously issued Preferred B and B-1 Warrants) for a purchase price of $26.91 per share to certain investors, including the following investors each holding more than 5% of the Company's issued and outstanding share capital: (i) Arkin Bio Ventures, Limited Partnership, (ii) Marstrand Partners, Limited Partnership, (iii) Odesey I, Limited Partnership, (iv) Ilan Holdings (M&I) Ltd., (v) Tech Pe Investments Corp., (vi) Arkin Communication Ltd.; (vii) Israel Biotech Fund I, Limited Partnership, and (viii) Israel Biotech Fund II, Limited Partnership. The preferred shares were issued in three tranches throughout the year, an initial tranche, a milestone tranche, and deferred closing tranche. The total consideration paid for these securities was $42.0 million (excluding the consideration paid pursuant to the CSA).

**Advaxis Transactions**

Advaxis' policy is to enter into transactions with related parties on terms that, on the whole, are no more favorable, or no less favorable, than those available from unaffiliated third parties. Based on our experience in the business sectors in which we operate and the terms of our transactions with unaffiliated third parties, we believe that all transactions that we enter will meet this policy standard at the time they occur.

**Indemnification Agreements**

Advaxis has offered to enter into indemnification agreements with all directors and has entered into an indemnification agreement with all directors except Samir Khleif. Advaxis has also entered into an indemnification agreement with three of its executive officers, Molly Henderson, Ken Berlin and Andres Gutierrez. The indemnification agreements and its amended and restated certificate of incorporation and amended and restated bylaws require Advaxis to indemnify its directors and executive officers to the fullest extent permitted by Delaware law.

**Support Agreements**

In connection with the execution of the Merger Agreement, certain Biosight directors, executive officers, and shareholders, who collectively beneficially own or control approximately 24.39% of Biosight's issued and outstanding share capital on a fully diluted, as-converted to ordinary shares basis as of June 30, 2021, entered into voting agreements with Advaxis under which such shareholders have agreed to, among other things, vote in favor of the merger and the Merger Agreement and against any competing transaction. For a more complete description, see the section titled "*Agreements Related to the Merger—Voting Agreements*" beginning on page 155 of this proxy statement/prospectus/information statement.

## UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS

The following unaudited pro forma condensed combined financial information is presented to illustrate the effect of the merger of Biosight and Advaxis. The information under "Unaudited Pro Forma Condensed Combined Balance Sheet" in the table below gives effect to the merger as if it had taken place on June 30, 2021. The information under "Unaudited Pro Forma Condensed Combined Statement of Operations" in the table below gives effect to the merger as if it had taken place on January 1, 2020, the first day of Biosight's 2020 fiscal year. This unaudited pro forma condensed combined financial information was prepared using the acquisition method of accounting where Biosight is considered the acquirer of Advaxis for accounting purposes.

Advaxis and Biosight have different fiscal years. Advaxis' fiscal year ends on October 31, whereas Biosight's fiscal year ends on December 31. The unaudited pro forma condensed combined balance sheet and statements of income have been prepared utilizing period ends that differ by less than 93 days, as permitted by Rule 11-02 of Regulation S-X of the Exchange Act. All dollar amounts, except per share, are in thousands. At the close of the merger, Advaxis will adopt Biosight's fiscal year end of December 31.

The unaudited pro forma condensed combined financial information is presented to illustrate the estimated effects of the pending merger between Biosight and Advaxis based on the historical financial position and results of operations of Biosight and Advaxis. It is presented as follows:

- The unaudited pro forma condensed combined balance sheet as of June 30, 2021 was prepared based on (i) the historical unaudited condensed consolidated balance sheet of Biosight as of June 30, 2021 and (ii) the historical unaudited condensed balance sheet of Advaxis as of April 30, 2021.

- The unaudited pro forma combined statement of operations for the year ended December 31, 2020 was prepared based on (i) the historical audited statement of operations of Biosight for the year ended December 31, 2020 and (ii) the historical audited statement of operations of Advaxis for the year ended October 31, 2020.

- The unaudited pro forma condensed combined statement of operations for the six months ended June 30, 2021 was prepared based on (i) the historical unaudited statement of operations of Biosight for the six months ended June 30, 2021 and (ii) the historical unaudited condensed statement of operations of Advaxis for the six months ended April 30, 2021.

The unaudited pro forma condensed combined financial information set forth below primarily gives effect to the following:

- the consummation of the merger;
- the application of the acquisition method of accounting in connection with the reverse merger in accordance with U.S. GAAP;
- the conversion of Biosight preferred stock into Advaxis common stock;
- exercise of Biosight warrants;
- transaction costs incurred in connection with the merger;
- 1-for-12 reverse stock split of Advaxis common stock.

Assumptions underlying the pro forma adjustments are described in the accompanying notes, which should be read in conjunction with the unaudited pro forma condensed combined financial information.

The unaudited pro forma condensed combined financial information has been presented for informational purposes only and is not necessarily indicative of what the combined company's financial position or results of operations actually would have been had the merger been completed as of the dates indicated. In addition, the unaudited pro forma condensed combined financial information does not purport to project the future financial position or operating results of the combined company. The historical consolidated financial information has been adjusted in the accompanying unaudited pro forma condensed combined financial information to give effect to unaudited pro forma events. The accompanying unaudited pro forma condensed combined statements of operations do not include any pro forma adjustments to reflect certain expected financial benefits of the merger, such as tax savings, cost synergies or revenue synergies, or the anticipated costs to achieve those benefits, including the cost of integration activities, or restructuring actions which may be achievable. Future results may vary significantly from the results reflected due to various factors, including those discussed in the section entitled "Risk Factors" beginning on page 17. The information presented below should be read in conjunction with the historical consolidated financial statements of Advaxis and Biosight, including the related notes, included in the proxy statement/prospectus filed with the SEC. See the sections entitled "Where You Can Find More Information" and "Unaudited Pro Forma Condensed Combined Financial Information," beginning on pages 207 and 214, respectively.

The unaudited pro forma condensed combined financial information has been prepared using the acquisition method of accounting under existing GAAP, which is subject to change. Biosight is deemed the accounting acquirer in the merger for accounting purposes and Advaxis is treated as the acquiree, based on a number of factors considered at the time of preparation of this Registration Statement, including control over the post-merger company as evidenced by the composition of the board of directors as well as the relative equity ownership after the closing of the merger. The application of acquisition accounting of Advaxis is dependent upon the working capital positions at the closing of the merger and on other factors such as the share price of Advaxis as well as certain valuations and other studies that have yet to progress to a stage where there is sufficient information for a definitive measurement. The combined company will complete the valuations and other studies upon completion of the merger and will finalize the purchase price allocation as soon as practicable within the measurement period, but in no event later than one year following the closing date of the merger. The assets and liabilities of Advaxis and other pro forma adjustments have been measured based on various preliminary estimates using assumptions that Advaxis and Biosight believe are reasonable, based on information that is currently available. Accordingly, the pro forma adjustments are preliminary. Differences between these preliminary estimates and the final acquisition accounting could be significant, and these differences could have a material impact on the accompanying unaudited pro forma condensed combined financial information and the combined company's future results of operation and financial position.

The unaudited pro forma condensed combined financial information has been compiled in a manner consistent with the accounting policies adopted by Biosight. Upon completion of the merger, the combined company will perform a detailed review of Advaxis' accounting policies and will conform the combined company policies. The combined company may identify differences between the accounting policies of the two companies that, when conformed, could have a material impact on the consolidated financial statements of the combined company. Transactions between Biosight and Advaxis during the periods presented in the unaudited pro forma condensed combined financial information were not significant.

This unaudited pro forma condensed combined financial information was derived from and should be read in conjunction with the accompanying notes, as well as the following historical financial statements and the related notes of Biosight and Advaxis:

- Separate historical audited financial statements of Biosight as of and for the years ended December 31, 2020 and 2019 and unaudited condensed consolidated financial statements of Biosight as of June 30, 2021 and for the six months ended June 30, 2021 and 2020 and the related notes included in this proxy statement/prospectus/information statement; and
- Separate historical audited financial statements of Advaxis as of and for the years ended October 31, 2020 and 2019 and unaudited financial statements of Advaxis as of and for the six months ended April 30, 2021 and the related notes included elsewhere in this proxy statement/prospectus/information statement or separately filed with the SEC on Form 10-Q on June 16, 2021, as applicable.

**Unaudited Pro Forma Condensed Balance Sheet**
**As of June 30, 2021**
(in thousands)

| ASSETS | Biosight LTD. June 30, 2021 | Advaxis, Inc. April 30, 2021 | Pro Forma Adjustments | | Pro Forma Combined |
|---|---|---|---|---|---|
| Current assets: | | | | | |
| Cash and cash equivalents | $ 24,434 | $ 48,110 | (2,485) | **5 C** | $ 77,956 |
| | | | (1,750) | **5 D** | |
| | | | (2,000) | **5 E** | |
| | | | 11,647 | **5 F** | |
| Accounts receivable | - | 1,375 | - | | 1,375 |
| Deferred expenses | - | 1,333 | - | | 1,333 |
| Prepaid expenses and other current assets | - | 1,295 | - | | 1,295 |
| Other receivables | 460 | - | - | | 460 |
| Total current assets | 24,894 | 52,113 | 5,412 | | 82,419 |
| | | | | | |
| Non-current assets: | | | | | |
| Operating lease right of use | 167 | - | - | | 167 |
| Property and equipment, net | 146 | 333 | - | | 479 |
| Intangible assets (net of accumulated amortization) | - | 3,325 | 10,325 | **5 B** | 13,650 |
| Goodwill | - | - | 21,442 | **5 A** | 21,442 |
| Total assets | $ 25,207 | $ 55,771 | $ 37,179 | | $ 118,157 |
| | | | | | |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | | | | |
| Current liabilities: | | | | | |
| Trade payables | 745 | 1,156 | - | | 1,901 |
| Other payables and accrued expenses | 173 | 2,133 | - | | 2,306 |
| Operating lease liabilities | 99 | - | - | | 99 |
| Deferred revenue | - | - | - | | - |
| Warrants | 5,236 | 4,931 | (5,236) | **5 F** | 29 |
| | | | (4,902) | **5 G** | |
| Total current liabilities | 6,253 | 8,220 | (10,138) | | 4,335 |
| | | | | | |
| Operating lease liabilities | 86 | - | - | | 86 |
| Total liabilities | 6,339 | 8,220 | (10,138) | | 4,421 |
| | | | | | |
| Commitments and Contingencies | | | | | |
| | | | | | |
| Mezzanine equity | | | | | |
| Preferred A-1 Shares | 3,850 | - | (3,850) | | - |
| Preferred A-3 Shares | 200 | - | (200) | | - |
| Preferred B Shares | 4,122 | - | (4,122) | | - |
| Preferred B-1 Shares | 4,369 | - | (4,369) | | - |
| Preferred C Shares | 44,482 | - | (44,482) | | - |
| Total mezzanine equity | 57,023 | - | (57,023) | **5 H** | - |
| | | | | | |
| Capital deficiency/shareholders' equity (deficit): | | | | | |
| Preferred stock | - | - | - | | - |
| Common stock | - | 146 | (97) | **5 J** | 49 |
| Ordinary shares | 2 | - | (2) | **5 I** | - |
| Additional paid-in capital | 6,833 | 467,227 | 21,442 | **5 A** | 164,912 |
| | | | 10,325 | **5 B** | |
| | | | 16,883 | **5 F** | |
| | | | 4,902 | **5 G** | |
| | | | 57,023 | **5 H** | |
| | | | 2 | **5 I** | |
| | | | (419,725) | **5 J** | |
| Accumulated deficit | (44,990) | (419,822) | (2,485) | **5 C** | (51,225) |
| | | | (1,750) | **5 D** | |
| | | | (2,000) | **5 E** | |
| | | | 419,822 | **5 J** | |
| Total stockholders' equity | (38,155) | 47,551 | 104,340 | | 113,736 |
| Total liabilities and stockholders' equity | $ 25,207 | $ 55,771 | $ 37,179 | | $ 118,157 |

**Unaudited Pro Forma Condensed Combined Statement of Operations**
**Year ended December 31, 2020**
(in thousands, except share and per share data)

| | Biosight LTD. December 31, 2020 | Advaxis, Inc. October 31, 2020 | Pro Forma Adjustments | | Pro Forma Combined |
|---|---|---|---|---|---|
| Revenue | $ - | $ 253 | $ - | | $ 253 |
| Operating expenses: | | | | | |
| Research and development | 9,920 | 15,612 | - | | 25,532 |
| General and administrative | 1,657 | 11,090 | (137) | **6 A** | 18,845 |
| | | | 2,485 | **6 B** | |
| | | | 2,000 | **6 C** | |
| | | | 1,750 | **6 D** | |
| Total operating expenses | 11,577 | 26,702 | 6,098 | | 44,377 |
| Loss from operations | (11,577) | (26,449) | (6,098) | | (44,124) |
| Other income (expense): | | | | | |
| Gain from change in fair value of warrants and convertible security | 718 | - | (1,396) | **6 E** | (678) |
| Finance income | 264 | 110 | - | | 374 |
| Finance expenses | (40) | - | - | | (40) |
| Loss on shares issued in settlement of warrants | - | (77) | - | | (77) |
| Other expense | - | (3) | - | | (3) |
| Net loss before income taxes | (10,635) | (26,419) | (7,494) | | (44,548) |
| Income tax expense | - | 50 | - | | 50 |
| Net loss | $ (10,635) | $ (26,469) | $ (7,494) | | $ (44,598) |
| Net income (loss) per share basic & diluted | $ (12.33) | $ (0.43) | $ - | | $ (1.06) |
| Weighted average number of common shares outstanding basic & diluted | 862,877 | 61,003,839 | | | 41,921,210 |

**Unaudited Pro Forma Condensed Combined Statement of Operations**
**Six months ended June 30, 2021**
(in thousands, except share and per share data)

| | Biosight LTD. June 30, 2021 | Advaxis, Inc. April 30, 2021 | Pro Forma Adjustments | | Pro Forma Combined |
|---|---|---|---|---|---|
| Revenue | $ - | $ 2,990 | $ - | | $ 2,990 |
| Operating expenses: | | | | | |
| Research and development | 5,859 | 6,914 | - | | 12,773 |
| General and administrative | 981 | 6,360 | (135) | **6 A** | 7,206 |
| Total operating expenses | 6,840 | 13,274 | (135) | | 19,979 |
| Operating Loss | (6,840) | (10,284) | 135 | | (16,989) |
| Other income (expense): | | | | | |
| Gain from change in fair value of warrants and convertible security | 398 | - | (398) | **6 E** | - |
| Finance income | 96 | 3 | - | | 99 |
| Finance expense | (2) | - | - | | (2) |
| Net changes in fair value of derivative liabilities | - | 968 | (980) | **6 E** | (12) |
| Other expense | - | 229 | - | | 229 |
| Net loss before income taxes | (6,348) | (9,084) | (1,243) | | (16,675) |
| Income tax expense | - | - | - | | - |
| Net loss | $ (6,348) | $ (9,084) | $ (1,243) | | $ (16,675) |
| Net income (loss) per share basic & diluted | $ (7.20) | $ (0.08) | $ - | | $ (0.36) |
| Weighted average number of common shares outstanding basic & diluted | 877,976 | 111,895,403 | - | | 46,162,174 |

1. Description of the Merger

On July 4, 2021, Advaxis, Biosight and Merger Sub entered into the Merger Agreement. Pursuant to the terms of the Merger Agreement, Merger Sub will merge with and into Biosight, with Biosight surviving the merger as a wholly owned subsidiary of Advaxis. For financial reporting and accounting purposes, Biosight will be the acquirer of Advaxis upon completion of the merger.

The Merger Agreement provides, among other things, that on the terms and subject to the conditions set forth therein: (i) Merger Sub will merge with and into Biosight, with Biosight being the surviving entity as a wholly-owned subsidiary of Advaxis (the "Merger" and collectively with the other transactions contemplated by the Merger Agreement, the "Transactions"), (ii) each share of Biosight issued and outstanding immediately prior to the Merger (excluding certain dormant shares under Israeli law, which will be cancelled, retired and cease to exist) will automatically be deemed to have been transferred to Biosight in exchange for the right to receive 118.2009 shares (the "Exchange Ratio") of common stock, par value $0.001 per share (the "Common Stock") of the Company, (iii) any outstanding options or other rights to purchase ordinary or preferred shares of Biosight (the "Biosight Options") will be assumed by the Company and converted into options to purchase shares of Common Stock of the Company at the Exchange Ratio, at an exercise price obtained by dividing the exercise prior per share of the Biosight Option prior to the merger by the Exchange Ratio, (iv) to the extent reasonably necessary to comply with the listing criteria of The Nasdaq Stock Market LLC (the "Nasdaq"), the Company will submit for the approval of the Company's stockholders a proposal to effect a reverse stock split at a ratio to be mutually agreed between the Company and Biosight (the "Reverse Split"), and (v) the Company will file an amendment to its certificate of incorporation to, among other items, (a) increase the number of authorized shares of Common Stock, if necessary to effect the Merger, (b) change the name of the Company to Biosight, Inc. or some other name to be determined by Biosight, and (c) effect the Reverse Split, if necessary.

2. Basis of Presentation

The following unaudited pro forma condensed combined financial information has been prepared in accordance with Article 11 of Regulation S-X as amended by the final rule, Release No. 33-10786 “Amendments to Financial Disclosures about Acquired and Disposed Businesses.” Release No. 33-10786 replaces the existing pro forma adjustment criteria with simplified requirements to depict the accounting for the transaction (“Transaction Accounting Adjustments”) and present the reasonably estimable synergies and other transaction effects that have occurred or are reasonably expected to occur (“Management’s Adjustments”). Only Transaction Accounting Adjustments are presented in the following unaudited pro forma condensed combined financial information.

The merger is treated as a business combination for accounting purposes, with Biosight as the deemed accounting acquirer and Advaxis as the deemed accounting acquiree. Therefore, the historical basis of Biosight’s assets and liabilities will not be remeasured as a result of the merger. In identifying Biosight as the acquiring entity, the companies considered the structure of the merger, relative outstanding share ownership at closing and the composition of the combined company’s board of directors and senior management.

The unaudited pro forma condensed combined financial information was prepared using the acquisition method of accounting in accordance with ASC 805, which requires, among other things, that assets acquired and liabilities assumed in a business combination be recognized at their fair values as of the acquisition date. The acquisition method of accounting uses the fair value concepts defined in ASC Topic 820, “Fair Value Measurement” (“ASC 820”). Fair value is defined in ASC 820 as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Market participants are assumed to be buyers or sellers in the most advantageous market for the asset or liability. Fair value measurement for an asset assumes the highest and best use by these market participants.

Fair value measurements can be highly subjective, and it is possible the application of reasonable judgment could develop different assumptions resulting in a range of alternative estimates using the same facts and circumstances.

Fair value estimates were determined based on preliminary discussions between Biosight and Advaxis management, and a preliminary valuation of Advaxis’ assets and liabilities using June 30, 2021 as the measurement date. The allocation of the aggregate merger consideration used in the preliminary unaudited pro forma condensed combined financial information is based on preliminary estimates. The estimates and assumptions are subject to change as of the effective time of the merger. The final determination of the allocation of the aggregate merger consideration will be based on the actual tangible and intangible assets and the liabilities of Advaxis at the effective time of the merger. Refer to Note 4 for additional information.

For pro forma purposes, the valuation of consideration transferred is based on, among other things, the number of Advaxis common shares outstanding and price per share as of the close of business on September 28, 2021. Refer to Note 4 for additional information. This is used for pro forma purposes only. The consideration transferred will ultimately be based on the number of Advaxis common shares outstanding and price per share as of immediately prior to the effective time of the merger, which could materially change from the assumptions included in this pro forma financial information. Additionally, for the purposes of this pro forma financial information, the consideration transferred ascribes value to outstanding Advaxis warrants and Advaxis options based on the fair value of the instruments.

The unaudited pro forma combined balance sheet data gives effect to the merger as if it had occurred on June 30, 2021. The unaudited pro forma combined statement of operations data gives effect to the merger as if it had occurred on January 1, 2020.

The unaudited pro forma condensed combined financial information is presented solely for informational purposes and is not necessarily indicative of the combined results of operations or financial position that might have been achieved for the period or date indicated, nor is it necessarily indicative of the future results of the combined company. The unaudited pro forma condensed combined financial information has not been adjusted to give effect to certain expected financial benefits of the merger, such as cost synergies or the anticipated costs to achieve these benefits, including the cost of integration activities.

3. Accounting Policies

The unaudited pro forma condensed combined financial information has been compiled in a manner consistent with the accounting policies of Biosight. Following the merger, the combined company will conduct a review of accounting policies of Advaxis in an effort to determine if differences in accounting policies require further reclassification of results of operations or reclassification of assets or liabilities to conform to Biosight's accounting policies and classifications. As a result of that review, the combined company may identify differences among the accounting policies of the companies that, when conformed, could have a material impact on the unaudited pro forma condensed combined financial information.

4. Reverse acquisition and purchase price allocation

Fair Value of Total Consideration Transferred

The fair value of preliminary purchase consideration expected to be transferred on the closing date includes the value of the number of shares of the combined company to be owned by Advaxis shareholders at closing of the merger and the fair value of common share stock options and warrants outstanding ("Share-based Instruments") at such date using a Black-Scholes model. The fair value per share of Advaxis' common stock used for the preliminary purchase price allocation was $0.50 per share the closing price of Advaxis common stock on September 28, 2021. The estimated value of the purchase consideration reflected in this pro forma condensed combined financial information does not purport to represent the actual value of the purchase consideration that will be deemed to be received by Advaxis shareholders when the Merger is consummated. The fair value of equity securities issued as part of the purchase consideration will be measured on the Closing Date at the then-current market price of Advaxis common stock. This requirement will likely result in a per share equity component different from the $0.50 assumed in this pro forma condensed combined financial information and that difference may be material.

| **Purchase consideration (thousands in USD except share and per share amounts)** | | **Amounts** |
|---|---|---|
| Number of Advaxis common shares outstanding as of September 28, 2021 | | 145,638,459 |
| Advaxis price per share as of September 28, 2021 | $ | 0.500 |
| Fair value of common shares | $ | 72,819 |
| Fair value of share-based instruments | $ | 11,430 |
| Fair value of total purchase consideration transferred | $ | 84,249 |

*Purchase Price Allocation*

The following is a preliminary estimate of the allocation of the purchase price to acquired identifiable assets and assumed liabilities, which includes preliminary purchase accounting adjustments to reflect the fair value of intangible assets acquired:

| **(thousands in USD)** | **Amounts** |
|---|---|
| Cash and cash equivalents | $ 48,110 |
| Accounts receivable | $ 1,375 |
| Deferred expenses | 1,333 |
| Prepaid expenses and other current assets | 1,295 |
| Property and equipment, net | 333 |
| IP R&D | 12,800 |
| License Agreements | 850 |
| Goodwill | 21,442 |
| Total assets | 87,538 |
| | |
| Current liabilities | (3,289) |
| Total liabilities | (3,289) |
| Estimated purchase price | $ 84,249 |

The fair value estimate for all identifiable intangible assets is preliminary and is based on assumptions that market participants would use in pricing an asset, based on the most advantageous market for the asset (i.e., its highest and best use). The residual goodwill value includes the fair value of Advaxis' workforce (including the Chief Executive Officer and other key employees). It also reflects the synergies Biosight expects to receive by combining operations with Advaxis. This preliminary fair value estimate could include assets that are not intended to be used, may be sold, or are intended to be used in a manner other than their best use. The final determination of fair value of intangible assets, as well as estimated useful lives, remains subject to change. The finalization may have a material impact on the valuation of intangible assets and the purchase price allocation, which is expected to be finalized subsequent to the merger. A 10% change in the valuation of intangible assets would cause a corresponding increase or decrease to goodwill of approximately $1,365 at the merger date but would not significantly affect amortization expense as amortization of license agreements will be recorded based on revenue from the underlying contracts.

| **(thousands in USD)** | **Advaxis Historical Carrying Value** | **June 30, 2021 Estimated Fair Value** | **Incremental Amortization and Abandonment of Intangible Expense for the Six Months Ended June 30, 2021** | **Incremental Amortization and Abandonment of Intangible Expense for the Year Ended December 31, 2020** |
|---|---|---|---|---|
| Patents | $ 3,325 | $ - | $ (135) | $ (337) |
| IP R&D | - | 12,800 | - | - |
| License Agreements | - | 850 | - | 200 |
| Total | $ 3,325 | $ 13,650 | $ (135) | $ (137) |

5. Unaudited Pro Forma Combined Balance Sheet Adjustments

The following provides explanations of the various adjustments to the unaudited pro forma combined balance sheet:

A. Represents an adjustment related to record goodwill of $21,442 determined by the net acquired identifiable assets and assumed liabilities of Advaxis. Refer to Note 4 on discussion of this reverse merger and purchase price allocation.
B. Represents an increase of $10,325 over Advaxis historical book value of intangible assets representing fair value of $13,650 less historical carrying amount of $3,325 recorded in conjunction with the purchase price allocation arising from the merger. Refer to Note 4 on discussion of this reverse merger and purchase price allocation.
C. Represents $4,000 of transaction costs expected to be incurred in connection with the merger, of which approximately $1,515 was incurred or accrued for on the balance sheet as of June 30, 2021. The remaining transaction costs of $2,485 were not yet accrued or incurred and reflected in the balance sheet as of June 30, 2021 and are recorded as a reduction in cash and an increase to accumulated deficit. See also note 6B.
D. Represents bonuses of $1,100 and $650 to be paid to Advaxis and Biosight employees, respectively, as a result of the merger recorded as a reduction in cash and increase to accumulated deficit.
E. Represents insurance costs required to be paid as a result of the merger.
F. Represents an increase in cash of $11,647, decrease in warrant liability of $5,236 and increase in additional paid-in capital of $16,883 for the exercise of Biosight's outstanding warrants. The increase in cash assumes all warrants are exercised with cash. If the holders elect to use cashless exercise, cash in the proforma may decease up to $11,647.
G. Represents a decrease in warrants and increase in additional paid-in capital of $4,902, as a result of the 1-for-12 reverse stock split increasing the number of available common stock.
H. Represents the conversion of Biosight's preferred shares of $57,023 prior to the closing of the reverse merger, causing a conversion of the preferred shares into ordinary shares. The preferred shares are required to be converted prior to the closing.
I. Represents ordinary shares exchanged for common shares as a result of the merger.
J. Represents the elimination of Advaxis common stock, paid-in capital and accumulated deficits as well as the adjustments to reflect the capital structure of the combined company. See the explanation of the adjustments:

    i. Adjustments to common stock: a decrease in common stock of $97 represents the adjustment to the aggregate historical par value of Biosight and Advaxis of $146, to reflect 48,974,095 shares outstanding at a total par value of $49 ($0.0001 par value per share) calculated as follows:

| (thousands in USD except share and per share amounts) | Amounts |
|---|---|
| Shares of Advaxis common stock outstanding on April 30, 2021 | 145,638,459 |
| Advaxis common stock to be issued to Biosight shareholders as of closing of Merger | 442,050,681 |
| Total shares of Advaxis common stock outstanding as of merger close | 587,689,140 |
| Total shares of Advaxis common stock after 1-for-12 reverse stock split | 48,974,095 |
| Par value per common share | $ 0.001 |
| Common stock total par value at merger | $ 49 |
| Common stock total par value of Advaxis prior to closing of Merger | 146 |
| Total pro forma merger adjustments | $ (97) |

ii. Adjustments to paid-in capital as follows:

| (thousands in USD) | Amounts |
|---|---|
| Merger consideration | $ 84,249 |
| Elimination of Advaxis historical additional paid-in capital | (467,227) |
| Adjustments related to purchase price consideration | (31,767) |
| Adjustment related to warrant liability | (4,931) |
| Par value common stock | (49) |
| Total pro forma merger adjustments | $ (419,725) |

iii. Adjustments to accumulated deficit as follows:

| (thousands in USD) | Amounts |
|---|---|
| Pro forma merger adjustments: | |
| Elimination of historical Advaxis accumulated deficit | $ 419,822 |
| Total pro forma merger adjustments | $ 419,822 |

6. Unaudited Pro Forma Statement of Operations Adjustments

The following provides explanations of the various adjustments to the unaudited pro forma combined statement of operations:

A. Represents a decrease to amortization expense of $135 and $137 for the six months ended June 30, 2021 and the year ended and December 31, 2020, respectively, related to the fair value adjustments to intangible assets discussed above in Note 4. The amortization expense is recorded in general and administrative expenses based on Biosight's accounting policy.
B. Represents $2,485 of additional transaction costs for the year ended December 31, 2020 expected to be incurred by the combined companies in conjunction with this reverse merger for transaction related fees and expenses. Total transaction costs of $4,000 are expected, of which, $746 and $769 was expensed during the six months ended June 30, 2021 and the year ended December 31, 2020, respectively.
C. Represents insurance costs required to be paid as a result of the merger.
D. Represents bonuses of $1,100 and $650 to be paid to Advaxis and Biosight employees, respectively, as a result of the merger.
E. Represents the removal of Biosight's gain resulting from the change in fair value of warrants of $1,396 and $398, for the year ended December 31, 2020 and six months ended June 30, 2021, respectively, as these warrants are assumed to be exercised prior to the merger. Also, the adjustment represents the removal of Advaxis' gain resulting from the change in value of derivative liabilities of $980 for the six months ended June 30, 2021 related to warrants that will be classified in equity based on the assumed reverse stock split causing authorized shares to be available to settle Advaxis' warrants.

7. Loss per Share

The unaudited pro forma weighted average number of basic and diluted shares outstanding is calculated as follows:

| (thousands in USD except share and per share amounts) | For the six months ended June 30, 2021 | For the year ended December 31, 2020 |
|---|---|---|
| Weighted average Advaxis shares outstanding - basic | 111,895,403 | 61,003,839 |
| Adjusted for: | | |
| Biosight weighted average shares outstanding as if the merger occurred on November 1, 2019 | 442,050,681 | 442,050,681 |
| Pro forma adjusted weighted average shares outstanding – basic and dilutive | 553,946,084 | 503,054,520 |
| | | |
| Pro forma adjusted weighted average shares outstanding – basic and dilutive after 1-for-12 reverse split | 46,162,174 | 41,921,210 |
| | | |
| Pro forma net loss attributable to common shareholders – basic and dilutive | $ (16,675) | $ (44,598) |
| | | |
| Pro forma net loss per common share – basic and dilutive | $ (0.36) | $ (1.06) |

The unaudited pro forma weighted average number of basic shares outstanding is calculated by adding the number of combined company shares expected to be issued to the stockholders of Biosight after giving effect to the Biosight 2,366,119 preferred shares conversions and exercises of 495,730 warrants at the noted Exchange Ratio, and the historical weighted average number of basic shares of Advaxis, which will remain outstanding as shares in the combined company on a 1:1 basis. The 1-for-12 reverse stock split is an estimate. The range of potential estimates varies from a 1-for-10 to a 1-for-30 reverse stock split. Changes in the reverse stock split would cause a corresponding increase or decrease to net loss per common share. A 1-for-10 reverse stock split would decrease the net loss per common share to $(0.30) and $(0.89) for the six months ended June 30, 2021 and for the year ended December 31, 2020, respectively. A 1-for-30 reverse stock split would increase the net loss per common share to $(0.90) and $(2.66) for the six months ended June 30, 2021 and for the December 31, 2020, respectively.

## MARKET PRICE AND DIVIDEND INFORMATION

The Advaxis common stock is currently listed on The Nasdaq Capital Market under the symbol "ADXS."

The closing price of the Advaxis common stock on July 2, 2021, the last day of trading prior to the announcement of the merger, as reported on The Nasdaq Capital Market, was $0.47 per share, and the closing price of Advaxis common stock on October 12, 2021 was $0.51 per share, in each case as reported on The Nasdaq Capital Market.

Because the market price of the Advaxis common stock is subject to fluctuation, the market value of the shares of the Advaxis common stock that Biosight shareholders will be entitled to receive in the merger may increase or decrease.

Biosight is a private company and its ordinary shares and preferred shares are not publicly traded.

Assuming approval of Proposal Nos. 1, 2, and 3, and successful application for initial listing with The Nasdaq Capital Market, following the consummation of the merger the Advaxis common stock will trade on The Nasdaq Capital Market under Advaxis' new name, "Biosight Therapeutics Inc.," and new trading symbol "BSTX."

As of September 17, 2021, there were approximately 95 registered holders of record of the Advaxis common stock. As of June 30, 2021, Biosight had 55 holders of record of Biosight ordinary shares and preferred shares that may be converted to ordinary shares. For detailed information regarding the beneficial ownership of certain Advaxis and Biosight shareholders, see the sections of this proxy statement/prospectus/information statement titled "*Principal Stockholders of Advaxis*" and "*Principal Stockholders of Biosight*."

**Dividends**

Advaxis has never declared or paid any cash dividends on the Advaxis common stock and does not anticipate paying cash dividends on the Advaxis common stock for the foreseeable future. Notwithstanding the foregoing, any determination to pay cash dividends subsequent to the merger will be at the discretion of the combined organization's then-current board of directors and will depend upon a number of factors, including the combined organization's results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors the then-current board of directors deems relevant. Biosight has never paid or declared any cash dividends on the Biosight share capital. If the merger does not occur, Biosight does not anticipate paying any cash dividends on the Biosight share capital in the foreseeable future, and Biosight intends to retain all available funds and any future earnings to fund the development and expansion of its business. Any future determination to pay dividends will be at the discretion of the Biosight board of directors and will depend upon a number of factors, including its results of operations, financial condition, future prospects, contractual restrictions, and restrictions imposed by applicable laws and other factors the Biosight board of directors deems relevant.

## DESCRIPTION OF ADVAXIS CAPITAL STOCK

The following description of Advaxis capital stock and provisions of Advaxis' amended and restated certificate of incorporation, exclusive of the potential amendments described herein in Proposals No. 2 and 3, and second amended and restated bylaws are summaries and are qualified by reference to such restated certificate of incorporation and amended and restated bylaws and applicable provisions of Delaware corporate law. Advaxis has filed copies of these documents with the SEC as exhibits to its periodic filings.

### General

Under Advaxis' amended and restated certificate of incorporation, Advaxis is authorized to issue 170 million shares of common stock, par value $0.001 per share (for purposes of this description, the "Common Stock"), and 5 million shares of "blank check" preferred stock, par value $0.001 per share.

### Common Stock

*Dividends*

Holders of our Common Stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock ("Preferred Stock"). All outstanding shares are fully paid and non-assessable.

*Conversion Rights*

The shares of Common Stock are not convertible into other securities.

*Sinking Fund Provisions*

Our Common Stock has no sinking fund provisions.

*Redemption Provisions*

Our Common Stock has no right to redemption.

*Voting Rights*

The holders of our Common Stock are entitled to one vote for each share held of record on each matter submitted to a vote of stockholders. Holders of our Common Stock do not have a cumulative voting right, which means that the holders of more than one-half of the outstanding shares of Common Stock, subject to the rights of the holders of the Preferred Stock, if any, can elect all of our directors if they choose to do so. In this event, the holders of the remaining shares of Common Stock would not be able to elect any directors. Our board of directors is not classified.

Except as otherwise required by Delaware law, and subject to the rights of the holders of Preferred Stock, if any, all stockholder action is taken by the vote of a majority of the outstanding shares of Common Stock voting as a single class present at a meeting of stockholders at which a quorum consisting of one-third of the outstanding shares of Common Stock is present in person or proxy.

*Liquidation Rights*

In the event of any voluntary or involuntary liquidation, dissolution or winding up of our affairs, holders of Common Stock would be entitled to share ratably in our assets that are legally available for distribution to stockholders after payment of liabilities and applicable distribution to the holders of our Preferred Stock (if any outstanding).

*Preemption Rights*

Our Common Stock has no right to preemption.

**Anti-Takeover Provisions**

*Delaware Law*

We are subject to Section 203 of the DGCL, an anti-takeover law. In general, Section 203 prohibits a Delaware corporation from engaging in any "business combination" with any "interested stockholder" for a period of three years following the date the stockholder became an interested stockholder, unless:

- prior to such date, the board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (a) those shares owned by persons who are directors and also officers and (b) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or subsequent to such date, the business combination is approved by the board of directors and authorized at an annual meeting or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines a "business combination" to include:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an "interested stockholder" as any entity or person beneficially owning 15% or more of the outstanding voting stock of a corporation, or an affiliate or associate of the corporation and was the owner of 15% or more of the outstanding voting stock of a corporation at any time within three years prior to the time of determination of interested stockholder status; and any entity or person affiliated with or controlling or controlled by such entity or person.

These statutory provisions could delay or frustrate the removal of incumbent directors or a change in control of our company. They could also discourage, impede, or prevent a merger, tender offer, or proxy contest, even if such event would be favorable to the interests of stockholders.

*Certificate of Incorporation and Bylaws Provisions*

Our amended and restated certificate of incorporation and second amended and restated bylaws contain provisions that could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. In particular, the amended and restated certificate of incorporation and second amended and restated bylaws, as applicable, among other things:

- provide our board of directors with the ability to alter our bylaws without stockholder approval; and
- provide that vacancies on our board of directors may be filled by a majority of directors in office, although less than a quorum.

Such provisions may have the effect of discouraging a third party from acquiring us, even if doing so would be beneficial to our stockholders. These provisions are intended to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by them, and to discourage some types of transactions that may involve an actual or threatened change in control of Advaxis. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage some tactics that may be used in proxy fights. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure Advaxis outweigh the disadvantages of discouraging such proposals because, among other things, negotiation of such proposals could result in an improvement of their terms. However, these provisions could have the effect of discouraging others from making tender offers for our shares that could result from actual or rumored takeover attempts. These provisions also may have the effect of preventing changes in our management.

*Stock Exchange Listing*

Our Common Stock is listed on the Nasdaq Global Select Market under the symbol “ADXS.”

*Transfer Agent and Registrar*

The transfer agent and registrar for our Common Stock is Continental Stock Transfer and Trust Company, 17 Battery Place, 8th Floor, New York, NY 10004.

**Preferred Share Purchase Rights**

The Company is a party to that certain Rights Agreement, dated as of September 29, 2020 (the “Rights Agreement”), by and between the Company and Continental Stock Transfer and Trust Company, as Rights Agent (the “Rights Agent”). Pursuant to the Rights Agreement, the board of directors declared a dividend of one preferred share purchase right (each, a “Right”) for each outstanding Common Share. The Rights are distributable to stockholders of record as of the close of business on October 12, 2020 (for purposes of this description, the “Record Date”). One Right also will be issued together with each Common Share issued by the Company after October 12, 2020, but before the Distribution Date (as defined below) (or the earlier redemption or expiration of the Rights) and, in certain circumstances, after the Distribution Date.

Generally, the Rights Agreement works by causing substantial dilution to any person or group that acquires beneficial ownership of 10% or more of the Common Shares without the approval of the board of directors. As a result, the overall effect of the Rights Agreement and the issuance of the Rights may be to render more difficult or discourage a merger, tender or exchange offer or other business combination involving the Company that is not approved by the board of directors. The Rights Agreement is not intended to interfere with any merger, tender or exchange offer or other business combination approved by the board of directors. The Rights Agreement also does not prevent the board of directors from considering any offer that it considers to be in the best interest of its stockholders.

The following is a summary description of the Rights and material terms and conditions of the Rights Agreement. This summary is intended to provide a general description only, does not purport to be complete and is qualified in its entirety by reference to the complete text of the Rights Agreement, a copy of which is filed as Exhibit 4.10 to the Annual Report on Form 10-K to which this is filed as an exhibit. All capitalized terms used but not defined herein shall have the meanings ascribed to such terms in the Rights Agreement.

*The Rights*

Subject to the terms, provisions and conditions of the Rights Agreement, if the Rights become exercisable, each Right would initially represent the right to purchase from the Company one one-thousandth of a share of a newly designated series of preferred stock, Series C Junior Participating Preferred Stock, par value $0.001 per share, of the Company (each, a "Series C Preferred Share," and, collectively, the "Series C Preferred Shares") at an exercise price of $1.95 per one one-thousandth of a Series C Preferred Share, subject to adjustment (the "Exercise Price"). If issued, each one one-thousandth of a Series C Preferred Share would give the stockholder approximately the same dividend, voting and liquidation rights as does one Common Share. However, prior to exercise, a Right does not give its holder any rights as a stockholder of the Company, including, without limitation, any dividend, voting or liquidation rights. A copy of the Certificate of Designation of Series C Junior Participating Preferred Stock (the "Series C Certificate of Designation") that the Company intends to file with the Secretary of State of the State of Delaware on September 29, 2020 to designate the Series C Preferred Shares is filed as Exhibit 3.1 to this Current Report on Form 8-K and is incorporated herein by reference.

*Initial Exercisability*

Initially, the Rights will not be exercisable, certificates will not be sent to stockholders and the Rights will automatically trade with the Common Shares. Until the Rights separate from the Common Shares and become exercisable (or the earlier redemption or expiration of the Rights), the Rights will be evidenced by Common Share certificates, Rights relating to any uncertificated Common Shares that are registered in book entry form will be represented by a notation in book entry on the records of the Company, and the surrender for transfer of any Common Shares will also constitute the transfer of the associated Rights.

Subject to certain exceptions specified in the Rights Agreement, the Rights will separate from the Common Shares and become exercisable following the earlier to occur of (i) the 10th business day (or such later date as may be determined by the board of directors) after the day on which a public announcement or filing with the SEC is made indicating that a person has become an Acquiring Person (as defined below) or that discloses information that reveals the existence of an Acquiring Person (the "Shares Acquisition Date"), or (ii) the 10th business day (or such later date as may be determined by the board of directors) after the commencement by any person (other than certain exempted persons) of, or the first public announcement of the intent of any person (other than certain exempted persons) to commence, a tender or exchange offer by or on behalf of a person, the successful consummation of which would result in any person (other than certain exempted persons) becoming an Acquiring Person, irrespective of whether any shares are actually purchased or exchanged pursuant to such offer (the earlier of these dates is called the "Distribution Date").

After the Distribution Date, separate rights certificates will be issued and the Rights may be transferred other than in connection with the transfer of the underlying Common Shares unless and until the board of directors has determined to effect an exchange pursuant to the Rights Agreement (as described below).

*Acquiring Person*

Under the Rights Agreement, an Acquiring Person is any person who or that, together with all Affiliates and Associates (as defined in the Rights Agreement) of such person, from and after the first public announcement by the Company of the adoption of the Rights Agreement, is or becomes the beneficial owner of 10% or more of the Common Shares outstanding, subject to various exceptions. For purposes of the Rights Agreement, beneficial ownership is defined to include the ownership of derivative securities.

The Rights Agreement provides that an Acquiring Person does not include the Company, any subsidiary of the Company, any employee benefit plan of the Company or any subsidiary of the Company, or any person organized, appointed, or established to hold Common Shares pursuant to any employee benefit plan of the Company or for the purpose of funding any such plan.

The Rights Agreement also provides that the following persons shall not be deemed an Acquiring Person thereunder: (i) any person who becomes the beneficial owner of 10% or more of the shares of Common Stock of the Company then outstanding solely as a result of the initial grant or vesting of any options, warrants, rights or similar interests (including restricted shares and restricted stock units) by the Company to its directors, officers and employees pursuant to any employee benefit or stock ownership plan of the Company, or the acquisition of shares of Common Stock of the Company upon the exercise or conversion of any such securities so granted; (ii) any person who as the result of an acquisition of shares of Common Stock by the Company (or any subsidiary of the Company, or any person organized, appointed, established or holding shares of Common Stock of the Company for or pursuant to the terms of any such plan) that, by reducing the number of shares of Common Stock of the Company outstanding, increases the proportionate number of shares of Common Stock of the Company beneficially owned by such person to 10% or more of the Common Shares then outstanding; (iii) any person who or that became the beneficial owner of 10% or more of the Common Shares then outstanding as a result of the acquisition of Common Shares directly from the Company; or (iv) any person who or that would otherwise be an Acquiring Person who or that the board of directors determines had become such inadvertently (including, without limitation, because (A) such person was unaware that it beneficially owned a percentage of the Common Shares that would otherwise cause such person to be an "Acquiring Person," or (B) such person was aware of the extent of its beneficial ownership of Common Shares but had no actual knowledge of the consequences of such beneficial ownership under the Rights Agreement), and who or that thereafter, within five business days of being requested by the Company, reduces such person's beneficial ownership to less than 10% of the Common Shares then outstanding.

*"Grandfathering" of Existing Holders*

The Rights Agreement also provides that any person who beneficially owned 10% or more of the Common Shares immediately prior to the first public announcement by the Company of the adoption of the Rights Agreement (each a "Grandfathered Person") shall not be deemed to be an "Acquiring Person" for purposes of the Rights Agreement unless and until a Grandfathered Person becomes the beneficial owner of one or more additional Common Shares after the first public announcement by the Company of the adoption of the Rights Agreement (other than pursuant to a dividend or distribution paid or made by the Company on the outstanding Common Shares, pursuant to a split, reclassification or subdivision of the outstanding Common Shares or pursuant to the acquisition of beneficial ownership of Common Shares upon the vesting or exercise of any option, warrants or other rights, or upon the initial grant or vesting of restricted stock, granted or issued by the Company to its directors, officers and employees, pursuant to a compensation or benefits plan or arrangement adopted by the board of directors). However, if upon acquiring beneficial ownership of one or more additional Common Shares at any time after the first public announcement by the Company of the adoption of the Rights Agreement, the Grandfathered Person does not, at such time, beneficially own 10% or more of the Common Shares then outstanding, the Grandfathered Person will not be treated as an "Acquiring Person" for purposes of the Rights Agreement.

*Flip-In Trigger*

If a person becomes an Acquiring Person, then, following the occurrence of the Distribution Date and subject to the terms, provisions and conditions of the Rights Agreement, each Right will entitle the holder thereof to purchase from the Company, upon payment of the Exercise Price, in lieu of a number of one one-thousandths of a Series C Preferred Share, a number of Common Shares (or, in certain circumstances, cash, property or other securities of the Company) having a then-current market value of twice the Exercise Price. However, the Rights are not exercisable until such time as the Rights are no longer redeemable by the Company, as further described below.

Following the occurrence of an event set forth in the preceding paragraph, all Rights that are or, under certain circumstances specified in the Rights Agreement, were beneficially owned by an Acquiring Person or certain of its transferees will become null and void and non-transferable.

*Flip-Over Trigger*

If, after an Acquiring Person obtains beneficial ownership of 10% or more of the Common Shares, (i) the Company merges into another entity, (ii) an acquiring entity merges into the Company, or (iii) the Company sells or transfers more than 50% of its assets, cash flow or earning power, then each Right (except for Rights that have previously been voided as set forth above) will entitle the holder thereof to purchase, upon payment of the Exercise Price, in accordance with the terms of the Rights Agreement, a number of shares of common stock of the person engaging in the transaction having a then-current market value of twice the Exercise Price.

*Redemption of the Rights*

At any time until the close of business on the 10th business day after the Shares Acquisition Date (or, if the 10th business day after the Shares Acquisition Date occurs before the Record Date, the close of business on the Record Date), or thereafter under certain circumstances, the Company may redeem the Rights in whole, but not in part, at a price of $0.001 per Right (the "Redemption Price"). The Redemption Price may be paid in cash, Common Shares or other forms of consideration, as determined by the board of directors, in the exercise of its sole discretion. The redemption of the Rights may be made effective at such time, on such basis and subject to such conditions as the board of directors in its sole discretion may establish. Immediately upon any redemption of the Rights, the right to exercise the Rights will terminate and the only right of the holders of Rights will be to receive the Redemption Price without any interest thereon.

*Exchange of the Rights*

At any time after any person becomes an Acquiring Person, and prior to the acquisition by any person of beneficial ownership of 50% or more of the Common Shares, the board of directors may, at its option, cause the Company to exchange all or part of the then-outstanding and exercisable Rights (other than Rights held by the Acquiring Person or any Affiliate or Associate thereof, which would have become null and void and non-transferable in accordance with the terms of the Rights Agreement), in whole or in part, for Common Shares at an exchange ratio (subject to adjustment) of one Common Share for each Right.

In any exchange of the Rights pursuant to the Rights Agreement, the Company, at its option, may, and to the extent there are an insufficient number of authorized Common Shares not reserved for any other purpose to exchange for all of the outstanding Rights shall, substitute preferred stock or other securities of the Company for some or all of the Common Shares exchangeable for Rights such that the aggregate value received by a holder of Rights in exchange for each Right is substantially the same value as one Common Share. The exchange of the Rights by the board of directors may be made effective at such time, on such basis, and subject to such conditions as the board of directors in its sole discretion may establish. Immediately upon the action of the board of directors authorizing the exchange of the Rights, the right to exercise the Rights will terminate, and the only right of the holders of Rights will be to receive the Common Shares or other consideration issuable in connection with the exchange.

*Expiration of the Rights*

The Rights and the Rights Agreement will expire upon the earliest to occur of (i) the date on which all of the Rights are redeemed, (ii) the date on which the Rights are exchanged, and (iii) the close of business on September 28, 2021.

*Amendment of Rights Agreement*

Except as otherwise provided in the Rights Agreement, the Company, by action of the board of directors, may from time to time, in its sole and absolute discretion, supplement or amend any provision of the Rights Agreement in any respect without the approval of any holders of Rights, including, without limitation, in order to (i) cure any ambiguity in the Rights Agreement, (ii) correct or supplement any provision contained in the Rights Agreement that may be defective or inconsistent with any other provisions contained therein, (iii) shorten or lengthen any period in the Rights Agreement, or (iv) otherwise change, amend, or supplement any provisions in the Rights Agreement in any manner that the Company may deem necessary or desirable; provided, however, that from and after such time as any person becomes an Acquiring Person, the Rights Agreement may not be supplemented or amended in any manner that would adversely affect the interests of the holders of Rights (other than Rights that have become null and void pursuant to the Rights Agreement) as such or cause the Rights Agreement to become amendable other than in accordance with the terms of the Rights Agreement. Without limiting the foregoing, the Company, by action of the board of directors, may at any time before any person becomes an Acquiring Person amend the Rights Agreement to make the provisions of the Rights Agreement inapplicable to a particular transaction by which a person might otherwise become an Acquiring Person or to otherwise alter the terms and conditions of the Rights Agreement as they may apply with respect to any such transaction.

*Rights of Holders*

Until a Right is exercised, a Right does not give its holder any rights as a stockholder of the Company, including, without limitation, any dividend, voting or liquidation rights.

*Anti-Dilution Provisions*

The board of directors may adjust the Exercise Price, the number of Series C Preferred Shares issuable and the number of outstanding Rights to prevent dilution that may occur from a stock dividend, a stock split or a reclassification of the Series C Preferred Shares or Common Shares.

With certain exceptions, no adjustments to the Exercise Price will be made until the cumulative adjustments amount to at least 1% of the Exercise Price. No fractional Series C Preferred Shares will be issued other than fractions that are integral multiples of one one-thousandth of a share and, in lieu thereof, an adjustment in cash will be made based on the current market price of the Series C Preferred Shares.

*Tax Consequences*

The adoption of the Rights Agreement and the subsequent distribution of the Rights to stockholders should not be a taxable event for the Company or its stockholders under presently existing U.S. federal income tax laws. However, if the Rights become exercisable or if the Rights are redeemed, stockholders may recognize taxable income, depending on the circumstances then existing.

*Accounting Treatment*

The distribution of the Rights as a dividend to the Company's stockholders is not expected to have any financial accounting or reporting impact. The fair value of the Rights is expected to be zero when they are distributed because the Rights will be "out of the money" when distributed and no value should be attributable to them. Additionally, the Rights do not meet the definition of a liability under generally accepted accounting principles in the United States and are therefore not accounted for as a long-term obligation.

*Authority of the Board*

When evaluating decisions relating to the redemption of the Rights or any amendment to the Rights Agreement to delay or prevent the Rights from detaching and becoming exercisable as a result of a particular transaction, pursuant to the Rights Agreement, the board of directors, or any future board of directors, would not be subject to restrictions such as those commonly known as "dead-hand," "slow-hand," "no-hand," or similar provisions.

*Certain Anti-Takeover Effects*

The Rights are not intended to prevent a takeover of the Company and should not interfere with any merger or other business combination approved by the board of directors. However, the Rights may cause substantial dilution to a person or group that acquires beneficial ownership of 10% or more of the issued and outstanding Common Shares (which includes for this purpose stock referenced in derivative transactions and securities) without the approval of the board of directors.

*SEC Registration*

Since the Rights are not exercisable immediately, registration with the SEC of the Series C Preferred Shares issuable upon exercise of the Rights is not required until the Rights become exercisable.

## COMPARISON OF RIGHTS OF HOLDERS OF ADVAXIS CAPITAL STOCK AND BIOSIGHT SHARE CAPITAL

If the merger is completed, Biosight shareholders will receive shares of Advaxis common stock, pursuant to the terms of the Merger Agreement. Additionally, immediately prior to the closing of the merger, Advaxis' certificate of incorporation will be amended to (i) change the name of the company, and (ii) effect the reverse stock split, as set forth in the forms of certificates of amendment attached as *Annex E* and *Annex F* to this proxy statement/prospectus/information statement. The following is a summary of certain differences between (i) the current rights of Biosight shareholders under its current articles of association, (ii) the rights of Advaxis stockholders under its amended and restated certificate of incorporation, and its second amended and restated bylaws, and (iii) the Israeli Companies Law—1999, or the ICL, and the DGCL. The summary set forth below is not intended to provide a comprehensive discussion of each company's governing documents or relevant corporate law. This summary is qualified in its entirety by reference to the full text of each company's governing documents, the DGCL and the ICL. See "*Where You Can Find More Information*" beginning on page 238 of this proxy statement/prospectus/information statement for information on how to obtain a copy of these documents.

**General**

Advaxis is incorporated under the laws of the State of Delaware and Biosight is incorporated under the laws of the State of Israel. Accordingly, the rights of Advaxis stockholders and Biosight shareholders are governed by the DGCL and the ICL, respectively. As a result of the merger, Biosight shareholders who receive shares of Advaxis common stock will become Advaxis stockholders, and their rights as stockholders will be governed by the DGCL and the Advaxis organizational documents.

Following is a comparison of the rights of Advaxis stockholders and Biosight shareholders:

| **Advaxis** | **Biosight** |
|---|---|
| *Organizational Documents* | |
| The rights of Advaxis stockholders are governed by Advaxis' amended and restated certificate of incorporation, Advaxis' second amended and restated bylaws and the DGCL. | The rights of Biosight shareholders are governed by Biosight's Amended Fourth Amended and Restated Articles of Association (the "Articles of Association"), Biosight's Amended and Restated Memorandum of Incorporation and the ICL. |
| *Authorized Capital Stock* | |
| Advaxis is authorized to issue two classes of capital stock, which are designated, respectively, "common stock" and "preferred stock." The total number of shares that Advaxis is authorized to issue is 175,000,000, of which 100,000,000 shares are common stock, par value $0.001 per share, and 5,000,000 shares are preferred stock, par value $0.001 per share. The number of authorized shares of Advaxis preferred stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the voting power of the capital stock of the corporation entitled to vote thereon, voting as a single class, irrespective of the provisions of Section 242(b)(2) of the DGCL. The number of authorized shares of common stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of common stock entitled to vote, subject to the provisions of Section 242(b)(2) of the DGCL. | The registered share capital of Biosight is NIS 89,000, divided into: (i) 4,771,488 Ordinary Shares, par value NIS 0.01 per share; (ii) 344,452 Ordinary A-1 Shares par value NIS 0.01 per share; (iii) 40,676 Ordinary A-2 Shares par value NIS 0.01 per share; (iv) 43,384 Ordinary A-3 Shares par value NIS 0.01 per share; (v) 400,000 Series B Preferred Shares par value NIS 0.01 per share; (vi) 300,000 Series B-1 Preferred Shares par value NIS 0.01 per share; and (vii) 3,000,000 Series C Preferred Shares par value NIS 0.01 per share. According to Biosight's Articles of Association, it may, from time to time, via a shareholders' resolution approved by a majority of the participating votes cast by holders of shares present or represented by proxy (subject to the quorum requirements set forth in the Articles of Association and the veto rights of holders of certain classes of preferred shares as specified therein): (i) increase its authorized share capital by creating new shares of an existing or new class, as shall be determined in the resolution of the general meeting; (ii) cancel registered share capital that has not yet been allocated, on condition that there are no undertakings of the company, including conditional undertakings, to allocate the shares; and (iii) subject to applicable law, reduce its share capital by cancelling such shares and registering the par value paid for such shares as paid premiums remaining in the issued share capital. |

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| *Common Stock / Ordinary Shares* | |
| Advaxis' authorized common stock consists of 170,000,000 shares of common stock.<br><br>Each holder of a share of Advaxis common stock is entitled to one vote for each such share held of record on the applicable record date on each matter voted on at a meeting of stockholders. | Biosight's registered share capital consists of 4,771,488 ordinary shares.<br><br>According to Biosight's Articles of Association, every shareholder has one vote for each ordinary share held of record, on every shareholder resolution (subject to any provisions under Biosight's Articles of Association or the Israeli Companies Law conferring special rights as to voting).<br><br>Any shareholder entitled to vote may vote either in person or by proxy, or if the shareholder is a company or other corporate body, by representative duly authorized by it.<br><br>Except as required by the ICL or Biosight's Articles of Association (and subject to the quorum requirements thereof), a resolution of the shareholders is adopted if approved by the holders of a simple majority of the voting power represented at a shareholder meeting in person or by proxy and voting thereon, as one class, and disregarding abstentions from the count of the voting power present and voting. |
| *Preferred Stock / Preferred Shares* | |
| Advaxis' authorized preferred stock consists of 5,000,000 shares of preferred stock. No shares of Advaxis preferred stock are currently outstanding. | Biosight's authorized share capital consists of 344,452 Ordinary A-1 shares, 40,676 Ordinary A-2 shares, 43,384 Ordinary A-3 shares, 400,000 Preferred B shares, 300,000 Preferred B-1 shares and 3,000,000 Preferred C shares, of which 210,723 Ordinary A-1 shares, n43,384 Ordinary A-3 shares, 215,420 Preferred B shares, 170,377 Preferred B-1 shares and 1,726,215 Preferred C shares are currently outstanding. |
| *Number and Qualification of Directors* | |
| The Advaxis board of directors consists of no less than one and no more than nine members, and the number of directors is fixed from time to time by resolution of the Advaxis board of directors. The Advaxis board of directors currently consists of six members. | Under Biosight's Articles of Association, the number of directors shall be up to seven directors. Biosight's board of directors currently consists of five directors. |

*Structure of Board of Directors; Term of Directors; Election of Directors*

Each director will hold office until the next annual meeting of stockholders and until his successor is duly elected and qualified, subject to his earlier resignation or removal.

Under Biosight's Articles of Association, directors will be appointed as follows:

1. One director shall be the Biosight's chief executive officer, ex-officio;

2. One director appointed by Arkin Bio Ventures Limited Partnership and its permitted transferees ("Arkin Director");

3. One director appointed by Odesey I, L.P. and Marstrand Partners, L.P. and their permitted transferees (jointly);

4. One director appointed by Israel Biotech Fund I, L.P., Israel Biotech Fund II, L.P. and their permitted transferees (jointly) ("IBF Director");

5. One director shall be appointed by Deferred Investors holding a majority of interest in the Series C Preferred Shares purchased in the Deferred Closing under the Series C Share Purchase Agreement of Biosight ("PC Director"); and

6. Two industry experts appointed by a unanimous consent of the board of directors (excluding the vote of such elected directors), one of whom shall also act as the Chairman of the board of directors.

*Removal of Directors*

Any director may be removed at any time for cause or without cause by the vote of the holders of a majority of the common stock then entitled to vote at an election of directors. The vacancy on the board of directors caused by any such removal may be filled by the stockholders at such meeting or as provided below.

According to Biosight's Articles of Association, directors may be removed from office by the designator who has elected such director, and any vacancy, however created, in the board of directors may only be filled by the designator entitled to fill such vacancy.

Any appointment, removal from office or replacement, of any member of the board of directors shall become effective (i) only pursuant to a written notice given to the company by the applicable designator, and (ii) on the date fixed in such notice, or upon the delivery thereof to the company, whichever is later.

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| | Subject to Biosight's Articles of Association, the office of a director shall be vacated in the following events:<br>1. if such director has resigned from office and has delivered a notice thereof to the company or to the board of directors;<br>2. if removed from office by the applicable designator or if the right of the Designator has been terminated;<br>3. upon such director's death;<br>4. if such director is adjudged bankrupt;<br>5. if such director is pronounced of unsound mind or an incapacitated person;<br>6. if convicted of a felony as provided in the ICL;<br>7. by resolution of a court as provided in the ICL. |
| *Vacancies on the Board of Directors* | |
| Vacancies, and newly created directorships resulting from any increase in the authorized number of directors, may be filled by vote of a majority of the directors then in office (even if such remaining directors constitute less than a quorum) or of the sole remaining director, and the directors so chosen shall hold office until the next annual election and until their successors are duly elected and qualified, or until their earlier resignation or removal. | According to Biosight's Articles of Association, any vacancy, however created, in the board of directors may only be filled by the designator entitled to fill such vacancy. |
| *Stockholder/Shareholders Action by Written Consent* | |
| Unless otherwise provided in the amended and restated certificate of incorporation, any action required or permitted to be taken at any annual or special meeting of stockholders of the corporation may be taken without a meeting, without prior notice and without a vote, in a consent in writing, setting forth the action so taken, signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted. | According to Biosight's Articles of Association, any resolution which may be adopted at a shareholders meeting, shall be deemed adopted if approved by a unanimous written consent of all shareholders (or all holders of any class of shares in a class meeting) entitled to participate in, and vote at, such meeting. |
| *Quorum for a Board meeting* | |
| Except as otherwise provided by law or by amended and restated certificate of incorporation, the holders of one-third of the capital stock issued and outstanding and entitled to vote thereat, present in person or represented by proxy, shall constitute a quorum at all meetings of the stockholders for the transaction of business. If, however, such quorum shall not be present or represented at any meeting of the stockholders, the stockholders entitled to vote thereat, present in person or represented by proxy, shall have power to adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum shall be present or represented. At such adjourned meeting at which a quorum shall be present or represented, any business may be transacted which might have been transacted at the meeting as originally noticed. If the adjournment is for more than 30 days, or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder entitled to vote at the meeting. | According to Biosight's Articles of Association, the majority of the members of the board of directors then in office which will include at least the IBF Director and the Arkin Director, shall constitute a legal quorum in any meeting of the board of directors. If, within 30 minutes of the time appointed for the holding of a meeting of the board of directors, no legal quorum is present, such meeting shall be adjourned to a date which is three days following the original meeting, at the same time and place, or to such day and place as shall be decided by the Chairman, or in his absence by the majority of the board members present, provided that in such event that other day and place is determined it shall be communicated in writing to all members of the board of directors, and any two members of the board of directors attending such adjourned meeting, in person or by proxy, shall constitute a legal quorum. |

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| | Except as otherwise required by the ICL:<br><br>1. Each director shall have one vote at any meeting of the board of directors. The chairman of the board shall not have an additional vote.<br><br>2. Subject to the veto rights set forth in Biosight's Articles of Association, resolutions of the board of directors shall be adopted by a simple majority of the directors present and voting at that meeting. |
| *Special Meetings of Stockholders/shareholders* | |
| Unless otherwise prescribed by law or by the amended and restated certificate of incorporation, special meetings of stockholders for any purpose or purposes may be called at any time by the board of directors. Written notice of a special meeting stating the place, date and hour of the meeting and the purpose or purposes for which the meeting is called shall be given not less than 10 nor more than 60 days before the date of the meeting to each stockholder entitled to vote at such meeting. | Under the ICL and Biosight's Articles of Association, the board of directors (i) may convene from time to time a special meeting at its discretion, and (ii) shall convene a special meeting upon receipt of a written notice (the "Special Meeting Notice") in accordance with the ICL by a person entitled to deliver such notice (the "Requesting Person"). A Special Meeting Notice shall (i) specify the matters to be addressed at such special meeting requested therein (ii) be signed by the person making the request, and (iii) be delivered to the company.<br><br>The board of directors shall convene a special meeting pursuant within 21 days after receipt of a Special Meeting Notice.<br><br>In the event that the board of directors does not convene such requested special meeting within such 21 day period, any or all of the requesting persons holding at least 50% of the voting power of all requesting persons, and any director of the company, may convene such requested special meeting themselves in a manner which is as close as possible to the manner in which general meetings are convened by the board of directors, provided that a meeting so convened shall not be held if to be held later than three months following delivery of the Special Meeting Notice. |

*Notice of Stockholder/Shareholders Meetings*

Notice of all meetings of stockholders is to be given in writing in the manner provided by law and Advaxis' second amended and restated bylaws, stating the place, if any, date and hour, of the meeting and, in the case of a special meeting, the purpose or purposes of the meeting. Unless otherwise required by applicable law, such notice is to be given not less than 10 or more than 60 days before the date of the meeting to each stockholder of record entitled to vote at such meeting.

According to Biosight's Articles of Association, an invitation to a general meeting shall be delivered to everyone entitled to receive an invitation thereto, participate therein, and vote thereat, no later than seven days prior to the date of the meeting, and shall set out (i) the time and place of such general meeting, (ii) the agenda of the general meeting in reasonable detail, and (iii) in the event of a proposed amendment of Biosight's Articles of Association, the proposed amendment.

Subject to applicable law, non-receipt of a notice given as aforesaid shall not invalidate any resolution adopted at, or the proceedings held at, that meeting, provided that Biosight delivered such notice in accordance with the Biosight's Articles of Association.

*Advance Notice Requirements for Stockholder/Shareholders Proposals*

To be properly brought before an annual meeting of stockholders, business must be of a nature that is appropriate for consideration at an annual meeting and must be (i) specified in the notice of meeting (or any supplement thereto) given by or at the direction of the board of directors, (ii) otherwise properly brought before the meeting by or at the direction of the board of directors, or (iii) otherwise properly brought before the meeting by a stockholder or qualified representative of such stockholder at the meeting who (A) is a record owner of shares of Advaxis' capital stock at the time of giving the notice provided for in this paragraph, (B) is a record owner of shares of Advaxis' capital stock as of the record date for the determination of stockholders entitled to notice of and to vote at the meeting in question, (C) is a record owner of shares of Advaxis' capital stock at the time of the meeting, (D) is entitled to vote at the meeting, and (E) complies with the requirements set forth in this paragraph in all applicable respects.

See in- *"Notice of Stockholder/Shareholders Meetings"* above

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| *Amendment of Certificate of Incorporation*/Articles of Association | |
| The affirmative vote of holders of at least a majority of shares present in person or represented by proxy at the meeting and entitled to vote will be required to amend certain provisions of Advaxis' amended and restated certificate of incorporation, including provisions relating to the size of the board, removal of directors, actions by written consent, forum selection and indemnification of directors, officers and agents of Advaxis.<br><br>Notwithstanding any other provisions of Advaxis' amended and restated certificate of incorporation, Advaxis' second amended and restated bylaws, or any provision of law which might otherwise permit a lesser vote or no vote, stockholders may vote to amend Advaxis' amended and restated certificate of incorporation pursuant to Section 242 of the DGCL. | Under the ICL, the articles of association set forth substantially all of the provisions that under Delaware law are split between the certificate of incorporation and the bylaws of a company.<br><br>In this respect, Biosight's Articles of Association provide that (subject to the veto rights set forth in Biosight's Articles of Association), any amendment of any provision of the Articles of Association which derogates from, the rights, preferences or privileges of any class or series of the Biosight's issued share capital or conferred upon certain shareholder(s) of Biosight, without correspondingly derogating from, as applicable, the rights, preferences or privileges of all classes and series of the Biosight's issued share capital or of all of the shareholders of the company, as applicable, shall require the written consent or affirmative vote of, as applicable: the holders of a majority of any such class or series, or such shareholder(s), as applicable (or if such other majority is required pursuant to the provisions of Biosight's Articles of Association, such other majority), the rights, preferences or privileges of which were derogated, if such amendment derogates from the rights, preferences or privileges of certain (but not all) classes or series of the Biosight's issued share capital, or of certain (but not all) of the shareholders of Biosight, as applicable. |
| *Amendment of Bylaws* | |
| The second amended and restated bylaws may be altered, amended or repealed, in whole or in part, or new bylaws may be adopted by the stockholders or by the board of directors; provided, however, that notice of such alteration, amendment, repeal or adoption of new bylaws be contained in the notice of such meeting of stockholders or board of directors, as the case may be. All such amendments must be approved by either of the holders of a majority of the outstanding capital stock entitled to vote thereon or by a majority of the entire board of directors then in office. | N/A |
| *Limitation on Director Liability* | |
| The liability of the Advaxis directors for monetary damages is and will be eliminated to the fullest extent under applicable law. If applicable law is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director to Advaxis will be eliminated or limited to the fullest extent permitted by applicable law as so amended. | An Israeli company may exculpate an office holder in advance from liability to the company, in whole or in part, for damages caused to the company as a result of a breach of duty of care (other than liability arising out of a prohibited dividend or distribution to shareholders) but only if a provision authorizing such exculpation is included in its articles of association. Biosight's Articles of Association include such a provision. |

*Indemnification*

To the fullest extent permitted by applicable law, Advaxis is authorized to provide indemnification of (and advancement of expenses to) directors, officers and agents of Advaxis (and any other persons to which applicable law permits Advaxis to provide indemnification) (i) by a majority vote of the directors who were not parties to such action, suit or proceeding even though less than a quorum; or (ii) if there are no such directors, or, if such directors so direct, by independent legal counsel in a written opinion; or (iii) by the stockholders. If applicable law is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director to Advaxis will be eliminated or limited to the fullest extent permitted by applicable law as so amended.

As permitted under the ICL Biosight's Articles of Association provide that Biosight may indemnify a director (among other "Office Holders", as such term is defined in Biosight's Articles of Association) with respect to any of the following:

1. A monetary liability imposed on such Office Holder, or incurred by such Office Holder, in favor of a third party in any judgment, including any settlement confirmed as judgment and an arbitrator's award which has been confirmed by court, in respect of an act performed by such Office Holder in its capacity as an Office Holder of Biosight;
2. Reasonable litigation expenses, including legal fees paid for by the Office Holder, due to investigation or proceeding brought against such Office Holder by authority authorized to hold such investigation or bring such proceeding, in which such Office Holder is not indicted and is not fined (as an alternative to a criminal proceeding), or in which such Office Holder is not indicted but fined (as an alternative to a no fault criminal proceeding), provided that the alleged criminal offense in question does not require proof of criminal intent.

3. Reasonable litigation expenses, including legal fees paid for by the Office Holder, or which such Office Holder is obligated to pay under a court order, in a proceeding brought against such Office Holder by Biosight, or on its behalf, or by a third party, or in a criminal proceeding in which such Office Holder is found not guilty or in a no fault criminal charge, even if such Office Holder is found guilty, in each case, with respect to an act performed by such Office Holder in its capacity as an Office Holder of Biosight.

4. Subject to the ICL, Biosight may procure, for the benefit of any of its Office Holders, Office Holders' liability insurance with respect to any of the following:

    a. a breach of the duty of care owed to Biosight or any other person;

    b. a breach of the fiduciary duty owed to Biosight, provided that such Office Holder acted in good faith and had reasonable grounds to assume that the action would not injure Biosight; or

c. a monetary liability imposed on such Office Holder in favor of a third party, in respect of an act performed by such Office Holder in its capacity as an Office Holder of Biosight.

5. Subject to the ICL Law, Biosight may undertake to indemnify Office Holders as aforesaid: (i) prospectively, for any of the following: (a) as set forth in Section 1 above, provided, however, that the undertaking is limited to events which in the opinion of the board of directors are foreseen in light of the actual activity of Biosight when the undertaking to indemnify is given, and to an amount or criteria set by the board of directors as reasonable under the circumstances, and that the undertaking to indemnify shall specify such events and amount or criteria, or (b) as set forth in Section 2 or 3; and (ii) retroactively.

*Conversion Rights*

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| The shares of Advaxis' common stock are not convertible into other securities. | The preferred shares of Biosight are convertible into ordinary shares pursuant to the provisions of Biosight's Articles of Association. |

*Right of First Refusal*

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| Advaxis does not have a right of first refusal in place. | Biosight's Articles of Association include rights of first refusal to which certain eligible shareholders are entitled. |

*Right of Co-Sale*

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| Advaxis does not have a right of co-sale in place. | Biosight's Articles of Association include co-sale rights to which certain eligible shareholders are entitled. |

*Preemptive Rights*

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| Advaxis stockholders do not have preemptive rights. Thus, if additional shares of Advaxis common stock are issued, the current holders of Advaxis common stock will own a proportionately smaller interest in a larger number of outstanding shares of common stock to the extent that they do not participate in the additional issuance. | Biosight's Articles of Association include preemptive rights to which certain eligible shareholders are entitled. |

*Distributions to Stockholders/shareholders*

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| Dividends upon Advaxis capital stock, subject to the provisions of Advaxis' amended and restated certificate of incorporation and applicable law, if any, may be declared by the Advaxis board of directors pursuant to law at any regular or special meeting. Dividends may be paid in cash, in property, or in shares of the capital stock, subject to the provisions of Advaxis' amended and restated certificate of incorporation and applicable law. Before payment of any dividend, there may be set aside out of any funds of Advaxis available for dividends such sum or sums as the board of directors from time to time, in its absolute discretion, deems proper as a reserve or reserves to meet contingencies, or for equalizing dividends, or for repairing or maintaining any property of Advaxis, or for any proper purpose, and the board of directors may modify or abolish any such reserve. The Advaxis board of directors may fix a record date for the determination of holders of Advaxis common stock entitled to receive payment of a dividend or distribution declared thereon, which record date is to be not to precede the date upon which the resolution fixing the record date is adopted, and which record date may not be more than 60 days prior to the date fixed for the payment thereof. | Biosight's board of directors may, before making any decision on the distribution of any dividend in respect of any financial year, set aside out of the profits of Biosight, such sums as the board of directors may deem proper as a reserve fund or a general fund for any needs and purposes which the board of directors may determine at its discretion.<br><br>Biosight's Articles of Association include dividend preference rights to holders of preferred shares of Biosight.<br><br>Subject to the provisions of the ICL and to the veto rights set forth in Biosight's Articles of Association, the board of directors may adopt a resolution for the distribution of a dividend. The board of directors may also resolve that the dividend may be paid in whole or in part, either in cash or in kind by way of distribution of other assets, including securities or in any other way at its discretion. No dividend shall be payable except out of the profits of Biosight and no dividend shall carry interest as against Biosight.<br><br>A transfer of shares shall not pass the right to any dividend declared thereon before the registration of the transfer unless another instruction has been issued to Biosight signed by the transferor and the transferee.<br><br>Except in the event where the requesting shareholder has instructed otherwise, any dividend may be paid to such shareholder by a crossed cheque sent by registered mail to the address of such shareholder or of the person entitled to receive it, or in the case of joint owners, to the person first mentioned in the Register of the Shareholders in respect of the joint ownership. Every such cheque shall be drawn in favor of the person to whom it is mailed. Biosight will not be liable or responsible in respect of any cheque lost in the mail, or in respect of any dividend lost by any shareholder or any person entitled thereto, as a result of forged endorsement of any cheque, any fraudulent collection or by any other improper collection thereof.<br><br>The shareholders entitled to a dividend shall be the shareholders on the date on which the resolution for the distribution of the dividend is adopted, or at a later date if such later date was specified in such resolution.<br><br>The board of directors may invest unclaimed dividends within a year after they have been declared, or use them for the benefit of Biosight until such time as they are demanded. |
| *Registration Rights* | |
| Advaxis does not have registration rights in place. | The Amended and Restated Investors Rights Agreement of Biosight includes registration rights as set forth therein. |
| *Stock Transfer Restrictions Applicable to Stockholders/Shareholders* | |
| Shares of Advaxis are transferable in the manner prescribed by the law and in the second amended and restated bylaws. | Shares of Biosight are transferable in the manner prescribed by the law and in Biosight's Articles of Association. |

## PRINCIPAL STOCKHOLDERS OF ADVAXIS

*Except where specifically noted, the following information and all other information contained in this proxy statement/prospectus/information statement does not give effect to the proposed reverse stock split.*

The following table and accompanying footnotes set forth certain information with respect to the beneficial ownership of Advaxis common stock as of September 17, 2021 for:

- each person, or group of affiliated persons, who is known by Advaxis to beneficially own more than 5% of Advaxis' common stock;
- each of Advaxis' named executive officers;
- all of Advaxis' directors as of October 31, 2020; and
- all of Advaxis' executive officers and directors as a group.

Beneficial ownership prior to the completion of the merger is based on 145,638,459 shares of Advaxis common stock outstanding as of September 17, 2021.

Advaxis has determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, these rules require that Advaxis includes shares of common stock issuable pursuant to the vesting of restricted stock units and the exercise of stock options and warrants that are either immediately exercisable or exercisable within 60 days of September 17, 2021. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Unless otherwise indicated by footnote, the address for each of the beneficial owners set forth in the table below is c/o Advaxis, Inc., 9 Deer Park Drive, Suite K-1, Monmouth Junction, NJ 08852.

| Name of Beneficial Owner | Total # of Shares Beneficially Owned | Percentage of Ownership |
|---|---|---|
| Kenneth Berlin[(1)] | 143,000 | *% |
| Igor Gitelman[(2)] | 16,667 | *% |
| David Sidransky[(3)] | 29,021 | *% |
| Roni Appel[(4)] | 32,659 | *% |
| Richard Berman[(5)] | 24,112 | *% |
| Samir Khleif[(6)] | 27,973 | *% |
| James Patton[(7)] | 39,878 | *% |
| Andres Gutierrez[(8)] | 62,084 | *% |
| **All Current Directors and Officers as a Group (8 People)[(9)]** | **375,394** | ***%** |

* Represents beneficial ownership of less than 1%.

(1) Represents 21,667 issued shares of Advaxis common stock, and options to purchase 103,111 shares of our common stock exercisable within 60 days.
(2) Represents options to purchase 16,667 shares of our common stock exercisable within 60 days.
(3) Represents 7,355 issued shares of our common stock and options to purchase 21,666 shares of our common stock exercisable within 60 days.
(4) Represents 10,476 issued shares of our common stock, options to purchase 20,294 shares of our common stock exercisable within 60 days and warrants to purchase 1,889 shares of our common stock exercisable within 60 days.
(5) Represents 3,711 issued shares of our common stock and options to purchase 20,401 shares of our common stock exercisable within 60 days.
(6) Represents 4,639 issued shares of our common stock and options to purchase 23,334 shares of our common stock exercisable within 60 days.
(7) Represents 19,117 issued shares of our common stock and options to purchase 20,761 shares of our common stock exercisable within 60 days.
(8) Represents 3,750 issued shares of our common stock and options to purchase 58,334 shares of our common stock exercisable within 60 days.
(9) Represents 70,715 issued shares of our common stock and options to purchase 302,790 shares of our common stock exercisable within 60 days and warrants to purchase 1,889 shares of our common stock exercisable within 60 days.

## PRINCIPAL STOCKHOLDERS OF BIOSIGHT

The following table and accompanying footnotes set forth certain information with respect to the beneficial ownership of Biosight ordinary shares, on an as-converted to ordinary shares basis as of August 23, 2021 for:

- each person, or group of affiliated persons, who is known by Biosight to beneficially own more than 5% of Biosight's ordinary shares;
- each of Biosight's executive officers;
- all of Biosight's directors as of August 23, 2021; and
- all of Biosight's executive officers and directors as a group.

Biosight has determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, these rules require that Biosight include ordinary shares issuable pursuant to the vesting of restricted stock units and the exercise of stock options and warrants that are either immediately exercisable or exercisable within 60 days of August 23, 2021. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers of Biosight as a group. However, notwithstanding the foregoing, all ordinary shares issuable upon conversion of outstanding preferred shares are deemed to be outstanding for the purpose of computing the percentage ownership of each person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as described above, beneficial ownership prior to the completion of the merger is based on 3,244,095 shares of Biosight common stock outstanding as of August 23, 2021. Unless otherwise indicated by footnote, the address for each of the beneficial owners set forth in the table below is c/o Biosight, Ltd., 3 Hayarden St., Airport City, P.O.B 1083, Lod 7019802, Israel.

| Name of Beneficial Owner | Total # of Shares Beneficially Owned | Percentage of Ownership |
|---|---|---|
| Ruth Ben Yakar[1] | 85,002 | 2.6% |
| Pini Orbach[2] | — | — |
| Briggs Morrison[3] | 13,753 | * |
| Gary Gordon[4] | 3,359 | * |
| Aaron Sasson | — | — |
| Roy Golan[5] | 19,732 | * |
| Darrel Cohen | — | — |
| Liat Flaishon[6] | 8,817 | * |
| Shoshi Tessler[7] | 8,976 | * |
| **All Current Directors and Officers as a Group (9 People)[8]** | **139,639** | **4.1%** |
| Entities affiliated with Moshe Arkin[9] | 739,903 | 21.6% |
| Israel Biotech Fund I, L.P. and Israel Biotech Fund II, L.P.[10] | 420,382 | 12.8% |
| Ilan Holdings (M&I) Ltd.[11] | 355,852 | 10.8% |
| Marstrand Partners L.P.[12] | 291,687 | 8.8% |
| Odesey I, L.P.[13] | 291,686 | 8.8% |
| Tech PE Investments Corp.[14] | 266,708 | 8.1% |
| Stela Gengrinovitch[15] | 188,570 | 5.8% |
| Entities affiliated with Phoenix Insurance Company Ltd.[16] | 185,805 | 5.7% |
| Migdal Insurance & Financial Holdings Ltd.[17] | 185,804 | 5.7% |

* Represents beneficial ownership of less than 1%.

[1] Consists of 61,674 ordinary shares and options to purchase 23,328 ordinary shares.

(2) Excludes options to purchase 9.902 ordinary shares granted to Arkin Bio Ventures Limited Partnership in lieu of a grant to Mr. Orbach.

(3) Consists of options to purchase 13,753 ordinary shares.

(4) Consists of options to purchase 3,359 ordinary shares.

(5) Consists of options to purchase 19,732 ordinary shares.

(6) Consists of options to purchase 8,817 ordinary shares.

(7) Consists of options to purchase 8,976 ordinary shares.

(8) Consists of 61,674 ordinary shares and options to purchase 87,867 ordinary shares.

(9) Consists of (a) 544,196 ordinary shares consisting of (i) 48,384 ordinary shares, (ii) ordinary shares issuable upon conversion of 82,854 preferred B shares, 65,529 preferred B-1 shares, 181,160 preferred C shares, 166,269 preferred C shares issuable upon exercise of warrants and 9,902 ordinary shares issuable upon exercise of options, held by Arkin Bio Ventures Limited Partnership, and (b) 185,805 ordinary shares issuable upon conversion of preferred C shares held by Arkin Communication Ltd. Arkin Bio Venture Partners Ltd. is the general partner of Arkin Bio Ventures Limited Partnership and the sole shareholder and chairman of the board of Arkin Bio Venture Partners Ltd. is Moshe Arkin. As a result, Arkin Bio Venture Partners Ltd. and Mr. Arkin may be deemed to share beneficial ownership of the shares held by Arkin Bio Ventures Limited Partnership. Mr. Moshe Arkin is the sole beneficial owner of Arkin Communication Ltd. The business address of Arkin Bio Ventures Limited Partnership, Arkin Communication Ltd., Arkin Bio Venture Partners Ltd. and Mr. Arkin is 6 HaChoshlim St., Bldg. C, Herzliya 46724, Israel.

(10) Consists of 420,382 ordinary shares issuable (i) upon conversion of preferred C shares and (ii) upon conversion of 48,774 preferred C shares issuable upon exercise of warrants, held by Israel Biotech Fund I, L.P. (“IBF I”) and Israel Biotech Fund II, L.P. (“IBF II”). Israel Biotech Fund GP Partners, L.P. (“IBF I GP”) is the sole general partner of IBF I and Israel Biotech Fund GP Partners II, L.P. (“IBF II GP”) is the sole general partner of IBF II. I.B.F. Management, Ltd. (“IBF Management”) is the sole general partner of IBF I GP and IBF II GP. IBF I GP, IBF II GP and IBF Management may be deemed to have sole voting and dispositive with respect to the ordinary shares issuable (i) upon conversion of preferred C shares and (ii) upon conversion of preferred C shares issuable upon exercise of warrants held by IBF I and IBF II. The address of IBF I, IBF II, IBF I GP, IBF II GP and IBF Management is Ruhrberg Science Center, Bell Entrance, 4th Floor, 3 Pekeris Street, Rabin Science Park, Rehovot 7670212, Israel.

(11) Consists of 355,852 ordinary shares consisting of (a) 93,148 ordinary shares and 145,896 ordinary A1 shares, (b) ordinary shares issuable upon conversion of (i) 24,856 preferred B shares, (ii) 19,659 preferred B-1 shares, (iii) 28,799 preferred C shares and (iv) 43,494 preferred C shares issuable upon exercise of warrants, held by Ilan Holdings (M&I) Ltd. Arrow Pride (Eran Ilan) is the controlling shareholder of Ilan Holdings (M&I) Ltd.. The business address of Ilan Holdings (M&I) Ltd. and Arrow Pride (Eran Ilan) is Lev Hasharon Industrial Park, Kadima, P.O. Box 5062, Israel 6092000.

(12) Consists of 291,687 ordinary shares issuable upon conversion of (i) 41,427 preferred B shares, (ii) 32,765 preferred B-1 shares, and (iii) 140,468 preferred C shares, and 77,027 preferred C shares issuable upon exercise of warrants, in each case, held by Marstrand Partners L.P. The general partner of Marstrand Partners L.P. is Aaron Sasson. The managing member is Aaron Sasson. The business address of Marstrand Partners L.P. is 2535 Lyon Street, San Francisco, CA 94123.

(13) Consists of 291,686 ordinary shares issuable upon conversion of (i) 41,427 preferred B shares, (ii) 32,765 preferred B-1 shares, and (iii) 140,468 preferred C shares, 77,027 preferred C shares issuable upon exercise of warrants, in each case, held by Odesey I, L.P. The general partner of Odesey I, L.P. is Ori Sasson. The managing member is Ori Sasson. The business address of Odesey I, L.P. is 11 El Sueno, Orinda, CA 94563.

(14) Consists of 266,708 ordinary shares as follows: (a) 149,900 ordinary shares, (b) ordinary shares issuable upon conversion of (i) 24,856 preferred B shares, (ii) 19,659 preferred B-1 shares, (iii) 28,799 preferred C shares and (iv) 43,494 preferred C shares issuable upon exercise of warrants, held by Tech PE Investments Corp. The registered address of Tech PE Investments Corp. is Mandar House, Suite 301, 3rd Floor, Road Town, Tortola, British Virgin Islands.

(15) Consists of 188,570 issued shares of our ordinary shares held by Stela Gengrinovitch.

(16) Consists of 185,805 ordinary shares issuable upon conversion of (i) 124,893 preferred C shares held by The Phoenix Insurance Company Ltd. ("Phoenix"), (ii) 23,226 preferred C shares held by The Phoenix Insurance Company Ltd. (for Nostro) ("Nostro") and (iii) 37,686 preferred C shares held by The Phoenix Excellence Pension and Provident Fund Ltd ("Phoenix Excellence"). Haggai Schreiber, Deputy Chief Executive Officer and Chief Investment Officer of Phoenix, Nostro and Phoenix Excellence may be deemed to have voting and dispositive power with respect to the shares held by Phoenix, Nostro and Phoenix Excellence. The business address of these entities is Derech Hashalom 53, Givatayim, Israel 5345433.

(17) Consists of 185,805 ordinary shares issuable upon conversion of (i) 115,357 preferred C shares held by Migdal Insurance Company Ltd. ("Migdal Insurance") and (ii) 70,447 preferred C shares held by Migdal Makefet Pension and Provident Funds Ltd. ("Migdal Makefet"). Migdal Insurance and Migdal Makefet are subsidiaries of Migdal Insurance & Financial Holdings Ltd, an Israeli public company. Migdal Insurance and Migdal Makefet operating under independent management and making independent voting and investment decisions. The Investment Committee of Migdal Insurance & Financial Holdings Ltd has adopted a policy for voting in general meetings, as required under regulation, and Migdal votes in accordance therewith. The Investment Committee is also in charge of investment strategy and allocation, carried out by investment division employees. The Investment Committee may therefore be deemed to have voting and dispositive power with respect to the shares held by Migdal Insurance and Migdal Makefet. The Investment Committee consists of more than three members. The business address of these entities is 42 Hayarkon Street, Yavne, Israel 8122745.

## PRINCIPAL STOCKHOLDERS OF PROPOSED COMBINED COMPANY

*Except where specifically noted, the following information and all other information contained in this proxy statement/prospectus/information statement does not give effect to the proposed reverse stock split.*

The following table and accompanying footnotes set forth certain information with respect to the beneficial ownership of the common stock of the combined company, assuming the closing of the merger will occur on November 18, 2021 for:

- each person, or group of affiliated persons, who is known by Advaxis or Biosight to become the beneficial owner of more than 5% of the combined company's common stock upon the consummation of the merger;
- each of the combined company's named executive officers and directors; and
- all of the combined company's executive officers and directors as a group.

Beneficial ownership is based on 58,768,914 shares of combined company common stock anticipated to be outstanding as of November 18, 2021. The following table also assumes that Advaxis management's and Biosight management's options will accelerate and a reverse stock split at 10 to 1.

Beneficial ownership is reported below in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, these rules require that the table below include shares of common stock issuable pursuant to the vesting of restricted stock units and the exercise of stock options and warrants that are either immediately exercisable or exercisable within 60 days of September 17, 2021. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Unless otherwise indicated by footnote, the address for each of the beneficial owners set forth in the table below is c/o Advaxis, Inc., 9 Deer Park Drive, Suite K-1, Monmouth Junction, NJ 08852.

| Name of Beneficial Owner | Total # of Shares Beneficially Owned | Percentage of Ownership |
|---|---|---|
| Kenneth A. Berlin[1] | 19,300 | *% |
| Roy Golan[2] | 622,233 | 1.0% |
| Andres Gutierrez, M.D., Ph.D.[3] | 6,208 | *% |
| David Sidransky[4] | 4,971,855 | 8.5% |
| Pini Orbach | — | — |
| Aaron Sasson | — | — |
| Briggs Morrison[5] | 292,795 | *% |
| Gary Gordon[6] | 177,112 | *% |
| Gary Titus | 177,112 | * |
| Yuval Cabilly | — | — |
| Samir Khleif [7] | 2,797 | *% |
| **All Directors and Officers as a Group (11 People)** [8] | 6,269,412 | 10.5% |
| Entities affiliated with Moshe Arkin[9] | 8,915,964 | 15.1% |
| Israel Biotech Fund I, L.P. and Israel Biotech Fund II, L.P.[10] | 4,968,953 | 8.5% |
| Ilan Holdings (M&I) Ltd.[11] | 4,206,202 | 7.2% |
| Marstrand Partners L.P.[12] | 3,447,766 | 5.9% |
| Odesey I, L.P.[13] | 3,447,754 | 5.9% |
| Tech PE Investments Corp.[14] | 3,152,512 | 5.4% |
| Stela Gengrinovitch[15] | 2,228,914 | 3.8% |
| Entities affiliated with Phoenix Insurance Company Ltd.[16] | 2,196,231 | 3.7% |
| Migdal Insurance & Financial Holdings Ltd.[17] | 2,196,220 | 3.7% |

* Represents beneficial ownership of less than 1%.

(1) Represents 2,167 shares of combined company common stock, and options to purchase 17,133 shares of the combined company common stock exercisable within 60 days.

(2) Represents options to purchase 622,233 shares of the combined company common stock.

(3) Represents 375 shares of combined company common stock and options to purchase 5,833 shares of the combined company common stock exercisable within 60 days.

(4) Consists of 4,969,689 shares of combined company common stock, including the shares held by Israel Biotech Fund I, L.P. and Israel Biotech Fund II, L.P., because Mr. Sidransky is a founder and options to purchase 2,166 shares of combined company common stock exercisable within 60 days.

(5) Represents options to purchase 292,795 shares of the combined company common stock.

(6) Represents options to purchase 177,112 shares of the combined company common stock.

(7) Represents 464 shares of combined company common stock and options to purchase 2,333 shares of the combined company common stock exercisable within 60 days.

(8) Consists of 5,149,807 shares of combined company common stock, options to purchase 1,119,605 shares of combined company common stock exercisable within 60 days.

(9) Consists of (a) (i) 6,432,446 shares of combined company common stock and (ii) options to purchase 170,244 shares of the combined company common stock, held by Arkin Bio Ventures Limited Partnership and (b) 2,196,232 shares of combined company common stock held by Arkin Communication Ltd. Arkin Bio Venture Partners Ltd. is the general partner of Arkin Bio Ventures Limited Partnership and the sole shareholder and chairman of the board of Arkin Bio Venture Partners Ltd. is Moshe Arkin. As a result, Arkin Bio Venture Partners Ltd. and Mr. Arkin may be deemed to share beneficial ownership of the shares held by Arkin Bio Ventures Limited Partnership. Mr. Moshe Arkin is the sole beneficial owner of Arkin Communication Ltd. The business address of Arkin Bio Ventures Limited Partnership, Arkin Communication Ltd., Arkin Bio Venture Partners Ltd. and Mr. Arkin is 6 HaChoshlim St., Bldg. C, Herzliya 46724, Israel.

(10) Consists of 4,968,953 shares of combined company common stock held by Israel Biotech Fund I, L.P. (“IBF I”) and Israel Biotech Fund II, L.P. (“IBF II”). Israel Biotech Fund GP Partners, L.P. (“IBF I GP”) is the sole general partner of IBF I and Israel Biotech Fund GP Partners II, L.P. (“IBF II GP”) is the sole general partner of IBF II. I.B.F. Management, Ltd. (“IBF Management”) is the sole general partner of IBF I GP and IBF II GP. IBF I GP, IBF II GP and IBF Management may be deemed to have sole voting and dispositive with respect to the ordinary shares issuable (i) upon conversion of preferred C shares and (ii) upon conversion of preferred C shares issuable upon exercise of warrants held by IBF I and IBF II. The address of IBF I, IBF II, IBF I GP, IBF II GP and IBF Management is Ruhrberg Science Center, Bell Entrance, 4th Floor, 3 Pekeris Street, Rabin Science Park, Rehovot 7670212, Israel.

(11) Consists of 4,206,202 shares of combined company common stock held by Ilan Holdings (M&I) Ltd. Arrow Pride (Eran Ilan) is the controlling shareholder of Ilan Holdings (M&I) Ltd.. The business address of Ilan Holdings (M&I) Ltd. and Arrow Pride (Eran Ilan) is Lev Hasharon Industrial Park, Kadima, P.O. Box 5062, Israel 6092000.

(12) Consists of 3,447,766 shares of combined company common stock held by Marstrand Partners L.P. The general partner of Marstrand Partners L.P. is Aaron Sasson. The managing member is Aaron Sasson. The business address of Marstrand Partners L.P. is 2535 Lyon Street, San Francisco, CA 94123.

(13) Consists of 3,447,754 shares of combined company common stock held by Odesey I, L.P. The general partner of Odesey I, L.P. is Ori Sasson. The managing member is Ori Sasson. The business address of Odesey I, L.P. is 11 El Sueno, Orinda, CA 94563.

(14) Consists of 3,152,512 shares of combined company common stock held by Tech PE Investments Corp. The registered address of Tech PE Investments Corp. is Mandar House, Suite 301, 3rd Floor, Road Town, Tortola, British Virgin Islands.

(15) Consists of 2,228,914 shares of combined company common stock held by Stela Gengrinovitch.

(16) Consists of 2,196,231 shares of combined company common stock held by The Phoenix Insurance Company Ltd. (for Nostro) (“Nostro”) and The Phoenix Excellence Pension and Provident Fund Ltd. (“Phoenix Excellence”). Haggai Schreiber, Deputy Chief Executive Officer and Chief Investment Officer of Phoenix, Nostro and Phoenix Excellence may be deemed to have voting and dispositive power with respect to the shares held by Phoenix, Nostro and Phoenix Excellence. The business address of these entities is Derech Hashalom 53, Givatayim, Israel 5345433.

(17) Consists of 2,196,220 shares of combined company common stock held by Migdal Insurance Company Ltd. (“Migdal Insurance”) and Migdal Makefet Pension and Provident Funds Ltd. (“Migdal Makefet”). Migdal Insurance and Migdal Makefet are subsidiaries of Migdal Insurance & Financial Holdings Ltd., an Israeli public company. Migdal Insurance and Migdal Makefet operating under independent management and making independent voting and investment decisions. The Investment Committee of Migdal Insurance & Financial Holdings Ltd. has adopted a policy for voting in general meetings, as required under regulation, and Migdal votes in accordance therewith. The Investment Committee is also in charge of investment strategy and allocation, carried out by investment division employees. The Investment Committee may therefore be deemed to have voting and dispositive power with respect to the shares held by Migdal Insurance and Migdal Makefet. The Investment Committee consists of more than three members. The business address of these entities is 42 Hayarkon Street, Yavne, Israel 8122745.

## LEGAL MATTERS

Morgan, Lewis & Bockius LLP will pass upon the validity of Advaxis' common stock offered by this proxy statement/prospectus/information statement.

## EXPERTS

The financial statements of Advaxis, Inc. as of October 31, 2020 and 2019 and for each of the two years in the period ended October 31, 2020 included in this proxy statement/prospectus/information statement have been so included in reliance on the report of Marcum LLP, an independent registered public accounting firm, given on the authority of such firm as experts in auditing and accounting.

The financial statements of Biosight Ltd. as of December 31, 2020 and 2019 and for each of the two years in the period ended December 31, 2020 included in this proxy statement/prospectus/information statement have been so included in reliance on the report (which contains an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 1b to the financial statements) of Kesselman & Kesselman, Certified Public Accountants (Isr.) a member firm of PricewaterhouseCoopers International Limited, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

## WHERE YOU CAN FIND MORE INFORMATION

Advaxis is subject to the informational requirements of the Exchange Act and, in accordance therewith, files annual, quarterly and current reports, proxy statements and other information with the SEC electronically, and the SEC maintains a website that contains Advaxis' filings as well as reports, proxy and information statements, and other information issuers file electronically with the SEC at *www.sec.gov*.

Advaxis also makes available free of charge on or through its website at *www.advaxis.com* its Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after Advaxis electronically files such material with or otherwise furnishes it to the SEC. The website addresses for the SEC and Advaxis are inactive textual references and information on those websites is not part of this proxy statement/prospectus/information statement.

Advaxis has filed with the SEC a registration statement on Form S-4, of which this proxy statement/prospectus/information statement is a part, under the Securities Act to register the shares of Advaxis common stock to be issued to Biosight shareholders in the merger. This proxy statement/prospectus/information statement is a part of that registration statement and constitutes a prospectus of Advaxis, as well as a proxy statement of Advaxis for its special meeting, and it will also serve as an information statement for the stockholders of Biosight. The registration statement, including the attached annexes, exhibits and schedules, contains additional relevant information about Advaxis and Advaxis common stock. This proxy statement/prospectus/information statement does not contain all of the information set forth in the registration statement because certain parts of the registration statement are omitted in accordance with the rules and regulations of the SEC.

Advaxis has supplied all the information contained in this proxy statement/prospectus/information statement relating to Advaxis, and Biosight has supplied all information contained in this proxy statement/prospectus/information statement relating to Biosight.

If you would like to request documents from Advaxis or Biosight, please send a request in writing or by telephone to either Advaxis or Biosight at the following addresses:

Advaxis, Inc.
9 Deer Park Drive, Suite K-1
Monmouth Junction, New Jersey 08852
Attn: Igor Gitelman, VP of Finance
Tel: (917) 940-5651

Biosight Ltd.
3 Hayarden St., Airport City
P.O.B 1083
Lod 7019802 Israel
Attn: Roy Golan, Executive VP & Chief Financial Officer
Tel: +972.3.6568669

If you are an Advaxis stockholder and would like additional copies, without charge, of this proxy statement/prospectus/information statement or if you have questions about the merger, including the procedures for voting your shares, you should contact Advaxis' proxy solicitor, Kingsdale Advisors, at the following address and telephone number:


**Strategic Shareholder Advisor and Proxy Solicitation Agent**
745 Fifth Avenue, 5th Floor, New York, NY 10151
North American Toll Free Phone:
**1-888-518-1560**
Email: contactus@kingsdaleadvisors.com
Call Collect Outside North America: 416-867-2272

**TRADEMARK NOTICE**

Advaxis Immunotherapies™, *Lm* Technology™ and KEYTRUDA® are trademarks of Advaxis, Inc. in the United States. Astarabine™ is a trademark of Biosight Ltd in the United States. Other third-party logos and product/trade names are registered trademarks or trade names of their respective companies.

**OTHER MATTERS**

**Stockholder Proposals**

Stockholders may present proper proposals for inclusion in our proxy statement and for consideration at the next annual meeting of stockholders by submitting their proposals in writing to our Corporate Secretary in a timely manner. For a stockholder proposal to be considered for inclusion in our proxy statement for the 2022 Annual Meeting, our Corporate Secretary must receive the written proposal at our principal executive offices no later than December 22, 2021; provided, however, that in the event that we hold the 2022 Annual Meeting more than 30 days before or after the one-year anniversary date of the Annual Meeting, we will disclose the new deadline by which stockholders proposals must be received under Item 5 of our earliest possible Quarterly Report on Form 10-Q or, if impracticable, by any means reasonably calculated to inform stockholders. In addition, stockholder proposals must otherwise comply with the requirements of Rule 14a-8 of the Exchange Act. Such proposals also must comply with SEC regulations under Rule 14a-8 regarding the inclusion of stockholder proposals in company-sponsored proxy materials. Proposals should be addressed to:

Advaxis Inc.
Attn: Corporate Secretary
9 Deer Park Drive, Suite K-1
Monmouth Junction, NJ 08852

Stockholder proposals to be presented at the 2022 Annual Meeting other than stockholder proposals submitted pursuant to Exchange Act Rule 14a-8 for inclusion in the proxy statement for the 2021 Annual Meeting must be received in writing at our corporate offices not earlier than the close of business on the 120th calendar day and not later than the close of business on the 90th calendar day prior to the one-year anniversary of the date this year's annual meeting and must comply with the other requirements set forth in our bylaws.

**Stockholder Communication with the Advaxis Board**

Stockholders may contact an individual director, the board of directors as a group, or a specified board of directors committee or group, including the non-employee directors as a group, by writing to the following address:

Advaxis, Inc.
9 Deer Park Drive, Suite K-1
Monmouth Junction, NJ 08852
Attn: Board of Directors

Each communication should specify the applicable addressee or addressees to be contacted as well as the general topic of the communication. We will initially receive and process communications before forwarding them to the addressee. We generally will not forward to the directors a stockholder communication that we determine to be primarily commercial in nature or that relates to an improper or irrelevant topic, or that requests general information about us.

**Householding of Proxy Statement/Prospectus/Information Statement**

The SEC has adopted rules that permit companies and intermediaries (e.g., brokers) to satisfy the delivery requirements for Notices of Internet Availability of Proxy Materials or other special meeting materials with respect to two or more stockholders sharing the same address by delivering a single Notice of Internet Availability of Proxy Materials or other special meeting materials addressed to those stockholders. This process, which is commonly referred to as "householding," potentially means extra convenience for stockholders and cost savings for companies.

In connection with the Advaxis special meeting, a number of brokers with account holders who are Advaxis stockholders will be "householding" Advaxis' proxy materials. A single Notice of Internet Availability of Proxy Materials will be delivered to multiple stockholders sharing an address unless contrary instructions have been received from the affected stockholders. Once the stockholder has received notice from his or her broker that the broker will be "householding" communications to the stockholder's address, "householding" will continue until the stockholder are notified otherwise or until the stockholder revokes his or her consent. If, at any time, the stockholder no longer wishes to participate in "householding" and would prefer to receive a separate Notice of Internet Availability of Proxy Materials, please notify the broker or Advaxis. Direct the written request to 9 Deer Park Drive, Suite K-1, Monmouth Junction, New Jersey 08852, attention Investor Relations, telephone number (609) 452-9813. Stockholders who currently receive multiple copies of the Notices of Internet Availability of Proxy Materials at their addresses and would like to request "householding" of their communications should contact their brokers.

**FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**INDEX TO FINANCIAL STATEMENTS**

**ADVAXIS, INC.**



**BIOSIGHT LTD.**

**ADVAXIS, INC.**
**CONDENSED CONSOLIDATED BALANCE SHEETS**
(In thousands, except share and per share data)

| | July 31, 2021 (Unaudited) | October 31, 2020 |
|---|---|---|
| ASSETS | | |
| Current Assets: | | |
| Cash and cash equivalents | $ 45,257 | $ 25,178 |
| Deferred expenses | 1,047 | 1,808 |
| Prepaid expenses and other current assets | 1,138 | 865 |
| Total current assets | 47,442 | 27,851 |
| | | |
| Property and equipment (net of accumulated depreciation) | 278 | 2,393 |
| Intangible assets (net of accumulated amortization) | 3,291 | 3,261 |
| Operating right-of-use asset (net of accumulated amortization) | - | 4,839 |
| Other assets | 11 | 182 |
| Total assets | $ 51,022 | $ 38,526 |
| | | |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | $ 454 | $ 410 |
| Accrued expenses | 2,206 | 1,737 |
| Common stock warrant liability | 4,085 | 17 |
| Current portion of operating lease liability | - | 962 |
| Deferred revenue | - | 165 |
| Total current liabilities | 6,745 | 3,291 |
| | | |
| Operating lease liability, net of current portion | - | 5,055 |
| Total liabilities | 6,745 | 8,346 |
| | | |
| Commitments and contingencies – Note 9 | | |
| | | |
| Stockholders' equity: | | |
| Preferred stock, $0.001 par value; 5,000,000 shares authorized; Series B Preferred stock; 0 shares issued and outstanding at July 31, 2021 and October 31, 2020. Liquidation preference of $0 at July 31, 2021 and October 31, 2020 | - | - |
| Common stock - $0.001 par value; 170,000,000 shares authorized, 145,638,459 and 78,074,023 shares issued and outstanding at July 31, 2021 and October 31, 2020 | 146 | 78 |
| Additional paid-in capital | 467,287 | 440,840 |
| Accumulated deficit | (423,156) | (410,738) |
| Total stockholders' equity | 44,277 | 30,180 |
| Total liabilities and stockholders' equity | $ 51,022 | $ 38,526 |

The accompanying notes should be read in conjunction with the financial statements.

**ADVAXIS, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)**
(In thousands, except share and per share data)

| | Three Months Ended July 31, | | Nine Months Ended July 31, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Revenue | $ 250 | $ - | $ 3,240 | $ 253 |
| Operating expenses: | | | | |
| Research and development expenses | 1,703 | 3,458 | 8,616 | 12,239 |
| General and administrative expenses | 2,678 | 2,384 | 9,038 | 8,063 |
| Total operating expenses | 4,381 | 5,842 | 17,654 | 20,302 |
| Loss from operations | (4,131) | (5,842) | (14,414) | (20,049) |
| Other income (expense): | | | | |
| Interest income, net | 1 | 7 | 3 | 108 |
| Net changes in fair value of derivative liabilities | 846 | 7 | 1,814 | (16) |
| Other (expense) income | - | (1) | 229 | (2) |
| Net loss before income taxes | (3,284) | (5,829) | (12,368) | (19,959) |
| Income tax expense | 50 | - | 50 | 50 |
| Net loss | $ (3,334) | $ (5,829) | $ (12,418) | $ (20,009) |
| Net loss per common share, basic and diluted | $ (0.02) | $ (0.09) | $ (0.10) | $ (0.35) |
| Weighted average number of common shares, basic and diluted | 145,638,459 | 61,634,031 | 123,514,178 | 57,963,228 |

The accompanying notes should be read in conjunction with the financial statements.

**ADVAXIS, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)**
(In thousands)

| | Nine Months Ended July 31, | |
|---|---|---|
| | 2021 | 2020 |
| OPERATING ACTIVITIES | | |
| Net loss | $ (12,418) | $ (20,009) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Share based compensation | 511 | 708 |
| Employee stock purchase plan expense | - | 1 |
| (Gain) loss on change in value of warrants | (1,814) | 16 |
| Loss on disposal of property and equipment | 1,530 | - |
| Abandonment of intangible assets | 90 | 892 |
| Depreciation expense | 366 | 683 |
| Amortization expense of intangible assets | 203 | 263 |
| Amortization of right-of-use asset | 327 | 553 |
| Net gain on write-off of right-of-use asset and lease liability | (1,116) | - |
| Change in operating assets and liabilities: | | |
| Prepaid expenses, other current assets and deferred expenses | 488 | 977 |
| Other assets | 171 | 1 |
| Accounts payable and accrued expenses | 513 | (2,251) |
| Deferred revenue | (165) | 50 |
| Operating lease liabilities | (389) | (606) |
| Net cash used in operating activities | (11,703) | (18,722) |
| INVESTING ACTIVITIES | | |
| Proceeds from disposal of property and equipment | 219 | - |
| Cost of intangible assets | (323) | (421) |
| Net cash used in investing activities | (104) | (421) |
| FINANCING ACTIVITIES | | |
| Net proceeds of issuance of common stock and warrants | 28,115 | 10,621 |
| Warrant exercises | 3,771 | - |
| Proceeds from employee stock purchase plan | - | 5 |
| Employee tax withholdings paid on equity awards | - | (2) |
| Tax shares sold to pay for employee tax withholdings on equity awards | - | 2 |
| Net cash provided by financing activities | 31,886 | 10,626 |
| Net increase (decrease) in cash and cash equivalents | 20,079 | (8,517) |
| Cash and cash equivalents at beginning of period | 25,178 | 32,363 |
| Cash and cash equivalents at end of period | $ 45,257 | $ 23,846 |
| SUPPLEMENTAL CASH FLOW INFORMATION | | |
| Cash paid for taxes | $ 50 | $ 50 |
| SUPPLEMENTAL DISCLOSURE OF NON-CASH AND FINANCING ACTIVITIES | | |
| Warrant liability reclassified into equity | - | 2 |
| Amounts accrued for offering costs | - | 37 |
| Commitment fee shares issued for equity line | - | 644 |

The accompanying notes should be read in conjunction with the financial statements.

## 1. NATURE OF OPERATIONS

Advaxis, Inc. ("Advaxis" or the "Company") is a clinical-stage biotechnology company focused on the development and commercialization of proprietary *Listeria monocytogenes* ("*Lm*")-based antigen delivery products. The Company is using its *Lm* platform directed against tumor-specific targets in order to engage the patient's immune system to destroy tumor cells. Through a license from the University of Pennsylvania, Advaxis has exclusive access to this proprietary formulation of attenuated *Lm* called *Lm* Technology™. Advaxis' proprietary approach is designed to deploy a unique mechanism of action that redirects the immune system to attack cancer in three distinct ways:

- Alerting and training the immune system by activating multiple pathways in Antigen-Presenting Cells ("APCs") with the equivalent of multiple adjuvants;
- Attacking the tumor by generating a strong, cancer-specific T cell response; and
- Breaking down tumor protection through suppression of the protective cells in the tumor microenvironment ("TME") that shields the tumor from the immune system. This enables the activated T cells to begin working to attack the tumor cells.

Advaxis' proprietary *Lm* platform technology has demonstrated clinical activity in several of its programs and has been dosed in over 470 patients across multiple clinical trials and in various tumor types. The Company believes that *Lm* Technology immunotherapies can complement and address significant unmet needs in the current oncology treatment landscape. Specifically, its product candidates have the potential to work synergistically with other immunotherapies, including checkpoint inhibitors, while having a generally well-tolerated safety profile.

### Merger with Biosight

On July 4, 2021, the Company entered into a Merger Agreement (the "Merger Agreement"), subject to shareholder approval, with Biosight Ltd. ("Biosight") and Advaxis Ltd. ("Merger Sub"), a direct, wholly-owned subsidiary of Advaxis. Under the terms of the agreement, Biosight will merge with and into Merger Sub, with Biosight continuing as the surviving company and a wholly-owned subsidiary of Advaxis (the "Merger"). Immediately after the merger, Advaxis stockholders as of immediately prior to the merger are expected to own approximately 25% of the outstanding shares of the combined company and former Biosight shareholders are expected to own approximately 75% of the outstanding shares of the combined company. The merger will be accounted for a reverse acquisition pursuant to ASC 805-40.

At the effective time of the Merger (the "Effective Time"), each share of share capital of Biosight (excluding certain Biosight shares that may be cancelled pursuant to the terms of the Merger Agreement) issued and outstanding immediately prior to the Effective Time will be converted into the right to receive a number of shares of Advaxis common stock, par value $0.001 per share, equal to the exchange ratio, 118.2009 shares of Advaxis common stock per Biosight share (subject to adjustment to account for the proposed Advaxis reverse stock split).

If the Merger Agreement is terminated under certain circumstances, Advaxis or Biosight, as applicable, will be required to pay the other party a termination fee up to $7,500,000.

### Liquidity and Capital Resources

*Liquidity and Management's Plans*

Similar to other development stage biotechnology companies, the Company's products that are being developed have not generated significant revenue. As a result, the Company has suffered recurring losses and requires significant cash resources to execute its business plans. These losses are expected to continue for the foreseeable future.

As of July 31, 2021, the Company had approximately $45.3 million in cash and cash equivalents. Although the Company expects to have sufficient capital to fund its obligations, as they become due, in the ordinary course of business until at least October 2022, the actual amount of cash that it will need to operate is subject to many factors. Over the past year, the Company has taken steps to obtain additional financing, including conducting sales of its common stock through its at-the-market ("ATM") program through A.G.P./Alliance Global Partners, an equity line financing arrangement with Lincoln Park Capital and the completion of a registered direct offering and concurrent private placement with two healthcare-focused, institutional investors in April 2021, as further described below. The Company also received aggregate proceeds of about $3.8 million during the nine months ended July 31, 2021 upon the exercise of outstanding warrants, which were payable upon exercise.

In April 2021, the Company entered into definitive agreements with two healthcare-focused, institutional investors for the purchase of (i) 17,577,400 shares of common stock, (ii) 7,671,937 pre-funded warrants to purchase 7,671,937 shares of common stock and (iii) registered common share purchase warrants to purchase 11,244,135 shares of common stock ("Accompanying Warrants") in a registered direct offering (the "April 2021 Registered Direct Offering"). The Company also issued to the investors, in a concurrent private placement (the "April 2021 Private Placement" and together with the April 2021 Registered Direct Offering, the "April 2021 Offering"), unregistered common share purchase warrants to purchase 14,005,202 shares of the Company's common stock (the "Private Placement Warrants"). The Company received gross proceeds of approximately $20 million, before deducting the fees and expenses payable by the Company in connection with the April 2021 Offering.

On November 27, 2020, the Company completed an underwritten public offering of 26,666,666 shares of common stock and common stock warrants to purchase up to 13,333,333 shares of common stock (the "November 2020 Offering"). On November 24, 2020, the underwriters notified the Company that they had exercised their option to purchase an additional 3,999,999 shares of common stock and 1,999,999 warrants in full. The Company received gross proceeds of approximately $9.2 million, before deducting the fees and expenses payable by the Company in connection with the November 2020 Offering.

The Company recognizes it will need to raise additional capital in order to continue to execute its business plan in the future. There is no assurance that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to the Company or whether the Company will become profitable and generate positive operating cash flow. If the Company is unable to raise sufficient additional funds, it will have to further scale back its operations.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND BASIS OF PRESENTATION**

*Basis of Presentation/Estimates*

The accompanying unaudited interim condensed consolidated financial statements and related notes have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information, and in accordance with the rules and regulations of the Securities and Exchange Commission ("SEC") with respect to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements and the accompanying unaudited interim condensed consolidated balance sheet as of July 31, 2021 has been derived from the Company's October 31, 2020 audited financial statements. In the opinion of management, the unaudited interim condensed consolidated financial statements furnished include all adjustments (consisting of normal recurring accruals) necessary for a fair statement of the results for the interim periods presented.

Operating results for interim periods are not necessarily indicative of the results to be expected for the full year. The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and the related disclosures at the date of the financial statements and during the reporting period. Significant estimates include the timelines associated with revenue recognition on upfront payments received, fair value and recoverability of the carrying value of property and equipment and intangible assets, fair value of warrant liability, grant date fair value of options, deferred tax assets and any related valuation allowance and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates, based on historical experience and on various other assumptions that it believes to be reasonable under the circumstances. Actual results could materially differ from these estimates.

These unaudited interim condensed consolidated financial statements should be read in conjunction with the financial statements of the Company as of and for the fiscal year ended October 31, 2020 and notes thereto contained in the Company's 2020 Annual Report on Form 10-K, as filed with the SEC on January 22, 2021.

*Principles of Consolidation*

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All significant intercompany accounts and transactions have been eliminated.

*Net Income (Loss) per Share*

Basic net income or loss per common share is computed by dividing net income or loss available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted earnings per share give effect to dilutive options, warrants, restricted stock units and other potential common stock outstanding during the period. In the case of a net loss, the impact of the potential common stock resulting from warrants, outstanding stock options and convertible debt are not included in the computation of diluted loss per share, as the effect would be anti-dilutive. In the case of net income, the impact of the potential common stock resulting from these instruments that have intrinsic value are included in the diluted earnings per share. The table below sets forth the number of potential shares of common stock that have been excluded from diluted net loss per share. As of July 31, 2021 and July 31, 2020, 0 and 327,338 warrants, respectively, are included in the basic earnings per share computation because the exercise price was $0.

| | As of July 31, | |
|---|---|---|
| | 2021 | 2020 |
| Warrants | 30,225,397 | 5,070,888 |
| Stock options | 900,472 | 914,577 |
| Restricted stock units | - | 5,818 |
| Total | 31,125,869 | 5,991,283 |

Sequencing Policy

The Company adopted a sequencing policy under ASC 815-40-35, if reclassification of contracts from equity to liabilities is necessary pursuant to ASC 815 due to the Company's inability to demonstrate it has sufficient authorized shares. This was due to the Company committing more shares than authorized. Certain instruments are classified as liabilities, after allocating available authorized shares on the basis of the most recent grant date of potentially dilutive instruments. Pursuant to ASC 815, issuances of securities granted as compensation in a share-based payment arrangement are not subject to the sequencing policy.

*Recent Accounting Standards*

Management does not believe that any recently issued, but not yet effective accounting pronouncements, if adopted, would have a material impact on the accompanying condensed consolidated financial statements.

**3. PROPERTY AND EQUIPMENT**

Property and equipment, net consisted of the following (in thousands):

| | July 31, 2021 | October 31, 2020 |
|---|---|---|
| Leasehold improvements | $ - | $ 2,335 |
| Laboratory equipment | 373 | 1,218 |
| Furniture and fixtures | - | 744 |
| Computer equipment | 409 | 409 |
| Construction in progress | - | 19 |
| Total property and equipment | 782 | 4,725 |
| Accumulated depreciation and amortization | (504) | (2,332) |
| Net property and equipment | $ 278 | $ 2,393 |

Depreciation expense for the three months ended July 31, 2021 and 2020 was approximately $50,000 and $0.2 million, respectively. Depreciation expense for the nine months ended July 31, 2021 and 2020 was approximately $0.4 million and $0.7 million, respectively. During the nine months ended July 31, 2021, the Company incurred a loss on disposal of equipment of approximately $1.5 million, $1.0 million of which is reflected in the research and development expenses and $0.5 million of which is reflected in the general and administrative expenses in the statement of operations.

**4. INTANGIBLE ASSETS**

Intangible assets, net consisted of the following (in thousands):

| | July 31, 2021 | October 31, 2020 |
|---|---|---|
| Patents | $ 4,705 | $ 4,479 |
| Licenses | 777 | 777 |
| Software | 117 | 117 |
| Total intangibles | 5,599 | 5,373 |
| Accumulated amortization | (2,308) | (2,112) |
| Intangible assets | $ 3,291 | $ 3,261 |

The expiration dates of the existing patents range from 2021 to 2039 but the expiration dates can be extended based on market approval if granted and/or based on existing laws and regulations. Capitalized costs associated with patent applications that are abandoned without future value are charged to expense when the determination is made not to further pursue the application. Patent applications having a net book value of approximately $21,000 and $0.3 million were abandoned and were charged to general and administrative expenses in the statement of operations for each of the three months ended July 31, 2021 and 2020, respectively. Patent applications having a net book value of approximately $90,000 and $0.9 million were abandoned and were charged to general and administrative expenses in the statement of operations for the nine months ended July 31, 2021 and 2020, respectively. Amortization expense for intangible assets that was charged to general and administrative expense in the statement of operations aggregated approximately $68,000 and $79,000 for the three months ended July 31, 2021 and 2020, respectively. Amortization expense for intangible assets that was charged to general and administrative expense in the statement of operations aggregated approximately $0.2 and $0.3 million for each of the nine months ended July 31, 2021 and 2020, respectively.

Management has reviewed its long-lived assets for impairment whenever events and circumstances indicate that the carrying value of an asset might not be recoverable. Net assets are recorded on the balance sheet for patents and licenses related to axalimogene filolisbac (AXAL), ADXS-HOT, ADXS-PSA and other products that are in development. However, if a competitor were to gain FDA approval for a similar treatment before the Company or if future clinical trials fail to meet the targeted endpoints, the Company will likely record an impairment related to these assets. In addition, if an application is rejected or fails to be issued, the Company would record an impairment of its estimated book value. Lastly, if the Company is unable to raise enough capital to continue funding its studies and developing its intellectual property, the Company would likely record an impairment to these assets.

As of July 31, 2021, the estimated amortization expense by fiscal year based on the current carrying value of intangible assets is as follows (in thousands):

| | Fiscal year ending October 31, |
|---|---|
| 2021 (Remaining) | $ 68 |
| 2022 | 273 |
| 2023 | 273 |
| 2024 | 273 |
| 2025 | 273 |
| Thereafter | 2,131 |
| Total | $ 3,291 |

**5. ACCRUED EXPENSES:**

The following table summarizes accrued expenses included in the condensed consolidated balance sheets (in thousands):

| | July 31, 2021 | October 31, 2020 |
|---|---|---|
| Salaries and other compensation | $ 634 | $ 737 |
| Vendors | 1,168 | 671 |
| Professional fees | 404 | 329 |
| Total accrued expenses | $ 2,206 | $ 1,737 |

**6. COMMON STOCK PURCHASE WARRANTS AND WARRANT LIABILITY**

*Warrants*

As of July 31, 2021, there were outstanding and exercisable warrants to purchase 30,225,397 shares of our common stock with exercise prices ranging from $0.30 to $281.25 per share. Information on the outstanding warrants is as follows:

| Exercise Price | Number of Shares Underlying Warrants | Expiration Date | Type of Financing |
|---|---|---|---|
| $ 281.25 | 25 | N/A | Other warrants |
| $ 0.30 | 70,297 | July 2024 | September 2018 Public Offering |
| $ 2.80 | 327,338 | September 2024 | July 2019 Public Offering |
| $ 0.35 | 4,578,400 | November 2025 | November 2020 Public Offering |
| $ 0.70 | 11,244,135 | April 2026 | April 2021 Registered Direct Offering (Accompanying Warrants) |
| $ 0.70 | 14,005,202 | 5 years after the date such warrants become exercisable, if ever | April 2021 Private Placement (Private Placement Warrants) |
| **Grand Total** | 30,225,397 | | |

As of October 31, 2020, there were outstanding warrants to purchase 398,226 shares of our common stock with exercise prices ranging from $0 to $281.25 per share. Information on the outstanding warrants is as follows:

| Exercise Price | Number of Shares Underlying Warrants | Expiration Date | Type of Financing |
|---|---|---|---|
| $ - | 327,338 | July 2024 | July 2019 Public Offering |
| $ 281.25 | 25 | N/A | Other Warrants |
| $ 0.372 | 70,863 | September 2024 | September 2018 Public Offering |
| **Grand Total** | 398,226 | | |

A summary of warrant activity for the nine months ended July 31, 2021 is as follows (in thousands, except share and per share data):

| | Warrants | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life In Years | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding and exercisable warrants at October 31, 2020 | 398,226 | $ 0.08 | 3.76 | $ 110,640 |
| Issued | 48,254,606 | 0.48 | | |
| Exercised | (18,427,435) | 0.20 | | |
| Outstanding and exercisable warrants at July 31, 2021 | 30,225,397 | $ 0.64 | 4.62 | $ 282,437 |

As of July 31, 2021, the Company had 18,910,965 of its total 30,225,397 outstanding warrants classified as equity (equity warrants). At October 31, 2020, the Company had 327,363 of its total 398,226 outstanding warrants classified as equity (equity warrants). At issuance, equity warrants are recorded at their relative fair values, using the relative fair value method, in the stockholders' equity section of the condensed consolidated balance sheets.

*Warrant Liability*

As of July 31, 2021, the Company had 11,314,432 of its total 30,225,397 outstanding warrants from April 2021 Private Placement Offering and September 2018 Public Offering classified as liabilities (liability warrants). At October 31, 2020, the Company had 70,863 of its total 398,226 outstanding warrants classified as liabilities (liability warrants).

The warrants issued in the April 2021 Private Placement will become exercisable only on such day, if ever, that is 14 days after the Company files an amendment to the Company's Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock, $0.001 par value per share from 170,000,000 shares to 300,000,000 shares. These warrants expire five years after the date they become exercisable. As a result, liability classification is warranted. For these liability warrants, the Company utilized the Black Scholes model to calculate the fair value of these warrants at issuance and at each subsequent reporting date.

In measuring the warrant liability for the warrants issued in the April 2021 Private Placement at July 31, 2021 and April 14, 2021 (issuance date), the Company used the following inputs in its Black Scholes model:

| | July 31, 2021 | April 14, 2021 |
|---|---|---|
| Exercise Price | $ 0.70 | $ 0.70 |
| Stock Price | $ 0.41 | $ 0.57 |
| Expected Term | 5.00 years | 5.00 years |
| Volatility % | 107% | 106% |
| Risk Free Rate | 0.69% | 0.85% |

The September 2018 Public Offering warrants contain a down round feature, except for exempt issuances as defined in the warrant agreement, in which the exercise price would immediately be reduced to match a dilutive issuance of common stock, options, convertible securities and changes in option price or rate of conversion. As of July 31, 2021, the down round feature was triggered three times and the exercise price of the warrants were reduced from $22.50 to $0.30. The warrants require liability classification as the warrant agreement requires the Company to maintain an effective registration statement and does not specify any circumstances under which settlement in other than cash would be permitted or required. As a result, net cash settlement is assumed and liability classification is warranted. For these liability warrants, the Company utilized the Monte Carlo simulation model to calculate the fair value of these warrants at issuance and at each subsequent reporting date.

In measuring the warrant liability for the September 2018 Public Offering warrants at July 31, 2021 and October 31, 2020, the Company used the following inputs in its Monte Carlo simulation model:

| | July 31, 2021 | October 31, 2020 |
|---|---|---|
| Exercise Price | $ 0.30 | $ 0.37 |
| Stock Price | $ 0.41 | $ 0.34 |
| Expected Term | 3.12 years | 3.87 years |
| Volatility % | 123% | 106% |
| Risk Free Rate | 0.35% | 0.29% |

**7. SHARE BASED COMPENSATION**

The following table summarizes share-based compensation expense included in the condensed consolidated statements of operations (in thousands):

| | Three Months Ended July 31, | | Nine Months Ended July 31, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Research and development | $ 29 | $ 79 | $ 142 | $ 233 |
| General and administrative | 31 | 176 | 369 | 475 |
| Total | $ 60 | $ 255 | $ 511 | $ 708 |

*Restricted Stock Units (RSUs)*

A summary of the Company's RSU activity and related information for the nine months ended July 31, 2021 is as follows:

| | Number of RSUs | Weighted-Average Grant Date Fair Value |
|---|---|---|
| Balance at October 31, 2020 | 5,556 | $ 24.32 |
| Vested | (5,555) | |
| Cancelled | (1) | |
| Balance at July 31, 2021 | - | $ - |

As of July 31, 2021, there was no unrecognized compensation cost related to non-vested RSUs.

*Employee Stock Awards*

Common Stock issued to executives and employees related to vested incentive retention awards and employment inducements totaled 0 shares during each of the three months ended July 31, 2021 and 2020, respectively. Total stock compensation expense associated with employee awards for the three months ended July 31, 2021 and 2020 was approximately $0 and $40,000, respectively.

Common Stock issued to executives and employees related to vested incentive retention awards and employment inducements totaled 5,555 shares and 8,608 shares during the nine months ended July 31, 2021 and 2020, respectively. Total stock compensation expense associated with employee awards for the nine months ended July 31, 2021 and 2020 was approximately $67,000 and $0.1 million, respectively.

*Stock Options*

A summary of changes in the stock option plan for the nine months ended July 31, 2021 is as follows:

| | Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life In Years | Aggregate Intrinsic Value (in thousands) |
|---|---|---|---|---|
| Outstanding as of October 31, 2020 | 1,011,768 | $ 33.43 | 8.04 | $ 4 |
| Granted | 50,000 | 0.39 | | |
| Exercised | (333) | 0.30 | | |
| Cancelled or expired | (160,963) | 102.78 | | |
| Outstanding as of July 31, 2021 | 900,472 | $ 19.21 | 8.01 | $ 14 |
| Vested and exercisable at July 31, 2021 | 365,964 | $ 46.14 | 6.85 | $ 4 |

The following table summarizes information about the outstanding and exercisable options at July 31, 2021:

| Options Outstanding | | | | Options Exercisable | | |
|---|---|---|---|---|---|---|
| Exercise Price Range | Number Outstanding | Weighted Average Remaining Contractual | Weighted Average Exercise Price | Number Exercisable | Weighted Average Remaining Contractual | Weighted Average Exercise Price |
| $ .30-$10.00 | 734,033 | 8.68 | $ 1.06 | 200,080 | 8.35 | $ 1.86 |
| $ 10.01-$100.00 | 90,750 | 6.48 | $ 29.01 | 90,195 | 6.47 | $ 29.12 |
| $ 100.01-$200.00 | 50,965 | 3.73 | $ 162.16 | 50,965 | 3.73 | $ 162.16 |
| $ 200.01-$277.50 | 24,724 | 2.47 | $ 227.40 | 24,724 | 2.47 | $ 227.40 |

During the nine months ended July 31, 2021, the Company granted options to purchase 50,000 shares of its common stock to an employee. The stock options have a ten-year term, vest over three years from the date of grant, and have an exercise price of $0.39.

Total compensation cost related to the Company's outstanding stock options, recognized in the statement of operations for the three months ended July 31, 2021 and 2020 was approximately $60,000 and $0.2 million, respectively. For the nine months ended July 31, 2021 and 2020, compensation cost related to the Company's outstanding stock options was approximately $0.4 million and $0.6 million, respectively

As of July 31, 2021, there was approximately $0.2 million of unrecognized compensation cost related to non-vested stock option awards, which is expected to be recognized over a remaining weighted average vesting period of 1.63 years.

As of July 31, 2021, the aggregate intrinsic value of vested and exercisable options was approximately $4,000 and the aggregate intrinsic value of non-vested options was approximately $10,000.

In determining the fair value of the stock options granted during the nine months ended July 31, 2021, the Company used the following inputs in its Black Scholes Merton model:

| | Nine Months Ended July 31, 2021 |
|---|---|
| Expected Term | 6 years |
| Expected Volatility | 103.27% |
| Expected Dividends | 0% |
| Risk Free Interest Rate | 0.53% |

*Employee Stock Purchase Plan*

During the nine months ended July 31, 2021 and 2020, the Company issued 1,000 and 11,148 shares, respectively, that were purchased under the 2018 Employee Stock Purchase Plan ("ESPP"). In July 2021, the ESPP was terminated.

*Potential Acceleration of Stock Options*

In the event of a merger transaction, similar to the Merger Agreement described in Note 1, all of the Chief Executive Officer's 73,777 unvested stock options, pursuant to his employment agreement, would accelerate.

**8. LICENSING AGREEMENTS**

*OS Therapies LLC*

On September 4, 2018, the Company entered into a development, license and supply agreement with OS Therapies ("OST") for the use of ADXS31-164, also known as ADXS-HER2, for evaluation in the treatment of osteosarcoma in humans. Under the terms of the license agreement, as amended, OST will be responsible for the conduct and funding of a clinical study evaluating ADXS-HER2 in recurrent, completely resected osteosarcoma. Under the most recent amendment to the licensing agreement, OST agreed to pay Advaxis $25,000 per month ("Monthly Payment") starting on April 30, 2020 until it achieved its funding milestone of $2,337,500. Upon receipt of the first Monthly Payment, Advaxis initiated the transfer of the intellectual property and licensing rights of ADXS31-164, which were licensed pursuant to the Penn Agreement, back to the University of Pennsylvania. Contemporaneously, OST entered into negotiations with the University of Pennsylvania to establish a licensing agreement for ADXS31-164 to OST for clinical and commercial development of the ADXS31-164 technology.

In December 2020 and January 2021, the Company received an aggregate of $1,615,000 from OS Therapies upon achievement of the funding milestone set forth in the license agreement, and recorded $1,615,000 in revenue. The Company therefore transferred and OST took full ownership of the IND application for ADXS31-164 in its entirety along with agreements and promises contained therein, as well as all obligations associated with this IND or any HER2 product/program development.

On April 26, 2021, the Company achieved the second milestone set forth in the license agreement for evaluation in the treatment of osteosarcoma in humans and recorded $1,375,000 in revenue. The Company received the amount due from OS Therapies of $1,375,000 in May 2021.

*Global BioPharma Inc.*

On December 9, 2013, the Company entered into an exclusive licensing agreement for the development and commercialization of axalimogene filolisbac with Global BioPharma, Inc. ("GBP"), a Taiwanese based biotech company funded by a group of investors led by Taiwan Biotech Co., Ltd (TBC). During each of the nine months ended July 31, 2021 and 2020, the Company recorded $0.3 million in revenue for the annual license fee renewal.

**9. COMMITMENTS AND CONTINGENCIES**

*Legal Proceedings*

The Company is from time to time involved in legal proceedings in the ordinary course of our business. The Company does not believe that any of these claims or proceedings against the Company is likely to have, individually or in the aggregate, a material adverse effect on the financial condition or results of operations.

*Merger Agreement*

In the event of the closing of the Merger Agreement, the Company may be required under certain circumstances to pay the following:

- Board-approved employee bonuses totaling approximately $1 million
- In the event of involuntary termination, approximately $2.5 million in termination payments to Advaxis' current executives
- A tail insurance policy with a premium of approximately $2 million
- Success fee to bankers of approximately $0.5 million

**10. LEASES**

*Operating Leases*

The Company previously leased a corporate office and manufacturing facility in Princeton, New Jersey under an operating lease that was set to expire in November 2025. On March 26, 2021, the Company entered into a Lease Termination and Surrender Agreement with respect to this lease agreement. The Lease Termination and Surrender Agreement provides for the early termination of the lease, which became effective on March 31, 2021. In connection with the early termination of the lease, the Company was required to pay a $1,000,000 termination payment. The unapplied security deposit totaling approximately $182,000 was credited against the termination fee for a net payment of approximately $818,000. The Company wrote off of the remaining right-of-use asset of approximately $4.5 million and lease liability of approximately $5.6 million. After consideration of the termination payment and write off of remaining right-of-use asset and lease liability, the Company recorded a net gain of approximately $0.1 million.

On March 25, 2021, the Company entered into a new lease agreement for its corporate office/lab with base rent of approximately $29,000 per year, plus other expenses. The lease expires on March 25, 2022 and the Company has the option to renew the lease for one additional successive one-year term upon six months written notice to the landlord. This new lease is accounted for as a short-term lease and the Company has elected to not recognize the right-of-use asset and lease liability.

As a result of the termination of the Company's prior lease agreement pursuant to the Lease Termination and Surrender Agreement, the Company does not have an outstanding lease liability or operating right-of-use asset recorded as of July 31, 2021.

Supplemental lease expense related to leases was as follows (in thousands):

| Lease Cost (in thousands) | Statements of Operations Classification | For the Three Months Ended July 31, 2021 | For the Nine Months Ended July 31, 2021 |
|---|---|---|---|
| Operating lease cost | General and administrative | - | 1,301 |
| Short-term lease cost | General and administrative | 12 | 16 |
| Variable lease cost | General and administrative | $ 4 | 165 |
| Total lease expense | | $ 16 | 1,482 |

| Lease Cost (in thousands) | Statements of Operations Classification | For the Three Months Ended July 31, 2020 | For the Nine Months Ended July 31, 2020 |
|---|---|---|---|
| Operating lease cost | General and administrative | 290 | 869 |
| Short-term lease cost | General and administrative | 83 | 249 |
| Variable lease cost | General and administrative | $ 108 | 282 |
| Total lease expense | | $ 481 | 1,400 |

Supplemental cash flow information related to operating leases was as follows:

| | For the Three Months Ended July 31, 2021 | For the Nine Months Ended July 31, 2021 |
|---|---|---|
| Cash paid for operating lease liabilities | $ - | 1,363 |

| | For the Three Months Ended July 31, 2020 | For the Nine Months Ended July 31, 2020 |
|---|---|---|
| Cash paid for operating lease liabilities | $ 311 | 922 |

**11. STOCKHOLDERS' EQUITY**

*Public Offerings*

In April 2021, the Company entered into a securities purchase agreement (the "Purchase Agreement") with certain investors. The Purchase Agreement provided for the sale and issuance by the Company of an aggregate of 17,577,400 shares (the "Shares") of the Company's common stock, $0.001 par value (the "Common Stock"), at an offering price of $0.7921 per Share and 7,671,937 pre-funded warrants to certain purchasers whose purchase of additional Shares would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 9.99% of the Company's outstanding Common Stock immediately following the consummation of the offering (the "Pre-Funded Warrants"). The Shares and Pre-Funded Warrants were sold together with warrants to purchase up to 11,244,135 shares of Common Stock (the "Accompanying Warrants" and together with the Shares and the Pre-Funded Warrants, the "Securities"). The Pre-Funded Warrants were sold for a purchase price of $0.7911 per share and have an exercise price of $0.001 per share. The Pre-Funded Warrants were immediately exercisable and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. Each Accompanying Warrant has an exercise price per share of $0.70, became exercisable immediately and will expire on the fifth anniversary of the original issuance date.

The Purchase Agreement also provided for a concurrent private placement (the "Private Placement") of 14,005,202 warrants to purchase the Company's Common Stock (the "Private Placement Warrants") with the purchasers in the Registered Offering. The Private Placement Warrants will be exercisable for an aggregate of 14,005,202 shares of Common Stock at any time on or after such date, if ever, that is 14 days after the Company files an amendment (the "Authorized Shares Amendment") to the Company's Amended and Restated Certificate of Incorporation to increase the number of authorized shares of Common Stock, $0.001 par value per share from 170,000,000 shares to 300,000,000 shares with the Delaware Secretary of State and on or prior to the date that is five years after such date. The Private Placement Warrants have an exercise price of $0.70 per share.

In March 2021, the Company sold 886,048 shares of its common stock via the at-the-market ("ATM") program through A.G.P./Alliance Global Partners netting approximately $0.7 million in proceeds.

In November 2020, the Company closed on a public offering of 30,666,665 shares of its common stock at a public offering price of $0.30 per share, for gross proceeds of approximately $9.2 million, which gives effect to the exercise of the underwriter's option in full. In addition, the Company also undertook a concurrent private placement of warrants to purchase up to 15,333,332 shares of common stock. The warrants have an exercise price per share of $0.35, are exercisable immediately and will expire five years from the date of issuance. The warrants also provide that if there is no effective registration statement registering, or no current prospectus available for, the issuance or resale of the warrant shares, the warrants may be exercised via a cashless exercise. After deducting the underwriting discounts and commissions and other offering expenses, the net proceeds from the offering were approximately $8.5 million.

During the nine months ended July 31, 2021, warrant holders from the Company's November 2020 offering exercised 10,754,932 warrants in exchange for 10,754,932 shares of the Company's common stock and warrant holders from the Company's April 2021 Offering exercised 7,671,937 pre-funded warrants in exchange for 7,671,937 shares of the Company's common stock. Pursuant to these warrant exercises, the Company received aggregate proceeds of approximately $3.8 million which were payable upon exercise.

A summary of the changes in stockholders' equity for the three and nine months ended July 31, 2021 and 2020 is presented below (in thousands, except share data):

| | Preferred Stock | | Common Stock | | Additional Paid-In | Accumulated | Total Shareholders' |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Capital | Deficit | Equity |
| Balance at November 1, 2019 | - | $ - | 50,201,671 | $ 50 | $ 423,750 | $ (384,269) | $ 39,531 |
| Stock-based compensation | - | - | 2,957 | - | 242 | - | 242 |
| Advaxis public offerings, net of offering costs | - | - | 10,000,000 | 10 | 9,618 | - | 9,628 |
| Warrant exercises | - | - | 26,416 | - | 2 | - | 2 |
| Issuance of shares to employees under ESPP Plan | - | - | 5,555 | - | 2 | - | 2 |
| Net Loss | - | - | - | - | - | (7,857) | (7,857) |
| Balance at January 31, 2020 | - | $ - | 60,236,599 | $ 60 | $ 433,614 | $ (392,126) | $ 41,548 |
| Stock-based compensation | - | - | 5,651 | - | 210 | - | 210 |
| Warrant exercises | - | - | 7,500 | - | - | - | - |
| Issuance of shares to employees under ESPP Plan | - | - | 2,694 | - | 2 | - | 2 |
| Net Loss | - | - | - | - | - | (6,323) | (6,323) |
| Balance at April 30, 2020 | - | $ - | 60,252,444 | $ 60 | $ 433,826 | $ (398,449) | $ 35,437 |
| Stock-based compensation | - | - | - | - | 255 | - | 255 |
| Tax withholdings paid on equity awards | - | - | - | - | (1) | - | (1) |
| Tax shares sold to pay for tax withholdings on equity awards | - | - | - | - | 1 | - | 1 |
| Issuance of shares to employees under ESPP Plan | - | - | 2,899 | - | 2 | - | 2 |
| At-the-market shares issued, net of offering costs | - | - | 1,375,337 | 1 | 956 | - | 957 |
| Commitment fee shares issued for equity line | - | - | 1,084,266 | 1 | 643 | - | 644 |
| Net Loss | - | - | - | - | - | (5,829) | (5,829) |
| Balance at July 31, 2020 | - | $ - | 62,714,946 | $ 62 | $ 435,682 | $ (404,278) | $ 31,466 |

| | Preferred Stock | | Common Stock | | Additional Paid-In | Accumulated | Total Shareholders' |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Capital | Deficit | Equity |
| Balance at November 1, 2020 | - | $ - | 78,074,023 | $ 78 | $ 440,840 | $ (410,738) | $ 30,180 |
| Stock-based compensation | - | - | - | - | 236 | - | 236 |
| Advaxis public offerings, net of offering costs | - | - | 30,666,665 | 31 | 8,519 | - | 8,550 |
| Warrant exercises | - | - | 7,390,000 | 7 | 2,579 | - | 2,586 |
| Net Loss | - | - | - | - | - | (3,977) | (3,977) |
| Balance at January 31, 2021 | - | $ - | 116,130,688 | $ 116 | $ 452,174 | $ (414,715) | $ 37,575 |
| Stock-based compensation | - | - | 5,888 | - | 215 | - | 215 |
| Stock option exercises | 333 | - | - | - | - | - | - |
| Advaxis public offerings, net of offering costs | - | - | 18,463,448 | 19 | 13,664 | - | 13,683 |
| Warrant exercises | - | - | 11,037,435 | 11 | 1,174 | - | 1,185 |
| Issuance of shares to employees under ESPP Plan | - | - | 1,000 | - | - | - | - |
| Net Loss | - | - | - | - | - | (5,107) | (5,107) |
| Balance at April 30, 2021 | - | $ - | 145,638,459 | $ 146 | $ 467,227 | $ (419,822) | $ 47,551 |
| Stock-based compensation | - | - | - | - | 60 | - | 60 |
| Net Loss | - | - | - | - | - | (3,334) | (3,334) |
| Balance at July 31, 2021 | - | $ - | 145,638,459 | $ 146 | $ 467,287 | $ (423,156) | $ 44,277 |

**12. FAIR VALUE**

The authoritative guidance for fair value measurements defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or the most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Market participants are buyers and sellers in the principal market that are (i) independent, (ii) knowledgeable, (iii) able to transact, and (iv) willing to transact. The guidance describes a fair value hierarchy based on the levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

● Level 1 — Quoted prices in active markets for identical assets or liabilities.

● Level 2— Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or corroborated by observable market data or substantially the full term of the assets or liabilities.

● Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the value of the assets or liabilities.

The following table provides the assets and liabilities carried at fair value measured on a recurring basis as of July 31, 2021 and October 31, 2020 (in thousands):

| July 31, 2021 | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| Common stock warrant liability, warrants exercisable at $0.30 through September 2024 | - | - | $ 24 | $ 24 |
| Common stock warrant liability, warrants exercisable at $0.70 through 5 years after the date such warrants become exercisable, if ever (Private Placement Warrants) | - | - | $ 4,061 | $ 4,061 |
| Total | - | - | $ 4,085 | $ 4,085 |

| October 31, 2020 | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| Common stock warrant liability, warrants exercisable at $0.372 through September 2024 | - | - | $ 17 | $ 17 |

The following table sets forth a summary of the changes in the fair value of the Company's warrant liabilities (in thousands):

| | For the Nine Months Ended July 31, 2021 |
|---|---|
| Beginning balance | $ 17 |
| Warrants issued | 5,882 |
| Warrant exercises | - |
| Change in fair value | (1,814) |
| Ending Balance | $ 4,085 |

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Advaxis, Inc.

**Opinion on the Financial Statements**

We have audited the accompanying balance sheets of Advaxis, Inc. (the "Company") as of October 31, 2020 and 2019, the related statements of operations, stockholders' equity and cash flows for each of the two years in the period ended October 31, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of October 31 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended October 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

**Change in Accounting Principle**

As discussed in Note 2 to the financial statements, the Company has changed its method of accounting for leases in 2020 due to the adoption of the guidance in ASC Topic 842, Leases ("Topic 842"), as amended, effective November 1, 2019, using the modified retrospective transition approach.

**Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

*/s/ Marcum LLP*

Marcum LLP

We have served as the Company's auditor since 2012.

New York, NY
January 22, 2021

**ADVAXIS, INC.**
**BALANCE SHEETS**
(In thousands, except share and per share data)

| | October 31, | |
|---|---|---|
| | 2020 | 2019 |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $ 25,178 | $ 32,363 |
| Deferred expenses | 1,808 | 2,353 |
| Prepaid expenses and other current assets | 865 | 1,433 |
| Total current assets | 27,851 | 36,149 |
| | | |
| Property and equipment (net of accumulated depreciation) | 2,393 | 4,350 |
| Intangible assets (net of accumulated amortization) | 3,261 | 4,575 |
| Operating right-of-use asset (net of accumulated amortization) | 4,839 | - |
| Other assets | 182 | 183 |
| | | |
| Total assets | $ 38,526 | $ 45,257 |
| | | |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | $ 410 | $ 976 |
| Accrued expenses | 1,737 | 3,478 |
| Current portion of operating lease liability | 962 | - |
| Deferred revenue | 165 | - |
| Common stock warrant liability | 17 | 19 |
| Other current liabilities | - | 48 |
| Total current liabilities | 3,291 | 4,521 |
| | | |
| Operating lease liability, net of current portion | 5,055 | - |
| Other liabilities | - | 1,205 |
| Total liabilities | 8,346 | 5,726 |
| | | |
| Commitments and contingencies – Note 9 | | |
| | | |
| Stockholders' equity: | | |
| Preferred stock, $0.001 par value; 5,000,000 shares authorized; Series B Preferred Stock; 0 shares issued and outstanding at October 31, 2020 and 2019. Liquidation preference of $0 at October 31, 2020 and 2019. | - | - |
| Common stock - $0.001 par value; 170,000,000 shares authorized, 78,074,023 and 50,201,671 shares issued and outstanding at October 31, 2020 and 2019. | 78 | 50 |
| Additional paid-in capital | 440,840 | 423,750 |
| Accumulated deficit | (410,738) | (384,269) |
| Total stockholders' equity | 30,180 | 39,531 |
| Total liabilities and stockholders' equity | $ 38,526 | $ 45,257 |

The accompanying notes should be read in conjunction with the financial statements.

**ADVAXIS, INC.**
**STATEMENTS OF OPERATIONS**
(In thousands, except share and per share data)

| | Year Ended October 31, | |
|---|---|---|
| | 2020 | 2019 |
| Revenue | $ 253 | $ 20,884 |
| Operating expenses: | | |
| Research and development expenses | 15,612 | 26,677 |
| General and administrative expenses | 11,090 | 12,179 |
| Total operating expenses | 26,702 | 38,856 |
| Loss from operations | (26,449) | (17,972) |
| Other income (expense): | | |
| Interest income | 110 | 435 |
| Net changes in fair value of derivative liabilities | - | 2,589 |
| Loss on shares issued in settlement of warrants | (77) | (1,607) |
| Other expense | (3) | (7) |
| Net loss before income tax benefit | (26,419) | (16,562) |
| Income tax expense | 50 | 50 |
| Net loss | $ (26,469) | $ (16,612) |
| Net loss per common share, basic and diluted | $ (0.43) | $ (1.09) |
| Weighted average number of common shares outstanding, basic and diluted | 61,003,839 | 15,207,637 |

The accompanying notes should be read in conjunction with the financial statements.

**ADVAXIS, INC.**
**STATEMENTS OF STOCKHOLDERS' EQUITY**
(In thousands, except share and per share data)

| | Preferred Stock | | Common Stock | | Additional Paid-In | Accumulated | Total Shareholders' |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Capital | Deficit | Equity |
| Balance at October 31, 2018 | - | $ - | 4,634,189 | $ 5 | $ 391,703 | $ (367,657) | $ 24,051 |
| Stock-based compensation | | | 12,220 | | 2,002 | - | 2,002 |
| Tax withholdings paid on equity awards | - | - | - | - | (15) | - | (15) |
| Tax shares sold to pay for tax withholdings on equity awards | - | - | - | - | 14 | - | 14 |
| Issuance of shares to employees under ESPP Plan | - | - | 7,435 | - | 20 | - | 20 |
| ESPP Expense | - | - | - | - | 2 | | 2 |
| Pre-funded warrant exercises | - | - | 13,656,000 | 13 | - | - | 13 |
| Warrant exercises | - | - | 17,884,962 | 18 | 104 | - | 122 |
| Shares issued in settlement of warrants | - | - | 856,865 | 1 | 5,462 | - | 5,463 |
| Advaxis public offerings | - | - | 13,150,000 | 13 | 24,458 | - | 24,471 |
| Net Loss | - | - | - | - | | (16,612) | (16,612) |
| Balance at October 31, 2019 | - | $ - | 50,201,671 | $ 50 | $ 423,750 | $ (384,269) | $ 39,531 |
| Stock-based compensation | - | - | 8,870 | - | 891 | - | 891 |
| Tax withholdings paid on equity awards | - | - | - | - | (1) | - | (1) |
| Tax shares sold to pay for tax withholdings on equity awards | - | - | - | - | 1 | - | 1 |
| Issuance of shares to employees under ESPP Plan | - | - | 14,148 | - | 7 | - | 7 |
| ESPP Expense | - | - | - | - | 1 | - | 1 |
| Warrant exercises | - | - | 33,916 | - | 2 | - | 2 |
| Shares issued in settlement of warrants | - | - | 3,000,000 | 3 | 74 | - | 77 |
| Advaxis public offerings | - | - | 10,000,000 | 10 | 9,618 | - | 9,628 |
| At-the-market shares issued | - | - | 2,489,104 | 3 | 1,435 | - | 1,438 |
| Commitment fee shares issued for equity line | - | - | 1,084,266 | 1 | 643 | - | 644 |
| Shares issued under equity line | - | - | 11,242,048 | 11 | 4,419 | - | 4,430 |
| Net Loss | - | - | - | - | - | (26,469) | (26,469) |
| Balance at October 31, 2020 | - | $ - | 78,074,023 | $ 78 | $ 440,840 | $ (410,738) | $ 30,180 |

The accompanying notes should be read in conjunction with the financial statements.

**ADVAXIS, INC.**
**STATEMENT OF CASH FLOWS**
(In thousands, except share and per share data)

| | Year Ended October 31, | |
|---|---|---|
| | 2020 | 2019 |
| OPERATING ACTIVITIES | | |
| Net loss | $ (26,469) | $ (16,612) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock compensation | 891 | 2,002 |
| Employee stock purchase plan expense | 1 | 3 |
| Gain on change in value of warrants | - | (2,589) |
| Loss on shares issued in settlement of warrants | 77 | 1,607 |
| Loss on disposal of property and equipment | - | 344 |
| Loss on write-down of property and equipment | 1,060 | 943 |
| Abandonment of intangible assets | 1,725 | 1,104 |
| Depreciation expense | 897 | 1,097 |
| Amortization of deferred offering costs | 644 | - |
| Amortization expense of intangible assets | 337 | 386 |
| Amortization expense of right-of-use assets | 744 | - |
| Change in operating assets and liabilities: | | |
| Accounts receivable | - | 1,664 |
| Prepaid expenses and other current assets | 1,113 | (103) |
| Other assets | 1 | 18 |
| Accounts payable and accrued expenses | (2,307) | (7,377) |
| Deferred revenue | 165 | (18,665) |
| Operating lease liabilities | (819) | - |
| Other liabilities | - | 50 |
| Net cash used in operating activities | (21,940) | (36,128) |
| | | |
| INVESTING ACTIVITIES | | |
| Purchase of property and equipment | - | (54) |
| Proceeds from disposal of property and equipment | - | 83 |
| Cost of intangible assets | (748) | (1,227) |
| Net cash used in investing activities | (748) | (1,198) |
| | | |
| FINANCING ACTIVITIES | | |
| Net proceeds from issuance of common stock and pre-funded warrants | 15,496 | 24,471 |
| Warrant exercises | - | 68 |
| Pre-funded warrant exercises | - | 13 |
| Proceeds from employee stock purchase plan | 7 | 20 |
| Employee tax withholdings paid on equity awards | (1) | (15) |
| Tax shares sold to pay for employee tax withholdings on equity awards | 1 | 14 |
| Net cash provided by financing activities | 15,503 | 24,571 |
| | | |
| Net decrease in cash and cash equivalents | (7,185) | (12,755) |
| Cash and cash equivalents at beginning of year | 32,363 | 45,118 |
| Cash and cash equivalents at end of year | $ 25,178 | $ 32,363 |

The accompanying notes should be read in conjunction with the financial statements.

**Supplemental Disclosures of Cash Flow Information**

| | Year Ended October 31, | |
|---|---|---|
| | 2020 | 2019 |
| Cash paid for taxes | $ 50 | $ 50 |

**Supplemental Schedule of Noncash Investing and Financing Activities**

| | Year Ended October 31, | |
|---|---|---|
| | 2020 | 2019 |
| Shares issued in settlement of warrants | $ 77 | $ 5,463 |
| Warrant liability reclassified into equity | $ - | $ 54 |
| Reclass of security deposit to property and equipment for delivered equipment | $ - | $ 79 |
| Commitment fee shares issued for equity line | $ 644 | $ - |
| Cashless exercise of warrants | $ 2 | $ - |

The accompanying notes should be read in conjunction with the financial statements.

## 1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Advaxis, Inc. ("Advaxis" or the "Company") is a clinical-stage biotechnology company focused on the development and commercialization of proprietary *Listeria monocytogenes* ("*Lm*")-based antigen delivery products. The Company is using its *Lm* platform directed against tumor-specific targets in order to engage the patient's immune system to destroy tumor cells. Through a license from the University of Pennsylvania, Advaxis has exclusive access to this proprietary formulation of attenuated *Lm* called *Lm* Technology™. Advaxis' proprietary approach is designed to deploy a unique mechanism of action that redirects the immune system to attack cancer in three distinct ways:

- Alerting and training the immune system by activating multiple pathways in Antigen-Presenting Cells ("APCs") with the equivalent of multiple adjuvants;
- Attacking the tumor by generating a strong, cancer-specific T cell response; and
- Breaking down tumor protection through suppression of the protective cells in the tumor microenvironment ("TME") that shields the tumor from the immune system. This enables the activated T cells to begin working to attack the tumor cells.

Advaxis' proprietary *Lm* platform technology has demonstrated clinical activity in several of its programs and has been dosed in over 470 patients across multiple clinical trials and in various tumor types. The Company believes that *Lm* Technology immunotherapies can complement and address significant unmet needs in the current oncology treatment landscape. Specifically, its product candidates have the potential to work synergistically with other immunotherapies, including checkpoint inhibitors, while having a generally well-tolerated safety profile.

*Liquidity and Managements Plans*

The Company has not yet commercialized any human products and the products that are being developed have not generated significant revenue. As a result, the Company has suffered recurring losses and requires significant cash resources to execute its business plans. These losses are expected to continue for an extended period of time. The aforementioned factors raise substantial doubt about the Company's ability to continue as a going concern.

Historically, the Company's major sources of cash have been comprised of proceeds from various public and private offerings of its common stock, debt financings, clinical collaborations, option and warrant exercises, income earned on investments and grants and interest income. From October 2013 through October 2020, the Company raised approximately $309.4 million in gross proceeds ($17.2 million in fiscal year 2020) from various public and private offerings of its common stock.

As of October 31, 2020, the Company had approximately $25.2 million in cash and cash equivalents. Although the Company expects to have sufficient capital to fund its obligations, as they become due, in the ordinary course of business until at least January 2022, the actual amount of cash that it will need to operate is subject to many factors. Over the past several months, the Company has taken steps to obtain additional financing, including the at-the-market ("ATM") program and the equity line with Lincoln Park Capital. Due to the current state of the Company's stock price and general market conditions, these programs have not been utilized to the fullest extent, thereby resulting in lower capital availability than anticipated. Management's plans to mitigate an expected shortfall of capital and to support future operations include obtaining additional funds through partnerships or strategic or financing investors. The Company was able to raise additional funds subsequent to year end more fully described in the subsequent events footnote (Note 15). The Company has reduced its operating expenses to $26.7 million for the fiscal year ended October 31, 2020 as compared to $38.9 million during the comparable prior period. With these funds raised and a reduction in the operating expenses the Company believes that it has enough cash to fund its operations for one year from the date of filing. Therefore, such conditions of substantial doubt as of October 31, 2020 have subsequently been alleviated.

The Company recognizes it will need to raise additional capital in order to continue to execute its business plan in the future. There is no assurance that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to the Company or whether the Company will become profitable and generate positive operating cash flow. If the Company is unable to raise sufficient additional funds, it will have to further scale back its operations.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

*Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Estimates are used when accounting for such items as the fair value and recoverability of the carrying value of property and equipment and intangible assets (patents and licenses), determining the Incremental Borrowing Rate ("IBR") for calculating Right-Of-Use ("ROU") assets and lease liabilities, deferred expenses, deferred revenue, the fair value of options, warrants and related disclosure of contingent assets and liabilities. The Company bases its estimates on historical experience and on various other assumptions that it believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. On an ongoing basis, the Company reviews its estimates to ensure that they appropriately reflect changes in the business or as new information becomes available. Actual results may differ from these estimates.

*Revenue Recognition*

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company enters into licensing agreements that are within the scope of ASC 606, under which it may exclusively license rights to research, develop, manufacture and commercialize its product candidates to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, upfront license fees; reimbursement of certain costs; customer option exercise fees; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for these arrangements, the Company must use significant judgment to determine: (a) the number of performance obligations based on the determination under step (ii) above; (b) the transaction price under step (iii) above; and (c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above. The Company uses judgment to determine whether milestones or other variable consideration, except for royalties, should be included in the transaction price as described further below. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied.

Amounts received prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

*Exclusive Licenses.* If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. In assessing whether a performance obligation is distinct from the other performance obligations, the Company considers factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the collaboration partner can benefit from a performance obligation for its intended purpose without the receipt of the remaining performance obligation, whether the value of the performance obligation is dependent on the unsatisfied performance obligation, whether there are other vendors that could provide the remaining performance obligation, and whether it is separately identifiable from the remaining performance obligation. For licenses that are combined with other performance obligation, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the research and development and licensing agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

*Research and Development Services.* The performance obligations under the Company's collaboration agreements may include research and development services to be performed by the Company on behalf of the partner. Payments or reimbursements resulting from the Company's research and development efforts are recognized as the services are performed and presented on a gross basis because the Company is the principal for such efforts.

*Milestone Payments.* At the inception of each arrangement that includes research or development milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. An output method is generally used to measure progress toward complete satisfaction of a milestone. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and earnings in the period of adjustment.

*Royalties.* For arrangements that include sales-based royalties, including milestone payments based on a level of sales, which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied.

*Collaborative Arrangements*

The Company analyzes its collaboration arrangements to assess whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities and therefore within the scope of ASC Topic 808, *Collaborative Arrangements* (ASC 808). This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and which elements of the collaboration are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to ASC 606. Amounts that are owed to collaboration partners are recognized as an offset to collaboration revenue as such amounts are incurred by the collaboration partner. For those elements of the arrangement that are accounted for pursuant to ASC 606, the Company applies the five-step model described above under ASC 606.

*Cash and Cash Equivalents*

The Company considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents.

*Concentration of Credit Risk*

The Company maintains its cash in bank deposit accounts (checking) that at times exceed federally insured limits. Approximately $24.1 million is subject to credit risk at October 31, 2020. The Company has not experienced any losses in such accounts.

*Deferred Expenses*

Deferred expenses consist of advanced payments made on research and development projects. Expense is recognized in the Statement of Operations as the research and development activity is performed.

*Property and Equipment*

Property and equipment is stated at cost. Additions and improvements that extend the lives of the assets are capitalized, while expenditures for repairs and maintenance are expensed as incurred. Leasehold improvements are amortized on a straight-line basis over the shorter of the asset's estimated useful life or the remaining lease term. Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets ranging from three to ten years.

When depreciable assets are retired or sold the cost and related accumulated depreciation are removed from the accounts and any resulting gain or loss is recognized in operations.

*Intangible Assets*

Intangible assets are recorded at cost and include patents and patent application costs, licenses and software. Intangible assets are amortized on a straight-line basis over their estimated useful lives ranging from 3 to 20 years. Patent application costs are written-off if the application is rejected, withdrawn or abandoned.

*Impairment of Long-Lived Assets*

The Company periodically assesses the carrying value of intangible and other long-lived assets, and whenever events or changes in circumstances indicate that the carrying amount of an asset might not be recoverable. The assets are considered to be impaired if the Company determines that the carrying value may not be recoverable based upon its assessment, which includes consideration of the following events or changes in circumstances:

- the asset's ability to continue to generate income from operations and positive cash flow in future periods;
- loss of legal ownership or title to the asset(s);
- significant changes in the Company's strategic business objectives and utilization of the asset(s); and
- the impact of significant negative industry or economic trends.

If the assets are considered to be impaired, the impairment recognized is the amount by which the carrying value of the assets exceeds the fair value of the assets. Fair value is determined by the application of discounted cash flow models to project cash flows from the assets. In addition, the Company bases estimates of the useful lives and related amortization or depreciation expense on its subjective estimate of the period the assets will generate revenue or otherwise be used by it. Assets to be disposed of are reported at the lower of the carrying amount or fair value, less selling costs. The Company also periodically reviews the lives assigned to long-lived assets to ensure that the initial estimates do not exceed any revised estimated periods from which the Company expects to realize cash flows from its assets.

*Leases*

Effective November 1, 2019, the Company adopted ASC Topic 842, *Leases* ("ASC 842") using the modified retrospective transition approach by applying the new standard to all leases existing as of the date of initial application. Results and disclosure requirements for reporting periods beginning after November 1, 2019 are presented under ASC 842, while prior period amounts have not been adjusted and continue to be reported in accordance with the previous guidance in ASC 840, *Leases*.

At the inception of an arrangement, the Company determines whether an arrangement is or contains a lease based on the facts and circumstances present in the arrangement. An arrangement is or contains a lease if the arrangement conveys the right to control the use of an identified asset for a period of time in exchange for consideration. Most leases with a term greater than one year are recognized on the balance sheet as operating lease right-of-use assets and current and long-term operating lease liabilities, as applicable. The Company has elected not to recognize on the balance sheet leases with terms of 12 months or less. The Company typically only includes the initial lease term in its assessment of a lease arrangement. Options to extend a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew.

Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as prepaid or accrued rent. The interest rate implicit in the Company's leases is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. In transition to ASC 842, the Company utilized the remaining lease term of its leases in determining the appropriate incremental borrowing rates.

*Net Income (Loss) per Share*

Basic net income or loss per common share is computed by dividing net income or loss available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted earnings per share give effect to dilutive options, warrants, restricted stock units and other potential common stock outstanding during the period. In the case of a net loss, the impact of the potential common stock resulting from warrants, outstanding stock options and convertible debt are not included in the computation of diluted loss per share, as the effect would be anti-dilutive. In the case of net income, the impact of the potential common stock resulting from these instruments that have intrinsic value are included in the diluted earnings per share. The table sets forth the number of potential shares of common stock that have been excluded from diluted net loss per share (as of October 31, 2020, 327,338 warrants are included in the basic earnings per share computation because the exercise price is $0, and as of October 31, 2019, 13,079,000 pre-funded warrants are included in the basic earnings per share computation because the exercise price is nominal):

| | As of October 31, | |
|---|---|---|
| | 2020 | 2019 |
| Warrants | 398,226 | 432,142 |
| Stock options | 1,011,768 | 560,490 |
| Restricted stock units | 5,556 | 14,706 |
| Total | 1,415,550 | 1,007,338 |

*Research and Development Expenses*

Research and development costs are expensed as incurred and include but are not limited to clinical trial and related manufacturing costs, payroll and personnel expenses, lab expenses, and related overhead costs.

*Stock Based Compensation*

The Company has an equity plan which allows for the granting of stock options to its employees, directors and consultants for a fixed number of shares with an exercise price equal to the fair value of the shares at date of grant. The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. The fair value of the award is measured on the grant date and is then recognized over the requisite service period, usually the vesting period, in both research and development expenses and general and administrative expenses on the statement of operations, depending on the nature of the services provided by the employees or consultants.

The process of estimating the fair value of stock-based compensation awards and recognizing stock-based compensation cost over their requisite service period involves significant assumptions and judgments. The Company estimates the fair value of stock option awards on the date of grant using the Black Scholes Model ("BSM") for the remaining awards, which requires that the Company makes certain assumptions regarding: (i) the expected volatility in the market price of its common stock; (ii) dividend yield; (iii) risk-free interest rates; and (iv) the period of time employees are expected to hold the award prior to exercise (referred to as the expected holding period). As a result, if the Company revises its assumptions and estimates, stock-based compensation expense could change materially for future grants.

The Company accounts for stock-based compensation using fair value recognition and records forfeitures as they occur. As such, the Company recognizes stock-based compensation cost only for those stock-based awards that vest over their requisite service period, based on the vesting provisions of the individual grants.

*Fair Value of Financial Instruments*

The carrying value of financial instruments, including cash and cash equivalents, restricted cash and accounts payable approximated fair value as of the balance sheet date presented, due to their short maturities.

*Derivative Financial Instruments*

The Company does not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. The Company evaluates all of its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the statements of operations. For stock-based derivative financial instruments, the Company used the Monte Carlo simulation model to value the derivative instruments at inception and on subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the instrument could be required within 12 months of the balance sheet date.

*Income Taxes*

The Company uses the asset and liability method of accounting for income taxes in accordance with ASC Topic 740, "*Income Taxes.*" Under this method, income tax expense is recognized for the amount of: (i) taxes payable or refundable for the current year and (ii) deferred tax consequences of temporary differences resulting from matters that have been recognized in an entity's financial statements or tax returns. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the results of operations in the period that includes the enactment date. A valuation allowance is provided to reduce the deferred tax assets reported if based on the weight of the available positive and negative evidence, it is more likely than not some portion or all of the deferred tax assets will not be realized.

*Recent Accounting Standards*

In December 2019, the FASB issued authoritative guidance intended to simplify the accounting for income taxes (ASU 2019-12, "*Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*"). This guidance eliminates certain exceptions to the general approach to the *income* tax accounting model and adds new guidance to reduce the complexity in accounting for income taxes. This guidance is effective for annual periods after December 15, 2020, including interim periods within those annual periods. The Company is currently evaluating the potential impact of this guidance on its consolidated financial statements.

*Recently Adopted Accounting Standards*

On November 1, 2019, the Company adopted Accounting Standards Update No. 2016-02, *Leases* (Topic 842) (ASU 2016-02), as amended, which establishes ASC 842 and supersedes the lease accounting guidance under ASC 840, and generally requires lessees to recognize operating and financing lease liabilities and corresponding right-of-use (ROU) assets on the balance sheet and to provide enhanced disclosures surrounding the amount, timing and uncertainty of cash flows arising from leasing arrangements. We adopted the new guidance using the modified retrospective transition approach by applying the new standard to all leases existing at the date of initial application and not restating comparative periods.

In adopting the new standard, the Company elected to utilize the available package of practical expedients permitted under the transition guidance within the new standard, which does not require the reassessment of the following: (i) whether existing or expired arrangements are or contain a lease, (ii) the lease classification of existing or expired leases, and (iii) whether previous initial direct costs would qualify for capitalization under the new lease standard. Additionally, the Company elected to combine lease and non-lease components and to exclude leases with a term of 12 months or less.

As of the November 1, 2019 effective date, the Company had identified one operating lease arrangement and one short-term lease in which it is a lessee. The adoption of ASC 842 resulted in the recognition of an operating lease liability and a right-of-use asset of approximately $6.8 million and $5.6 million, respectively, on the Company's balance sheet relating to its leases, with the difference relating to reclassifications of the current accrued rent liability and the current lease incentive obligation of approximately $0.9 million and $0.3 million, respectively, as reductions to the right-of-use-asset for its operating lease. The adoption of the standard did not have a material effect on the Company's statements of operations or statements of cash flows.

Management does not believe that any other recently issued, but not yet effective accounting pronouncements, if adopted, would have a material impact on the accompanying financial statements.

**3. PROPERTY AND EQUIPMENT**

Property and equipment consists of the following (in thousands):

| | October 31, | |
|---|---|---|
| | 2020 | 2019 |
| Leasehold improvements | $ 2,335 | $ 2,335 |
| Laboratory equipment | 1,218 | 3,405 |
| Furniture and fixtures | 744 | 744 |
| Computer equipment | 409 | 409 |
| Construction in progress | 19 | 83 |
| Total property and equipment | 4,725 | 6,976 |
| Accumulated depreciation and amortization | (2,332) | (2,626) |
| Net property and equipment | $ 2,393 | $ 4,350 |

Depreciation expense for the years ended October 31, 2020 and 2019 was approximately $0.9 million and $1.1 million, respectively. Disposals of laboratory equipment resulted in losses of approximately $0 and $0.3 million for the years ended October 31, 2020 and 2019, respectively, that was charged to research and development expenses in the statement of operations.

Management has reviewed its property and equipment for impairment whenever events and circumstances indicate that the carrying value of an asset might not be recoverable. During the years ended October 31, 2020 and 2019, the Company recorded impairment losses on idle laboratory equipment of $1.1 million and $0.9 million, respectively, that was charged to research and development expenses in the statement of operations. Fair value for the idle assets was determined by a quoted purchase price for the assets.

**4. INTANGIBLE ASSETS**

Intangible assets consist of the following (in thousands):

| | October 31, | |
|---|---|---|
| | 2020 | 2019 |
| Patents | $ 4,479 | $ 5,833 |
| License | 777 | 777 |
| Software | 117 | 117 |
| Total intangibles | 5,373 | 6,727 |
| Accumulated amortization | (2,112) | (2,152) |
| Net intangible assets | $ 3,261 | $ 4,575 |

The expirations of the existing patents range from 2020 to 2040 but the expirations can be extended based on market approval if granted and/or based on existing laws and regulations. Capitalized costs associated with patent applications that are abandoned without future value are charged to expense when the determination is made not to pursue the application. Patent applications having a net book value of approximately $1.7 million and $1.1 million were abandoned and were charged to general and administrative expenses in the statement of operations for the years ended October 31, 2020 and 2019, respectively. Intangible asset amortization expense that was charged to general and administrative expense in the statement of operations was approximately $0.3 million and $0.4 million for each of the years ended October 31, 2020 and 2019, respectively.

Management has reviewed its intangible assets for impairment whenever events and circumstances indicate that the carrying value of an asset might not be recoverable. Net assets are recorded on the balance sheet for patents and licenses related to axalimogene filolisbac (AXAL), ADXS-HOT, ADXS-PSA ADXS-HER2 and other products that are in development or out-licensed. However, if a competitor were to gain FDA approval for a treatment before us or if future clinical trials fail to meet the targeted endpoints, the Company would likely record an impairment related to these assets. In addition, if an application is rejected or fails to be issued, the Company would record an impairment of its estimated book value. Lastly, if the Company is unable to raise enough capital to continue funding our studies and developing its intellectual property, the Company would likely record an impairment to certain of these assets.

At October 31, 2020, the estimated amortization expense by fiscal year based on the current carrying value of intangible assets is as follows (in thousands):

| | |
|---|---|
| 2021 | $ 289 |
| 2022 | 289 |
| 2023 | 289 |
| 2024 | 289 |
| 2025 | 289 |
| Thereafter | 1,816 |
| Total | $ 3,261 |

**5. ACCRUED EXPENSES:**

The following table represents the major components of accrued expenses (in thousands):

| | October 31, | |
|---|---|---|
| | 2020 | 2019 |
| Salaries and other compensation | $ 737 | $ 158 |
| Vendors | 671 | 3,194 |
| Professional fees | 329 | 126 |
| Total accrued expenses | $ 1,737 | $ 3,478 |

**6. COMMON STOCK PURCHASE WARRANTS AND WARRANT LIABILITY**

*Warrants*

As of October 31, 2020, there were outstanding warrants to purchase 398,226 shares of our common stock with exercise prices ranging from $0 to $281.25 per share. Information on the outstanding warrants is as follows:

| Exercise Price | Number of Shares Underlying Warrants | Expiration Date | Summary of Warrants |
|---|---|---|---|
| $ - | 327,338 | July 2024 | July 2019 Public Offering |
| $ 281.25 | 25 | N/A | Other Warrants |
| $ 0.372 | 70,863 | September 2024 | September 2018 Public Offering |
| **Grand Total** | 398,226 | | |

As of October 31, 2019, there were outstanding warrants to purchase 432,142 shares of our common stock with exercise prices ranging from $0 to $281.25 per share. Information on the outstanding warrants is as follows:

| Exercise Price | Number of Shares Underlying Warrants | Expiration Date | Summary of Warrants |
|---|---|---|---|
| $ - | 359,838 | July 2024 | July 2019 Public Offering |
| $ 281.25 | 25 | N/A | Other Warrants |
| $ 0.372 | 72,279 | September 2024 | September 2018 Public Offering |
| **Grand Total** | 432,142 | | |

A summary of warrant activity was as follows (In thousands, except share and per share data):

| | Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life In Years | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding and exercisable warrants at October 31, 2018 | 944,635 | $ 22.50 | 5.87 | $ - |
| Issued | 31,885,500 | - | | |
| Exercised * | (31,540,962) | - | | |
| Exchanged | (856,865) | 0.37 | | |
| Expired | (166) | 56.25 | | |
| Outstanding and exercisable warrants at October 31, 2019 | 432,142 | $ 0.08 | 4.76 | $ 114,069 |
| Issued | 5,000,000 | 1.25 | | |
| Exercised ** | (33,916) | 0.02 | | |
| Exchanged | (5,000,000) | 1.25 | | |
| Outstanding and exercisable warrants at October 31, 2020 | 398,226 | $ 0.08 | 3.76 | $ 110,640 |

* Includes the cashless exercise of 17,869,662 warrants that resulted in the issuance of 17,869,662 shares of common stock.

** Includes the cashless exercise of 32,500 warrants that resulted in the issuance of 32,500 shares of common stock.

At October 31, 2020, the Company had 327,363 of its total 398,226 outstanding warrants classified as equity (equity warrants). At October 31, 2019, the Company had 359,863 of its total 432,142 outstanding warrants classified as equity (equity warrants). At issuance, equity warrants are recorded at their relative fair values, using the Relative Fair Value Method, in the shareholders equity section of the balance sheet.

*Shares Issued in Settlement of Equity Warrants*

On October 16, 2020, the Company entered into private exchange agreements with certain holders of warrants issued in connection with the Company's January 2020 public offering of common stock and warrants. The warrants being exchanged provide for the purchase of up to an aggregate of 5,000,000 shares of our common stock at an exercise price of $1.25 per share. The warrants became exercisable on July 21, 2020 and have an expiration date of July 21, 2025. Pursuant to such exchange agreements, the Company agreed to issue 3,000,000 shares of common stock to the investors in exchange for the warrants. The fair value of these warrants approximated the fair value of shares issued in the exchange for these warrants. The Company used the closing stock price to value the shares and Black Scholes model to value these warrants on the date of the exchange. In determining the fair warrant of the warrants issued on October 16, 2020, the Company used the following inputs in its Black-Sholes model: exercise price $1.25, stock price $0.406, expected term 4.76 years, volatility 101.18% and risk-free interest rate 0.32%. In connection with the exchange of warrants for common stock, the Company recorded a loss of approximately $77 thousand as the fair value of the shares issued exceeded the fair value of warrants exchanged.

*Shares Issued in Settlement of Liability Warrants*

On March 14, 2019, the Company entered into private exchange agreements with certain holders of warrants issued in connection with the Company's September 2018 public offering of common stock and warrants. The warrants being exchanged provided for the purchase of up to an aggregate of 856,865 shares of the Company's common stock at an exercise price of $22.50, with an expiration date of September 11, 2024. Pursuant to such exchange agreements, the Company issued 856,865 shares of common stock to the investors in exchange for such warrants on a 1:1 basis. The exchange of warrants for common stock caused the down round provision to be triggered for the first time and the exercise price of the warrants that were not exchanged were reduced from $22.50 to $4.50. The warrants were valued at approximately $3.9 million on the March 14, 2019 using the Monte Carlo simulation model. In determining the fair warrant of the warrants issued on March 14, 2019, the Company used the following inputs in its Monte Carlo simulation model: exercise price $22.50, stock price $6.45, expected term 5.50 years, volatility 96.37% and risk-free interest rate 2.44%. In connection with the exchange of warrants for common stock, the Company recorded a loss of approximately $1.6 million as the fair value of the shares issued exceeded the fair value of warrants exchanged.

*Warrant Liability*

At October 31, 2020, the Company had 70,863 of its total 398,226 outstanding warrants classified as liabilities (liability warrants). At October 31, 2019, the Company had 72,279 of its total 432,142 outstanding warrants classified as liabilities (liability warrants). These warrants contain a down round feature, except for exempt issuances as defined in the warrant agreement, in which the exercise price would immediately be reduced to match a dilutive issuance of common stock, options, convertible securities and changes in option price or rate of conversion.

As of October 31, 2020, the down round feature was triggered three times and the exercise price of the warrants were reduced from $22.50 to $0.372. The warrants require liability classification as the warrant agreement requires the Company to maintain an effective registration statement and does not specify any circumstances under which settlement in other than cash would be permitted or required. As a result, net cash settlement is assumed and liability classification is warranted. For these liability warrants, the Company utilized the Monte Carlo simulation model to calculate the fair value of these warrants at issuance and at each subsequent reporting date.

At October 31, 2020 and October 31, 2019, the fair value of the warrant liability was approximately $17,000 and $19,000, respectively. For the years ended October 31, 2020 and 2019, the Company reported income of approximately $0 and $2.6 million, respectively, due to changes in the fair value of the warrant liability.

In measuring the warrant liability, the Company used the following inputs in its Monte Carlo simulation model:

| | October 31, 2020 | October 31, 2019 |
|---|---|---|
| Exercise Price | $ 0.37 | $ 0.37 |
| Stock Price | $ 0.34 | $ 0.32 |
| Expected Term | 3.87 years | 4.87 years |
| Volatility % | 105.58% | 100.99% |
| Risk Free Rate | 0.29% | 1.51% |

**7. SHARE BASED COMPENSATION**

The following table summarizes share-based compensation expense included in the statement of operations by expense category for the years ended October 31, 2020 and 2019 (in thousands):

| | Year Ended October 31, | |
|---|---|---|
| | 2020 | 2019 |
| Research and development | $ 308 | $ 1,036 |
| General and administrative | 583 | 966 |
| Total | $ 891 | $ 2,002 |

*Amendments*

The Advaxis, Inc. 2015 Incentive Plan (the "2015 Plan") was originally ratified and approved by the Company's stockholders on May 27, 2015. Subject to proportionate adjustment in the event of stock splits and similar events, the aggregate number of shares of common stock that may be issued under the 2015 Plan is 240,000 shares, plus a number of additional shares (not to exceed 43,333) underlying awards outstanding as of the effective date of the 2015 Plan under the prior plan that thereafter terminate or expire unexercised, or are cancelled, forfeited or lapse for any reason.

At the Annual Meeting of Stockholders of the Company held on February 21, 2019, the Company's stockholders voted to approve an amendment to increase the number of authorized shares of common stock from 95,000,000 to 170,000,000 and also voted to approve an amendment to allow the Company to execute a reverse stock split of common stock at the discretion of the Board of Directors. The amendment to increase the number of authorized shares of common stock became effective upon filing of the amendment with the Secretary of State of the State of Delaware on February 28, 2019. Additionally, on March 29, 2019, the Company executed a 1 for 15 reverse stock split. On January 1, 2020, 166,667 shares were added to the 2015 Plan.

At the Annual Meeting of Stockholders of the Company held on May 4, 2020, the Company's stockholders voted to approve an amendment to increase the number of shares authorized for issuance under the 2015 Plan from 877,744 shares to 6,000,000 shares.

As of October 31, 2020, there were 4,856,116 shares available for issuance under the 2015 Plan.

*Restricted Stock Units (RSUs)*

A summary of the Company's RSU activity and related information for the fiscal year ended October 31, 2020 and 2019 is as follows:

| | Number of RSU's | Weighted-Average Grant Date Fair Value |
|---|---|---|
| Unvested as of October 31, 2018 | 32,614 | $ 70.41 |
| Vested | (12,257) | 78.41 |
| Cancelled | (5,651) | 112.39 |
| Unvested as of October 31, 2019 | 14,706 | $ 47.62 |
| Vested | (8,870) | 60.59 |
| Cancelled | (280) | 98.80 |
| Unvested as of October 31, 2020 | 5,556 | $ 24.32 |

The fair value of the RSUs as of the respective vesting dates was approximately $5,000 and $51,000 for the years ended October 31, 2020 and 2019, respectively.

As of October 31, 2020, there was approximately $64,000 of unrecognized compensation cost related to non-vested RSUs, which is expected to be recognized over a remaining weighted average vesting period of approximately 0.47 years.

As of October 31, 2020, the aggregate intrinsic value of non-vested RSUs was approximately $2,000.

*Employee Stock Awards*

Common stock issued to executives and employees related to vested incentive retention awards, employment inducements, management purchases and employee excellence awards totaled 8,870 shares and 12,245 shares during the years ended October 31, 2020 and 2019, respectively. Total stock compensation expense associated with these awards for the years ended October 31, 2020 and 2019 was approximately $0.2 million and $0.8 million, respectively.

*Stock Options*

A summary of changes in the stock option plan for the years ended October 31, 2020 and 2019 is as follows (in thousands, except share and per share data):

| | Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life In Years | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding as of October 31, 2018 | 330,071 | $ 122.79 | 6.56 | $ - |
| Granted | 265,882 | 2.36 | | |
| Cancelled or expired | (35,463) | 29.52 | | |
| Outstanding as of October 31, 2019 | 560,490 | $ 71.56 | 7.34 | $ 1 |
| Granted | 645,000 | 0.61 | | |
| Cancelled or expired | (193,722) | 34.47 | | |
| Outstanding as of October 31, 2020 | 1,011,768 | $ 33.43 | 8.04 | $ 4 |
| Vested and exercisable at October 31, 2020 | 307,467 | $ 105.69 | 4.91 | $ 1 |

The following table summarizes information about the outstanding and exercisable options at October 31, 2020:

| Options Outstanding | | | | | Options Exercisable | | | |
|---|---|---|---|---|---|---|---|---|
| Exercise Price Range | Number Outstanding | Weighted Average Remaining Contractual | Weighted Average Exercise Price | Intrinsic Value | Number Exercisable | Weighted Average Remaining Contractual | Weighted Average Exercise Price | Intrinsic Value |
| $ .30-$10.00 | 746,579 | 9.41 | $ 1.10 | $ 1 | 68,655 | 8.67 | $ 2.62 | $ - |
| $ 10.01-$100.00 | 102,951 | 7.23 | $ 28.77 | $ - | 76,574 | 7.16 | $ 29.67 | $ - |
| $100.01-$200.00 | 92,847 | 2.76 | $ 166.04 | $ - | 92,847 | 2.76 | $ 166.04 | $ - |
| $200.01-$277.50 | 69,391 | 1.58 | $ 210.79 | $ - | 69,391 | 1.58 | $ 210.79 | $ - |

The fair value of each option granted from the Company's stock option plans during the years ended October 31, 2020 and 2019 was estimated on the date of grant using the Black-Scholes option-pricing model. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of the Company's common stock price, (ii) the periods of time over which employees and Board Directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on the Company's common stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating expected lives of the options. The Company used their own historical volatility in determining the volatility to be used. The expected term of the stock option grants was calculated using the "simplified" method in accordance with the SEC Staff Accounting Bulletin 107. The "simplified" method was used since the Company believes its historical data does not provide a reasonable basis upon which to estimate expected term and the Company does not have enough option exercise data from its grants issued to support its own estimate as a result of vesting terms and changes in the stock price. The expected dividend yield is zero as the Company has never paid dividends to common shareholders and does not currently anticipate paying any in the foreseeable future.

The following table provides the weighted average fair value of options granted to directors and employees and the related assumptions used in the Black-Scholes model:

| | Year Ended | |
|---|---|---|
| | October 31, 2020 | October 31, 2019 |
| Expected term | 5.50-6.50 years | 5.50-6.51 years |
| Expected volatility | 100.27-105.21% | 90.24-104.99% |
| Expected dividends | 0% | 0% |
| Risk free interest rate | 0.36-0.62% | 1.35-3.15% |

Total compensation cost related to the Company's outstanding stock options, recognized in the statement of operations for the years ended October 31, 2020 and 2019 was approximately $0.7 million and $1.2 million, respectively.

During the fiscal year ended October 31, 2020, 645,000 options were granted with a total grant date fair value of approximately $0.3 million. During the fiscal year ended October 31, 2019, 265,882 options were granted with a total grant date fair value of approximately $0.5 million.

As of October 31, 2020, there was approximately $0.6 million of unrecognized compensation cost related to non-vested stock option awards, which is expected to be recognized over a remaining weighted average vesting period of approximately 1.50 years.

*Employee Stock Purchase Plan*

The Advaxis, Inc. 2018 Employee Stock Purchase Plan (ESPP) was approved by the Company's shareholders on March 21, 2018. The 2018 ESPP allows employees to purchase common stock of the Company at a 15% discount to the market price on designated exercise dates. Employees were eligible to participate in the 2018 ESPP beginning May 1, 2018. 1,000,000 shares of the Company's Common stock are reserved for issuance under the 2018 ESPP.

During the fiscal year ended October 31, 2020, 14,148 shares were issued under the 2018 ESPP and the Company recorded an expense of approximately $1,000. During the fiscal year ended October 31, 2019, 7,435 shares were issued under the 2018 ESPP and the Company recorded an expense of approximately $2,000.

As of October 31, 2020, 976,517 shares of Company's common stock remain available for issuance under the 2018 ESPP.

**8. COLLABORATION AND LICENSING AGREEMENTS**

*OS Therapies LLC*

On September 4, 2018, the Company entered into a development, license and supply agreement with OS Therapies ("OST") for the use of ADXS31-164, also known as ADXS-HER2, for evaluation in the treatment of osteosarcoma in humans. Under the terms of the license agreement, as amended, OST will be responsible for the conduct and funding of a clinical study evaluating ADXS-HER2 in recurrent, completely resected osteosarcoma. Under the most recent amendment to the licensing agreement, OST agrees to pay Advaxis $25,000 per month ("Monthly Payment") starting on April 30, 2020 until it achieves its funding milestone of $2,337,500. Upon receipt of the first Monthly Payment, Advaxis will initiate the transfer of the intellectual property and licensing rights of ADXS31-164, which were licensed pursuant to the Penn Agreement, back to the University of Pennsylvania. Contemporaneously, OST will enter negotiations with the University of Pennsylvania to establish a licensing agreement for ADXS31-164 to OST for clinical and commercial development of the ADXS31-164 technology.

Provided that OST meets its ongoing obligation to make its Monthly Payments to Advaxis for six consecutive months, Advaxis agrees to transfer, and OST agrees to take full ownership of, the IND application for ADXS31-164 in its entirety to OST, along with agreements and promises contained therein, as well as all obligations associated with this IND or any HER2 product/program development. Until OST makes its Monthly Payments to Advaxis for six consecutive months, Advaxis will continue to bear the costs of the regulatory filing services related to the IND application for ADXS31-164.

Within five business days of achieving the funding milestone of $2,337,500 for the performance of the Children's Oncology Group study (knowns as the "License Commencement Date"), OST will make a non-refundable and non-creditable payment to Advaxis of $1,550,000 less the cumulative Monthly Payments previously made (the "License Commencement Payment"). Within five days following the License Commencement Date, Advaxis will provide existing drug supply "as is" to OST, and until the drug supply is supplied to OST, Advaxis will bear the storage costs for the drug product. Pursuant to the agreement, the Company is also to receive sales-based milestone payments and royalties on future product sales. In addition, the Company and OST will establish a Joint Steering Committee to oversee the R&D activities.

The promises to (1) Maintain the HER2 product until transfer to OST, (2) Provide the IND application ownership for ADX321-164 to OST, (3) Participate in the Joint Steering Committee, (4) Transfer of IP & licensing rights of ADXS31-164 and related Patents, and (5) Provide Clinical Drug Supply represent one combined performance obligation for revenue recognition purposes. The Company concluded that the transfer of the IP and licensing rights provides OST with a functional, or "right to use," license, and thus the Company will recognize the upfront fees of $1,550,000 from the license at a point in time. The revenue from the transfer of the license cannot be recognized until the transfer of the corresponding IP to OST has occurred and OST has the ability to benefit from the right to use the license. As the right to use the license begins when OST makes the upfront payment within five days of the License Commencement Date and the IP transfers to OST at that time, the upfront fees from the license will be recognized upon the transfer of the intellectual property to OST.

Since OST is making $25,000 monthly payments that will be creditable against the $1,550,000, as well as additional upfront payments not specified in the contract, the Company will receive payments prior to the performance of the single distinct performance obligation. Due to this, the Company will defer any of the monthly payments until the IP and licensing rights are transferred to OST. However, if OST terminates the contract, which they are able to do with 60-day notice, the Company would recognize any of the payments received when the contract terminates. As of October 31, 2020, OST has made payments totaling $164,653 and this has been recorded as other liabilities in the balance sheet.

*Amgen*

On August 1, 2016, the Company entered into a global agreement (the "Amgen Agreement") with Amgen for the development and commercialization of the Company's ADXS-NEO, a then- preclinical investigational immunotherapy, using the Company's proprietary Listeria monocytogenes attenuated bacterial vector which activates a patient's immune system to respond against unique mutations, or neoepitopes, contained in and identified from an individual patient's tumor. Under the terms of the Amgen Agreement, Amgen received an exclusive worldwide license to develop and commercialize ADXS-NEO. Amgen made an upfront payment to Advaxis of $40 million and purchased directly from Advaxis 203,163 shares of the Company's common stock, at approximately $123.00 per share (representing a purchase at market using a 20 day VWAP methodology) for a total of $25 million. Amgen assisted in funding the clinical development and commercialization of ADXS-NEO and Advaxis retained manufacturing responsibilities. Advaxis and Amgen collaborated through a joint steering committee for the development and commercialization of ADXS-NEO. Advaxis received reimbursements for research and development costs and Advaxis was eligible to receive future contingent payments based on development, regulatory and sales milestone payments of up to $475 million and high single digit to double digit royalty payments based on worldwide sales by Amgen.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, Amgen, is a customer. The Company identified the following material promises under the arrangement: (1) licenses, (2) research and development activities, (3) clinical supplies, (4) regulatory responsibilities and (5) participation on a Joint Steering Committee (JSC). The Company determined that the licenses and research and development activities were not distinct from another, as the licenses had limited value without the performance of the research and development activities. Participation on the JSC to oversee the research and development activities was determined to be quantitatively and qualitatively immaterial and therefore was excluded from performance obligations. The clinical supply and regulatory responsibilities did not represent separate performance obligations based on their dependence on the research and development efforts. Based on this assessment, the Company identified one performance obligation at the outset of the Amgen Agreement, which consists of: (1) licenses, (2) research and development activities, (3) clinical supplies and (4) regulatory responsibilities.

Under the Amgen Agreement, in order to evaluate the appropriate transaction price, the Company determined that the upfront amount of $40 million constituted the entirety of the consideration to be included in the transaction price as of the outset of the arrangement, which is allocated to the single performance obligation. The Company concluded that a time-based method was most appropriate to measuring progress toward completion given that the research and development services are satisfied reasonably evenly over the agreement and the Company has a stand-ready obligation to perform over such time. Accordingly, progress toward completion and related revenue recognition is measured using the input method of time elapsed relative to the estimated timeline for Advaxis to submit the Phase 2 package to Amgen, or perform the contractual research and development services, which was the predominant promise in the Company's combined performance obligation to Amgen.

The reimbursement for the research and development costs was variable consideration that was included in the transaction price at the outset, subject to the constraint. The Company estimated the consideration from the reimbursement of the research and development costs using the most-likely amount. When the research and development costs are no longer constrained, they are added to the transaction price for the single, combined performance obligation and recognized over the same recognition period as the rest of the performance obligation's allocated revenue. The potential milestone and sales-based royalty payments that the Company was eligible to receive were excluded from the transaction price, as all milestone and sales royalty amounts were fully constrained based on the probability of achievement. The Company reevaluated the transaction price at the end of each reporting period and as uncertain events were resolved or other changes in circumstances occurred, and, as necessary, adjusted its estimate of the transaction price.

On December 10, 2018, the Company received a written notice of termination from Amgen with respect to the Amgen Agreement. The termination became effective as of February 8, 2019, and the Company regained worldwide rights for the development and commercialization of its ADXS-NEO program. On October 24, 2019, Advaxis announced that it has enrolled its last patient in its ADXS-NEO program in monotherapy and will not enter Part B.

The remaining deferred revenue of approximately $18.2 million on December 10, 2018 related to the $40 million non-refundable, up-front payment received from Amgen was accounted for as of the modification date. As of that notification date, the Company adjusted revenue on a cumulative catch-up basis considering the revised measure of progress for the combined performance obligation based on the modified service period up to and through the contract termination date of February 8, 2019. The Company recognized cumulative catch-up revenue of approximately $15.6 million on December 10, 2018. The remaining $2.6 million was recognized over the subsequent 60 days until the performance obligation was satisfied on February 8, 2019.

During the years ended October 31, 2020 and 2019, the Company recognized revenue from the Amgen Agreement of approximately $0 and $20.6 million, respectively. During the years ended October 31, 2020 and 2019, the Company received reimbursement of research and development costs of approximately $0 and $2.0 million, which was included in revenue.

*Merck & Co., Inc.*

On August 22, 2014, the Company entered into a Clinical Trial Collaboration and Supply Agreement (the "Merck Agreement") with Merck, pursuant to which the parties collaborated on a Phase 1/2 dose-determination and safety trial. The Phase 1 portion of the trial evaluated the safety of our *Lm* -LLO based immunotherapy for prostate cancer, ADXS-PSA (the "Advaxis Compound") as monotherapy and in combination with KEYTRUDA® (pembrolizumab), Merck's humanized monoclonal antibody against PD-1, (the "Merck Compound") and has determined a recommended Phase 2 combination dose. The Phase 2 portion evaluated the safety and efficacy of the Advaxis Compound in combination with the Merck Compound. Both phases of the trial were in patients with previously treated metastatic castration-resistant prostate cancer. The last patient was dosed in August 2019 and the Company is in the surveillance stage of the study. A joint development committee, comprised of equal representatives from both parties, is responsible for coordinating all regulatory and other activities under, and pursuant to, the Merck Agreement.

Each party is responsible for their own internal costs and expenses to support the trial, while the Company was responsible for all third-party costs of conducting the trial. Merck was responsible for manufacturing and supplying the Merck Compound. The Company was responsible for manufacturing and supplying the Advaxis Compound. The Company is the sponsor of the trial and holds the IND related to the trial.

All data and results generated under the trial ("Collaboration Data") will be jointly owned by the parties, except that ownership of data and information generated from sample analysis to be performed by each party on its respective compound will be owned by the party conducting such testing. All rights to all inventions and discoveries, which claim or cover the combined use of the Advaxis Compound and the Merck Compound shall belong jointly to the parties. Inventions and discoveries relating solely to the Advaxis Compound, or a live attenuated bacterial vaccine, shall be the exclusive property of Advaxis. Inventions and discoveries relating solely to the Merck Compound, or a PD-1 antagonist, shall be the exclusive property of Merck.

During the each of the years ended October 31, 2020 and 2019, the Company incurred approximately $0.9 million in expenses pertaining to the Merck agreement, and such expenses were a component of research and development expenses in the statement of operations.

*Elanco Animal Health (formerly Aratana Therapeutics)*

On March 19, 2014, the Company and Aratana entered into a definitive Exclusive License Agreement (the "Aratana Agreement"). Pursuant to the Agreement, Advaxis granted Aratana an exclusive, worldwide, royalty-bearing, license, with the right to sublicense, certain Advaxis proprietary technology that enables Aratana to develop and commercialize animal health products that will be targeted for treatment of osteosarcoma and other cancer indications in animals. Under the terms of the Aratana Agreement, Aratana paid an upfront payment to the Company, of $1 million. As this license has stand-alone value to Aratana (who has the ability to sublicense) and was delivered to Aratana, upon execution of the Aratana Agreement, the Company recorded the $1 million payment as licensing revenue during the fiscal year ended October 31, 2014. Aratana will also pay the Company up to an additional $36.5 million based on the achievement of certain milestones with respect to the advancement of products pursuant to the terms of the Aratana Agreement. In addition, Aratana may pay the Company an additional $15 million in cumulative sales milestones pursuant to the terms of the Aratana Agreement.

During the fiscal year ended October 31, 2018, the USDA's Center for Veterinary Biologics granted Aratana conditional approval for its canine osteosarcoma vaccine using Advaxis' technology. During the years ended October 31, 2020 and 2019, Advaxis recognized royalty revenue totaling approximately $3,000 and $8,000, respectively, from Aratana's sales of the canine osteosarcoma vaccine. On July 16, 2019, Aratana announced their shareholders approved a merger agreement with Elanco Animal Health ("Elanco") whereby Elanco will be the majority shareholder in Aratana. On October 6, 2020, the Company received a notice from Aratana, dated September 17, 2020, indicating that Aratana was terminating the Exclusive License Agreement effective December 21, 2020. The Company did not incur any early termination penalties as a result of the termination. Aratana was required to make all payments to the Company that were otherwise payable under the Exclusive License Agreement through the effective date of termination.

*Global BioPharma Inc.*

On December 9, 2013, the Company entered into an exclusive licensing agreement for the development and commercialization of axalimogene filolisbac with Global BioPharma, Inc. (GBP), a Taiwanese based biotech company funded by a group of investors led by Taiwan Biotech Co., Ltd (TBC). During each of the years ended October 31, 2020 and 2019, the Company recorded $0.25 million in revenue for the annual license fee renewal. Since Advaxis has no significant obligation to perform after the license transfer and has provided GBP with the right to use its intellectual property, performance is satisfied when the license renews.

**9. COMMITMENTS AND CONTINGENCIES**

*Legal Proceedings*

*Stendhal*

On September 19, 2018, Stendhal filed a Demand for Arbitration before the International Centre for Dispute Resolution (Case No. 01-18-0003-5013) relating to the Co-development and Commercialization Agreement with Especificos Stendhal SA de CV (the "Stendhal Agreement"). In the demand, Stendhal alleged that (i) the Company breached the Stendhal Agreement when it made certain statements regarding its AIM2CERV program, (ii) that Stendhal was subsequently entitled to terminate the Agreement for cause, which it did so at the time and (iii) that the Company owes Stendhal damages pursuant to the terms of the Stendhal Agreement. Stendhal is seeking to recover $3 million paid to the Company in 2017 as support payments for the AIM2CERV clinical trial along with approximately $0.3 million in expenses incurred. Stendhal is also seeking fees associated with the arbitration and interest. The Company has answered Stendhal's Demand for Arbitration and denied that it breached the Stendhal Agreement. The Company also alleges that Stendhal breached its obligations to the Company by, among other things, failing to make support payments that became due in 2018 and that Stendhal therefore owes the Company $3 million. Advaxis is also seeking fees associated with the arbitration and interest.

From October 21-23, 2019, an evidentiary hearing for the arbitration was conducted. On April 1, 2020, the Arbitrator issued a final award denying Stendhal's claim in full. The Arbitrator found that the Company had not repudiated the Agreement and did not owe Stendhal damages, fees, or interest associated with the arbitration. The Arbitrator also denied the Company's claim that Stendhal breached its obligations to the Company. The parties were ordered to bear their own attorneys' fees and evenly split administrative fees and expenses for the arbitration.

**10. LEASES**

*Operating Leases*

The Company leases its corporate office and manufacturing facility in Princeton, New Jersey under an operating lease that expires in November 2025. The Company has the option to renew the lease term for two additional five-year terms. The renewal periods were not included the lease term for purposes of determining the lease liability or right-of-use asset. The Company has provided a security deposit of approximately $182,000, which is recorded as Other Assets in the balance sheet.

The Company identified and assessed the following significant assumptions in recognizing its right-of-use assets and corresponding lease liabilities:

- As the Company does not have sufficient insight to determine an implicit rate, the Company estimated the incremental borrowing rate in calculating the present value of the lease payments. The Company utilized a synthetic credit rating model to determine a benchmark for its incremental borrowing rate for its leases. The benchmark rate was adjusted to arrive at an appropriate discount rate for the lease.

- Since the Company elected to account for each lease component and its associated non-lease components as a single combined component, all contract consideration was allocated to the combined lease component.

- Renewal option periods have not been included in the determination of the lease terms as they are not deemed reasonably certain of exercise.
- Variable lease payments, such as common area maintenance, real estate taxes, and property insurance are not included in the determination of the lease's right-of-use asset or lease liability.

Supplemental balance sheet information related to leases as of October 31, 2020 was as follows (in thousands):

| | | |
|---|---|---|
| Operating Leases: | | |
| Operating lease right-of-use assets | $ | 4,839 |
| | | |
| Operating lease liability | $ | 962 |
| Operating lease liability, net of current portion | | 5,055 |
| Total operating lease liabilities | $ | 6,017 |

Supplemental lease expense related to leases was as follows (in thousands):

| Lease Cost (in thousands) | Statements of Operations Classification | | For the Year Months Ended October 31, 2020 |
|---|---|---|---|
| Operating lease cost | General and administrative | $ | 1,158 |
| Short-term lease cost | General and administrative | | 320 |
| Variable lease cost | General and administrative | | 547 |
| Total lease expense | | $ | 2,025 |

Other information related to leases where the Company is the lessee is as follows:

| | For the Fiscal Year Ended October 31, 2020 |
|---|---|
| Weighted-average remaining lease term | 5.1 years |
| Weighted-average discount rate | 6.5% |

Supplemental cash flow information related to operating leases was as follows:

| | | For the Fiscal Year Ended October 31, 2020 |
|---|---|---|
| Cash paid for operating lease liabilities | $ | 1,233 |

Future minimum lease payments under non-cancellable leases as of October 31, 2020 were as follows:

| Fiscal Year ending October 31, | | |
|---|---|---|
| 2021 | $ | 1,318 |
| 2022 | | 1,369 |
| 2023 | | 1,395 |
| 2024 | | 1,419 |
| 2025 | | 1,444 |
| Thereafter | | 120 |
| Total minimum lease payments | | 7,065 |
| Less: Imputed interest | | (1,048) |
| Total | $ | 6,017 |

Under ASC 840, future minimum payments under the Company's operating lease were as follows (in thousands):

| Fiscal Year ending October 31, | | |
|---|---|---|
| 2021 | $ | 1,318 |
| 2022 | | 1,369 |
| 2023 | | 1,395 |
| 2024 | | 1,419 |
| 2025 | | 1,444 |
| Thereafter | | 120 |
| Total | $ | 7,065 |

Under ASC 840, rent expense for the fiscal year ended October 31, 2019 was approximately $1.2 million.

**11. INCOME TAXES**

The income tax provision (benefit) consists of the following (in thousands):

| | October 31, 2020 | October 31, 2019 |
|---|---|---|
| Federal | | |
| Current | $ - | $ - |
| Deferred | (4,578) | 32,673 |
| State and Local | | |
| Current | - | - |
| Deferred | (1,445) | (1,634) |
| Change in valuation allowance | 6,023 | (31,039) |
| Income tax provision (benefit) | $ - | $ - |

The Company has U.S. federal net operating loss carryovers ("NOLs") of approximately $89.4 million and $74.0 million at October 31, 2020 and 2019 respectively, available to offset taxable income which expire beginning in 2023. If not used, these NOLs may be subject to limitation under Internal Revenue Code Section 382 should there be a greater than 50% ownership change as determined under the regulations. During the years ended October 31, 2020 and 2019, the Company performed a detailed analysis of any historical and/or current Section 382 ownership changes that may limit the utilization of the net operating loss carryovers. From the entire federal NOL of $299.2 million as of October 31, 2020, approximately $89.4 million is available for use based on Internal Revenue Code Section 382 analysis. The NOL and the deferred tax asset table below does not include approximately $209.8 million of NOL's that may expire unused. The Company also has New Jersey State Net Operating Loss carryovers of approximately $137.7 million as of October 31, 2020 available to offset future taxable income through 2040.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon future generation for taxable income during the periods in which temporary differences representing net future deductible amounts become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. After consideration of all the information available, management believes that significant uncertainty exists with respect to future realization of the deferred tax assets and has therefore established a full valuation allowance.

The Company evaluated the provisions of ASC 740 related to the accounting for uncertainty in income taxes recognized in an enterprise's financial statements. ASC 740 prescribes a comprehensive model for how a company should recognize, present, and disclose uncertain positions that the company has taken or expects to take in its tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. Differences between tax positions taken or expected to be taken in a tax return and the net benefit recognized and measured pursuant to the interpretation are referred to as "unrecognized benefits." A liability is recognized (or amount of net operating loss carry forward or amount of tax refundable is reduced) for unrecognized tax benefit because it represents an enterprise's potential future obligation to the taxing authority for a tax position that was not recognized as a result of applying the provisions of ASC 740.

If applicable, interest costs related to the unrecognized tax benefits are required to be calculated and would be classified as other expense in the statement of operations. Penalties would be recognized as a component of general and administrative expenses in the statement of operations.

No interest or penalties on unpaid tax were recorded during the years ended October 31, 2020 and 2019, respectively. As of October 31, 2020 and 2019, no liability for unrecognized tax benefits was required to be reported. The Company does not expect any significant changes in its unrecognized tax benefits in the next year.

The Company files tax returns in the U.S. federal and state jurisdictions and is subject to examination by tax authorities beginning with the fiscal year ended October 31, 2017.

The Company's deferred tax assets (liabilities) consisted of the effects of temporary differences attributable to the following (in thousands):

| | Years Ended | |
|---|---|---|
| | October 31, 2020 | October 31, 2019 |
| Deferred Tax Assets | | |
| Net operating loss carryovers | $ 28,553 | $ 22,627 |
| Stock-based compensation | 10,132 | 11,767 |
| Research and development credits | 10,742 | 10,234 |
| Capitalized R&D costs | 13,822 | 13,399 |
| Deferred revenue | - | - |
| Adoption of ASC 842 – Lease Liability | 1,691 | - |
| Other deferred tax assets | 224 | 405 |
| Total deferred tax assets | $ 65,164 | $ 58,432 |
| Valuation allowance | (62,845) | (56,822) |
| Deferred tax asset, net of valuation allowance | $ 2,319 | $ 1,610 |
| | | |
| Deferred Tax Liabilities | | |
| Adoption of ASC 842 – ROU Asset | (1,360) | - |
| Patent Cost | (917) | - |
| Other deferred tax liabilities | (42) | (1,610) |
| Total deferred tax liabilities | $ (2,319) | $ (1,610) |
| Net deferred tax asset (liability) | $ - | $ - |

The expected tax (expense) benefit based on the statutory rate is reconciled with actual tax expense benefit as follows:

| | Years Ended | |
|---|---|---|
| | October 31, 2020 | October 31, 2019 |
| US Federal statutory rate | 21.00% | 21.00% |
| State income tax, net of federal benefit | 5.48 | 9.84 |
| Permanent differences | (0.05) | 1.23 |
| Research and development credits | 1.73 | 17.30 |
| Change in valuation allowance | (22.82) | 186.84 |
| §382 Impact on NOL | - | (233.87) |
| Stock Option Expirations | (5.33) | (2.34) |
| Income tax (provision) benefit | 0.00% | 0.00% |

The statement of operations discloses income tax expense of $50. This is a Taiwan Excise tax of 50 levied in connection with the GPP Revenue.

**12. STOCKHOLDERS' EQUITY**

*Public Offerings*

In April 2019, the Company issued 2,500,000 shares of the Company's common stock in a public offering at $4.00 per share, less underwriting discounts and commissions. The net proceeds to the Company from the transaction was approximately $9 million.

In July 2019, the Company closed on an underwritten public offering of 10,650,000 shares of its common stock, pre-funded warrants to purchase 13,656,000 shares of common stock and warrants to purchase up to 17,142,000 shares of common stock for gross proceeds of $17.0 million. Each share of common stock was sold together in a fixed combination with a warrant to purchase 0.75 shares of common stock for $0.70, and each pre-funded warrant was sold together in a fixed combination with a warrant to purchase 0.75 shares of common stock for $0.699. The pre-funded warrants are exercisable immediately, do not expire and have an exercise price of $0.001 per share. The warrants are exercisable immediately, expire five years from the date of issuance, have an exercise price of $2.80 per share and are subject to anti-dilution and other adjustments for certain stock splits, stock dividends, or recapitalizations. The warrants also provide that if during the period of time between the date that is the earlier of (i) 30 days after issuance and (ii) if the common stock trades an aggregate of more than 35,000,000 shares after the pricing of the offering, and ending 15 months after issuance, the weighted-average price of common stock immediately prior to the exercise date is lower than the then-applicable exercise price per share, each Common Warrant may be exercised, at the option of the holder, on a cashless basis for one share of Common Stock. After deducting the underwriting discounts and commissions and other offering expenses, the net proceeds from the offering were approximately $15.5 million.

In January 2020, the Company closed on a public offering of 10,000,000 shares of its common stock at a public offering price of $1.05, for gross proceeds of $10.5 million. In addition, the Company also undertook a concurrent private placement of warrants to purchase up to 5,000,000 shares of common stock. The warrants have an exercise price per share of $1.25, are exercisable during the period beginning on the six-month anniversary of the date of its issuance (the "Initial Exercise Date") and will expire on the fifth anniversary of the Initial Exercise Date. The warrants contain a change of control provision whereby if the change of control is within the Company's control, the warrants could be settled in cash based on the Black-Scholes value of the warrants at the option of the warrant holder. The warrants also provide that if there is no effective registration statement registering, or no current prospectus available for, the issuance or resale of the warrant shares, the warrants may be exercised via a cashless exercise. After deducting the underwriting discounts and commissions and other offering expenses, the net proceeds from the offering were approximately $9.6 million.

In May 2020, the Company entered into a sales agreement related to an ATM equity offering program pursuant to which the Company may sell, from time to time, common stock with an aggregate offering price of up to $40 million through A.G.P./Alliance Global Partners, as sales agent. From May 2020 to October 2020, the Company sold 2,489,104 shares of its common stock under the ATM program for $1.583 million, or an average of $0.64 per share, and received net proceeds of $1.531 million, net of commissions of $52,000.

*Lincoln Park Purchase Agreement*

On July 30, 2020, the Company entered into a Purchase Agreement (the "Purchase Agreement") and a Registration Rights Agreement (the "Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Over the 36-month term of the Purchase Agreement, the Company has the right, but not the obligation, from time to time, to sell to Lincoln Park up to an aggregate amount of $20,000,000 of shares of common stock, in its sole discretion and subject to certain conditions, including that the closing price of its common stock is not below $0.10 per share, to direct Lincoln Park to purchase up to 1,000,000 shares (the "Regular Purchase Share Limit") of its Common Stock (each such purchase, a "Regular Purchase"). Lincoln Park's maximum obligation under any single Regular Purchase will not exceed $1,000,000, unless the parties mutually agree to increase the maximum amount of such Regular Purchase. The purchase price for shares of Common Stock to be purchased by Lincoln Park under a Regular Purchase will be the equal to the lower of (in each case, subject to the adjustments described in the Purchase Agreement): (i) the lowest sale price for the Company's common stock on the applicable purchase date, and (ii) the arithmetic average of the three lowest sale prices for the Company's common stock during the ten trading days prior to the purchase date.

As consideration for entering into the Purchase Agreement, the Company issued 1,084,266 shares of common stock to Lincoln Park as a commitment fee. The shares were valued at approximately $0.6 million and were recorded as deferred offering expenses in the balance sheet. The deferred charges were charged against paid-in capital upon future proceeds from the sale of common stock under the Lincoln Park Purchase Agreement.

From August 2020 to October 2020, Lincoln Park purchased 11,242,048 shares of common stock for gross proceeds of approximately $5.1 million. Approximately $50,000 of legal fees were netted against the gross proceeds.

**13. FAIR VALUE**

The authoritative guidance for fair value measurements defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or the most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Market participants are buyers and sellers in the principal market that are (i) independent, (ii) knowledgeable, (iii) able to transact, and (iv) willing to transact. The guidance describes a fair value hierarchy based on the levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.

- Level 2— Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or corroborated by observable market data or substantially the full term of the assets or liabilities.

- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the value of the assets or liabilities.

The following table provides the assets and liabilities carried at fair value measured on a recurring basis as of October 31, 2020 and October 31, 2019:

| October 31, 2020 | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| Common stock warrant liability, warrants exercisable at $0.372 through September 2024 | - | - | $ 17 | $ 17 |

| October 31, 2019 | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| Common stock warrant liability, warrants exercisable at $0.372 through September 2024 | - | - | $ 19 | $ 19 |

The following table sets forth a summary of the changes in the fair value of the Company's warrant liabilities:

| | Year Ended October 31, | |
|---|---|---|
| | 2020 | 2019 |
| Beginning balance | $ 19 | $ 6,517 |
| Shares issued in settlement of warrants | - | (3,856) |
| Warrant exercises | (2) | (53) |
| Change in fair value | - | (2,589) |
| Ending Balance | $ 17 | $ 19 |

**14. EMPLOYEE BENEFIT PLAN**

The Company sponsors a 401(k) Plan. Employees become eligible for participation upon the start of employment. Participants may elect to have a portion of their salary deferred and contributed to the 401(k) Plan up to the limit allowed under the Internal Revenue Code. The Company makes a matching contribution to the plan for each participant who has elected to make tax-deferred contributions for the plan year. The Company made matching contributions which amounted to approximately $0.1 million and $0.2 million for the years ended October 31, 2020 and 2019, respectively. These amounts were charged to the statement of operations. The employer contributions vest immediately.

**15. SUBSEQUENT EVENTS**

In November 2020, the Company closed on a public offering of 30,666,665 shares of its common stock at a public offering price of $0.30, for gross proceeds of $9.2 million, which gives effect to the exercise of the underwriter's option in full. In addition, the Company also undertook a concurrent private placement of warrants to purchase up to 15,333,332 shares of common stock. The warrants have an exercise price per share of $0.35, are exercisable immediately and will expire five years from the date of issuance. The warrants also provide that if there is no effective registration statement registering, or no current prospectus available for, the issuance or resale of the warrant shares, the warrants may be exercised via a cashless exercise. After deducting the underwriting discounts and commissions and other offering expenses, the net proceeds from the offering were approximately $8.5 million.

Subsequent to year end, warrant holders from the Company's November 2020 offering exercised 4,610,000 warrants in exchange for 4,610,000 shares of the Company's common stock. Pursuant to these warrant exercises, the Company received aggregate proceeds of about $1.6 million which were payable upon exercise.

In December 2020 and January 2021, the Company received an aggregate of $1,345,000 from OS Therapies upon achievement of the $1,550,000 funding milestone set forth in the license agreement. For more information on the license agreement with OS Therapies, please see Note 8 – "Collaboration and Licensing Agreements" above.

**BIOSIGHT LTD.**
CONDENSED CONSOLIDATED UNAUDITED FINANCIAL STATEMENTS
AS OF JUNE 30, 2021

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**BIOSIGHT LTD.**
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(U.S. dollars in thousands, except per share data)

| | June 30, 2021 | December 31, 2020 |
|---|---|---|
| **Assets** | | |
| **CURRENT ASSETS:** | | |
| Cash and cash equivalents | 24,434 | 32,272 |
| Other receivables | 460 | 176 |
| **TOTAL CURRENT ASSETS** | 24,894 | 32,448 |
| | | |
| **NON-CURRENT ASSETS:** | | |
| Operating lease right of use assets | 167 | 205 |
| Property and equipment, net | 146 | 152 |
| **TOTAL NON-CURRENT ASSETS** | 313 | 357 |
| | | |
| **TOTAL ASSETS** | 25,207 | 32,805 |

**The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.**

**BIOSIGHT LTD.**
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(U.S. dollars in thousands, except per share data)

| | June 30, 2021 | December 31, 2020 |
|---|---|---|
| **Liabilities, and redeemable convertible preferred shares net of capital deficiency** | | |
| **CURRENT LIABILITIES:** | | |
| Trade payables | 745 | 1,715 |
| Accrued expenses and other payables | 173 | 248 |
| Operating lease liabilities | 99 | 95 |
| Warrants | 5,236 | 5,634 |
| **TOTAL CURRENT LIABILITIES** | 6,253 | 7,692 |
| **LONG-TERM LIABILITIES:** | | |
| Operating lease liabilities | 86 | 151 |
| **TOTAL LIABILITIES** | 6,339 | 7,843 |
| **COMMITMENTS AND CONTINGENCIES (Note 4)** | | |
| **REDEEMABLE CONVERTIBLE PREFERRED SHARES** | | |
| Preferred A-1 Shares, NIS 0.01 par value, 344,452 Preferred A-1 shares authorized; issued and outstanding: 210,723 Preferred A-1 shares as of June 30, 2021 and December 31, 2020 | 3,850 | 3,850 |
| Preferred A-3 Shares, NIS 0.01 par value, 43,384 Preferred A-3 shares authorized; issued and outstanding: 43,384 Preferred A-3 shares as of June 30, 2021 and December 31, 2020 | 200 | 200 |
| Preferred B Shares, NIS 0.01 par value, 400,000 Preferred B shares authorized; issued and outstanding: 215,420 Preferred B shares as of June 30, 2021 and December 31, 2020 | 4,122 | 4,122 |
| Preferred B-1 Shares, NIS 0.01 par value, 300,000 Preferred B-1 shares authorized; issued and outstanding: 170,377 Preferred B-1 shares as of June 30, 2021 and December 31, 2020 | 4,369 | 4,369 |
| Preferred C Shares, NIS 0.01 par value, 3,000,000 Preferred C shares authorized; issued and outstanding: 1,726,215 Preferred C shares as of June 30, 2021 and December 31, 2020 | 44,482 | 44,482 |
| **TOTAL REDEEMABLE CONVERTIBLE PREFERRED SHARES** | 57,023 | 57,023 |
| **CAPITAL DEFICIENCY** | | |
| Ordinary Shares, NIS 0.01 par value - authorized: 2,771,488 Ordinary Shares as of June 30, 2021 and December 31, 2020; issued and outstanding: 877,976 Ordinary Shares as of June 30, 2021; 816,302 as of December 31, 2020 | 2 | 2 |
| Additional paid-in capital | 6,833 | 6,579 |
| Accumulated deficit | (44,990) | (38,642) |
| **TOTAL CAPITAL DEFICIENCY** | (38,155) | (32,061) |
| **TOTAL LIABILITIES, AND REDEEMABLE CONVERTIBLE PREFERRED SHARES, AND CAPITAL DEFICIENCY** | 25,207 | 32,805 |

**The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.**

**BIOSIGHT LTD.**
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(U.S. dollars in thousands, except per share data)

| | Six months ended June 30, | |
|---|---|---|
| | **2021** | **2020** |
| **OPERATING EXPENSES:** | | |
| Research and development | 5,859 | 3,953 |
| General and administrative | 981 | 678 |
| **TOTAL OPERATING EXPENSES** | 6,840 | 4,631 |
| **OPERATING LOSS** | 6,840 | 4,631 |
| **GAIN FROM CHANGE IN FAIR VALUE OF WARRANTS AND CONVERTIBLE SECURITY** | (398) | (792) |
| **FINANCE INCOME** | (96) | (238) |
| **FINANCE EXPENSES** | 2 | 4 |
| **FINANCE INCOME, NET** | (492) | (1,026) |
| **NET LOSS FOR THE YEAR** | 6,348 | 3,605 |
| | | |
| **LOSS PER SHARE BASIC AND DILUTED** | 7.2 | 4.2 |
| | | |
| **WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE** | 877,976 | 861,019 |

**The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.**

**BIOSIGHT LTD.**

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES OF REDEEMABLE CONVERTIBLE PREFERRED SHARES AND OF CAPITAL DEFICIENCY

(Unaudited)

(U.S. dollars in thousands, except per share data)

| | Redeemable Convertible Preferred Shares | | Ordinary Shares | | Additional paid-in capital | Accumulated deficit Amount | Total |
|---|---|---|---|---|---|---|---|
| | Number of shares | Amount | Number of shares | Amount | | | |
| **BALANCE AT JANUARY 1, 2020** | **565,293** | **12,541** | **816,302** | **2** | **6,339** | **(28,007)** | **(21,666)** |
| **CHANGES DURING THE PERIOD:** | | | | | | | |
| Net loss | - | - | - | - | - | (3,605) | (3,605) |
| Conversion of convertible security | 154,393 | 4,045 | - | - | - | - | - |
| Share-based compensation | - | - | - | - | 92 | - | 92 |
| Issuance of Preferred C shares | 558,226 | 13,485 | - | - | - | - | - |
| **BALANCE AT June 30, 2020** | **1,277,912** | **30,071** | **816,302** | **2** | **6,431** | **(31,612)** | **(25,179)** |
| | | | | | | | |
| **BALANCE AT JANUARY 1, 2021** | **2,366,119** | **57,023** | **816,302** | **2** | **6,579** | **(38,642)** | **(32,061)** |
| **CHANGES DURING THE PERIOD:** | | | | | | | |
| Net loss | - | - | - | - | - | (6,348) | (6,348) |
| Exercise of options | - | - | 61,674 | * | * | - | * |
| Share-based compensation | - | - | - | - | 254 | - | 254 |
| **BALANCE AT JUNE 30, 2021** | **2,366,119** | **57,023** | **877,976** | **2** | **6,833** | **(44,990)** | **(38,155)** |

*Represents an amount lower than 1.

**The accompanying notes are an integral part of these unaudited condensed consolidated financial statements**

**BIOSIGHT LTD.**
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(U.S. dollars in thousands, except share and per share amounts)

| | Six Months ended June 30, | |
|---|---|---|
| | **2021** | **2020** |
| **CASH FLOWS FROM OPERATING ACTIVITIES:** | | |
| Net Loss | (6,348) | (3,605) |
| Adjustments required to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 12 | 12 |
| Share-based compensation | 254 | 92 |
| Finance income, net | (25) | (9) |
| Change in fair value of convertible security | | 678 |
| Change in fair value of warrants | (398) | (1,470) |
| Changes in operating asset and liabilities: | | |
| Increase in other receivables | (284) | (40) |
| Increase (decrease) in trade payables | (970) | 1,142 |
| Increase (decrease) in accrued expenses and other payables | (75) | 78 |
| Net cash used in operating activities | (7,834) | (3,122) |
| **CASH FLOWS FROM INVESTING ACTIVITIES:** | | |
| Purchase of fixed assets | (6) | (2) |
| Net cash used in investing activities | (6) | (2) |
| **CASH FLOWS FROM FINANCING ACTIVITIES:** | | |
| Proceeds from the issuance of Preferred C Shares and Warrants ($6,425 from related parties) | - | 15,000 |
| Net cash provided by financing activities | - | 15,000 |
| **INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS** | (7,840) | 11,876 |
| **EFFECT OF EXCHANGE RATE ON CASH AND CASH EQUIVALENTS** | 2 | 7 |
| **CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD** | 32,272 | 894 |
| **CASH AND CASH EQUIVALENTS AT END OF THE PERIOD** | 24,434 | 12,777 |

| | Six Months ended June 30, | |
|---|---|---|
| | **2021** | **2020** |
| **SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:** | | |
| **Additions of operating lease right-of-use assets and operating lease liabilities** | - | 50 |
| **Conversion of convertible security into Preferred C shares and warrants** | - | 4,500 |

**The accompanying notes are an integral part of these unaudited condensed consolidated financial statements**

**NOTE 1 - NATURE OF OPERATIONS:**

a. Biosight Ltd. (hereinafter - the Company) is an Israeli company incorporated in 1999.

The Company is a Phase 2 clinical stage specialty pharmaceutical company focused on developing and commercializing therapeutics for hematological malignancies and disorders.

Biosight's lead product, BST-236 (INN aspacytarabine), is a proprietary anti-metabolite designed to enable high-dose therapy with reduced systemic toxicity. BST-236 is currently being investigated as a single agent in a Phase 2b for first-line treatment of acute myeloid leukemia (AML), after successfully completing Phase 1/2a, which demonstrated tolerability in the population of AML patients unfit for standard therapy.

b. Since the Company is engaged in research and development activities, it has not derived income from its activities and has incurred accumulated losses in the amount of $45 million through June 30, 2021 and negative cash flows from operating activities. The Company's management is of the opinion that its available funds as of the date these financial statements are available to be issued, is not sufficient to meet its liquidity requirements for the following twelve months. These factors raise substantial doubt as to the Company's ability to continue as a going concern.

Management is in the process of evaluating various financing alternatives in the public or private equity markets, government grants or capital inflows from strategic partnerships, as the Company will need to finance future research and development activities, general and administrative expenses and working capital through fund raising. However, there is no certainty about the Company's ability to obtain such funding.

For information regarding the merger agreement signed with Advaxis Inc. on July 4, 2021, see Note 10b.

The financial information has been prepared on a going concern basis, which assumes the Company will continue to realize its assets and discharge its liabilities in the normal course of business. If the Company does not raise the requisite funds, it will need to curtail or cease operations. These financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern.

c. On March 12, 2020, the World Health Organization declared COVID-19 a global pandemic. In an effort to contain and mitigate the spread of COVID-19, many countries have imposed unprecedented restrictions on travel, mandatory business closures and other measures designed to mitigate the spread, leading to a substantial reduction in economic activities in countries around the world.

In response to the pandemic, the Company has implemented the mandatory as well as recommended measures to safeguard the health and safety of employees and clinical trial participants, and expects to continue to take actions as may be required or recommended by government authorities or as it determines are in the best interests of employees, clinical trial participants and others in light of COVID-19. To-date, COVID-19 has not adversely impacted the Company's business operations, international supply chain, productivity or clinical development timelines. However, uncertainty remains as to the potential impact of COVID-19 our future research and development activities and the potential for a material impact on the Company increases the longer the virus impacts certain aspects of economic activity around the world. The full extent to which COVID-19 will directly or indirectly impact the Company's business, results of operations and financial condition, including clinical trials, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international markets, the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, the ultimate impact on financial markets and the global economy, the effectiveness of vaccines and vaccine distribution efforts and the effectiveness of other actions taken in the United States and other countries to contain and treat the disease. It is not currently possible to predict how long the pandemic will last, what the long-term global effects will be, or the time that it will take for economic activity to return to pre-pandemic levels, and the Company does not yet know the full impact on its business and operations. The Company will continue to monitor COVID-19 closely and follow health and safety guidelines as they evolve.

## NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES:

### a. Unaudited Condensed Consolidated Financial Statements

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") and in accordance with the rules and regulations of the Securities and Exchange Commission ("SEC") with respect to Form 10-Q and Rule 10-01 of Regulation S-X for condensed financial information. They do not include all the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments considered necessary for a fair statement have been included (consisting only of normal recurring adjustments).

The unaudited financial information contained in this report should be read in conjunction with the audited financial statements as included in Advaxis Inc.'s Form S-4.

### b. Principles of Consolidation

The condensed consolidated financial statements include the accounts of the Company and its subsidiary. Intercompany balances and transactions have been eliminated upon consolidation.

### c. Use of estimates in the preparation of financial statements

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from those estimates. As applicable to these financial statements, the most significant estimates and assumptions relate to the fair value of share-based compensation and warrants, as well as the value of clinical trial accruals.

### d. Loss per share

The Company's basic net loss per share is calculated by dividing net loss attributable to ordinary shareholders by the weighted-average number of shares of ordinary shares outstanding for the period, without consideration of potentially dilutive securities. The diluted net loss per share is calculated by giving effect to all potentially dilutive securities outstanding for the period using the treasury share method or the if-converted method based on the nature of such securities. Diluted net loss per share is the same as basic net loss per share in periods when the effects of potentially dilutive shares of ordinary shares are anti-dilutive.

(U.S. dollars in thousands, except share and per share amounts)

**NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES** (continued):

The Company computes net loss per share using the two-class method required for participating securities. The two-class method requires income available to ordinary shareholders for the period to be allocated between ordinary shares and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed. The Company considers its redeemable convertible preferred shares to be participating securities as the holders of the redeemable convertible preferred shares would be entitled to dividends that would be distributed to the holders of ordinary shares, on a pro-rata basis assuming conversion of all redeemable convertible preferred shares into ordinary shares. These participating securities do not contractually require the holders of such shares to participate in the Company's losses. As such, net loss for the periods presented was not allocated to the Company's preferred shares.

The calculation of the loss per share includes fully vested options for the Company's Ordinary Shares at an exercise price of NIS 0.01 per share, as the Company considers these shares to be exercised for no additional consideration. As of June 30, 2021, there were no such options, and as of June 30, 2020, there were 44,717 such options.

The following share options, warrants and preferred shares were excluded from the calculation of diluted net loss per Ordinary Share because their effect would have been anti-dilutive for the year presented (share data):

| | Six Months ended June 30, | |
|---|---|---|
| | **2021** | **2020** |
| Outstanding share options | 250,773 | 220,369 |
| Warrants | 495,730 | 495,730 |
| Redeemable convertible preferred shares | 2,366,119 | 1,277,912 |

**e. Fair value measurement**

Fair value is based on the price that would be received from the sale of an asset or that would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, the guidance establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data or active market data of similar or identical assets or liabilities.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers credit risk in its assessment of fair value.

**NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES** (continued):

**f. Recently issued accounting pronouncements, not yet adopted**

i. In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation— Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815- 40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options ("ASU 2021-04"). The guidance is effective for the Company on January 1, 2022. The Company is currently evaluating the impact of adopting this standard and does not expect the guidance to have a material impact on its financial statements.

ii. In August 2020, the FASB issued ASU2020-06 "Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815 – 40)". This guidance simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The amendments to this guidance are effective for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years. The Company is currently evaluating this guidance to determine the impact it may have on its financial statements.

**NOTE 3 - SIGNIFICANT EVENTS DURING THE REPORTING PERIOD**

On April 21, 2021, the Company founded a wholly owned subsidiary in the United States, formed in the State of Delaware.

The Company has started consolidating the financial results of the subsidiary at the date of the subsidiary's founding.

**NOTE 4 – COMMITMENTS AND CONTINGENCIES**

The Company is obligated to pay royalties to the IIA on proceeds from the sale of products developed from research and development activities that were funded, partially, by grants from the IIA.

Under the terms of the funding arrangements with the IIA, royalties of 3% are payable on the sale of products developed from product candidates funded by the IIA, which payments shall not exceed, in the aggregate, 100% of the amount of the grant received (dollar linked), plus interest at annual rate based on LIBOR.

The Company did not receive any grants from the IIA for the six months ended June 30, 2021 and for the year ended December 31, 2020.

At the time the grants were received, successful development of the related projects was not assured. The total amount that was received through June 30, 2021 was $2,350. All grants received were recorded as a reduction of research and development expenses.

(U.S. dollars in thousands, except share and per share amounts)

## NOTE 5 – CONVERTIBLE SECURITY

**a.** On June 16, 2019 the Company entered a convertible security (hereinafter – "the Convertible Security") agreement, in which several shareholders agreed to provide the Company with a loan of $3,600 in several installments in exchange for a convertible security (out of which $2,100 are from related parties). The security is accounted for as a liability in accordance with ASC 480, and subsequently measured at fair value with changes in fair value recognized in earnings in accordance with ASC 480-10-35-5.

**b.** On March 29, 2020, as part of the Preferred C Shares Share Purchase Agreement, the Company converted the Convertible Security into 154,393 Preferred C Shares and 38,599 Preferred C Warrants. The conversion reflected a 20% discount on the price per share of Preferred C Shares.

**c.** The main assumptions of the fair value of the convertible security are that the security will be converted at a 20% discount and the expected timing of the Qualified Financing.

The table below sets forth a summary of changes in the fair value of the convertible security classified as Level 3:

| | **Convertible security June 30 2020** |
|---|---|
| Balance at beginning of year | 3,822 |
| Receipt of convertible security | - |
| Changes in fair value | 678 |
| Conversion to preferred C shares and warrants | (4,500) |
| Balance at end of interim period | - |

## NOTE 6 – WARRANTS

**a.** The Company issued warrants for Preferred Shares. For issuance of warrants in connection with the issuance of Preferred C shares, see Note 7c.

**b.** The fair value of the warrants was determined according to the option-price method ("OPM") as part of each investment round under the following assumptions:

| | **Value as of** | | |
|---|---|---|---|
| | **June 30** | | **March 29** |
| | **2021** | **2020** | **2020** |
| Expected volatility | 105.6% | 117.8% | 109.4% |
| Expected term | 1.5 | 2.5 | 2.8 |
| *Assumptions regarding price of the underlying shares* | | | |
| Discount rate | 0.2% | 0.2% | 0.4% |

(U.S. dollars in thousands, except share and per share amounts)

**NOTE 6 – WARRANTS** (continued):

**c.** The table below sets forth a summary of changes in the fair value of the warrants for preferred shares classified as Level 3:

| | Value of warrants measured at fair value | | Amount of warrants as of | |
|---|---|---|---|---|
| | June 30 | | June 30 | |
| | 2021 | 2020 | 2021 | 2020 |
| Balance at the beginning of the year | 5,634 | 5,060 | 495,730 | 314,546 |
| Warrants issued through the conversion of a convertible security | - | 455 | - | 38,599 |
| Warrants issued through issuance of Preferred C Shares | - | 1,515 | - | 142,585 |
| Changes in fair value | (398) | (1,470) | - | - |
| Balance at the end of the year | 5,236 | 5,560 | 495,730 | 495,730 |

**NOTE 7 - REDEEMABLE CONVERTIBLE PREFERRED SHARES:**

**a.** The Redeemable Convertible Preferred Shares as of June 30, 2021 are composed as follows (each share of NIS 0.01 par value):

| | Number of shares | | Amount (par value USD) | | Liquidation Value per Share | Liquidation Value |
|---|---|---|---|---|---|---|
| | Authorized | Issued | Authorized | Issued | | |
| Preferred A-1 shares | 344,452 | 210,723 | 1 | * | 18.3 | 3,850 |
| Preferred A-2 shares | 40,676 | - | * | - | - | - |
| Preferred A-3 shares | 43,384 | 43,384 | * | * | 4.6 | 200 |
| Preferred B shares | 400,000 | 215,420 | 1 | * | 30.2 | 6,500 |
| Preferred B-1 shares | 300,000 | 170,377 | * | * | 38.2 | 6,500 |
| Preferred C shares | 3,000,000 | 1,726,215 | 9 | 5 | 28.1 | 48,558 |
| | 4,128,512 | 2,366,119 | 11 | 5 | | 65,608 |

*Represents an amount lower than 1.

b. During the six months ended June 30, 2020, the Company issued 669,125 Preferred C Shares and 181,184 Preferred C Warrants for a purchase price of $26.91 per share. The preferred shares were issued in two tranches throughout the six months ended 2020, including an initial tranche and a milestone tranche. The total consideration of this investment round is $15 million, out of which $6,425 were related parties.

**NOTE 8 - SHARE CAPITAL:**

**a. Rights of the Company's Ordinary Shares**

Each Ordinary Share is entitled to one vote. The holders of Ordinary Shares are also entitled to receive dividends whenever funds are legally available, when and if declared by the Board of Directors. Since its inception, the Company has not declared any dividends.

(U.S. dollars in thousands, except share and per share amounts)

**NOTE 8 - SHARE CAPITAL** (continued):

**b. Share Based Compensation**

***Equity incentive plan:***

On June 28, 2009 the Company's shareholders approved an equity incentive plan (the "Plan"). As of June 30, 2021, 137,988 shares remain available for grant under the Plan.

The fair value of options granted during the first six months of 2020 was $453.

The fair value of options granted during the first six months of 2021 was $831.

The underlying data used for computing the fair value of the options are as follows:

| | Six months ended June 30 | |
|---|---|---|
| | **2021** | **2020** |
| Value of ordinary share | 15.54 | 6.82-6.92 |
| Expected volatility | 105.57% | 98.77%-113.72% |
| Risk-free interest rate | 1.63% | 0.45%-0.72% |
| Expected term | 10 years | 6.1-10 years |

*Share-based compensation expenses:*

The following table illustrates the effect of share-based compensation on the statements of operations:

| | Six Months ended June 30, | |
|---|---|---|
| | **2021** | **2020** |
| Research and development expenses | 30 | 22 |
| General and administrative expenses | 224 | 70 |
| | 254 | 92 |

On January 26, 2021, an executive officer exercised 61,674 options for ordinary shares at an exercise price per share lower than $0.01.

On May 10, 2021 the company issued 58,634 options to purchase Ordinary Shares of the Company, par value NIS 0.01 each, at an exercise price of US$ 15.54 per share (the "Options"). The Options shall be subject to a vesting period of 4 years, such that, 25% of the shares underlying the Option shall vest on May 10, 2022, during the 3 years thereafter 1/16 of the Shares underlying the Option shall vest upon the end of each subsequent quarter, subject, in the case of each of clause.

**NOTE 9 – RELATED PARTIES:**

**a.** Related parties include shareholders who are principal owners according to ASC 850-10-20, directors and executive officers.

**b.** As to options granted to directors and executive officers, see Note 8.

**c.** As to the issuance of a convertible security to existing shareholders in a private placement for a total consideration of $3,600, see Note 5.

**d.** As to the issuance of Preferred C Shares to existing shareholders, see Note 7b.

**NOTE 10 – SUBSEQUENT EVENTS:**

**a.** Subsequent events were evaluated through the date these financial statements are available to be issued, August 25, 2021.

**b. Merger agreement with Advaxis**

On July 4, 2021, Biosight entered into an Agreement and Plan of Merger (the "Merger Agreement") with Advaxis, Inc. ("Advaxis"). Under the terms of the agreement, Biosight will become a wholly-owned subsidiary of Advaxis (the "Merger"). On July 4, 2021, the Company entered into a Merger Agreement (the "Merger Agreement") with Advaxis, Inc. ("Advaxis") and Advaxis Ltd. ("Merger Sub"), a direct and wholly-owned subsidiary of Advaxis. Under the terms of the agreement, Merger Sub will merge with and into the Company, with the Company continuing as the surviving corporation and a wholly-owned subsidiary of Advaxis. Immediately after the merger, Advaxis stockholders as of immediately prior to the merger are expected to own approximately 25% of the outstanding shares of the combined company and former Biosight shareholders are expected to own approximately 75% of the outstanding shares of the combined company.

At the effective time of the Merger (the "Effective Time"), each Biosight Ordinary Share and Redeemable Convertible Preferred Share, par value NIS 0.01 per share, issued and outstanding immediately prior to the Effective Time will be converted into the right to receive a number of shares of Advaxis common stock, par value $0.001 per share (the "Advaxis Common Stock"), equal to the exchange ratio, 118.2009 shares of Advaxis Common Stock per Biosight share (subject to adjustment to account for the proposed Advaxis reverse stock split).

If the Merger Agreement is terminated under certain circumstances, Advaxis or Biosight, as applicable, will be required to pay the other party a termination fee equal to $7,500.

**NOTE 11- SUBSEQUENT EVENTS (unaudited)**

In October 2021, the Company received a letter from counsel to Foodronix Ltd., an Israeli company ("Foodronix"), claiming that Foodronix is entitled to an amount equal to 4.8% of the share capital to be allocated and/or issued to Biosight shareholders in connection with the merger. The asserted entitlement is alleged to arise pursuant to a purported agreement between Biosight and Foodronix, which Foodronix claims was entered into in 2011. Foodronix did not provide a copy of the purported agreement or any other evidence of an agreement or commitment to this effect.

Based on a discussion with the Company's former chief executive officer, and an Israeli court ruling dated July 14, 2015 from a lawsuit in which Foodronix was sued by an affiliate of one of Biosight's current shareholders (the "Ruling"), Biosight believes that during March 2011, meetings were held by Biosight's former chief executive officer with several companies in an effort to identify a shell company listed on the Tel Aviv Stock Exchange to merge with Biosight in order for Biosight to become public. The Company believes that the meetings were held in the presence of Foodronix and that there was some arrangement under which Foodronix would have been entitled to compensation for its role in facilitating a transaction with a Tel Aviv Stock Exchange listed shell company. However, while a proposal was ultimately presented to Biosight's board of directors, in or around March 2011, for a proposed merger with such a shell company. Biosight's board of directors rejected this proposal, Biosight notified Foodronix that it did not intend to proceed and discussions with all such shell companies were discontinued. There is no further indication that Foodronix continued its efforts to identify such a company or to facilitate any transaction involving Biosight.

The Company has responded to Foodronix and rejected all claims asserted in the letter, including the entitlement of Foodronix to any equity as a result of the currently contemplated merger or any transaction involving Biosight other than a potential transaction with a shell company listed on the Tel Aviv Stock Exchange. The response notes that Foodronix's assertion of this entitlement comes 10 years after the last interaction between the parties, and relates to a transaction as to which Foodronix has had no involvement.

The Company believes that the claim by Foodronix lacks merit, and if Foodronix files a claim against the Company it has meritorious defenses to any potential claim. Given the inherent uncertainty involved in litigation, management cannot predict the outcome of any potential legal proceedings.

**BIOSIGHT LTD.**

FINANCIAL STATEMENTS
AS OF DECEMBER 31, 2020

INDEX

**Report of Independent Registered Public Accounting Firm**

To the board of directors and shareholders of Biosight Ltd.

***Opinion on the Financial Statements***

We have audited the accompanying balance sheets of Biosight Ltd. (the "Company") as of December 31, 2020 and 2019, and the related statements of operations, of changes in redeemable convertible preferred shares and capital deficiency and of cash flows for the years then ended, including the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

*Substantial Doubt About the Company's Ability to Continue as a Going Concern*

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1b to the financial statements, the Company has not derived income from its activities and has negative cash flows from operating activities that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1b. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

***Basis for Opinion***

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

***Critical Audit Matters***

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the board of directors and that (i) relates to accounts or disclosures that are material to the financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

*Fair Value of Warrants Issued*

As described in Note 7 to the financial statements, the Company issued warrants (the "Warrants") for preferred shares as part of the issuances of Preferred B Shares, Preferred B-1 Shares and Preferred C Shares. The cash proceeds from the issuances were bifurcated between the preferred shares and Warrants at the time of issuance based on a fair value of the Warrants. The Warrants are classified as Level 3 securities and are measured using internal methods and assumptions that management believes a hypothetical market participant would use to determine their fair value. The significant assumptions used included volatility and expected term.

The principal considerations for our determination that performing procedures relating to the fair value of the Warrants is a critical audit matter are the complexity and judgment by management in the valuation of the Warrants, which required the involvement of specialists due to the judgmental nature of the assumptions related to volatility and expected term used in the measurement process. These assumptions have a significant effect on the fair value measurement of the Warrants. This in turn led to a high degree of auditor judgment, subjectivity and effort in performing procedures and in evaluating the audit evidence obtained related to the underlying data used in evaluating the measurement and valuation of the Warrants. In addition, the audit effort involved the use of professionals with specialized skill and knowledge to assist in performing these procedures and evaluating the audit evidence obtained.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. These procedures included, among others (i) evaluating the valuation methodology used (ii) evaluating the significant assumptions discussed above, and (iii) evaluating the underlying data used by management. Professionals with specialized skill and knowledge were used to assist in the evaluation of audit evidence related to the valuation of the Warrants.

Tel-Aviv, Israel
August 25, 2021

*/s/ Kesselman & Kesselman*
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited

We have served as the Company's auditor since 2018.

**BIOSIGHT LTD.**

BALANCE SHEETS

(U.S. dollars in thousands)

| | December 31 | |
|---|---|---|
| | **2020** | **2019** |
| **Assets** | | |
| **CURRENT ASSETS:** | | |
| Cash and cash equivalents | 32,272 | 894 |
| Other receivables | 176 | 55 |
| **TOTAL CURRENT ASSETS** | 32,448 | 949 |
| | | |
| **NON-CURRENT ASSETS:** | | |
| Operating lease right of use assets | 205 | 232 |
| Property and equipment, net | 152 | 172 |
| **TOTAL NON-CURRENT ASSETS** | 357 | 404 |
| | | |
| **TOTAL ASSETS** | 32,805 | 1,353 |

**The accompanying notes are an integral part of these financial statements.**

**BIOSIGHT LTD.**

BALANCE SHEETS

(U.S. dollars in thousands)

| | December 31 | |
|---|---|---|
| | **2020** | **2019** |
| **Liabilities and redeemable convertible preferred shares, net of capital deficiency** | | |
| **CURRENT LIABILITIES:** | | |
| | | |
| Trade payables | 1,715 | 921 |
| Accrued expenses and other payables | 248 | 432 |
| Operating lease liabilities (Note 4) | 95 | 68 |
| Warrants (Note 7) | 5,634 | 5,060 |
| Convertible security (Note 6) ($2,100 from related parties) | - | 3,822 |
| **TOTAL CURRENT LIABILITIES** | 7,692 | 10,303 |
| | | |
| **LONG-TERM LIABILITIES:** | | |
| Operating lease liabilities (Note 4) | 151 | 175 |
| **TOTAL LIABILITIES** | 7,843 | 10,478 |
| | | |
| **COMMITMENTS AND CONTINGENCIES (Note 5)** | | |
| | | |
| **REDEEMABLE CONVERTIBLE PREFERRED SHARES** | | |
| Preferred A-1 Shares, NIS 0.01 par value, 344,452 Preferred A-1 shares authorized; issued and outstanding: 210,723 Preferred A-1 shares as of December 31, 2020, 207,363 as of December 31 2019 | 3,850 | 3,850 |
| Preferred A-3 Shares, NIS 0.01 par value, 43,384 Preferred A-3 shares authorized; issued and outstanding: 43,384 Preferred A-3 shares as of December 31, 2020 and 2019 | 200 | 200 |
| Preferred B Shares, NIS 0.01 par value, 400,000 Preferred B shares authorized; issued and outstanding: 215,420 Preferred B shares as of December 31, 2020; 186,470 as of December 31, 2019 | 4,122 | 4,122 |
| Preferred B-1 Shares, NIS 0.01 par value, 300,000 Preferred B-1 shares authorized; issued and outstanding: 170,377 Preferred B-1 shares as of December 31, 2020; 128,076 as of December 31, 2019 | 4,369 | 4,369 |
| Preferred C Shares, NIS 0.01 par value, 3,000,000 Preferred C shares authorized as of December 31, 2020; 0 as of December 31, 2019; issued and outstanding: 1,726,215 Preferred C shares as of December 31, 2020; 0 as of December 31, 2019 | 44,482 | - |
| **TOTAL REDEEMABLE CONVERTIBLE PREFERRED SHARES** | 57,023 | 12,541 |
| | | |
| **CAPITAL DEFICIENCY** | | |
| Ordinary Shares, NIS 0.01 par value - authorized: 2,771,488 Ordinary Shares as of December 31, 2020 and December 31, 2019; issued and outstanding: 816,302 Ordinary Shares as of December 31, 2020 and December 31, 2019 | 2 | 2 |
| Additional paid-in capital | 6,579 | 6,339 |
| Accumulated deficit | (38,642) | (28,007) |
| **TOTAL CAPITAL DEFICIENCY** | (32,061) | (21,666) |
| **TOTAL LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED SHARES AND CAPITAL DEFICIENCY** | 32,805 | 1,353 |

**The accompanying notes are an integral part of these financial statements**

**BIOSIGHT LTD.**

STATEMENTS OF OPERATIONS

(U.S. dollars in thousands, except per share data)

| | Year ended December 31 | |
|---|---|---|
| | **2020** | **2019** |
| **OPERATING EXPENSES:** | | |
| Research and development | 9,920 | 6,841 |
| General and administrative | 1,657 | 884 |
| **TOTAL OPERATING EXPENSES** | 11,577 | 7,725 |
| **OPERATING LOSS** | 11,577 | 7,725 |
| **LOSS (GAIN) FROM CHANGE IN FAIR VALUE OF WARRANTS AND CONVERTIBLE SECURITY** | (718) | 372 |
| **FINANCE INCOME** | (264) | (68) |
| **FINANCE EXPENSES** | 40 | 18 |
| **FINANCE EXPENSES (INCOME), net** | (942) | 322 |
| **NET LOSS FOR THE YEAR** | 10,635 | 8,047 |
| | | |
| **LOSS PER SHARE BASIC AND DILUTED** | 12.33 | 9.43 |
| | | |
| **WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE** | 862,877 | 852,902 |

**The accompanying notes are an integral part of these financial statements.**

**BIOSIGHT LTD.**

STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED SHARES AND OF CAPITAL DEFICIENCY

(U.S. dollars in thousands, except share data)

| | Redeemable Convertible Preferred Shares | | Ordinary Shares | | Additional paid-in capital | Accumulated deficit | Total |
|---|---|---|---|---|---|---|---|
| | Number of shares | Amount | Number of shares | Amount | | Amount | |
| **BALANCE AT JANUARY 1, 2019** | 565,293 | 12,541 | 816,302 | 2 | 6,151 | (19,960) | (13,807) |
| **CHANGES DURING 2019:** | | | | | | | |
| Net loss | - | - | - | - | - | (8,047) | (8,047) |
| Share-based compensation (Note 9b) | - | - | - | - | 188 | - | 188 |
| **BALANCE AT DECEMBER 31, 2019** | **565,293** | **12,541** | **816,302** | **2** | **6,339** | **(28,007)** | **(21,666)** |
| **CHANGES DURING 2020:** | | | | | | | |
| Net loss | - | - | - | - | - | (10,635) | (10,635) |
| Conversion of convertible security (note 6) | 154,393 | 4,045 | - | - | - | - | - |
| Issuance of Preferred C shares (note 8d) | 1,646,433 | 40,437 | - | - | - | - | - |
| Share-based compensation (Note 9b) | - | - | - | - | 240 | - | 240 |
| **BALANCE AT DECEMBER 31, 2020** | **2,366,119** | **57,023** | **816,302** | **2** | **6,579** | **(38,642)** | **(32,061)** |

**The accompanying notes are an integral part of these financial statements**

**BIOSIGHT LTD.**

STATEMENTS OF CASH FLOWS

(U.S. dollars in thousands)

| | Year ended December 31 | |
|---|---|---|
| | **2020** | **2019** |
| **CASH FLOWS FROM OPERATING ACTIVITIES:** | | |
| Net loss | (10,635) | (8,047) |
| Adjustments required to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 23 | 26 |
| Share-based compensation | 240 | 188 |
| Finance expenses, net | 58 | 40 |
| Change in fair value of convertible security | 678 | 222 |
| Change in fair value of warrants | (1,396) | 151 |
| Changes in operating asset and liabilities: | | |
| Decrease (increase) in other receivables | (121) | 155 |
| Increase in trade payables | 794 | 286 |
| Increase (decrease) in accrued expenses and other payables | (184) | 303 |
| Net cash used in operating activities | (10,543) | (6,676) |
| **CASH FLOWS FROM INVESTING ACTIVITIES:** | | |
| Purchase of fixed assets | (3) | (102) |
| Net cash used in investing activities | (3) | (102) |
| **CASH FLOWS FROM FINANCING ACTIVITIES:** | | |
| Proceeds from the issuance of a convertible security ($2,100 from related parties) | - | 3,600 |
| Proceeds from the issuance of Preferred C Shares and Warrants ($11,425 from related parties) | 41,952 | - |
| Net cash provided by financing activities | 41,952 | 3,600 |
| **INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS** | 31,406 | (3,178) |
| **EFFECT OF EXCHANGE RATE ON CASH AND CASH EQUIVALENTS** | (28) | (29) |
| **CASH AND CASH EQUIVALENTS AT BEGINNING OF THE YEAR** | 894 | 4,101 |
| **CASH AND CASH EQUIVALENTS AT END OF THE YEAR** | 32,272 | 894 |

| | Year ended December 31 | |
|---|---|---|
| | **2020** | **2019** |
| **SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:** | | |
| Additions of operating lease right-of-use assets and operating lease liabilities | 50 | 270 |
| Conversion of convertible security into Preferred C shares and warrants | 4,500 | -,- |

**The accompanying notes are an integral part of these financial statements.**

## NOTE 1 - NATURE OF OPERATIONS

**a.** Biosight Ltd. (hereinafter – the Company) is an Israeli company incorporated in 1999.

The Company is a Phase 2 clinical stage specialty pharmaceutical company focused on developing and commercializing therapeutics for hematological malignancies and disorders.

Biosight's lead product, BST-236 (INN aspacytarabine), is a proprietary anti-metabolite designed to enable high-dose therapy with reduced systemic toxicity. BST-236 is currently being investigated as a single agent in a Phase 2b for first-line treatment of acute myeloid leukemia (AML), after successfully completing Phase 1/2a, which demonstrated tolerability in the population of AML patients unfit for standard therapy.

**b.** Since the Company is engaged in research and development activities, it has not derived income from its activities and has incurred accumulated losses in the amount of $38.6 million through December 31, 2020 and negative cash flows from operating activities. The Company's management is of the opinion that as of the date these financial statements are available to be issued its available funds are not sufficient to meet its liquidity requirements for the following twelve months. These factors raise substantial doubt as to the Company's ability to continue as a going concern.

Management is in the process of evaluating various financing alternatives in the public or private equity markets, government grants or capital inflows from strategic partnerships, as the Company will need to finance future research and development activities, general and administrative expenses and working capital through fund raising. However, there is no certainty about the Company's ability to obtain such funding.

The financial information has been prepared on a going concern basis, which assumes the Company will continue to realize its assets and discharge its liabilities in the normal course of business. If the Company does not raise the requisite funds, it will need to curtail or cease operations. These financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern.

**c.** For information regarding the merger agreement signed with Advaxis Inc. on July 4, 2021, see Note 13b.

**d.** On March 12, 2020, the World Health Organization declared COVID-19 a global pandemic. In an effort to contain and mitigate the spread of COVID-19, many countries have imposed unprecedented restrictions on travel, mandatory business closures and other measures designed to mitigate the spread, leading to a substantial reduction in economic activities in countries around the world.

In response to the pandemic, the Company has implemented the mandatory as well as recommended measures to safeguard the health and safety of employees and clinical trial participants, and expects to continue to take actions as may be required or recommended by government authorities or as it determines are in the best interests of employees, clinical trial participants and others in light of COVID-19. To-date, COVID-19 has not adversely impacted the Company's business operations, international supply chain, productivity or clinical development timelines. However, uncertainty remains as to the potential impact of COVID-19 our future research and development activities and the potential for a material impact on the Company increases the longer the virus impacts certain aspects of economic activity around the world. The full extent to which COVID-19 will directly or indirectly impact the Company's business, results of operations and financial condition, including clinical trials, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international markets, the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, the ultimate impact on financial markets and the global economy, the effectiveness of vaccines and vaccine distribution efforts and the effectiveness of other actions taken in the United States and other countries to contain and treat the disease. It is not currently possible to predict how long the pandemic will last, what the long-term global effects will be, or the time that it will take for economic activity to return to pre-pandemic levels, and the Company does not yet know the full impact on its business and operations. The Company will continue to monitor COVID-19 closely and follow health and safety guidelines as they evolve.

## NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES:

### a. Basis of presentation

The Company's financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP").

### b. Use of estimates in the preparation of financial statements

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from those estimates. As applicable to these financial statements, the most significant estimates and assumptions relate to the fair value of share based compensation and warrants, as well as the value of clinical trial accruals.

### c. Functional currency

The U.S. dollar ("dollar") is the currency of the primary economic environment in which the operations of Biosight are conducted. Almost all Company operational expenses are in dollars and the Company's financing has been provided in dollars. Accordingly, the functional currency of the Company is the dollar.

Transactions and balances originally denominated in dollars are presented at their original amounts. Balances in non-dollar currencies are translated into dollars using historical and current exchange rates for non-monetary and monetary balances, respectively. For non-dollar transactions and other items in the statements of operations (indicated below), the following exchange rates are used: (i) for transactions - exchange rates at transaction dates or average rates; and (ii) for other items (derived from non-monetary balance sheet items such as depreciation and amortization, etc.) - historical exchange rates. Currency transaction gains and losses are presented in financial income or expenses, as appropriate.

### d. Cash and cash equivalents

The Company considers as cash equivalents all short-term, highly liquid investments, which include short-term bank deposits with original maturities of three months or less from the date of purchase that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash.

### e. Property and equipment

1) Property and equipment are stated at cost, net of accumulated depreciation and amortization.

2) The Company's property and equipment are depreciated by the straight-line method based on their estimated useful life.

(U.S. dollars in thousands, except share and per share amounts)

**NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES** (continued):

3) Annual rates of depreciation are as follows:

| | % |
|---|---|
| Laboratory equipment | 10-15 |
| Computers and software | 33 |

Leasehold improvements are amortized by the straight-line method over the shorter of the expected lease term, or the estimated useful life of the improvements.

**f. Impairment of long-lived assets**

The Company tests long-lived assets for impairment whenever events or circumstances present an indication of impairment. If the sum of expected future cash flows (undiscounted and without interest charges) of the assets is less than the carrying amount of such assets, an impairment loss would be recognized. The assets would be written down to their estimated fair values, calculated based on the present value of expected future cash flows (discounted cash flows), or some other fair value measure.

The Company did not recognize an impairment loss for its long-lived assets.

**g. Leases**

In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standard Update (“ASU”) No. 2016-02, Leases (Topic 842), which supersedes the previous guidance for lease accounting, Leases (Topic 840). The new standard requires lessees to record assets and liabilities on the balance sheet for all leases. Leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The Company recognizes the lease payments in the statements of operations on a straight-line basis over the lease period.

The Company adopted the standard as of January 1, 2019 on a modified retrospective basis and did not restate comparative periods. The Company elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed the Company to carryforward the historical lease classification and not separate lease and non-lease components for the leases. The adoption of the standard resulted in recognition of $11 of lease assets and lease liabilities as of January 1, 2019 on the Company’s balance sheets. The weighted-average interest rate used to discount future lease payments was 14.34%.

Upon initial recognition, the Company recognizes a liability at the present value of the lease payments to be made over the lease term, and concurrently recognizes a ROU asset at the same amount of the liability, adjusted for any prepaid or accrued lease payments, plus initial direct costs incurred in respect of the lease. The Company uses its incremental borrowing rate based on the information available at the commencement date to determine the present value of the lease payments. The subsequent measurement depends on whether the lease is classified as finance lease or an operating lease. During the reporting periods, the Company has only operating leases.

The Company recognizes the lease payments of operating lease in the statement of operations on a straight-line basis over the lease period.

**h. Contingencies**

Certain conditions may exist as of the date of the financial statements, which may result in a loss to the Company, but which will only be resolved when one or more future events occur or fail to occur. The Company’s management assesses such contingent liabilities and such assessment inherently involves an exercise of judgment.

**NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES** (continued):

Management applies the guidance in ASC 450-20-25 when assessing losses resulting from contingencies. If the assessment of a contingency indicates that it is probable that a material loss has been incurred and the amount of the liability can be estimated, then the estimated liability is recorded as accrued expenses in the Company's financial statements. If the assessment indicates that a potential material loss contingency is not probable but is reasonably possible, or is probable but cannot be estimated, then the nature of the contingent liability, together with an estimate of the range of possible loss if determinable and material are disclosed.

Loss contingencies considered to be remote by management are generally not disclosed unless they involve guarantees, in which case the guarantees are disclosed.

**i. Financial Instruments**

The Company's preferred shares have voting rights, may be converted into ordinary shares, and are prioritized over ordinary shares in case of dividend or redemption.

When the Company issues preferred shares, it considers the provisions of Accounting Standards Codification ("ASC") 480, Distinguishing Liabilities from Equity ("ASC 480") in order to determine whether the preferred share should be classified as a liability. If the instrument is not within the scope of ASC 480, the Company further analyzes the instrument's characteristics in order to determine whether it should be classified within temporary equity (mezzanine) or within permanent equity in accordance with the provisions of ASC 480-10-S99. The Company's redeemable convertible preferred shares are not mandatorily or currently redeemable. However, they include a liquidation or deemed liquidation events that would constitute a redemption event that is outside of the Company's control. As such, all shares of redeemable preferred shares have been presented outside of permanent equity.

The Company's issued financial instruments (warrants and convertible security) are in the scope of ASC 480, mainly since they are convertible into redeemable convertible preferred shares which their redemption is outside of the Company's control. For further details see Note 7 regarding warrants to purchase preferred shares and Note 6 regarding the convertible security.

**j. Share-based compensation**

The Company accounts for employees' and directors' share-based payment awards classified as equity awards using the grant-date fair value method. The fair value of share-based payment transactions is recognized as an expense over the requisite service period using the straight-line method. Forfeitures are recognized as they occur.

The Company elected to recognize compensation costs for awards conditioned only on continued service that have a graded vesting schedule using the straight-line method based on the multiple-option award approach.

On January 1, 2018 the Company adopted early the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718) Improvements to Nonemployee Share-based Payments. This ASU was issued to simplify the accounting for share-based transactions by expanding the scope of Topic 718 from only being applicable to share-based payments to employees to also include share-based payment transactions for acquiring goods and services from nonemployees.

**k. Employee severance benefits**

The Company is required to make severance payments upon dismissal of an employee or upon termination of employment in certain circumstances.

**NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES** (continued):

In accordance with the current employment terms with all of its employees (Section 14 of the Israeli Severance Pay Law, 1963) located in Israel, the Company makes regular deposits, at a rate of 8.33% of their monthly salary, with certain insurance companies for accounts controlled by each applicable employee in order to secure the employee's full retirement benefit obligation. The Company is relieved from any severance pay liability with respect to each such employee after it makes the payments on behalf of the employee. The liability accrued in respect of these employees and the amounts funded, as of the respective agreement dates, are not reflected on the Company's consolidated balance sheet, as the amounts funded are not under the control and management of the Company and the pension or severance pay risks have been irrevocably transferred to the applicable insurance companies.

The amounts of severance payment expenses were $67 and $58 and for the years ended December 31, 2020 and 2019, respectively.

**l. Research and development costs**

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of clinical trials, clinical trial supplies, salaries, share-based compensation expenses, payroll taxes and other employee benefits, lab expenses, consumable equipment and consulting fees. All costs associated with research and developments are expensed as incurred.

Grants received from the Israeli Innovation Authority ("IIA") for approved research and development projects are recognized at the time the Company is entitled to such grants, on the basis of the costs incurred and included as a deduction from research and development expenses. See note 5.

**m. Clinical trial accruals**

Clinical trial expenses are charged to research and development expense as incurred. The Company accrues for expenses resulting from obligations under contracts with clinical research organizations (CROs). The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided. The Company's objective is to reflect the appropriate trial expense in the financial statements by matching the appropriate expenses with the period in which services and efforts are expended. In the event advance payments are made to a CRO, the payments are recorded as other assets, which will be recognized as expenses as services are rendered.

**n. Income taxes:**

1) Deferred taxes

Income taxes are computed using the asset and liability method. Under the asset and liability method, deferred income tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the currently enacted tax rates and laws. A valuation allowance is recognized to the extent that it is more likely than not that the deferred taxes will not be realized in the foreseeable future. Given the Company's losses, the Company has provided a full valuation allowance with respect to its deferred tax assets.

(U.S. dollars in thousands, except share and per share amounts)

**NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES** (continued):

2) Uncertainty in income tax

The Company follows a two-step approach in recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the available evidence indicates that it is more likely than not that the position will be sustained based on technical merits. If this threshold is met, the second step is to measure the tax position as the largest amount that has more than a 50% likelihood of being realized upon ultimate settlement.

**o. Segment reporting**

An operating segment is defined as a component that engages in business activities whose operating results are reviewed by the chief operating decision maker for the purpose of assessing performance and allocating resources and for which discrete financial information is available. The Company operates in one operating segment.

**p. Comprehensive loss**

Comprehensive loss includes no items other than net loss.

**q. Loss per share**

The Company's basic net loss per share is calculated by dividing net loss attributable to ordinary shareholders by the weighted-average number of shares of ordinary shares outstanding for the period, without consideration of potentially dilutive securities. The diluted net loss per share is calculated by giving effect to all potentially dilutive securities outstanding for the period using the treasury share method or the if-converted method based on the nature of such securities. Diluted net loss per share is the same as basic net loss per share in periods when the effects of potentially dilutive shares of ordinary shares are anti-dilutive.

The Company computes net loss per share using the two-class method required for participating securities. The two-class method requires income available to ordinary shareholders for the period to be allocated between ordinary shares and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed. The Company considers its redeemable convertible preferred shares to be participating securities as the holders of the redeemable convertible preferred shares would be entitled to dividends that would be distributed to the holders of ordinary shares, on a pro-rata basis assuming conversion of all redeemable convertible preferred shares into ordinary shares. These participating securities do not contractually require the holders of such shares to participate in the Company's losses. As such, net loss for the periods presented was not allocated to the Company's preferred shares.

The calculation of the loss per share includes fully vested options for the Company's Ordinary Shares at an exercise price of NIS 0.01 per share, as the Company considers these shares to be exercised for no additional consideration. As of December 31, 2020 the amount of such options was 46,575 and as of December 31, 2019, 36,600.

The following share options, warrants and preferred shares were excluded from the calculation of diluted net loss per Ordinary Share because their effect would have been anti-dilutive for the year presented (share data):

| | Year ended December 31 | |
|---|---|---|
| | **2020** | **2019** |
| Outstanding share options | 312,447 | 146,494 |
| Warrants | 495,730 | 314,546 |
| Redeemable convertible preferred shares | 2,366,119 | 565,293 |
| Convertible security | - | 88,668 |

**NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES** (continued):

**r. Fair value measurement**

Fair value is based on the price that would be received from the sale of an asset or that would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, the guidance establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data or active market data of similar or identical assets or liabilities.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers credit risk in its assessment of fair value.

**s. Concentration of credit risks**

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash and cash equivalents. The Company deposits cash and cash equivalents with highly rated financial institutions and, as a matter of policy, limits the amounts of credit exposure to any single financial institution. The Company has not experienced any material credit losses in these accounts and does not believe it is exposed to significant credit risk on these instruments.

**t. Recently issued accounting pronouncements, not yet adopted**

i. In August 2020, the FASB issued ASU2020-06 “Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity’s Own Equity (Subtopic 815 – 40).” This guidance simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity’s own equity. The amendments to this guidance are effective for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years. The Company is currently evaluating this guidance to determine the impact it may have on its financial statements.

ii. In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation— Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815- 40): Issuer’s Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (“ASU 2021-04”). The guidance is effective for the Company on January 1, 2022. The Company is currently evaluating the impact of adopting this standard and does not expect the guidance to have a material impact on its financial statements.

(U.S. dollars in thousands, except share and per share amounts)

## NOTE 3 – PROPERTY AND EQUIPMENT

| | December 31 | |
|---|---|---|
| | **2020** | **2019** |
| Cost: | | |
| Leasehold improvements | 84 | 84 |
| Computers and software | 311 | 308 |
| Laboratory equipment | 121 | 121 |
| | 516 | 513 |
| Less: | | |
| Accumulated depreciation and amortization | (364) | (341) |
| Property and Equipment, net | 152 | 172 |

Depreciation and amortization expense totaled $23 and $26 for the years ended December 31, 2020 and 2019 respectively.

The Company's long-term assets are located in Israel.

## NOTE 4 – OPERATING LEASE

The Company leases a research and development facility in Israel and vehicles under several lease agreements. The lease agreement for the facility in Israel is linked to the Israeli consumer price index ("CPI"). The lease began on March 10, 2019 for a period of twelve months, with an option to extend the lease for three additional periods of twelve months. As of the date of signing the financial statements the Company has exercised two options to extend the lease and intends to exercise the third option in March 2022.

During the years ended December 31, 2020 and 2019, the Company entered into several operating lease agreements in connection with the leasing of its vehicles. The lease periods are usually three years with the payments being linked to the Israeli CPI.

Operating lease costs for the year ended December 31, 2020 are as follows:

| | **Year Ended December 31 2020** | **Year Ended December 31 2019** |
|---|---|---|
| Office lease expenses | 82 | 66 |
| Vehicles lease expenses | 25 | 14 |

Operating cash flows, for amounts included in the measurement of lease liabilities are as follows:

| | **Year Ended December 31 2020** | **Year Ended December 31 2019** |
|---|---|---|
| Office lease expenses | 82 | 66 |
| Vehicles lease expenses | 25 | 14 |

(U.S. dollars in thousands, except share and per share amounts)

**NOTE 4 – OPERATING LEASE** (continued):

Supplemental information related to leases are as follows:

| | December 31 2020 | December 31 2019 |
|---|---|---|
| Operating lease right-of-use assets | 205 | 232 |
| Operating lease liabilities | 246 | 243 |
| Weighted average remaining lease term | 2.4 | 2.3 |
| Weighted average discount rate | 11.59%-13.21% | 13.35%-14.34% |

Maturities of lease liabilities are as follows:

| | |
|---|---|
| 2021 | 119 |
| 2022 | 118 |
| 2023 | 32 |
| Total lease payments | 269 |
| Less imputed interest | (23) |
| Total lease liability | 246 |

**NOTE 5 – COMMITMENTS AND CONTINGENCIES**

The Company is obligated to pay royalties to the IIA on proceeds from the sale of products developed from research and development activities that were funded, partially, by grants from the IIA.

Under the terms of the funding arrangements with the IIA, royalties of 3% are payable on the sale of products developed from product candidates funded by the IIA, which payments shall not exceed, in the aggregate, 100% of the amount of the grant received (dollar linked), plus interest at annual rate based on LIBOR.

The Company did not receive any grants from the IIA for the years ended December 31, 2020, and December 31, 2019.

At the time the grants were received, successful development of the related projects was not assured. The total amount that was received through December 31, 2020 was $2,350. All grants received were recorded as a reduction of research and development expenses.

**NOTE 6 - CONVERTIBLE SECURITY**

**a.** On June 16, 2019 the Company entered a convertible security (hereinafter – “the Convertible Security”) agreement, in which several existing shareholders agreed to provide the Company with a loan of $3,600 in several installments in exchange for a convertible security (out of which $2,100 are related parties).

The security is convertible into the most senior class of preferred shares under the following conditions:

i. Automatic conversion – the automatic conversion will occur in one of the following occasions: (a) an investment in the Company of no less than $25,000 (“Qualified Financing”). In this case, the Security is convertible into the most senior class of shares with a varying discount of either 10% on the price per share in case the financing is received within 90 days, or 20% thereafter; or (b) a financing round in which the majority of investors of the convertible security will participate.

(U.S. dollars in thousands, except share and per share amounts)

**NOTE 6 - CONVERTIBLE SECURITY (continued):**

ii. Elective conversion – at the discretion of the investors, in case there of an investment which does not constitute a "Qualified Financing". The conversion price is similar to the case of an automatic conversion, assuming that the decision made to convert by the investor majority is agreed upon by all investors.

iii. In case the Security is not converted within 18 months, or other events of default, the security shall be returned to investors with a compounded interest of 5% per year.

At the date of the inception of the security, the Company evaluated that the most likely scenario is a conversion with a 20% discount, as the Company initiated steps to begin the financing round for preferred C shares.

**b.** The security is accounted for as a liability in accordance with ASC 480, and subsequently measured at fair value with changes in fair value recognized in earnings in accordance with ASC 480-10-35-5.

**c.** On March 29, 2020, as part of the Preferred C Shares Share Purchase Agreement, (see Note 8d), the Company converted the Convertible Security into 154,393 Preferred C Shares and 38,599 Preferred C Warrants. The conversion reflected a 20% discount on the price per share of Preferred C Shares.

**d.** The main assumptions of the fair value of the convertible security are that the security will be converted at a 20% discount and the expected timing of the Qualified Financing.

**e.** The table below sets forth a summary of changes in the fair value of the convertible security classified as Level 3:

| | Convertible security | |
|---|---|---|
| | December 31 | |
| | 2020 | 2019 |
| Balance at beginning of year | 3,822 | - |
| Receipt of convertible security | - | 3,600 |
| Changes in fair value | 678 | 222 |
| Conversion to preferred C shares and warrants | (4,500) | - |
| Balance at end of year | - | 3,822 |

**NOTE 7 – WARRANTS**

**a.** Warrants for preferred shares were issued to investors as part of the issuance of Preferred B Shares, Preferred B-1 Shares and Preferred C Shares (see Note 8). Each warrant share may be exercised either by paying the exercise price or cashless according to the cashless mechanism set forth into redeemable convertible preferred shares. Warrants are measured at fair value. In March 2020, as part of the Initial investment trench in Preferred C Shares (see Note 8d), all Preferred B Warrants and Preferred B-1 Warrants were converted to Preferred C Warrants.

**b.** Since the warrants are convertible into Preferred Shares, which have a redemption feature, the warrants are within the scope of ASC 480 and are classified as liabilities. For subsequent periods, the warrants are measured at fair value, with changes in fair value recognized in earnings, in accordance with ASC 480-10-35-5.

Accordingly, proceeds from the issuance of preferred shares and warrants were initially allocated to warrants according to their fair value, with the rest of the consideration being allocated to preferred shares.

(U.S. dollars in thousands, except share and per share amounts)

**NOTE 7 – WARRANTS** (continued):

**c.** The fair value of the warrants was determined according to the option-price method ("OPM") as part of each investment round under the following assumptions:

| | Value as of | | |
|---|---|---|---|
| | December 31 | | March 29 |
| | 2020 | 2019 | 2020 |
| Expected volatility | 102.4% | 100% | 109.4% |
| Expected life term | 2 | 3 | 2.8 |
| *Assumptions regarding price of the underlying shares* | | | |
| Discount rate | 0.2% | 1.6% | 0.4% |

**d.** The table below sets forth a summary of changes in the fair value of the warrants for preferred shares classified as Level 3:

| | Value of warrants measured at fair value | | Amount of warrants as of | |
|---|---|---|---|---|
| | December 31 | | December 31 | |
| | 2020 | 2019 | 2020 | 2019 |
| Balance at the beginning of the year | 5,060 | 4,909 | 314,546 | 314,546 |
| Warrants issued through the conversion of a convertible security | 455 | - | 38,599 | - |
| Warrants issued through an issuance of Preferred C Shares | 1,515 | - | 142,585 | - |
| Changes in fair value | (1,396) | 151 | - | - |
| Balance at the end of the year | 5,634 | 5,060 | 495,730 | 314,546 |

**e.** As of December 31, 2020, the Company had 495,730 outstanding Preferred C warrants. Warrants are exercisable to preferred C Shares at a price per share of either: (a) $26.91 in case the warrant was initially issued as a Preferred C warrant, or; (b) $21.528 in case the warrant was initially a Preferred B warrant or Preferred B-1 warrant which was converted into a Preferred C warrant.

**NOTE 8 - REDEEMABLE CONVERTIBLE PREFERRED SHARES:**

**a.** The Redeemable Convertible Preferred Shares as of December 31, 2020 are composed as follows (each share of of NIS 0.01 par value):

| | Number of shares | | Amount (par value USD) | | Liquidation Value per Share | Liquidation Value |
|---|---|---|---|---|---|---|
| | Authorized | Issued | Authorized | Issued | | |
| Preferred A-1 shares | 344,452 | 210,723 | 1 | * | 18.3 | 3,850 |
| Preferred A-2 shares | 40,676 | - | * | - | - | - |
| Preferred A-3 shares | 43,384 | 43,384 | * | * | 4.6 | 200 |
| Preferred B shares | 400,000 | 215,420 | 1 | * | 30.2 | 6,500 |
| Preferred B-1 shares | 300,000 | 170,377 | * | * | 38.2 | 6,500 |
| Preferred C shares | 3,000,000 | 1,726,215 | 9 | 5 | 27.1 | 46,740 |
| | 4,128,512 | 2,366,119 | 11 | 5 | | 63,790 |

*Represents an amount lower than 1.

(U.S. dollars in thousands, except share and per share amounts)

**NOTE 8 - REDEEMABLE CONVERTIBLE PREFERRED SHARES** (continued):

The Redeemable Convertible Preferred Shares as of December 31, 2019 are composed as follows (each share of NIS 0.01 par value):

| | Number of shares | | Amount (par value USD) | | Liquidation Value per Share | Liquidation Value |
|---|---|---|---|---|---|---|
| | Authorized | Issued | Authorized | Issued | | |
| Preferred A-1 shares | 344,452 | 207,363 | 1 | * | 46.4 | 9,625 |
| Preferred A-2 shares | 40,676 | - | * | - | - | - |
| Preferred A-3 shares | 43,384 | 43,384 | * | * | 11.5 | 500 |
| Preferred B shares | 400,000 | 186,470 | 1 | * | 87.1 | 16,250 |
| Preferred B-1 shares | 300,000 | 128,076 | * | * | 126.9 | 16,250 |
| | 1,128,512 | 565,293 | 2 | * | | 42,625 |

*Represents an amount lower than 1.

**b. Rights of the Company's Preferred Shares:**

As of December 31, 2020, preferred shares are entitled to the following rights:

i. Voting – Each outstanding Preferred Share is entitled to a number of votes equal to the number of Ordinary Shares into which such Preferred Share is convertible to.

ii. Dividends – Preferred shares are entitled to non-cumulative dividends at a rate of 8% per year for Preferred C Shares, and 7% for all other Preferred Share classes, on the original price of the preferred share. Since inception, the Company has not declared any dividends.

iii. Preference upon liquidation – Preferred shares are entitled to be paid or distributed out of the proceeds available for distribution to shareholders, upon liquidation, the following amount: (a) the original price of the preferred share; (b) (preferred C shares only) an annual compounded interest at the rate of 8%; (c) any declared but unpaid dividends; less (d) any dividends paid. Each class receives preference according to seniority.

After paying the preference amounts as detailed above, any remaining distributable proceeds shall be distributed among all holders of Ordinary Shares and Preferred Shares, parri-passu and pro rata, in proportion to their holdings of the Company's Ordinary Shares and Preferred Shares, on an as-converted basis.

iv. Conversion – Preferred shares may be converted into Ordinary Shares, either voluntarily upon the written election of the shareholder, or automatically upon a an IPO with aggregate proceeds of at least US$50,000 thousand and a pre-money valuation of at least US$150,000 thousand ("qualified IPO") or at the discretion of the Preferred majority.

The applicable conversion price in the case of an elective conversion is the original purchase price of the preferred share. In case of an automatic conversion, no additional consideration will be required.

v. The Preferred shares have certain anti-dilution protection. According to the anti-dilution rights, the Conversion Price then in effect for such Preferred share shall be reduced, concurrently, for no additional consideration in an event the Company issues new securities for an effective price which is less than the applicable conversion price then in effect for each Preferred share.

vi. During March 2020, a Share Purchase Agreement was signed between the Company and new investor for issuance of C Preferred Shares. Following the issuance of Preferred C shares the Company's Articles of Association was amended to include the changes in the Company's Preferred Shares rights.

**NOTE 8 - REDEEMABLE CONVERTIBLE PREFERRED SHARES** (continued):

The Amendment of the Company's Articles of Association was accounted for as a modification of Preferred Shares A-1, A-2, A-3, B and B1. This is because the fair value of the preferred shares immediately after the amendment was not significantly different from the fair value before the amendment. The Company also considered qualitative factors that supported this conclusion.

The Company concluded that the Preferred shares, before and after the amendment of the Company's Articles of Association, should be presented outside permanent equity. This is because under both versions of the Articles of Association, they include liquidation or deemed liquidation events that would constitute a redemption event that is outside of the Company's control.

The Company accounted for the modification by analogizing to the guidance for stock-based compensation arrangements classified as equity in ASC 718. Since the modification resulted in a decrease in the fair value of Preferred shares, the modification did not have any accounting implications.

**c.** The Company's redeemable convertible preferred shares are not mandatorily or currently redeemable. However, they include a liquidation or deemed liquidation events that would constitute a redemption event that is outside of the Company's control.

Redeemable Shares are considered to be temporary equity and are therefore presented as part of the Company's temporary equity between liabilities and permanent equity.

**d. Issuance of Series C Preferred Shares and Warrants**

During 2020, the Company issued 1,726,215 Preferred C Shares and 181,184 Preferred C Warrants for a purchase price of $26.91 per share. The preferred shares were issued in three tranches throughout the year, an initial tranche, a milestone tranche, and deferred closing tranche. The total consideration of this investment round is $41,952, out of which $11,452 was from related parties.

**NOTE 9 - SHARE CAPITAL**

**a. Rights of the Company's Ordinary Shares**

Each Ordinary Share is entitled to one vote. The holders of Ordinary Shares are also entitled to receive dividends whenever funds are legally available, when and if declared by the Board of Directors. Since its inception, the Company has not declared any dividends.

**b. Share Based Compensation**

***Equity incentive plan:***

On June 28, 2009 the Company's shareholders approved an equity incentive plan (the "Plan"). As of December 31, 2020, 198,657 shares remain available for grant under the Plan.

The fair value of options granted during 2020 and 2019 was $1,704 and $311, respectively.

(U.S. dollars in thousands, except share and per share amounts)

**NOTE 9 - SHARE CAPITAL** (continued):

*Options granted to employees and directors:*

In the years ended December 31, 2020 and 2019, the Company granted options as follows:

| | Year ended December 31, 2020 | | | |
|---|---|---|---|---|
| | **Award amount** | **Exercise price range** | **Vesting period** | **Expiration** |
| Options for Employees and Directors: | 83,663 | $ 5.8 | 4 years | 10 years |

| | Year ended December 31, 2019 | | | |
|---|---|---|---|---|
| | **Award amount** | **Exercise price range** | **Vesting period** | **Expiration** |
| Options for Employees and Directors: | 40,905 | $ 10 | 4 years | 10 years |

The fair value of each option granted is estimated using the Black-Scholes option pricing method. The volatility is based on a combination of historical volatilities of companies in comparable stages as well as companies in the industry, by statistical analysis of weekly share pricing model. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of the options granted in dollar terms. The Company's management uses the expected term of each option as its expected life. The expected term of the options granted represents the period of time that the granted options are expected to remain outstanding.

The underlying data used for computing the fair value of the options are as follows:

| | Year ended December 31 | |
|---|---|---|
| | **2020** | **2019** |
| Value of ordinary share | $ 6.82-$15.54 | $ 6.16 |
| Expected volatility | 90.79%-113.72% | 101.91%-105.85% |
| Risk-free interest rate | 0.45%-0.92% | 2.64%-2.76% |
| Expected term | 6.1-10 years | 6.1-10 years |

*Options granted to consultants and service providers:*

In the years ended December 31, 2020 and 2019, the Company granted options as follows:

| | Year ended December 31, 2020 | | | |
|---|---|---|---|---|
| | **Award amount** | **Exercise price range** | **Vesting period** | **Expiration** |
| Options | 82,290 | $ 5.8 | 4 years | 10 years |

| | Year ended December 31, 2019 | | | |
|---|---|---|---|---|
| | **Award amount** | **Exercise price range** | **Vesting period** | **Expiration** |
| Options | 17,955 | * | 4 years | 10 years |

(U.S. dollars in thousands, except share and per share amounts)

**NOTE 9 - SHARE CAPITAL** (continued):

The underlying data used for computing the fair value of the options are as follows:

| | Year ended December 31 | |
|---|---|---|
| | **2020** | **2019** |
| Value of ordinary share | $ 6.82-$15.54 | $ 5.37 |
| Expected volatility | 90.79%-99.17% | 107.96%-109.28% |
| Risk-free interest rate | 0.71%-0.92% | 2.08%-2.12% |
| Contractual term | 10 years | 10 years |

*Summary of outstanding and exercisable options:*

The following table summarizes the number of options outstanding for the years ended December 31, 2020 and December 31, 2019, and related information:

| | Employees and directors | | Consultants and service providers | |
|---|---|---|---|---|
| | **Number of options** | **USD(1)** | **Number of options** | **USD(1)** |
| Outstanding at January 1, 2019 | 33,915 | $ 5.43 | 53,719 | $ 6.15 |
| Granted | 40,905 | $ 6.16 | 17,955 | $ 5.37 |
| Forfeited | - | - | - | - |
| Exercised | - | - | - | - |
| Outstanding at December 31, 2019 | 74,820 | $ 5.83 | 71,674 | $ 5.95 |
| Granted | 83,663 | $ 11.01 | 82,290 | $ 11.45 |
| Forfeited | - | - | - | - |
| Exercised | - | - | - | - |
| Outstanding at December 31, 2020 | 158,483 | $ 8.56 | 153,964 | $ 8.89 |

(1) Weighted average price per share

On December 31, 2020, there was $1,775 of total unrecognized compensation cost related to unvested stock options granted under the Plan. That cost is expected to be recognized over a weighted-average period of 3.7 years.

The following tables summarizes information concerning outstanding and exercisable options as of December 31, 2020:

| | December 31, 2020 | | | |
|---|---|---|---|---|
| | Options outstanding | | Options exercisable | |
| **Exercise prices per share (USD)** | **Number of Options outstanding at end of Year** | **Weighted Average Remaining Contractual Life** | **Number of options exercisable at end of year** | **Weighted Average Remaining contractual Life** |
| * | 61,674 | 3.4 | 61,674 | 3.4 |
| 5.8 | 165,953 | 8.9 | - | - |
| 10 | 84,820 | 6.8 | 59,936 | 6.8 |
| | 312,447 | | 121,610 | |

*Represents an amount lower than $0.01.

The aggregate intrinsic value of the total of both the outstanding and exercisable options as of December 31, 2020 is $3,049.

(U.S. dollars in thousands, except share and per share amounts)

**NOTE 9 - SHARE CAPITAL** (continued):

*Share-based compensation expenses:*

The following table illustrates the effect of share-based compensation on the statements of operations:

| | Year ended December 31 | |
|---|---|---|
| | **2020** | **2019** |
| Research and development expenses | 37 | 46 |
| General and administrative | 203 | 142 |
| | 240 | 188 |

**NOTE 10 - INCOME TAX:**

The Company is taxed under Israeli tax laws:

**a. Tax rates**

Income from Israel was taxed at the corporate tax rate of 23%.

**b. Tax assessments**

Biosight has tax assessments that are considered to be final through tax year 2013.

**c. Losses for tax purposes carried forward to future years**

As of December 31, 2020, Biosight had approximately $32.5 million net carry forward tax losses in Israel, which are available to reduce future taxable income with no limited period of use.

**d. Deferred income taxes:**

| | December 31, | |
|---|---|---|
| | **2020** | **2019** |
| In respect of: | | |
| Net operating loss carry forward | 7,474 | 4,986 |
| Research and development | 2,185 | 1,531 |
| Share based compensation | 302 | 142 |
| Warrants and convertible security measured at fair value | 13 | 178 |
| Operating lease right-of-use asset | (47) | (53) |
| Operating lease liability | 57 | 56 |
| Other | 23 | 39 |
| Less - valuation allowance | (10,007) | (6,879) |
| Net deferred tax assets | - | - |

Realization of deferred tax assets is contingent upon sufficient future taxable income during the period that deductible temporary differences and carry forward losses are expected to be available to reduce taxable income. As the achievement of required future taxable income is not more likely than not, the Company recorded a full valuation allowance.

(U.S. dollars in thousands, except share and per share amounts)

**NOTE 10 - INCOME TAX** (continued):

The following table summarizes the changes in the valuation allowance for deferred tax assets:

| | |
|---|---|
| Balance, January 1, 2019 | 4,505 |
| Additions during the year | 2,374 |
| Balance, December 31, 2019 | 6,879 |
| Additions during the year | 3,128 |
| Balance, December 31, 2020 | 10,007 |

**e. Reconciliation of theoretical tax expenses to actual expenses**

The primary reconciling items between the statutory tax rate of the Company and the effective rate are the full valuation allowance of deferred tax assets and nondeductible expenses.

**f. Uncertain tax positions:**

As of December 31, 2020 and 2019, the Company does not have a provision for uncertain tax positions.

**NOTE 11 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION:**

**Balance sheets:**

| | December 31 | |
|---|---|---|
| | **2020** | **2019** |
| **a. Other current assets:** | | |
| Institutions | 161 | 42 |
| Prepaid expenses | 7 | 8 |
| Other | 8 | 5 |
| | 176 | 55 |

**Statements of operations**

| | Year ended December 31 | |
|---|---|---|
| | **2020** | **2019** |
| **b. Research and development** | | |
| Salaries and related expenses | 1,259 | 1,190 |
| Car maintenance | 61 | 30 |
| Expenses related to clinical trial, phase II | 7,947 | 5,182 |
| Travel abroad | 28 | 191 |
| Other expenses | 625 | 248 |
| | 9,920 | 6,841 |
| **c. Finance expenses, net** | | |
| Bank fees | 8 | 10 |
| Exchange rate differences | (264) | (68) |
| Other expenses | 32 | 8 |
| | (224) | (50) |

**NOTE 12 – RELATED PARTIES:**

**a.** Related parties include shareholders which are principal owners according to ASC 850-10-20, directors and executive officers.

**b.** As to options granted to directors and executive officers, see Note 9b.

**c.** As to issuance of a convertible security to existing shareholders in a private placement for a total consideration of $3,600, see Note 6.

**d.** As to issuance of Preferred C Shares to existing shareholders, see Note 8d.

**NOTE 13 – SUBSEQUENT EVENTS:**

**a.** Subsequent events were evaluated through the date these financial statements are available to be issued, August 25, 2021.

**b. Merger agreement with Advaxis**

On July 4, 2021, Biosight entered into an Agreement and Plan of Merger (the "Merger Agreement") with Advaxis, Inc. ("Advaxis"). Under the terms of the agreement, Biosight will become a wholly-owned subsidiary of Advaxis (the "Merger"). On July 4, 2021, the Company entered into a Merger Agreement (the "Merger Agreement") with Advaxis, Inc. ("Advaxis") and Advaxis Ltd. ("Merger Sub"), a direct and wholly-owned subsidiary of Advaxis. Under the terms of the agreement, Merger Sub will merge with and into the Company, with the Company continuing as the surviving corporation and a wholly-owned subsidiary of Advaxis. Immediately after the merger, Advaxis stockholders as of immediately prior to the merger are expected to own approximately 25% of the outstanding shares of the combined company and former Biosight shareholders are expected to own approximately 75% of the outstanding shares of the combined company.

At the effective time of the Merger (the "Effective Time"), each Biosight Ordinary Share and Redeemable Convertible Preferred Share, par value NIS 0.01 per share, issued and outstanding immediately prior to the Effective Time will be converted into the right to receive a number of shares of Advaxis common stock, par value $0.001 per share (the "Advaxis Common Stock"), equal to the exchange ratio, 118.2009 shares of Advaxis Common Stock per Biosight share (subject to adjustment to account for the proposed Advaxis reverse stock split).

If the Merger Agreement is terminated under certain circumstances, Advaxis or Biosight, as applicable, will be required to pay the other party a termination fee equal to $7,500.

**c. Founding of Biosight Pharmaceuticals, Inc.**

On April 21, 2021, the Company founded a wholly owned subsidiary in the United States, formed in the State of Delaware.

The Company will consolidate the financial results of the subsidiary starting at the date of the subsidiary's founding.

**d.** On May 10, 2021, the Company issued 58,634 options to purchase Ordinary Shares of the Company, par value NIS 0.01 each, at an exercise price of $15.54 per share (the "Options"). The Options shall be subject to a vesting period of 4 years, such that, 25% of the shares underlying the Option shall vest on May 10, 2022, and during the 3 years thereafter 1/16 of the Shares underlying the Option shall vest upon the end of each subsequent quarter.

**NOTE 14 - SUBSEQUENT EVENTS (unaudited)**

In October 2021, the Company received a letter from counsel to Foodronix Ltd., an Israeli company ("Foodronix"), claiming that Foodronix is entitled to an amount equal to 4.8% of the share capital to be allocated and/or issued to Biosight shareholders in connection with the merger. The asserted entitlement is alleged to arise pursuant to a purported agreement between Biosight and Foodronix, which Foodronix claims was entered into in 2011. Foodronix did not provide a copy of the purported agreement or any other evidence of an agreement or commitment to this effect.

Based on a discussion with the Company's former chief executive officer, and an Israeli court ruling dated July 14, 2015 from a lawsuit in which Foodronix was sued by an affiliate of one of Biosight's current shareholders (the "Ruling"), Biosight believes that during March 2011, meetings were held by Biosight's former chief executive officer with several companies in an effort to identify a shell company listed on the Tel Aviv Stock Exchange to merge with Biosight in order for Biosight to become public. The Company believes that the meetings were held in the presence of Foodronix and that there was some arrangement under which Foodronix would have been entitled to compensation for its role in facilitating a transaction with a Tel Aviv Stock Exchange listed shell company. However, while a proposal was ultimately presented to Biosight's board of directors, in or around March 2011, for a proposed merger with such a shell company. Biosight's board of directors rejected this proposal, Biosight notified Foodronix that it did not intend to proceed and discussions with all such shell companies were discontinued. There is no further indication that Foodronix continued its efforts to identify such a company or to facilitate any transaction involving Biosight.

The Company has responded to Foodronix and rejected all claims asserted in the letter, including the entitlement of Foodronix to any equity as a result of the currently contemplated merger or any transaction involving Biosight other than a potential transaction with a shell company listed on the Tel Aviv Stock Exchange. The response notes that Foodronix's assertion of this entitlement comes 10 years after the last interaction between the parties, and relates to a transaction as to which Foodronix has had no involvement.

The Company believes that the claim by Foodronix lacks merit, and if Foodronix files a claim against the Company it has meritorious defenses to any potential claim. Given the inherent uncertainty involved in litigation, management cannot predict the outcome of any potential legal proceedings.

**Annex A**

CONFIDENTIAL EXECUTION VERSION

**AGREEMENT AND PLAN OF MERGER AND REORGANIZATION**

**AMONG**

**ADVAXIS, INC.,**

**ADVAXIS LTD.,**

**AND**

**BIOSIGHT LTD.**

**DATED AS OF JULY 4, 2021**

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AGREEMENT AND PLAN OF MERGER AND REORGANIZATION

**This Agreement and Plan of Merger and reorganization** (this "***Agreement***") is made and entered into as of July 4, 2021, by and among **Advaxis, Inc.**, a Delaware corporation ("***Advaxis***"), **Advaxis Ltd.**, a company organized under the laws of the State of Israel and a wholly owned Subsidiary of Advaxis ("***Merger Sub***"), and **Biosight Ltd.**, a company organized under the laws of the State of Israel ("***Biosight***"). Advaxis, Merger Sub and Biosight are referred to individually as a "***Party***" and collectively as the "***Parties***". Certain capitalized terms used in this Agreement are defined in Exhibit A.

Recitals

WHEREAS, the Parties wish to effect a merger of Merger Sub with and into Biosight, with Biosight being the surviving entity (the "***Merger***" and, collectively with the other transactions contemplated by this Agreement, the "***Transactions***") on the terms and subject to the conditions set forth in this Agreement and in accordance with the provisions of Sections 314-327 of the Companies Law 5759-1999 of the State of Israel (together with the rules and regulations promulgated thereunder, the "***ICL***"), following which Merger Sub will cease to exist, and Biosight will become a wholly-owned Subsidiary of Advaxis;

WHEREAS, the Board of Directors of Advaxis has (i) unanimously determined that the Merger is fair to, and in the best interests of, Advaxis and its stockholders, (ii) unanimously approved, adopted and declared advisable this Agreement, the Merger, the Reverse Split (if necessary), the issuance of shares of Advaxis Common Stock to the Biosight Shareholders pursuant to the terms of this Agreement (the "***Advaxis Stock Issuance***"), the change of control of Advaxis, the Advaxis Certificate of Incorporation Amendment, and the other Transactions, (iii) unanimously recommended that the Advaxis stockholders vote to approve the Advaxis Stock Issuance, the Reverse Split, the Advaxis Certificate of Incorporation Amendment and such other Transactions, (iv) unanimously directed that the Advaxis Stock Issuance be submitted to a vote at a meeting of Advaxis' stockholders, and (v) unanimously adopted a resolution having the effect of causing no rights to be distributed or exercisable under the Rights Agreement, and causing the Rights Agreement to have no force or effect, with respect to the Merger and the other Transactions;

WHEREAS, the Board of Directors of Merger Sub has unanimously (i) determined that the Merger is fair to, and in the best interests of, Merger Sub and Advaxis, as the sole shareholder of Merger Sub; (ii) approved, adopted and declared advisable this Agreement, the Merger, and the other Transactions; and (iii) recommended adoption of this Agreement by Advaxis in its capacity as the sole shareholder of Merger Sub;

WHEREAS, the Board of Directors of Biosight has unanimously (i) determined that the Merger is advisable and fair to, and in the best interests of, Biosight and its shareholders, (ii) approved, adopted and declared advisable this Agreement, the Merger and the other Transactions, (iii) recommended that the Biosight Shareholders vote to adopt this Agreement and thereby approve the Merger and such other Transactions, and (iv) determined that, considering the financial position of the merging companies, no reasonable concern exists that the Surviving Company will be unable to fulfill its obligations to its creditors;

WHEREAS, in order to induct Advaxis to enter into this Agreement and to cause the Merger to be consummated, the Persons listed on Schedule A hereto are executing concurrently with the execution and delivery of this Agreement support agreements in favor of Advaxis in the form substantially attached hereto as Exhibit B (the "***Biosight Support Agreements***");

WHEREAS, in order to induct Biosight to enter into this Agreement and to cause the Merger to be consummated, the Persons listed on Schedule B hereto are executing concurrently with the execution and delivery of this Agreement support agreements in favor of Biosight in the form substantially attached hereto as Exhibit C (the "***Advaxis Support Agreements***"); and

WHEREAS, the Parties intend, by approving resolutions authorizing this Agreement, to adopt this Agreement as a plan of reorganization within the meaning of Section 368(a) of the Code, and to cause the Transactions occurring at or immediately prior to the Closing, including the Merger, to qualify as a reorganization under the provisions of Section 368(a) of the Code and the Treasury Regulations promulgated thereunder or, if such treatment is disallowed pursuant to a "determination" within the meaning of Section 1313 of the Code or any analogous provision of applicable state, local or foreign Legal Requirements, as a transaction that qualifies under Section 351 of the Code.

NOW, THEREFORE, in consideration of the foregoing and their respective representations, warranties, covenants and agreements set forth in this Agreement, and intending to be legally bound hereby, the Parties agree as follows:

SECTION 1. Description of Transaction

**1.1** Structure of the Merger. Upon the terms and subject to the conditions set forth in this Agreement, and in accordance with the ICL, at the Effective Time, Merger Sub (as the target company (*Chevrat Ha'Ya'ad*) in the Merger) will be merged with and into Biosight (as the absorbing company (*HaChevra Ha'Koletet*) in the Merger), whereupon the separate existence of Merger Sub will cease, with Biosight surviving the Merger (Biosight, as the surviving entity in the Merger, sometimes being referred to herein as the "***Surviving Company***"), such that following the Merger, the Surviving Company will (a) be a wholly owned Subsidiary of Advaxis, (b) continue to be governed by the laws of the State of Israel, and (c) succeed to and assume all of the rights, properties and obligations of Merger Sub and Biosight in accordance with the ICL.

**1.2** Effects of the Merger. The Merger shall have the effects set forth in the ICL and this Agreement. Without limiting the generality of the foregoing, and subject thereto, at the Effective Time, by virtue of, and simultaneously with, the Merger and without any further action on the part of Advaxis, Merger Sub, Biosight or any Biosight Shareholder, (a) Merger Sub shall be merged with and into Biosight, the separate existence of Merger Sub shall cease and Biosight shall continue as the Surviving Company, (b) all the properties, rights, privileges, powers and franchises of Biosight and Merger Sub shall vest in the Surviving Company, (c) all debts, liabilities and duties of Biosight and Merger Sub shall become the debts, liabilities and duties of the Surviving Company, and (d) all the rights, privileges, immunities, powers and franchises of Biosight (as the Surviving Company) shall continue unaffected by the Merger in accordance with the ICL.

**1.3** Closing; Effective Time. Unless this Agreement is earlier terminated pursuant to the provisions of Section 9.1, and subject to the satisfaction or waiver of the conditions set forth in Section 6, Section 7 and Section 8, the consummation of the Merger (the "***Closing***") shall take place telephonically and/or by electronic exchange of documents, as promptly as practicable (but in no event later than the second ($2^{nd}$) Business Day following the satisfaction or waiver of the last to be satisfied or waived of the conditions set forth in Section 6, Section 7 and Section 8, other than those conditions that by their nature are to be satisfied at the Closing, but subject to the satisfaction or waiver of each of such conditions), or at such other time, date and place as Advaxis and Biosight may mutually agree in writing. The date on which the Closing actually takes place is referred to as the "***Closing Date***." As soon as practicable after the determination of the date on which the Closing is to take place, each of Biosight and Advaxis shall, and Advaxis shall cause Merger Sub to, in coordination with each other, deliver to the Companies Registrar of the Israeli Corporations Authority (the "***Companies Registrar***") a notice (the "***Merger Notice***") of the contemplated Merger and the proposed date on which the Companies Registrar is requested to issue a certificate evidencing the Merger in accordance with Section 323(5) of the ICL (the "***Certificate of Merger***") after notice that the Closing has occurred is served to the Companies Registrar, which the Parties shall deliver promptly following the Closing. The Merger will become effective upon the issuance by the Companies Registrar of the Certificate of Merger in accordance with Section 323(5) of the ICL (the time at which the Merger becomes effective is referred to herein as the "***Effective Time***"). The Parties shall use reasonable best efforts to coordinate with the Companies Registrar the issuance of the Certificate of Merger as of the Closing Date. If the Certificate of Merger is not issued on the Closing Date, Advaxis shall provide Biosight with a new Certificate of Merger.

**1.4** Articles of Association; Directors and Officers. At the Effective Time:

**(a)** the articles of association of Biosight, as in effect immediately prior to the Effective Time, shall be the articles of association of the Surviving Company, until such articles of association are thereafter duly changed or amended as provided therein or by applicable Legal Requirements; and

**(b)** the directors and officers of Biosight immediately prior to the Effective Time, shall be the directors and officers of the Surviving Company immediately after the Effective Time, and shall hold office in accordance with the articles of association of the Surviving Company, in each case until his or her successor is duly elected or appointed and qualified or until his earlier death, resignation or removal.

**1.5** Conversion of Shares and Other Securities.

**(a)** At the Effective Time, by virtue of the Merger and without any further action on the part of Advaxis, Merger Sub, Biosight or the holders of any share capital or equity interests of Merger Sub or Biosight:

**(i)** any Biosight Share owned by any of Biosight's Subsidiaries, Advaxis, Merger Sub or by any of their respective Subsidiaries immediately prior to the Effective Time shall remain outstanding and any Biosight Share that is a dormant share ('*menayah redumah*') under Israeli law immediately prior to the Effective Time shall be canceled and retired and shall cease to exist, and, in each case, no consideration shall be delivered in exchange therefor; and

**(ii)** subject to Section 1.5(d), each Biosight Share issued and outstanding immediately prior to the Effective Time (excluding shares to be canceled pursuant to Section 1.5(a)(i)) shall by virtue of the Merger and without any action on the part of the holder thereof, be deemed to have been transferred to Biosight in exchange for the right to receive 118.2009 shares of Advaxis Common Stock (and, with respect to 102 Biosight Shares, in exchange for the right to receive 102 Advaxis Shares) (the "***Exchange Ratio***" and, such shares, the "***Merger Consideration***"), without interest.

**(b)** At the Effective Time, each ordinary share, par value one (1) Israeli Agora (NIS 0.01) per share, of Merger Sub issued and outstanding immediately prior to the Effective Time shall be automatically and without further action converted into and become one (1) validly issued, fully paid and nonassessable ordinary share, par value one (1) Israeli Agora (NIS 0.01) per share, of the Surviving Company. Each certificate evidencing ownership of such shares of Merger Sub immediately prior to the Effective Time shall, as of the Effective Time, evidence ownership of such shares of Surviving Company.

**(c)** No later than five (5) Business Days prior to the Closing Date, each of Biosight and Advaxis shall take all actions necessary to provide that each Biosight Option outstanding and unexercised immediately before the Effective Time shall, as of the Effective Time, automatically and without any action on the part of the holder thereof, be assumed by Advaxis and converted into an Advaxis Option to purchase (a) that number of shares of Advaxis Common Stock (rounded down to the nearest whole share) equal to the product obtained by multiplying (i) the total number of shares of Biosight Shares subject to such Biosight Option immediately prior to the Effective Time by (ii) the Exchange Ratio, (b) at a per-share exercise price (rounded up to the nearest whole cent) equal to the quotient obtained by dividing (i) the exercise price per share of Biosight Share at which such Biosight Option was exercisable immediately prior to the Effective Time by (ii) the Exchange Ratio (rounding the resulting exercise price up to the nearest whole cent). Each such substituted Advaxis Option shall continue to have, and shall be subject to, the same terms and conditions (including the applicable time-vesting and/or performance-vesting conditions) as applied to the corresponding Biosight Option immediately prior to the Effective Time. Prior to the Effective Time, the Board of Directors of Biosight (or, if appropriate, any committee thereof administering the Biosight Employee Plan) shall pass resolutions to effect the foregoing provisions of this Section 1.5(c), and shall make any such changes to the Biosight Employee Plan as appropriate to give effect to the Merger and any rulings or tax benefits of the ITA with respect to the Advaxis Options, including the Option Tax Ruling filed as part of the 104(h) ruling referred to in Section 5.22(b). In the case of Advaxis Options issued in connection with the assumption of Biosight Options, which are subject to Tax pursuant to Sections 102(b)(2) or 102(b)(3) of the Ordinance (the "***102 Biosight Options***"), such Advaxis Options shall be deposited with the 102 Trustee subject to the provisions of Section 102 of the Ordinance and any Tax ruling received from the ITA regarding such 102 Biosight Options including the Option Tax Ruling and Interim Option Tax Ruling (the "***102 Advaxis Options***"). All other securities of Biosight shall be cancelled and shall be of no further force and effect from the Effective Time and shall not be assumed or converted into a right to receive any shares of Advaxis Common Stock.

**(d)** No fractional shares of Advaxis Common Stock shall be issued in connection with the Merger, and no certificates or scrip for any such fractional shares shall be issued, with no cash being paid for any fractional share eliminated by such rounding. Any fractional shares of Advaxis Common Stock a holder of Biosight Shares would otherwise be entitled to receive shall be aggregated together first prior to eliminating any remaining fractional share.

**(e)** If at any time during the period between the date of this Agreement and the Effective Time, any change in the outstanding shares, or securities convertible or exchangeable into or exercisable for Biosight Shares or shares of Advaxis Common Stock shall occur as a result of any merger, business combination, reclassification, recapitalization, stock split (including a reverse stock split) or subdivision or combination, exchange or readjustment of shares, or any share dividend or share distribution with a record date during such period, the Merger Consideration, the Exchange Ratio and any other similarly dependent items shall be equitably adjusted, without duplication, to reflect such change; *provided*, that nothing in this Section 1.5(e) shall be construed to permit Biosight or Advaxis to take any action with respect to its Securities that is prohibited by the terms of this Agreement.

**1.6** Closing of Biosight's Transfer Books. At the Effective Time: (a) all Biosight Shares issued and outstanding immediately prior to the Effective Time shall be treated in accordance with Section 1.5(a), and all holders of certificates representing Biosight Shares that were issued and outstanding immediately prior to the Effective Time shall cease to have any rights as Biosight Shareholders; and (b) the share transfer books or ledger of Biosight shall be closed with respect to all Biosight Shares issued and outstanding immediately prior to the Effective Time. No further transfer of any such Biosight Shares shall be made on such share transfer books or ledger after the Effective Time. If, after the Effective Time, a valid certificate previously representing any Biosight Shares issued and outstanding immediately prior to the Effective Time (a "***Biosight Share Certificate***") is presented to the Exchange Agent or to the Surviving Company, such Biosight Share Certificate shall be canceled and shall be exchanged as provided in Sections 1.5 and 1.7.

**1.7** Surrender of Certificates.

**(a)** On or prior to the Closing Date, Advaxis and Biosight shall mutually agree upon and select a reputable bank, transfer agent or trust company to act as exchange agent in the Merger (the "***Exchange Agent***"). At the Effective Time, Advaxis shall deposit with the Exchange Agent certificates or book entry shares representing the shares of Advaxis Common Stock issuable pursuant to Section 1.5(a). The shares of Advaxis Common Stock so deposited with the Exchange Agent, together with any dividends or distributions received by the Exchange Agent with respect to such shares, are referred to collectively as the "***Exchange Fund***."

**(b)** At or before the Effective Time, Biosight will deliver to Advaxis a true, complete and accurate listing of all record holders of Biosight Share Certificates at the Effective Time, including the number and class of Biosight Shares held by such record holder, and the number of shares of Advaxis Common Stock such holder is entitled to receive pursuant to Section 1.5. Promptly (and in any event within two (2) Business Days) after the Effective Time, the Parties shall cause the Exchange Agent to mail to the Persons who were record holders of Biosight Share Certificates immediately prior to the Effective Time a letter of transmittal in the form attached hereto as Exhibit D. Upon surrender of a Biosight Share Certificate to the Exchange Agent for exchange, together with a duly executed letter of transmittal that attaches correct, complete and duly executed copies of any applicable tax forms as instructed in such letter of transmittal, (1) the holder of such Biosight Share Certificate shall be entitled to receive in exchange therefor a certificate or book entry shares representing the number of whole shares of Advaxis Common Stock that such holder has the right to receive pursuant to the provisions of Section 1.5(a), all subject to Section 1.7(f); and (2) the Biosight Share Certificate so surrendered shall be canceled. Until surrendered as contemplated by this Section 1.7(b), each Biosight Share Certificate shall be deemed, from and after the Effective Time, to represent only the right to receive shares of Advaxis Common Stock. If any Biosight Share Certificate shall have been lost, stolen or destroyed, Advaxis may, in its discretion and as a condition precedent to the delivery of any shares of Advaxis Common Stock, require the owner of such lost, stolen or destroyed Biosight Share Certificate to provide an applicable affidavit with respect to such Biosight Share Certificate that includes an obligation of such owner to indemnify Advaxis on customary terms against any claim suffered by Advaxis related to the lost, stolen or destroyed Biosight Share Certificate as Advaxis may reasonably request. Notwithstanding anything to the contrary in this Section 1.7(b), any consideration including 102 Advaxis Shares received in consideration for Biosight Shares issued as a result of the exercise of 102 Biosight Options which are held by the 102 Trustee and are subject to Tax pursuant to Section 102(b)(2) of the Ordinance (the "***102 Biosight Shares***"), shall be transferred to the 102 Trustee subject to the provisions of Section 102 of the Ordinance and any Tax ruling received from the ITA regarding such 102 Biosight Shares including the Option Tax Ruling filed as part of the 104(h) ruling referred to in Section 5.22(b) and Interim Option Tax Ruling, if any. The Merger Consideration and any dividends or other distributions as are payable pursuant to Section 1.7(c) shall be deemed to have been in full satisfaction of any and all rights pertaining to the Biosight Shares formerly represented by such Biosight Share Certificate.

**(c)** No dividends or other distributions declared or made with respect to Advaxis Common Stock with a record date after the Effective Time shall be paid to the holder of any unsurrendered Biosight Share Certificate with respect to the shares of Advaxis Common Stock that such holder has the right to receive in the Merger until such holder surrenders such Biosight Share Certificate or an affidavit of loss or destruction in lieu thereof in accordance with this Section 1.7 (at which time such holder shall be entitled, subject to the effect of applicable abandoned property, escheat or similar Legal Requirements, to receive all such dividends and distributions, without interest).

**(d)** Any portion of the Exchange Fund that remains undistributed to holders of Biosight Share Certificates (or is not held thereby on behalf of such holder pursuant to the Option Tax Ruling filed as part of the 104(h) ruling referred to in Section 5.22(b)) as of the date that is 180 days after the Closing Date shall be delivered to Advaxis upon demand, and any holders of Biosight Share Certificates who have not theretofore surrendered their Biosight Share Certificates in accordance with this Section 1.7 shall thereafter look only to Advaxis (subject to abandoned property, escheat or other similar Legal Requirements) for satisfaction of their claims for Advaxis Common Stock in compliance with the procedures in Section 1.7(b), without any interest thereon.

**(e)** Notwithstanding any other provision in this Agreement, but subject to Section 1.7(f), each of Advaxis (or anyone on its behalf), Merger Sub, the Surviving Company, the Paying Agent, the Exchange Agent and the Section 102 Trustee (each, a "***Payor***") shall be entitled to deduct and withhold from any consideration otherwise deliverable under this Agreement such amounts as any such Payor determines are required to be deducted or withheld from such consideration under the Code, the Ordinance or under any other applicable Legal Requirement; *provided*, that before making any deduction or withholding pursuant to this Section 1.7(e), the Payor shall use commercially reasonable efforts to give the payee at least five (5) days' prior notice of any anticipated deduction or withholding (together with any legal basis therefor) to provide the payee sufficient opportunity to produce any Tax forms or other documentation, including an IRS Form W-9 or the appropriate IRS Form W-8, or the applicable successor form, as applicable, or take such other steps in order to avoid such deduction or withholding, and shall use commercially reasonable efforts to consult and cooperate with the payee in good faith to attempt to reduce or eliminate any amounts that would otherwise be deducted or withheld pursuant to this Section 1.7(e). To the extent any amounts are deducted or withheld pursuant to this Section 1.7(e), such amounts shall be (A) treated for all purposes under this Agreement as having been paid to the Person to whom such amounts would otherwise have been paid and (B) remitted in accordance with the applicable Legal Requirement by the Payor to the applicable Governmental Authority. In the case of any amounts so deducted or withheld, the withholding party shall provide to the Person from which such amounts were deducted or withheld written confirmation of the amount so deducted or withheld.

**(f)** Without derogating from the Option Tax Ruling filed as part of the 104(h) ruling referred to in Section 5.22(b) and unless otherwise determined thereunder, in the case of any payment payable to employees of Biosight or its Affiliates in connection with the Merger treated as compensation in exchange for services or work performed, the parties shall cooperate to pay such amounts through Biosight's or its Affiliate's payroll to facilitate applicable withholding. The Parties shall enter into a paying agent agreement with the Exchange Agent or any other paying agent mutually acceptable to the Parties (the "***Paying Agent***") with respect to withholding under the Ordinance. Notwithstanding Section 1.7(e) above and anything else in this Agreement, and in accordance with the Paying Agent undertaking provided by the Paying Agent to Advaxis as required under Section 6.2.4.3 of the Income Tax Circular 19/2018 (Transaction for Sale of Rights in a Corporation that includes Consideration that will be transferred to the Seller at Future Dates), with respect to Israeli Taxes, any amounts or other consideration deliverable to a recipient hereunder shall be delivered to and retained by the Paying Agent for the benefit of each such recipient for a period of one-hundred eighty (180) days from the Closing Date, or an earlier date required in writing by a payment recipient (the "***Withholding Drop Date***") (during which time unless requested otherwise by the ITA, no consideration shall be transferred by the Paying Agent to any recipient and no amounts for Israeli Taxes shall be withheld from the payments deliverable pursuant to this Agreement, except as provided below and during which time each recipient may obtain a Valid Tax Certificate). If a payment recipient delivers, no later than three (3) Business Days prior to the Withholding Drop Date a Valid Tax Certificate to the Paying Agent, then the deduction and withholding of any Israeli Taxes shall be made only in accordance with the provisions of such Valid Tax Certificate and the balance of the payment or other consideration that is not withheld shall be transferred to such recipient (subject to withholding on account of non-Israeli Taxes, if applicable). If any recipient (i) does not provide the Paying Agent with a Valid Tax Certificate by no later than three (3) Business Days before the Withholding Drop Date, or (ii) submits a written request to the Paying Agent to release his/her/its portion of such amounts or other consideration deliverable prior to the Withholding Drop Date and fails to submit a Valid Tax Certificate no later than three (3) Business Days before such time, then the amount to be withheld from such recipient's portion of such amounts or other consideration deliverable shall be calculated according to the applicable withholding rate as determined by the Paying Agent, which amount shall be calculated in NIS based on the US$:NIS exchange rate known on the date the consideration is actually transferred to such recipient, and the Paying Agent will transfer to such recipient the balance of the payment or other consideration due to such recipient that is not so withheld (subject to withholding on account of non-Israeli Taxes, if applicable).

**(g)** Notwithstanding anything to the contrary in this Agreement until the recipient of Advaxis Common Stock, or anyone on his/her/its behalf, presents to the Paying Agent, a Valid Tax Certificate, or evidence satisfactory to the Paying Agent that the full applicable Tax amount with respect to such recipient, as reasonably determined by Advaxis and the Paying Agent, is withheld or funded, (i) certificates of Advaxis Common Stock shall be issued only in the name of the Paying Agent to be held in trust for the relevant recipient and delivered to such recipient in compliance with the withholding requirements under this Section 1.7 and (ii) no portion of the Advaxis Common Stock shall be released to such recipient.

**(h)** Subject to Section 1.7(f) and (g), any amount required to be withheld with respect to Advaxis Common Stock deliverable under the Agreement, to the extent not otherwise funded by such recipient of such stock, shall be funded through the forfeiture or sale of the portion of the shares of Advaxis Common Stock otherwise deliverable or payable to such recipient that is required to enable Advaxis and the Paying Agent to comply with applicable deduction or withholding requirements. Each Biosight Shareholder hereby waives, releases and absolutely and forever discharges Advaxis, or anyone acting on its behalf, the Exchange Agent and the Paying Agent from and against any and all claims for any Costs in connection with the forfeiture or sale of any portion of the share of Advaxis Common Stock otherwise deliverable or payable to such recipient in compliance with the withholding requirements under this Section 1.7. To the extent that the Paying Agent is unable, for whatever reason, to sell the applicable portion of shares of Advaxis Common Stock required to finance the applicable deduction or withholding requirements, then the Paying Agent shall hold all of the Advaxis Common Stock otherwise deliverable or payable to the applicable Biosight Shareholder until the earlier of: (i) the receipt of a Valid Tax Certificate or other applicable Tax documentation from such Biosight Shareholder fully exempting the Paying Agent from Tax withholding; or (ii) such time when the Payor is able to sell the portion of such shares otherwise deliverable or payable to such Biosight Shareholder that is required to enable the Paying Agent to comply with such applicable deduction or withholding requirements. Any Costs or expenses incurred in connection with such sale shall be borne by, and deducted from the payment or other consideration deliverable to, the applicable Biosight Shareholder.

**1.8** Further Action. If, at any time after the Effective Time, any further action is determined by the Surviving Company to be necessary or desirable to carry out the purposes of this Agreement or to vest the Surviving Company with full right, title and possession of and to all rights and property of Biosight or Merger Sub, then the officers and directors of the Surviving Company shall be fully authorized, and shall use their commercially reasonable efforts (in the name of Biosight, in the name of Merger Sub and otherwise) to take such action.

**1.9** Tax Treatment. Each party hereto intends that, for U.S. federal income tax purposes, (i) the Transactions (including the Merger) shall constitute either (A) a reorganization within the meaning of Section 368(a) of the Code and the Treasury Regulations promulgated thereunder or (B), in the event that such treatment is disallowed pursuant to a "determination" within the meaning of Section 1313 of the Code or any analogous provision of applicable state, local or foreign Legal Requirements, a transaction that qualifies under Section 351 of the Code (the "***Intended Tax Treatment***") and (ii) this Agreement shall constitute a "plan of reorganization" within the meaning of Treasury Regulations Sections 1.368-2(g) and 1.368-3(a).

SECTION 2. Representations and Warranties of Advaxis and Merger Sub

Advaxis and Merger Sub each hereby represent and warrant to Biosight as follows, except as set forth in (i) the Advaxis SEC Reports (excluding, in each case, any disclosures contained therein under the captions "Risk Factors" or "Forward Looking Statements" and any other disclosures contained therein relating to information, factors or risks that are predictive, cautionary or forward looking in nature) filed or furnished with the SEC on or after January 1, 2019 and at least five (5) Business Days prior to the date of this Agreement (and (A) other than any matters required to be disclosed for purposes of Sections 2.3 and 2.17 which matters shall only be disclosed by specific disclosure in the corresponding section of the Advaxis Disclosure Schedule and (B) without giving effect to any amendment to any such documents filed on or after the date hereof) or (ii) the corresponding Section or Subsection of the written disclosure schedule delivered by Advaxis to Biosight (the "***Advaxis Disclosure Schedule***"). The Advaxis Disclosure Schedule shall be arranged in sections and subsections corresponding to the numbered and lettered sections and subsections contained in this Section 2. The disclosures in any section or subsection of the Advaxis Disclosure Schedule shall qualify other sections and subsections in this Section 2 to the extent it is reasonably clear from a reading of the disclosure that such disclosure is applicable to such other sections and subsections. The inclusion of any information in the Advaxis Disclosure Schedule (or any update thereto) shall not be deemed to be an admission or acknowledgment, in and of itself, that such information is required by the terms hereof to be disclosed, is material, has resulted in or would result in an Advaxis Material Adverse Effect, or is outside the Ordinary Course of Business.

**2.1** Subsidiaries; Due Organization.

**(a)** Advaxis has no Subsidiaries, and Advaxis does not own any capital stock of, or any equity interest of any nature in, any other Entity, other than the Entities identified in Part 2.1(a) of the Advaxis Disclosure Schedule. Advaxis has not agreed nor is obligated to make, nor is bound by any Contract under which it may become obligated to make, any future investment in or capital contribution to any other Entity. Advaxis has not, at any time, been a general partner of, or has otherwise been liable for any of the debts or other obligations of, any general partnership, limited partnership or other Entity.

**(b)** Each of Advaxis and its Subsidiaries is a legal entity duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization and has all requisite power and authority (i) to conduct its business in the manner in which its business is currently being conducted; (ii) to own and use its assets in the manner in which its assets are currently owned and used; and (iii) to perform its obligations under all Contracts by which it is bound.

**(c)** Each of Advaxis and its Subsidiaries is qualified to do business as a foreign corporation or other legal entity, and is in good standing, under the laws of all jurisdictions where the nature of its business requires such qualification other than in jurisdictions where the failure to be so qualified individually or in the aggregate would not be reasonably expected to have an Advaxis Material Adverse Effect.

**(d)** Advaxis is the record and Beneficial Owner of all of the outstanding capital stock of Merger Sub. Merger Sub has not conducted any business prior to the date of this Agreement and has no, and prior to the Effective Time will have no, assets, liabilities or obligations of any nature other than those incident to its formation and pursuant to this Agreement and the Transactions, including the Merger.

**(e)** Advaxis is not a "shell company" and has not been a "shell company" (as defined in Rule 12b-2 of the Exchange Act) for the past twelve (12) months.

**2.2** Certificate of Incorporation; Bylaws; Charters and Codes of Conduct; Advaxis has delivered to Biosight accurate and complete copies of the Constituent Documents, including all currently effective amendments thereto, for Advaxis and each of its Subsidiaries. Part 2.2 of the Advaxis Disclosure Schedule lists, and Advaxis has delivered to Biosight, accurate and complete copies of (a) the charters of all committees of Advaxis' Board of Directors; and (b) any code of conduct or similar policy adopted by Advaxis or by the Board of Directors, or any committee of the Board of Directors, of Advaxis. Neither Advaxis nor any of its Subsidiaries has taken any action in breach or violation in any material respect of any of the material provisions of its Constituent Documents nor is in breach or violation in any material respect of any of the material provisions of its Constituent Documents.

**2.3** Capitalization, Etc.

**(a)** The authorized capital stock of Advaxis as of the date of this Agreement consists of (i) 170,000,000 shares of Advaxis Common Stock, par value $0.001 per share, of which 145,638,459 shares have been issued and are outstanding as of the date of this Agreement, and (ii) 5,000,000 shares of preferred stock, par value $0.001 per share (the "***Advaxis Preferred Stock***"), none of which shares have been issued and are outstanding as of the date of this Agreement. Except as set forth in Part 2.3(a) of the Advaxis Disclosure Schedule, the authorized capital stock of Advaxis as of immediately prior to the Closing shall consist of (i) 170,000,000 shares of Advaxis Common Stock, 145,638,459 shares of which will be issued and outstanding, (ii) warrants to purchase 30,225,397 shares of Advaxis Common Stock of which 14,005,202 are private placement warrants for shares not yet authorized and (iii) 5,000,000 shares of Advaxis Preferred Stock, none of which shares of Advaxis Preferred Stock will be issued and outstanding. Advaxis does not hold any shares of its capital stock in its treasury. All of the outstanding shares of Advaxis Common Stock and Advaxis Preferred Stock have been duly authorized and validly issued, and are fully paid and nonassessable. Except as set forth in Part 2.3(a) of the Advaxis Disclosure Schedule, none of the outstanding shares of Advaxis Common Stock or Advaxis Preferred Stock is entitled or subject to any preemptive right, right of participation, right of maintenance or any similar right and none of the outstanding shares of Advaxis Common Stock or Advaxis Preferred Stock is subject to any right of first refusal in favor of Advaxis. Except as contemplated herein or as set forth in Part 2.3(a) of the Advaxis Disclosure Schedule, there is no Advaxis Contract relating to the voting or registration of, or restricting any Person from purchasing, selling, pledging or otherwise disposing of (or granting any option or similar right with respect to), any shares of Advaxis Common Stock or Advaxis Preferred Stock. Advaxis is not under any obligation, nor is it bound by any Contract pursuant to which it may become obligated, to repurchase, redeem or otherwise acquire any outstanding shares of Advaxis Common Stock or other Securities. Part 2.3(a) of the Advaxis Disclosure Schedule accurately and completely lists all repurchase rights held by Advaxis with respect to shares of Advaxis Common Stock (including shares issued pursuant to the exercise of stock options) and Advaxis Preferred Stock and specifies the number of shares of Advaxis Common Stock and Advaxis Preferred Stock subject to such repurchase rights, the purchase price paid by such holder, the vesting schedule under which such repurchase rights lapse, and whether, to the Knowledge of the Company, the holder of such Advaxis Common Stock or Advaxis Preferred Stock filed an election under Section 83(b) of the Code with respect to the Advaxis Common Stock or Advaxis Preferred Stock within thirty (30) days of purchase.

**(b)** Except for the Advaxis 2011 Omnibus Incentive Plan and the Advaxis 2015 Incentive Plan (the "***Advaxis Equity Plans***"), and except as set forth in Part 2.3(b) of the Advaxis Disclosure Schedule, Advaxis does not have any stock option plan or any other plan, program, agreement or arrangement providing for any equity-based compensation for any Person. Advaxis has reserved 6,000,000 shares of Advaxis Common Stock for issuance under the Advaxis Equity Plans. Of such reserved shares of Advaxis Common Stock, 333 shares have been issued pursuant to the exercise of outstanding options, options to purchase 1,031,323 shares have been granted and are currently outstanding (with a weighted average exercise price per share of $32.51), and 5,002,895 shares of Advaxis Common Stock remain available for future issuance pursuant to the Advaxis Equity Plans. No shares of Advaxis Common Stock are reserved for issuance pursuant to outstanding unsettled Advaxis RSUs. No other shares of capital stock or other voting securities of Advaxis are issued, reserved for issuance or outstanding. Part 2.3(b) of the Advaxis Disclosure Schedule sets forth the following information with respect to each Advaxis Option and Advaxis RSU outstanding as of the date of this Agreement (A) the name of the holder thereof; (B) the number of shares of Advaxis Common Stock issuable thereunder or otherwise subject thereto at the time of grant; (C) the number of shares of Advaxis Common Stock issuable thereunder or otherwise subject thereto as of the date of this Agreement; (D) if applicable, the exercise price; (E) the date on which such award was granted; (F) the applicable vesting schedule, including the number of vested and unvested shares; (G) the date on which such award expires; and (H) if applicable, whether such Advaxis Option is an "incentive stock option" (as defined in the Code) or a non-qualified stock option. Advaxis has made available to Biosight accurate and complete copies of the Advaxis Equity Plans and forms of all award agreements approved for use thereunder. No vesting of Advaxis Options will accelerate in connection with the closing of the Transactions.

**(c)** Except for the Rights Agreement, the outstanding Advaxis Options and Advaxis RSUs as set forth in Section 2.3(b), the warrants identified on Part 2.3(c) of the Advaxis Disclosure Schedule (the "***Advaxis Warrants***") or as otherwise set forth on Part 2.3(c) of the Advaxis Disclosure Schedule, there is no (i) outstanding subscription, option, call, warrant or right (whether or not currently exercisable) to acquire any shares of the capital stock or other Securities of Advaxis or any of its Subsidiaries; (ii) outstanding security, instrument or obligation that is or may become convertible into or exchangeable for any shares of the capital stock or other Securities of Advaxis or any of its Subsidiaries; (iii) stockholder rights plan (or similar plan commonly referred to as a "poison pill") or Contract under which Advaxis or any of its Subsidiaries is or may become obligated to sell or otherwise issue any shares of its capital stock or any other Securities; or (iv) condition or circumstance that may give rise to or provide a basis for the assertion of a claim by any Person to the effect that such Person is entitled to acquire or receive any shares of capital stock or other Securities of Advaxis or any of its Subsidiaries. There are no outstanding or authorized stock appreciation, phantom stock, profit participation or other similar rights with respect to Advaxis or any of its Subsidiaries. Except as expressly set forth on Part 2.3(c) of the Advaxis Disclosure Schedule, neither (x) the execution, delivery or performance of this Agreement by Advaxis, nor (y) the consummation of the Merger or any of the other Transactions, will directly or indirectly (with or without notice or lapse of time), (A) contravene, conflict with or result in a violation or breach of, or result in a default under, any provision of any Advaxis Warrant or (B) result in any right or payment due, or in the acceleration, cancelation, termination or modification of any Advaxis Warrant or any right of any Person thereunder.

**(d)** All outstanding shares of Advaxis Common Stock and Advaxis Preferred Stock, as well as all options, warrants and other Securities of Advaxis, have been issued and granted in material compliance with (i) all applicable securities laws and other applicable Legal Requirements and (ii) all requirements set forth in applicable Contracts. Advaxis has delivered to Biosight accurate and complete copies of all Advaxis Warrants.

**(e)** The shares of Advaxis Common Stock to be issued as Merger Consideration pursuant to this Agreement have been duly authorized and will, when issued in accordance with the provisions of this Agreement, be validly issued, fully paid, nonassessable and free of any Encumbrances and will not be subject to any restriction on resale under the Securities Act, other than restrictions imposed by Rules 144 and 145 under the Securities Act. The Advaxis Options issued in connection with the assumption of Biosight Options pursuant to Section 1.5(c) when issued in accordance with this Agreement, and any share of Advaxis Common Stock issued upon the exercise thereof according to the terms thereof, will be duly and validly issued, fully paid, non-assessable and free and clear of all Encumbrances.

**(f)** Advaxis has taken all actions necessary to (i) render the Rights Agreement inapplicable to this Agreement and the Transactions; (ii) ensure that in connection with the Transactions, (A) neither Advaxis, Merger Sub nor any of their "Affiliates" or "Associates" (each as defined in the Rights Agreement) is or will be (1) a "Beneficial Owner" of or deemed to "beneficially own" and have "Beneficial Ownership" (each as defined in the Rights Agreement) of any securities of Advaxis or (2) an "Acquiring Person" (as defined in the Rights Agreement) and (B) none of a "Shares Acquisition Date," a "Distribution Date" (as such terms are defined in the Rights Agreement) or a "Triggering Event" (as defined in the Rights Agreement) occurs or will occur, in each case of clauses (A) and (B), solely by reason of the execution of this Agreement, or the consummation of the Merger or the other Transactions; and (iii) provide that the "Final Expiration Date" (as defined in the Rights Agreement) shall occur immediately prior to the Effective Time, but only if the Effective Time shall occur. To the Knowledge of Advaxis, no Person is an "Acquiring Person" and no "Share Acquisition Date," "Distribution Date" (as such terms are defined in the Rights Agreement) or "Triggering Event" (as defined in the Rights Agreement) has occurred.

**2.4** Financial Statements; Advaxis Reports.

**(a)** Part 2.4(a) of the Advaxis Disclosure Schedule includes true and complete copies of (i) Advaxis' audited consolidated balance sheets at October 31, 2019 and October 31, 2020, (ii) the Advaxis Unaudited Interim Balance Sheet, (iii) Advaxis' audited consolidated statements of operations, cash flow and stockholders' equity for the years ended October 31, 2019 and October 31, 2020, and (iv) Advaxis' unaudited statements of operations, cash flow and shareholders' equity for the six months ended April 30, 2021 (collectively, the "***Advaxis Financial Statements***"). The Advaxis Financial Statements (i) were prepared in accordance with United States generally accepted accounting principles ("***GAAP***") (except as may be indicated in the footnotes to such Advaxis Financial Statements and that unaudited financial statements may not have notes thereto and other presentation items that may be required by GAAP and are subject to normal and recurring year-end adjustments that are not reasonably expected to be material in amount) applied on a consistent basis unless otherwise noted therein throughout the periods indicated and (ii) fairly present the financial condition and operating results of Advaxis and its consolidated Subsidiaries as of the dates and for the periods indicated therein.

**(b)** Each of Advaxis and its Subsidiaries maintains a system of internal accounting controls designed to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Advaxis and each of its Subsidiaries maintains internal control over financial reporting that provides reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP.

**(c)** Neither Advaxis, nor any of its Subsidiaries is, or has any commitment to become, a party to any joint venture, off-balance sheet partnership or any similar Contract, including any structured finance, special purpose or limited purpose entity or Person, or any "off-balance sheet arrangements" (as defined in Item 303(a) of Regulation S-K under the Securities Act), in each case, where the result, purpose or intended effect of such Contract is to avoid disclosure of any material transaction involving, or material liabilities of, Advaxis or any of its Subsidiaries in the Advaxis SEC Reports.

**(d)** Since November 1, 2017, there have been no formal internal investigations regarding financial reporting or accounting policies and practices discussed with, reviewed by or initiated at the direction of the chief executive officer, chief financial officer or general counsel of Advaxis, Advaxis' Board of Directors or any committee thereof. Since November 1, 2017, neither Advaxis nor its independent auditors have identified (i) any significant deficiency or material weakness in the system of internal accounting controls utilized by Advaxis and its Subsidiaries, (ii) any fraud, whether or not material, that involves Advaxis' management or other employees who have a role in the preparation of financial statements or the internal accounting controls utilized by Advaxis or any of its Subsidiaries or (iii) any claim or allegation regarding any of the foregoing.

**(e)** Advaxis has filed or furnished, as applicable, on a timely basis (taking into account all applicable grace periods) all Advaxis SEC Reports. Each of the Advaxis SEC Reports, at the time of its filing or being furnished (or, if amended, as of the time of such amendment), complied as to form in all material respects with the applicable requirements of the Securities Act, the Exchange Act and the Sarbanes-Oxley Act. as of their respective dates (or, if amended, as of the date of such amendment), the Advaxis SEC Reports did not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made therein, in light of the circumstances in which they were made, not misleading. As of the date hereof, there are no outstanding or unresolved comments from the SEC staff with respect to any of the Advaxis SEC Reports, and, to the Knowledge of Advaxis, none of the Advaxis SEC Reports is the subject of ongoing SEC review, outstanding SEC comment or outstanding SEC investigation.

**(f)** Advaxis has established and maintains "disclosure controls and procedures" and "internal controls over financial reporting" (as such terms are defined in paragraphs (e) and (f), respectively, of Rule 13a-15 under the Exchange Act) as required by Rules 13a-15 and 15d-15 under the Exchange Act. Such disclosure controls and procedures are designed and maintained to provide reasonable assurance that material information required to be disclosed by Advaxis in the reports and other documents that it files or furnishes pursuant to the Exchange Act is recorded and reported on a timely basis to the individuals responsible for the preparation of the Advaxis' filings with the SEC and other public disclosure documents. Since November 1, 2017, neither Advaxis nor, to the Knowledge of Advaxis, its independent registered public accounting firm has identified, been made aware of or received any written notification of any (A) "significant deficiency," (B) "material weakness" (as defined in Rule 13a-15 or 15d-15, as applicable, under the Exchange Act) or (C) fraud in the design or operation of Advaxis' internal controls over financial reporting or that involves management or other employees who have a significant role in the preparation of financial statements or the internal control over financial reporting utilized by Advaxis and its Subsidiaries.

**2.5** Absence of Changes. Except as set forth on Part 2.5 of the Advaxis Disclosure Schedule, since the date of the Advaxis Unaudited Interim Balance Sheet, (a) except as contemplated by this Agreement, the business of Advaxis and its Subsidiaries has been conducted in all material respects in the Ordinary Course of Business, (b) there has not been any Effect which has had an Advaxis Material Adverse Effect, and no Effect exists or has occurred which would reasonably be expected to have, individually or in the aggregate, an Advaxis Material Adverse Effect and (c) there has not been any action, event or occurrence that would have required consent of Biosight pursuant to Section 4.2(b) had such action, event or occurrence taken place after the execution and delivery of this Agreement.

**2.6** Title to Assets. Each of Advaxis and its Subsidiaries owns, and has good and valid title to, or, in the case of leased properties and assets, valid leasehold interests in, all tangible properties or assets and equipment used or held for use in its business or operations or purported to be owned by it, including (a) all assets reflected on the Advaxis Unaudited Interim Balance Sheet; and (b) all other assets reflected in the books and records of Advaxis or any of its Subsidiaries as being owned by Advaxis or such Subsidiary. All of said assets are owned by Advaxis free and clear of any Encumbrances, except for Permitted Encumbrances.

**2.7** Real Property; Leasehold

**(a)** Neither Advaxis nor any of its Subsidiaries owns any real property. Except as would not reasonably be expected to have, individually or in the aggregate, an Advaxis Material Adverse Effect, (i) each lease, sublease, license, concession and other agreement under which Advaxis or its Subsidiaries lease, sublease, use or occupy the real property leased, subleased, licensed or otherwise occupied by Advaxis or any of its Subsidiaries, including all material amendments, modifications, extensions and guaranties relating thereto (each, an "***Advaxis Lease***" and such real property, the "***Advaxis Leased Real Property***") is a valid and binding obligation on Advaxis and such of its Subsidiaries party thereto and, to the Knowledge of Advaxis, each other party thereto and is in full force and effect and enforceable in accordance with its terms (except that (A) such enforcement may be subject to the Bankruptcy and Equity Exception and (B) the remedy of specific performance and injunctive and other forms of equitable relief may be subject to equitable defenses and to the discretion of the court before which any proceedings therefor may be brought), (ii) there is no breach or default under any Advaxis Lease by Advaxis or any of its Subsidiaries or, to the Knowledge of Advaxis, any other party thereto, (iii) no event has occurred which, with notice, lapse of time or both, would constitute a default under any Advaxis Lease by any of Advaxis or its Subsidiaries and (iv) Advaxis or one of its Subsidiaries that is either the tenant, subtenant or licensee named under the Advaxis Lease has a good and valid leasehold interest in each Advaxis Leased Real Property which is subject to an Advaxis Lease and is in possession of such Advaxis Leased Real Property.

**(b)** There are no pending or, to the Knowledge of Advaxis, threatened condemnation or eminent domain proceedings that affect any Advaxis Leased Real Property and Advaxis has not received any written notice of the intention of any Governmental Authority or other Person to take any Advaxis Leased Real Property.

**2.8** Intellectual Property.

**(a)** Part 2.8(a) of the Advaxis Disclosure Schedule contains a complete and accurate list of all Advaxis IP Rights that are owned or purported to be owned by Advaxis or any of its Subsidiaries that are registered or the subject of a pending application for registration with any Governmental Authority (the "***Advaxis Registered IP***"). All Advaxis Registered IP is valid, subsisting and, to the Knowledge of Advaxis, enforceable, and each item of Advaxis Registered IP has been prosecuted in good faith, is in good administrative standing, and the deadlines for maintaining any registration for and prosecuting any application to register Intellectual Property included in the Advaxis Registered IP up to and including the Closing Date have been satisfied, and any such deadlines occurring in the period up to and including ninety (90) days after the Closing Date have been identified on Part 2.8(a) of the Advaxis Disclosure Schedule. All assignments and other vesting instruments pertaining to any Advaxis Registered IP have been timely and properly recorded with the applicable Governmental Authority. The owner of record of each item of Advaxis Registered IP is the beneficial and legal owner in fact of such Advaxis Registered IP and the entity identified as the current assignee and owner thereof on Part 2.8(a) of the Advaxis Disclosure Schedule.

**(b)** Advaxis or one of its Subsidiaries is the sole and exclusive owner of all right, title and interest in and to the Advaxis Registered IP, and owns or has a license, sublicense or otherwise possesses legally enforceable rights to use all other Advaxis IP Rights free and clear of all Encumbrances (other than Permitted Encumbrances). The Advaxis IP Rights include all of the material Intellectual Property necessary for Advaxis and each of its Subsidiaries to conduct their respective businesses as currently conducted.

**(c)** The operation of the business of Advaxis and its Subsidiaries as currently conducted, and the use of any Intellectual Property in connection therewith, do not conflict with, infringe, misappropriate, or otherwise violate the Intellectual Property, of any other Person.

**(d)** As of the date of this Agreement, there are no Legal Proceedings pending or, to the Knowledge of Advaxis, threatened in writing with respect to any Advaxis IP Rights owned or purported to be owned by Advaxis and its Subsidiaries, and neither Advaxis nor any of its Subsidiaries is a party to any Legal Proceeding relating to any Advaxis IP Rights. Within the past five (5) years (or prior thereto if the same is still pending or subject to appeal or reinstatement), neither Advaxis nor any of its Subsidiaries has been sued or charged in writing with or been a defendant in any Legal Proceeding that involves a claim of infringement or misappropriation of any Intellectual Property. None of the Advaxis IP Rights that is owned or purported to be owned by Advaxis and its Subsidiaries is subject to any pending or outstanding injunction, order, judgment, settlement, consent order, ruling or other disposition of dispute that adversely restricts the use, transfer or registration of, or adversely affects the validity or enforceability of, any such Intellectual Property.

**(e)** No past or present director, officer or employee of Advaxis or any of its Subsidiaries owns (or has any claim or any right (whether or not currently exercisable) to any ownership interest in or to) any Advaxis IP Rights. Advaxis and its Subsidiaries have taken commercially reasonable steps to maintain the secrecy, confidentiality and value of all Trade Secrets included in the Advaxis IP Rights. No material Trade Secret has been authorized to be disclosed, or, to the Knowledge of Advaxis, has been disclosed to any employees or other Person by Advaxis or any of its Subsidiaries, other than as subject to an agreement restricting the disclosure and use of such Trade Secret, and to the Knowledge of Advaxis, there is no uncured breach by any employee or other Person under any such agreement.

**(f)** Except as set forth in Part 2.8(f) of the Advaxis Disclosure Schedule, to the Knowledge of Advaxis, no funding, facilities or personnel of any Governmental Authority or any university, college, research institute or other educational institution has been or is being used in any material respect to create, in whole or in part, any material Advaxis IP Rights owned or purported to be owned by Advaxis or any of its Subsidiaries.

**(g)** Except with respect to the Contracts listed on Part 2.9(a)(xiii) of the Advaxis Disclosure Schedule and the Advaxis Standard Contracts, neither Advaxis nor any of its Subsidiaries is obligated under any Contract to make any payments by way of royalties, fees, or otherwise to any owner or licensor of, or other claimant to, any Advaxis IP Rights.

**(h)** To the Knowledge of Advaxis, the information technology networks, computer hardware, and software applications owned or used by Advaxis or any of its Subsidiaries (the "***Advaxis IT Systems***") are free of all viruses, worms, Trojan horses and other material known contaminants and do not contain any bugs, errors, or problems of a material nature that could materially disrupt or have a material adverse impact on the operation of the Advaxis IT Systems. The Advaxis IT Systems are adequate for the operation of the businesses of Advaxis and its Subsidiaries as currently conducted. In the last twelve (12) months, there have been no failures, breakdowns, continued substandard performance or other adverse events affecting any such Advaxis IT Systems that have caused or could reasonably be expected to result in a material disruption or interruption in or to the use of such Advaxis IT Systems or the conduct of the businesses of Advaxis or any of its Subsidiaries. Advaxis and each of its Subsidiaries have taken commercially reasonable actions intended to protect the security and integrity of the Advaxis IT Systems. Neither Advaxis nor any of its Subsidiaries has experienced any information security incident that has compromised the integrity or availability of the Advaxis IT Systems, and to the Knowledge of Advaxis, there has been no material loss, damage, or unauthorized access, disclosure, use, or breach of security of the Advaxis IT Systems or any data stored therein.

**2.9** Agreements, Contracts and Commitments.

**(a)** Except as listed in Part 2.9(a) of the Advaxis Disclosure Schedule, as of the date of this Agreement, neither Advaxis nor any of its Subsidiaries is a party to or bound by any:

**(i)** Advaxis Contract that would be required to be filed by Advaxis as a "material contract" pursuant to Item 601(b)(10) of Regulation S-K under the Securities Act or disclosed on a Current Report on Form 8-K that has not been filed or incorporated by reference in the Advaxis SEC Reports;

**(ii)** Advaxis Contract relating to any bonus, deferred compensation, severance, incentive compensation, pension, profit-sharing or retirement plans, or any other employee benefit plans or arrangements;

**(iii)** Advaxis Contract relating to the employment of, or the performance of employment-related services by, any Person, including any employee, consultant or independent contractor, not terminable by Advaxis or its Subsidiaries on ninety (90) days' notice without liability, except to the extent general principles of wrongful termination law may limit Advaxis', its Subsidiaries' or such successor's ability to terminate employees at will;

**(iv)** Advaxis Contract relating to any agreement or plan, including any stock option plan, stock appreciation right plan or stock purchase plan, any of the benefits of which will be increased, or the vesting of benefits of which will be accelerated, by the occurrence of any of the Transactions, including the Merger (either alone or in conjunction with any other event, such as termination of employment), or the value of any of the benefits of which will be calculated on the basis of any of the Transactions;

**(v)** indenture, credit agreement, loan agreement, security agreement, guarantee, note, mortgage or other evidence of indebtedness, in each case providing for indebtedness in excess of $100,000, other than indebtedness solely between or among any of Advaxis and any of its wholly owned Subsidiaries;

**(vi)** Advaxis Contract relating to any agreement, contract or commitment containing any covenant limiting the freedom of Advaxis, its Subsidiaries or the Surviving Company to engage in any line of business or compete with any Person;

**(vii)** Advaxis Contract that contains a put, call, right of first refusal or similar right pursuant to which Advaxis or any of its Subsidiaries would be required to purchase or sell, as applicable, any equity interests of any Person;

**(viii)** material settlement agreement or similar agreement with a Governmental Authority to which Advaxis or any of its Subsidiaries is a party that contains material obligations or limitations on Advaxis' or such Subsidiary's conduct;

**(ix)** Advaxis Contract relating to any agreement, contract or commitment relating to capital expenditures and involving obligations after the date of this Agreement in excess of $100,000 and not cancelable without penalty;

**(x)** Advaxis Contract relating to any agreement, contract or commitment currently in force relating to the disposition or acquisition of material assets or any ownership interest in any Entity in excess of $100,000;

**(xi)** Advaxis Contract relating to (i) any distribution agreement (identifying any that contain exclusivity provisions); (ii) any agreement involving provision of services or products with respect to any pre-clinical or clinical development activities of Advaxis (iii) any dealer, distributor, joint marketing, alliance, joint venture, cooperation, development or other agreement currently in force under which Advaxis or its Subsidiaries has continuing obligations to develop or market any product, technology or service, or any agreement pursuant to which Advaxis or its Subsidiaries has continuing obligations to develop any Intellectual Property that will not be owned, in whole or in part, by Advaxis or such Subsidiary; or (iv) any Contract currently in force to license any third party to manufacture or produce any Advaxis product, service or technology or any Contract currently in force to sell, distribute or commercialize any Advaxis products or service, except, in each case, agreements entered in the Ordinary Course of Business;

**(xii)** Advaxis Contract with any Person, including any financial advisor, broker, finder, investment banker or other Person, providing advisory services to Advaxis in connection with the transactions set forth in this Agreement, including the Merger;

**(xiii)** Advaxis Contract pursuant to which any Advaxis IP Rights are licensed by or to Advaxis or any of its Subsidiaries, other than (A) "shrink wrap" or other licenses for generally commercially available software (including open source software) or hosted services, (B) customer or channel partner Advaxis Contracts substantially on Advaxis' or any of its Subsidiaries' standard forms, (C) Advaxis Contracts that authorizes Advaxis or any of its Subsidiaries to identify another Person as a customer, vendor, supplier or partner or that authorizes another Person to identify Advaxis or any of its Subsidiaries as a customer, vendor, supplier or partner of such Person, (D) Advaxis Contracts that provide a limited, non-exclusive license to use the trademarks included in the Advaxis IP Rights to promote any products or services of Advaxis or its Subsidiaries or to otherwise provide such products or services to others, (E) Advaxis Contracts with Advaxis' or its Subsidiaries' employees or contractors substantially on Advaxis' or its Subsidiaries' standard forms, and (F) non-disclosure agreements (the "***Advaxis Standard Contracts***"); or

**(xiv)** other agreement, contract or commitment (i) which involves payment or receipt by Advaxis or its Subsidiaries under any such agreement, contract or commitment of $100,000 or more in the aggregate or obligations after the date of this Agreement in excess of $100,000 in the aggregate, or (ii) that may not be terminable with no liability or cost within ninety (90) days.

Each such Contract described in clauses (a) through (n) is referred to herein as an "***Advaxis Material Contract***".

**(b)** Advaxis has delivered to Biosight accurate and complete (except for applicable redactions thereto) copies of all Advaxis Material Contracts, including all amendments thereto. There are no Advaxis Material Contracts that are not in written form. Except as would not reasonably be expected to have, individually or in the aggregate, an Advaxis Material Adverse Effect, (i) neither Advaxis nor any of its Subsidiaries is (and, to the Knowledge of Advaxis, no other party is) in default under or breach of any Contract to which Advaxis is a party, there are no events or conditions, including with respect to any events or conditions as a result of the COVID-19 pandemic, which constitute, or, after notice or lapse of time or both, will constitute, a default on the part of Advaxis or any of its Subsidiaries or, to the Knowledge of Advaxis, any counterparty under such Advaxis Contract, (ii) each of the Advaxis Material Contracts is in full force and effect and is a valid, binding and enforceable obligation of Advaxis and its Subsidiaries, except (A) that such enforcement may be subject to the Bankruptcy and Equity Exception, (B) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to equitable defenses and to the discretion of the court before which any proceedings therefor may be brought, and (C) to the extent that any Advaxis Material Contract expires in accordance with its terms, and (iii) Advaxis and its Subsidiaries have performed all respective material obligations required to be performed by them to date under the Advaxis Material Contracts to which they are a party.

**2.10** Liabilities. Neither Advaxis nor any of its Subsidiaries has any liability, indebtedness, obligation, expense, claim, deficiency, guaranty or endorsement of any kind, whether accrued, absolute, contingent, matured, unmatured or other (whether or not required to be reflected in the financial statements in accordance with GAAP) (each a "***Liability***"), except for (a) Liabilities identified as such in the "liabilities" column of the Advaxis Unaudited Interim Balance Sheet; (b) normal and recurring current liabilities that have been incurred by Advaxis or its Subsidiaries since the date of the Advaxis Unaudited Interim Balance Sheet in the Ordinary Course of Business and which are not in excess of $100,000 in the aggregate; (c) Liabilities for performance in the Ordinary Course of Business of executory obligations of Advaxis or any of its Subsidiaries under Advaxis Contracts in accordance with their written terms (which would not include, for example, any instances of breach or indemnification or any violation of any Legal Requirement or Order); (d) Liabilities incurred in connection with this Agreement; and (e) Liabilities listed in Part 2.10 of the Advaxis Disclosure Schedule.

**2.11** Compliance; Permits; Restrictions.

**(a)** Advaxis and each of its Subsidiaries are, and since November 1, 2015 have been, in compliance in all material respects with all applicable Legal Requirements, including (i) the Federal Food, Drug and Cosmetic Act ("***FDCA***"); (ii) the Public Health Service Act ("***PHSA***"); (iii) all federal or state criminal or civil fraud and abuse Legal Requirements; (iv) any comparable state or local Legal Requirements; and (v) any applicable state licensing, disclosure and reporting requirements (all of the foregoing, collectively, "***Healthcare Laws***"). No investigation, claim, suit, proceeding, audit or other action by any Governmental Authority is pending or, to the Knowledge of Advaxis, threatened against Advaxis or any of its Subsidiaries, nor has any Governmental Authority indicated to Advaxis in writing an intention to conduct the same. There is no agreement, judgment, injunction, order or decree binding upon Advaxis or any of its Subsidiaries which (i) has or would reasonably be expected to have the effect of prohibiting or materially impairing any business practice of Advaxis or any of its Subsidiaries, any acquisition of material property by Advaxis or any of its Subsidiaries or the conduct of business by Advaxis or any of its Subsidiaries as currently conducted, (ii) may have an adverse effect on Advaxis' ability to comply with or perform any covenant or obligation under this Agreement, or (iii) may have the effect of preventing, delaying, making illegal or otherwise interfering with the Merger or any of the Transactions.

**(b)** Advaxis and its Subsidiaries hold all required Governmental Authorizations which are material to the operation of the business of Advaxis (the "***Advaxis Permits***") as currently conducted. Part 2.11(b) of the Advaxis Disclosure Schedule identifies each Advaxis Permit, including the holder of the Advaxis Permit, the name of the Advaxis Permit, and the date of expiration. Each of Advaxis and its Subsidiaries is in material compliance with the terms of the Advaxis Permits and the Advaxis Permits are in full force and effect. All fees and charges with respect to the Advaxis Permits, as of the date hereof, have been paid in full, and all filing, reporting, record keeping, and maintenance obligations required under the applicable Advaxis Permits and Healthcare Laws have been completely and timely satisfied. All such reports, records, and filings were complete and accurate in all material respects, or were subsequently updated, changed, corrected, or modified. No action, proceeding, revocation proceeding, amendment procedure, writ, injunction or claim is pending or, to the Knowledge of Advaxis, threatened, which seeks to revoke, materially limit, suspend, or materially modify any Advaxis Permit. The rights and benefits of each material Advaxis Permit will be available to the Surviving Company immediately after the Effective Time on terms substantially identical to those enjoyed by Advaxis and its Subsidiaries as of the date of this Agreement and immediately prior to the Effective Time. There have been no occurrences, events, or Legal Proceedings that are pending, under investigation, or to the Knowledge of Advaxis, threatened, nor has Advaxis received any written notice which has resulted in or would reasonably be expected to result in any material limitation, adverse modification, revocation, withdrawal, cancellation, lapse, integrity review, suspension, or any other adverse action against any Advaxis Permit.

**(c)** There are no proceedings pending or, to the Knowledge of Advaxis, threatened with respect to an alleged violation by Advaxis or any of its Subsidiaries of the FDCA, PHSA, Food and Drug Administration ("***FDA***") regulations adopted thereunder, the Controlled Substance Act or any other similar Legal Requirements promulgated by the FDA or other comparable Governmental Authority responsible for regulation of the development, clinical testing, manufacturing, sale, marketing, distribution and importation or exportation of drug products ("***Drug Regulatory Agency***"). Advaxis has not been restrained by any Governmental Authority or other Person in its ability to conduct or have conducted the manufacturing, clinical and pre-clinical investigation, handling, shipping, packaging, labeling, storage, import, export, or distribution of its Advaxis Product Candidates.

**(d)** Advaxis and each of its Subsidiaries holds all required Governmental Authorizations issuable by any Drug Regulatory Agency necessary for the conduct of the business of Advaxis or such Subsidiary as currently conducted, and, to the extent applicable, development, clinical testing, manufacturing, marketing, distribution and importation or exportation, as currently conducted, of any of its products or product candidates (the "***Advaxis Product Candidates***") (collectively, the "***Advaxis Regulatory Permits***"), and no such Advaxis Regulatory Permit has been (i) revoked, withdrawn, suspended, cancelled or terminated or (ii) modified in any adverse manner, other than immaterial adverse modifications. Advaxis and each of its Subsidiaries is in compliance in all material respects with the Advaxis Regulatory Permits and has not received any written notice or other written communication from any Drug Regulatory Agency regarding (A) any material violation of or failure to comply materially with any term or requirement of any Advaxis Regulatory Permit or (B) any revocation, withdrawal, suspension, cancellation, termination or material modification of any Advaxis Regulatory Permit. Except for the information and files identified in Part 2.11(d) of the Advaxis Disclosure Schedule, Advaxis has made available to Biosight all information requested by Biosight in Advaxis' or its Subsidiaries' possession or control relating to the Advaxis Product Candidates and the development, clinical testing, manufacturing, importation and exportation of the Advaxis Product Candidates, including complete copies of the following (to the extent there are any) (x) adverse event reports; clinical study reports and material study data; inspection reports, notices of adverse findings, warning letters, filings and letters and other written correspondence to and from any Drug Regulatory Agency; and meeting minutes with any Drug Regulatory Agency; and (y) similar reports, material study data, notices, letters, filings, correspondence and meeting minutes with any other Governmental Authority.

**(e)** All material preclinical and clinical investigations conducted or sponsored by or on behalf of and intended to be submitted to a Governmental Authority to support a Governmental Authorization are being and have been conducted in compliance in all material respects with all applicable Healthcare Laws administered or issued by the applicable Governmental Authority, including, as applicable, (i) the FDA regulations for conducting non-clinical laboratory studies contained in Title 21 part 58 of the Code of Federal Regulations, (ii) applicable FDA standards for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials contained in Title 21 parts 50, 54, 56 and 312 of the Code of Federal Regulations and (iii) applicable federal, state and foreign Healthcare Laws restricting the use and disclosure of individually identifiable health information, including HIPAA. Neither Advaxis or its Subsidiaries, nor, to the Knowledge of Advaxis, any of third party conducting a clinical or preclinical study on their behalf, has received any written notice, correspondence or other written communication from the FDA or any other Governmental Authority or from any institutional review board, ethics committee, or analogous review board (collectively "***IRB***") requiring or threatening the termination, suspension, delay, restriction, rejection, or material modification of any ongoing, completed, or planned clinical or pre-clinical trials conducted by, or on behalf of, Advaxis. The study reports, protocols, and statistical analysis plans for all such material preclinical and clinical investigations, accurately, completely, and fairly reflect the results from and plans for such studies. Advaxis has no Knowledge of any other studies, the results of which are inconsistent or otherwise call into question the results of the material preclinical and clinical investigations. Advaxis does not have any Knowledge of any material facts or circumstances related to the safety or efficacy of the Advaxis Product Candidates that would materially and adversely affect its ability to receive or maintain a Governmental Authorization.

**(f)** As of the date of this Agreement, no data generated by or on behalf of Advaxis or its Subsidiaries with respect to the Advaxis Product Candidates is the subject of any written regulatory investigation, claim, suit, proceeding, audit or other action, either pending, or to the Knowledge of Advaxis, threatened by any Governmental Authority relating to the truthfulness or scientific integrity of such data.

**(g)** Neither Advaxis, any of its Subsidiaries, nor, to the Knowledge of Advaxis, any Person providing services on their behalf, is the subject of any pending, or to the Knowledge of Advaxis, threatened investigation in respect of its business or the Advaxis Product Candidates by the FDA pursuant to its "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or otherwise with respect to any other untrue or false statement or omission. To the Knowledge of Advaxis, neither Advaxis nor any of its Subsidiaries or Persons proving services on their behalf, has committed any acts, made any statement, or failed to make any statement, in each case in respect of its business or the Advaxis Product Candidates that would violate the FDA's "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy, and any amendments thereto. None of Advaxis, any of its Subsidiaries, to the Knowledge of Advaxis, any of their respective officers, employees or agents, or to the Knowledge of Advaxis, any Person providing services on Advaxis' or its Subsidiaries' behalf, have been debarred, disqualified, or excluded, or have been convicted of any crime or engaged in any conduct that could result in a debarment, disqualification, or exclusion (i) under 21 U.S.C. Section 335a, (ii) under 42 U.S.C. §1320a-7, (iii) with respect to federal procurement or non-procurement programs, including those produced by the U.S. General Services Administration, (iv) under 21 C.F.R. Parts 312, 511, or 812 or otherwise with respect to the receipt of investigational products, or (v) any similar applicable Legal Requirement. To the Knowledge of Advaxis, no debarment, ineligibility, or exclusionary claims, actions, proceedings or investigations in respect of their business or the Advaxis Product Candidates are pending or threatened against Advaxis, any of its Subsidiaries, any of their respective officers, employees or agents, or any Person providing services on behalf of Advaxis or its Subsidiaries.

**(h)** To the Knowledge of Advaxis, no Advaxis Product Candidate manufactured or distributed by or on behalf of Advaxis or its Subsidiaries is (i) adulterated within the meaning of 21 U.S.C. §351 (or any similar Healthcare Law), (ii) misbranded within the meaning of 21 U.S.C. §352 (or any similar Healthcare Law); or (iii) otherwise prohibited from introduction into interstate commerce under applicable Legal Requirements. As of the date of this Agreement, neither the Advaxis or its Subsidiaries nor, to the Knowledge of Advaxis and with respect to services provided to Advaxis, any of their respective contractors, including, but not limited to, contract manufacturers, has received any FDA Form 483, warning letter, untitled letter, cyber letter, reprimand, regulatory letter, adverse inspectional findings, notice of integrity review or investigation, request for corrective or remedial action, deficiency notice, or other similar correspondence or written notice from the FDA or any other regulatory authority alleging or asserting material noncompliance with any applicable Healthcare Laws or Advaxis Permits issued to Advaxis or its Subsidiaries by the FDA or any other regulatory authority. No manufacturing site owned by Advaxis or its Subsidiaries, to the Knowledge of Advaxis, any of their respective contract manufacturers, is or has been subject to a shutdown or import or export prohibition imposed by FDA or another regulatory authority.

**(i)** No Advaxis Product Candidate has been or has been requested by a regulatory authority or other Person to be recalled, withdrawn, removed, suspended, seized, the subject of a corrective action, or discontinued (whether voluntarily or otherwise) (collectively "***Recall"***). Neither Advaxis, its Subsidiaries, nor, to the Knowledge of Advaxis, any regulatory authority or other Person, has sought, is seeking, or, to the Knowledge of Advaxis, has or is currently threatening or contemplating any Recall of any such Advaxis Product Candidate.

**2.12** Tax Matters.

**(a)** Advaxis and each of its Subsidiaries has duly timely filed all U.S. federal income Tax Returns and other material Tax Returns that they were required to file under applicable Legal Requirements (taking into account any valid applicable extension of time within which to file). All such Tax Returns are true, correct and complete in all material respects and have been prepared in material compliance with all applicable Legal Requirements. No claim has ever been made in writing by a Governmental Authority in a jurisdiction where Advaxis or any of its Subsidiaries does not file Tax Returns that any of them is or may be subject to taxation by that jurisdiction, which claim has not been resolved.

**(b)** All material Taxes due and payable by Advaxis or any of its Subsidiaries (whether or not shown on any Tax Return), other than Taxes that are being contested in good faith by appropriate proceedings and with respect to which adequate reserves have been made in accordance with GAAP, have been timely paid in full. All material Taxes of Advaxis and its Subsidiaries incurred but not yet due and payable (i) for periods covered by the Advaxis Financial Statements have been accrued and adequately disclosed on the Advaxis Financial Statements in accordance with GAAP and (ii) for periods not covered by the Advaxis Financial Statements have been accrued for on the books and records of Advaxis or the relevant Subsidiary of Advaxis. Since the date of the Advaxis Unaudited Interim Balance Sheet, neither Advaxis nor any of its Subsidiaries has incurred any Liability for Taxes outside the Ordinary Course of Business.

**(c)** Advaxis and each of its Subsidiaries have timely (i) withheld all material Taxes required to have been withheld in connection with any amounts paid or owing to any employee, independent contractor, creditor, stockholder or other third party and (ii) remitted such amounts required to be remitted to the appropriate Governmental Authority.

**(d)** There are no Encumbrances for Taxes upon any of the assets of Advaxis or any of its Subsidiaries (other than Permitted Encumbrances for Taxes).

**(e)** No material deficiencies for Taxes with respect to Advaxis or any of its Subsidiaries have been claimed, proposed or assessed by any Governmental Authority in writing that have not been fully resolved. There are no pending (or, based on written notice, threatened) audits, assessments or other actions for or relating to any Liability in respect of Taxes of Advaxis or any of its Subsidiaries. No issues relating to Taxes of Advaxis or any of its Subsidiaries were raised by the relevant Governmental Authority in any completed audit or examination that would reasonably be expected to result in a material amount of Taxes in a later taxable period that would not otherwise be expected to be imposed absent such audit or examination. Advaxis has delivered or made available to Biosight complete and accurate copies of all U.S. federal income Tax Returns and all other material Tax Returns of Advaxis and each of its Subsidiaries (and any predecessors of either) for all taxable years remaining subject to assessment under the applicable statute of limitations, and complete and accurate copies of all examination reports and statements of deficiencies assessed against or agreed to by Advaxis and each of its Subsidiaries (and any predecessors of either), with respect to U.S. federal income Taxes and all other material Taxes. Neither Advaxis nor any of its Subsidiaries (or any of their predecessors) has waived any statute of limitations in respect of Taxes or agreed to any extension of time with respect to a Tax assessment or deficiency that has not expired, nor has any request been made in writing for any such extension or waiver that is currently pending.

**(f)** Neither Advaxis nor any of its Subsidiaries will be required to include any material item of income in, or exclude any material item of deduction from, taxable income for any taxable period (or portion thereof) ending after the Closing Date as a result of any: (i) change in any method of accounting, or use of an impermissible period of accounting, in either case for a taxable period (or portion thereof) ending on or prior to the Closing Date; (ii) ruling by, or written agreement with, a Governmental Authority (including any closing agreement pursuant to Section 7121 of the Code or any similar provision of Tax Legal Requirement) issued or executed prior to the Closing; (iii) installment sale or open transaction disposition made prior to the Closing; (iv) prepaid amount received prior to the Closing; (v) intercompany transaction or excess loss accounts described in the Treasury Regulations promulgated under Section 1502 of the Code (or any corresponding or similar provision of state, local or foreign income Legal Requirement) that existed prior to the Closing; or (vi) Section 965 of the Code.

**(g)** Neither Advaxis nor any of its Subsidiaries has been a United States real property holding corporation within the meaning of Section 897(c)(2) of the Code during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code.

**(h)** Neither Advaxis nor any of its Subsidiaries is a party to, or bound by, or has any obligation to, any Governmental Authority or other Person any Tax allocation, Tax sharing or similar agreement (including Tax indemnity arrangements), other than commercial contracts entered into in the Ordinary Course of Business with vendors, customers and landlords.

**(i)** Neither Advaxis nor any of its Subsidiaries has ever been a member of an affiliated group filing a consolidated, combined, unitary or other group Tax Return (other than a group the common parent of which is Advaxis) for U.S. federal, state, local or foreign Tax purposes. Neither Advaxis nor any of its Subsidiaries has any Liability for the Taxes of any Person (other than Advaxis and its Subsidiaries) under Treasury Regulations Section 1.1502-6 (or any similar provision of state, local, or foreign Legal Requirement), as a transferee or successor, by Contract, or otherwise.

**(j)** Neither Advaxis nor any of its Subsidiaries has distributed stock of another Person, or has had its stock distributed by another Person, in a transaction that was purported or intended to be governed in whole or in part by Section 355 of the Code or Section 361 of the Code.

**(k)** Neither Advaxis nor any of its Subsidiaries is a partner for Tax purposes with respect to any joint venture, partnership, or, to the Knowledge of Advaxis, other arrangement or contract which is treated as a partnership for Tax purposes.

**(l)** Neither Advaxis nor any of its Subsidiaries has entered into any transaction identified as a “listed transaction” for purposes of Treasury Regulations Sections 1.6011-4(b).

**(m)** Neither Advaxis nor any of its Subsidiaries has taken any action, or has any knowledge of any fact or circumstance, that could reasonably be expected to prevent the Transactions, including the Merger, from qualifying for the Intended Tax Treatment.

**(n)** Immediately prior to the Merger, Advaxis will be in "control" of Merger Sub within the meaning of Section 368(c)(1) of the Code. Advaxis has no plan or intention to reacquire any of the Advaxis Common Stock issued in the Merger. Advaxis has no plan or intention to liquidate Biosight, merge Biosight with or into another corporation, sell or otherwise dispose of the stock of Biosight except for transfers of stock to corporations controlled by Advaxis, or cause Biosight to sell or otherwise dispose of any of its assets or any assets acquired from Merger Sub, except for distributions made in the Ordinary Course of Business or transfers of assets to a corporation controlled by Biosight. Advaxis does not own, nor has it owned during the past five (5) years, any shares of the stock of Biosight.

**2.13** Employee and Labor Matters; Benefit Plans.

**(a)** Part 2.13(a) of the Advaxis Disclosure Schedule sets forth, with respect to each current employee of Advaxis or any of its Subsidiaries, (i) the name of such employee and the date as of which such employee was originally hired by Advaxis or any of its Subsidiaries, and whether the employee is on an active or inactive status, (ii) such employee's title, (iii) such employee's monthly compensation as of the date of this Agreement, including base salary, bonus and commission potential, and (iv) whether such employee is not fully available to perform work because of a qualified disability or other leave and, if applicable, the type of leave (e.g., disability, workers compensation, family or other leave protected by applicable Legal Requirements) and the anticipated date of return to full service. Other than their salary, Advaxis' employees are not entitled to any payment or benefit that may be reclassified as part of their determining salary for all intents and purposes, including for social contributions and severance pay. No Advaxis employee is entitled (whether by virtue of any law, Contract or otherwise) to any benefits, entitlement or compensation that is not detailed in Part 2.13(a) of the Advaxis Disclosure Schedule.

**(b)** Part 2.13(b) of the Advaxis Disclosure Schedule sets forth a true and complete list of all present contractors of Advaxis who are entitled to an average monthly compensation of more than $10,000 in consideration for their services, and includes each such contractor's name, engaging entity, date of commencement, and rate of all regular compensation and benefits, bonus or any other compensation payable to such contractor. Except as set forth in Part 2.13(b) of the Advaxis Disclosure Schedule, all current and former contractors of Advaxis are (or were, as applicable) rightly classified as independent contractors and Advaxis has not engaged any consultants, sub-contractors, sales agents or freelancers who, according to any applicable Legal Requirement, would be entitled to the rights of an employee vis-à-vis Advaxis.

**(c)** Neither Advaxis nor any of its Subsidiaries is a party to, bound by, negotiating or required to negotiate any collective bargaining agreement or other agreement with a labor union or other labor organization. To the Knowledge of Advaxis, no employees of Advaxis or any of its Subsidiaries are represented by any labor union or other labor organization. To the Knowledge of Advaxis, there are no activities or proceedings of any labor union or other labor organization to organize any employees of Advaxis or any of its Subsidiaries and no demand for recognition or certification as the exclusive bargaining representative of any employees has been made by or on behalf of any labor union or other labor organization. There are no pending or, to the Knowledge of Advaxis, threatened, and, since November 1, 2017, there have been no, strikes, lockouts, union organization activities (including, but not limited to, union organization campaigns or requests for representation), pickets, slowdowns, stoppages, material grievances or collective labor disputes or similar activity in respect of the business of Advaxis or its Subsidiaries that may, individually or in the aggregate, interfere in any material respect with the respective business activities of Advaxis or any of its Subsidiaries. Advaxis and each of its Subsidiaries is not engaged in and, since November 1, 2017, have not engaged in any unfair labor practice that has resulted or could reasonably be expected to result, individually or in the aggregate, in any material liability to Advaxis or any of its Subsidiaries. There is no material unfair labor practice charge against Advaxis or any of its Subsidiaries pending or, to the Knowledge of Advaxis, threatened before the National Labor Relations Board or any similar Governmental Authority that could reasonably be expected to result in any material liability to Advaxis or any of its Subsidiaries.

**(d)** Advaxis and each of its Subsidiaries is, and, since November 1, 2017, has been, in compliance in all material respects with all applicable Legal Requirements respecting labor, employment, fair employment practices (including equal employment opportunity laws), terms and conditions of employment, classification of employees, workers' compensation, occupational safety and health, immigration, affirmative action, harassment (including sexual harassment), employee and data privacy, plant closings, wages and work and rest hours. There is no pending or, to the Knowledge of Advaxis, threatened charge, complaint, arbitration, audit or investigation brought by or on behalf of, or otherwise involving, any current or former employee, any Person alleged to be a current or former employee, any applicant for employment, or any class of the foregoing, or any Governmental Authority, that involve the labor or employment relations and practices of Advaxis or any of its Subsidiaries that could reasonably be expected to result, individually or in the aggregate, in any material liability to Advaxis or any of its Subsidiaries.

**(e)** To the Knowledge of Advaxis, no senior executive or other key employee of Advaxis or any of its Subsidiaries is party to any confidentiality, non-competition, non-solicitation, proprietary rights or other such agreement that would materially restrict the performance of such Person's employment duties with Advaxis or its Subsidiaries or the ability of Advaxis and/or any of its Subsidiaries to conduct its or their business.

**(f)** Neither Advaxis nor any of its Subsidiaries has incurred any material liability or obligation under the Worker Adjustment and Retraining Notification Act or any similar state or local Legal Requirement that remains unsatisfied.

**(g)** All material payments due from Advaxis and any of its Subsidiaries on account of wages or other compensation, and employee health and welfare insurance and other benefits, have been timely paid as and when they have become due and owing.

**(h)** To the Knowledge of Advaxis, in the last five (5) years, no allegations of sexual harassment have been made to Advaxis against any individual in his or her capacity as director or an employee of Advaxis at a level of Senior Vice President or above

**(i)** Advaxis has delivered to Biosight true and complete copies of the Advaxis Equity Plans and form of agreement evidencing each Advaxis Option or Advaxis RSU, and has also delivered any other stock option, RSU award or other equity or equity-related award agreements to the extent there are material variations from the applicable form of agreement, specifically identifying the Person(s) to whom such material variant forms apply. With respect to Advaxis Options granted pursuant to the Advaxis Equity Plans, (i) each Advaxis Option intended to qualify as an "incentive stock option" under Section 422 of the Code so qualifies, (ii) each grant of an Advaxis Option was duly authorized no later than the date on which the grant of such Advaxis Option was by its terms to be effective by all necessary corporate action, including, as applicable, approval by the Board of Directors of Advaxis (or a duly constituted and authorized committee thereof) and any required stockholder approval by the necessary number of votes or written consents, and the award agreement governing such grant (if any) was duly executed and delivered by each party thereto, (iii) each Advaxis Option grant was made in accordance with the terms of the Advaxis Equity Plans and all other Legal Requirements and (iv) the per share exercise price of each Advaxis Option was no less than the fair market value of a share of Advaxis Common Stock on the applicable effective date of such grant.

**(j)** Part 2.13(j) of the Advaxis Disclosure Schedule sets forth an accurate and complete list of each material Advaxis Benefit Plan. "***Advaxis Benefit Plan***" shall mean each benefit or compensation plan, program, policy, practice, contract, agreement or other arrangement, covering current or former employees, directors or independent contractors of Advaxis or any of its Subsidiaries, including, but not limited to, "employee benefit plans" within the meaning of Section 3(3) of ERISA, employment, consulting, retirement, pension, disability coverage, severance, termination or change in control agreements, deferred compensation, vacation, sick, stock option, stock purchase, stock appreciation rights, stock-based or other equity-based (including the Advaxis Equity Plans), incentive, bonus, supplemental retirement, profit-sharing, insurance, medical, welfare, fringe or other benefits or remuneration of any kind, whether or not in writing and whether or not funded, in each case, which is sponsored, maintained or contributed to by Advaxis or any of its Subsidiaries, or to which Advaxis or any of its Subsidiaries is obligated to contribute. Neither Advaxis nor any of its Subsidiaries has any Liability under Title IV of ERISA by reason of being treated as a single employer with any other employer (whether or not incorporated) under Section 414 of the Code.

**(k)** With respect to each Advaxis Benefit Plan listed on Part 2.13(k) of the Advaxis Disclosure Schedule, Advaxis has made available to Biosight, to the extent applicable, true, correct and complete copies of (A) the Advaxis Benefit Plan document, including any amendments thereto, and all related trust documents, insurance contracts or other funding vehicles, (B) a written description of such Advaxis Benefit Plan if such plan is not set forth in a written document, (C) the most recently prepared actuarial report, (D) the most recent summary plan description together with the summary or summaries of all material modifications thereto, (E) the most recent Internal Revenue Service determination or opinion letter, (F) the two most recent annual reports (Form 5500 or 990 series and all schedules and financial statements attached thereto or any similar form under applicable Legal Requirements), and (G) all material correspondence to or from the IRS, the United States or Department of Labor or any other Governmental Authority received in the last three years with respect to any Advaxis Benefit Plan.

**(l)** Each Advaxis Benefit Plan (including any related trusts), other than "multiemployer plans" within the meaning of Section 3(37) of ERISA (each, a "***Multiemployer Plan***") has been, in all material respects, established, operated and administered in compliance with its terms and applicable Legal Requirements, including ERISA and the Code. Neither Advaxis nor any of its Subsidiaries nor, to the Knowledge of Advaxis, any other Person, has made any binding commitment to materially modify, change or terminate any Advaxis Benefit Plan, other than with respect to a modification, change or termination required by ERISA or the Code, and there has been no amendment to, or written interpretation or announcement by Advaxis or any of its Subsidiaries regarding any Advaxis Benefit Plan that would materially increase the expense of maintaining such Advaxis Benefit Plan.

**(m)** Except as set forth on Part 2.13(m) of the Advaxis Disclosure Schedule, no Advaxis Benefit Plan is maintained outside the jurisdiction of the United States.

**(n)** Each Advaxis Benefit Plan intended to be "qualified" within the meaning of Section 401(a) of the Code has received a favorable determination or opinion letter from the Internal Revenue Service or is entitled to rely upon a favorable opinion issued by the Internal Revenue Service, and to the Knowledge of Advaxis, there are no existing circumstances that could reasonably be expected to affect adversely the qualified status of any such Advaxis Benefit Plan.

**(o)** Neither Advaxis, any Advaxis Benefit Plan nor, to the Knowledge of Advaxis, any trustee, administrator or other third-party fiduciary and/or party-in-interest thereof, has engaged in any breach of fiduciary responsibility or any "prohibited transaction" (as such term is defined in Section 406 of ERISA or Section 4975 of the Code) to which Section 406 of ERISA or Section 4975 of the Code applies and which could subject Advaxis or any of its Affiliates to the tax or penalty on prohibited transactions imposed by Section 4975 of the Code, which, assuming the taxable period of such transaction expired as of the date hereof, could reasonably be expected to result in a material liability to Advaxis or any of its Subsidiaries. Neither Advaxis nor any of its Subsidiaries has engaged in a transaction that would reasonably be expected to result in a material civil penalty under Sections 409 or 502(i) of ERISA.

**(p)** There are no pending, or to the Knowledge of Advaxis, threatened claims (other than routine claims for benefits) by, on behalf of or against or in connection with any Advaxis Benefit Plan or any trust related thereto which could reasonably be expected to result in any material liability to Advaxis or any of its Subsidiaries, and no audit or other proceeding by a Governmental Authority is pending, or to the Knowledge of Advaxis, threatened with respect to any Advaxis Benefit Plan.

**(q)** No Advaxis Benefit Plan is or has at any time within the past six years been covered by Title IV of ERISA or subject to Section 412 of the Code or Section 302 of ERISA, and neither Advaxis, any of its Subsidiaries has at any time within the past six (6) years participated in or contributed to, or is or has been obligated to contribute to, or has otherwise incurred any obligation or liability (including any contingent liability) under, any Multiemployer Plan.

**(r)** Except as required by applicable Legal Requirements, no Advaxis Benefit Plan provides retiree or post-employment medical, disability, life insurance or other welfare benefits to any Person, and none of Advaxis or any of its Subsidiaries has any obligation to provide such benefits.

**(s)** No Advaxis Benefit Plan is (i) a "multiple employer plan" (within the meaning of the Code or ERISA), (ii) a "multiple employer welfare arrangement" (within the meaning of Section 3(40) of ERISA), or (iii) a "funded welfare plan" within the meaning of Section 419 of the Code.

**(t)** Except as set forth on Part 2.13(t) of the Advaxis Disclosure Schedule, neither the execution and delivery of this Agreement, shareholder or other approval of this Agreement nor the consummation of the Merger could, either alone or in combination with another event, (i) entitle any employee, director, officer or independent contractor of Advaxis or any of its Subsidiaries to severance pay or any material increase in severance pay, (ii) accelerate the time of payment or vesting, or materially increase the amount of compensation due to any such employee, director, officer or independent contractor, (iii) directly or indirectly cause Advaxis to transfer or set aside any assets to fund any material benefits under any Advaxis Benefit Plan, (iv) otherwise give rise to any material liability under any Advaxis Benefit Plan, (v) limit or restrict the right to merge, materially amend, terminate or transfer the assets of any Advaxis Benefit Plan on or following the Effective Time, (vi) require a "gross-up," indemnification for, or payment to any individual for any taxes imposed under Section 409A Section 4999 of the Code or any other tax, or (vii) result in the payment of any amount that could, individually or in combination with any other such payment, constitute an "excess parachute payment" as defined in Section 280G(b)(1) of the Code.

**2.14** Environmental Matters. Advaxis and each of its Subsidiaries is in material compliance with all applicable Environmental Laws, which compliance includes the possession by Advaxis of all permits and other Governmental Authorizations required under applicable Environmental Laws and compliance with the terms and conditions thereof. Neither Advaxis nor any of its Subsidiaries has received since November 1, 2017 any written notice or other communication (in writing or otherwise), whether from a Governmental Authority, citizens group, employee or otherwise, that alleges that Advaxis or any of its Subsidiaries is not in material compliance with any Environmental Law, and, to the Knowledge of Advaxis, there are no circumstances that may prevent or interfere with Advaxis' or any of its Subsidiaries' material compliance with any Environmental Law in the future. To the Knowledge of Advaxis (i) no current or prior owner of any property leased or controlled by Advaxis or any of its Subsidiaries has received since November 1, 2017 any written notice or other communication relating to property owned or leased at any time by Advaxis or any of its Subsidiaries, whether from a Governmental Authority, citizens group, employee or otherwise, that alleges that such current or prior owner or Advaxis or any of its Subsidiaries is not in material compliance with or has violated in any material respect any Environmental Law relating to such property and (ii) neither it nor any of its Subsidiaries has any material liability under any Environmental Law.

**2.15** Insurance.

**(a)** Each of Advaxis and its Subsidiaries maintains insurance coverage with reputable insurers in such amounts and covering such risks as Advaxis reasonably believes, based on past experience, is adequate for the businesses and operations of Advaxis and its Subsidiaries (taking into account the cost and availability of such insurance). Neither Advaxis nor any of its Subsidiaries has received any written notice of any pending or threatened cancellation (other than in connection with ordinary renewals) or material premium increase (other than premium increases in the ordinary course) with respect to any such material insurance policy, and each Subsidiary of Advaxis is in compliance with all conditions contained therein, except for such noncompliance as has not had and would not reasonably be expected to have, individually or in the aggregate, an Advaxis Material Adverse Effect. All such material insurance policies are in full force and effect will not be affected by, or terminated or lapse by reason of, this Agreement or the consummation of the Merger. There is no material claim pending under any of Advaxis' insurance policies as to which coverage has been denied by the underwriters of such policies.

**(b)** Advaxis has delivered to Biosight accurate and complete copies of the existing policies (primary and excess) of directors' and officers' liability insurance maintained by Advaxis and each of its Subsidiaries as of the date of this Agreement (the "***Existing Advaxis D&O Policies***"). Part 2.15(b) of the Advaxis Disclosure Schedule accurately sets forth the most recent annual premiums paid by Advaxis and each of its Subsidiaries with respect to the Existing Advaxis D&O Policies.

**2.16** Legal Proceedings; Orders.

**(a)** There are no Legal Proceedings pending or, to the Knowledge of Advaxis, threatened in writing against Advaxis or any of its Subsidiaries.

**(b)** Neither Advaxis nor any of its Subsidiaries is a party to or subject to the provisions of any Order specifically imposed upon Advaxis or any of its Subsidiaries.

**2.17** Authority; Binding Nature of Agreement.

**(a)** Each of Advaxis and Merger Sub has all requisite corporate power and authority to execute and deliver this Agreement, to perform its obligations hereunder and, subject to the Advaxis Stockholder Approval, to consummate the Transactions. The execution, delivery and performance of this Agreement and the consummation of the Transactions have been duly and validly authorized by all necessary corporate action, and no other corporate proceedings on the part of either Advaxis or Merger Sub are necessary for it to authorize this Agreement or to consummate the Transactions, except for, in any such case, the adoption of this Agreement by the Advaxis Stockholder Approval. This Agreement has been duly and validly executed and delivered by each of Advaxis and Merger Sub and, assuming due authorization, execution and delivery by the other Parties, is a legal, valid and binding obligation of Advaxis and Merger Sub, enforceable against the Advaxis in accordance with its terms, subject to the Bankruptcy and Equity Exception.

**(b)** The Board of Directors of Advaxis, at a meeting duly called and held, has (i) determined that this Agreement and the Transactions, including the Advaxis Stock Issuance, the Advaxis Certificate of Incorporation Amendment and the Reverse Split, if applicable, are fair to and in the best interests of Advaxis and its stockholders, (ii) approved, adopted and declared advisable this Agreement and the Transactions (including the Advaxis Stock Issuance), (iii) directed that the Advaxis Certificate of Incorporation Amendment, the Reverse Split, if applicable, and the Advaxis Stock Issuance be submitted to a vote at a meeting of Advaxis' stockholders, (iv) recommended the approval of the Advaxis Certificate of Incorporation Amendment, the Reverse Split, if applicable, and the Advaxis Stock Issuance by Advaxis' stockholders (the "***Advaxis Board Recommendation***"), and (v) resolved that no rights be distributed or exercisable under the Rights Agreement, and determined that the Rights Agreement has no force or effect, with respect to the Merger and the other Transactions.

**(c)** The affirmative vote at the Advaxis Stockholders' Meeting or any adjournment or postponement thereof of the holders of a majority of stock represented and entitled to vote thereat in favor of (i) the Advaxis Certificate of Incorporation Amendment, (ii) the Reverse Split, if applicable, and (iii) the Advaxis Stock Issuance (the "***Advaxis Stockholder Approval***") is the only vote or consent of the holders of any class or series of Securities of Advaxis necessary in connection with the consummation of the Transactions, including the Merger.

**2.18** Takeover Statutes.

**(a)** Advaxis has taken all action necessary to exempt or exclude this Agreement and the Transactions, including the Merger, from: (i) the restrictions on business combinations set forth in Section 2 of the Israeli Anti-Trust Law-1988; and (ii) any other similar antitakeover law, statute or regulation (each, a "***Takeover Statute***"). Accordingly, no Takeover Statute applies to this Agreement or the Transactions, including the Merger, with respect to Advaxis.

**(b)** Other than as set forth in Part 2.18(b) of the Advaxis Disclosure Schedule, Advaxis is not party to a rights agreement, "poison pill" or similar agreement or plan.

**2.19** Non-Contravention; Consents. Subject to compliance with the HSR Act and any Foreign Competition Law, obtaining the Advaxis Stockholder Approval for the Transactions and the filing of the Certificate of Merger in accordance with the ICL, neither (x) the execution, delivery or performance of this Agreement by Advaxis, nor (y) the consummation of the Merger or any of the other Transactions, will directly or indirectly (with or without notice or lapse of time):

**(a)** contravene, conflict with or result in a violation of (i) any of the provisions of the Constituent Documents of Advaxis or any of its Subsidiaries, or (ii) any resolution adopted by the stockholders, the Board of Directors or any committee of the Board of Directors of Advaxis;

**(b)** contravene, conflict with or result in a material violation of, or give any Governmental Authority or other Person the right to challenge the Merger or any of the other Transactions or to exercise any remedy or obtain any relief under, any Legal Requirement or any Order to which Advaxis or its Subsidiaries, or any of the assets owned or used by Advaxis or its Subsidiaries, is subject;

**(c)** contravene, conflict with or result in a material violation of any of the terms or requirements of, or give any Governmental Authority the right to revoke, withdraw, suspend, cancel, terminate or modify, any Governmental Authorization that is held by Advaxis or its Subsidiaries or that otherwise relates to the business of Advaxis or its Subsidiaries or to any of the assets owned or used by Advaxis or its Subsidiaries;

**(d)** contravene, conflict with or result in a violation or breach of, or result in a default under, any provision of any Advaxis Contract, or give any Person the right to (i) declare a default or exercise any remedy under any Advaxis Contract; (ii) a rebate, chargeback, penalty or change in delivery schedule under any such Advaxis Contract; (iii) accelerate the maturity or performance of any Advaxis Contract; or (iv) cancel, terminate or modify any term of any Advaxis Contract, except, in the case of any Advaxis Material Contract, any non-material breach, default, penalty or modification and, in the case of all other Advaxis Contracts, any breach, default, penalty or modification that would not result in an Advaxis Material Adverse Effect or default;

**(e)** result in the imposition or creation of any Encumbrance upon or with respect to any asset owned or used by Advaxis or its Subsidiaries (except for minor liens that will not, in any case or in the aggregate, materially detract from the value of the assets subject thereto or materially impair the operations of Advaxis); or

**(f)** result in, or increase the likelihood of, the transfer of any material asset of Advaxis or its Subsidiaries to any Person.

Except (i) for any Consent set forth on Part 2.19 of the Advaxis Disclosure Schedule under any Advaxis Contract, (ii) the Advaxis Stockholder Approval, (iii) the filing of the Certificate of Merger in accordance with the ICL, (iv) any required filings under the HSR Act and any Foreign Competition Law and (v) such consents, waivers, approvals, orders, authorizations, registrations, declarations and filings as may be required under applicable federal and state securities laws, neither Advaxis nor any of its Subsidiaries was, is or will be required to make any filing with or give any notice to, or to obtain any Consent from, any Person in connection with (x) the execution, delivery or performance of this Agreement or (y) the consummation of the Transactions, including the Merger.

**2.20** Bank Accounts; Receivables.

**(a)** Part 2.20(a) of the Advaxis Disclosure Schedule provides accurate information with respect to each account maintained by or for the benefit of Advaxis or any of its Subsidiaries at any bank or other financial institution, including the name of the bank or financial institution, the account number, the balance as of June 30, 2021 and the names of all individuals authorized to draw on or make withdrawals from such accounts.

**(b)** All existing accounts receivable of Advaxis or any of its Subsidiaries (including those accounts receivable reflected on the Advaxis Unaudited Interim Balance Sheet that have not yet been collected and those accounts receivable that have arisen since the date of the Advaxis Unaudited Interim Balance Sheet and have not yet been collected) (i) represent valid obligations of customers of Advaxis or any of its Subsidiaries arising from bona fide transactions entered into in the Ordinary Course of Business, and (ii) are current and are expected to be collected in full when due, without any counterclaim or set off, net of applicable reserves for bad debts on the Advaxis Unaudited Interim Balance Sheet.

**2.21** Brokers and Finders. No Person other than the Advaxis Financial Advisor is entitled to any brokerage, financial advisory, finder's or similar fee or commission payable by any Party in connection with the Transactions, including the Merger, based upon arrangements made by or on behalf of the Board of Directors of Advaxis (or any committee thereof), Advaxis or any of its Subsidiaries (including Merger Sub). Advaxis has made available to Biosight a true, correct and complete copy of each agreement between Advaxis or any of its Subsidiaries and the Advaxis Financial Advisor relating to the Transactions.

**2.22** TID US Business. As of the date of this Agreement, to the Knowledge of Advaxis, none of Advaxis, any of its Subsidiaries, or any of its Affiliates (a) produce, design, test, manufacture, fabricate or develop "critical technologies" as that term is defined in 31 C.F.R. § 800.215; (b) perform the functions as set forth in column 2 of Appendix A to 31 C.F.R. part 800 with respect to covered investment critical infrastructure; or (c) maintain or collect, directly or indirectly, "sensitive personal data" as that term is defined in 31 C.F.R. § 800.241.

**2.23** CARES Act. Advaxis has not applied for or received loans or payments under the CARES Act, claimed any tax credits under the CARES Act or deferred the deposit or payment of any payroll Taxes pursuant to the CARES Act.

**2.24** Disclosure. The information supplied by Advaxis and each of its Subsidiaries for inclusion in the Proxy Statement/Prospectus/Information Statement (including any Advaxis Financial Statements) will not, as of the date of the Proxy Statement/Prospectus/Information Statement or as of the date such information is prepared or presented, (i) contain any statement that is inaccurate or misleading with respect to any material facts or (ii) omit to state any material fact necessary in order to make such information, in the light of the circumstances under which such information is provided, not false or misleading.

**2.25** No Other Representations and Warranties. Except for the representations and warranties contained in this Section 2 neither Advaxis nor any other Person acting on behalf of Advaxis makes any other express or implied representation or warranty. In particular, and without limiting the generality of the foregoing, except for the representations and warranties contained in this Section 2, neither Advaxis nor any other Person makes or has made any express or implied representation or warranty to Biosight or any of its representatives with respect to (a) any financial projection, forecast, estimate, budget or prospect information relating to Advaxis, any of its Subsidiaries or their respective businesses or (b) any oral, written, video, electronic or other information presented to Biosight or any of its authorized representatives in the course of their due diligence investigation of Advaxis, the negotiation of this Agreement or the course of the Transactions (including with respect to the accuracy and completeness thereof). Neither Advaxis nor any other Person will have or be subject to any liability to Biosight or any other Person resulting from the distribution to Biosight, or Biosight's use of, any such information, including any information, documents, projections, forecasts or other material made available to Biosight or any of its authorized representatives in management presentations or otherwise in expectation of the Transactions, unless and to the extent any such information is included in the representations and warranties contained in this Section 2.

SECTION 3. Representations and Warranties of Biosight

Biosight represents and warrants to Advaxis as follows, except as set forth in the corresponding Section or Subsection of the written disclosure schedule delivered by Biosight to Advaxis (the "***Biosight Disclosure Schedule***"). The Biosight Disclosure Schedule shall be arranged in sections and subsections corresponding to the numbered and lettered sections and subsections contained in this Section 3. The disclosures in any section or subsection of the Biosight Disclosure Schedule shall qualify other sections and subsections in this Section 3 to the extent it is reasonably clear from a reading of the disclosure that such disclosure is applicable to such other sections and subsections. The inclusion of any information in the Biosight Disclosure Schedule (or any update thereto) shall not be deemed to be an admission or acknowledgment, in and of itself, that such information is required by the terms hereof to be disclosed, is material, has resulted in or would result in a Biosight Material Adverse Effect, or is outside the Ordinary Course of Business.

**3.1** Subsidiaries; Due Organization.

**(a)** Biosight does not own any capital stock of, or any equity interest of any nature in, any other Entity, other than in its wholly-owned Subsidiary, Biosight Pharmaceuticals Inc., a company incorporated under the laws of the State of Delaware. Biosight has not agreed nor is obligated to make, nor is bound by any Contract under which it may become obligated to make, any future investment in or capital contribution to any other Entity. Biosight has not, at any time, been a general partner of, or has otherwise been liable for any of the debts or other obligations of, any general partnership, limited partnership or other Entity.

**(b)** Each of Biosight and its Subsidiaries is a legal entity duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization and has all requisite power and authority (i) to conduct its business in the manner in which its business is currently being conducted; (ii) to own and use its assets in the manner in which its assets are currently owned and used; and (iii) to perform its obligations under all Contracts by which it is bound.

**(c)** Each of Biosight and its Subsidiaries is qualified to do business as a foreign corporation or other legal entity, and is in good standing, under the laws of all jurisdictions where the nature of its business requires such qualification other than in jurisdictions where the failure to be so qualified individually or in the aggregate would not be reasonably expected to have a Biosight Material Adverse Effect.

**3.2** Articles of Association; Charters and Codes of Conduct. Biosight has delivered to Advaxis accurate and complete copies of the Constituent Documents, including all currently effective amendments thereto, for Biosight and each of its Subsidiaries. Part 3.2 of the Biosight Disclosure Schedule lists, and Biosight has delivered to Advaxis, accurate and complete copies of (a) the charters of all committees of Biosight's Board of Directors; and (b) any code of conduct or similar policy adopted by Biosight or by the Board of Directors, or any committee of the Board of Directors, of Biosight. Neither Biosight nor any of its Subsidiaries has taken any action in breach or violation in any material respect of any of the material provisions of its Constituent Documents nor is in breach or violation in any material respect of any of the material provisions of its Constituent Documents.

**3.3** Capitalization, Etc.

**(a)** The registered share capital of Biosight as of the date of this Agreement consists of 8,900,000 Biosight Shares, par value NIS 0.01 per share, divided into 4,771,488 Biosight Ordinary Shares, 344,452 Ordinary A-1 shares, 40,676 Ordinary A-2 shares, 43,384 Ordinary A-3 shares, 400,000 Preferred B shares, 300,000 Preferred B-1 shares and 3,000,000 Preferred C shares, of which 877,976 Biosight Ordinary Shares, 210,723 Ordinary A-1 shares, 43,384 Ordinary A-3 shares, 215,420 Preferred B shares, 170,377 Preferred B-1 shares and 1,726,215 Preferred C shares are issued and outstanding as of the date of this Agreement as reflected in Part 3.3(a) of the Biosight Disclosure Schedule. All of the outstanding Biosight Shares have been duly authorized and validly issued, and are fully paid and nonassessable. Except as set forth in Part 3.3(a) of the Biosight Disclosure Schedule, none of the outstanding Biosight Shares is entitled or subject to any preemptive right, right of participation, right of maintenance or any similar right and none of the outstanding shares of Biosight is subject to any right of first refusal in favor of Biosight. Except as contemplated herein or as set forth in Part 3.3(a) of the Biosight Disclosure Schedule, there is no Biosight Contract relating to the voting or registration of, or restricting any Person from purchasing, selling, pledging or otherwise disposing of (or granting any option or similar right with respect to), any Biosight Shares. Biosight is not under any obligation, nor is it bound by any Contract pursuant to which it may become obligated, to repurchase, redeem or otherwise acquire any outstanding Biosight Shares or other Securities. Part 3.3(a) of the Biosight Disclosure Schedule accurately and completely lists all repurchase rights held by Biosight with respect to Biosight Shares (including shares issued pursuant to the exercise of stock options) and specifies the number of Biosight Shares subject to such repurchase rights, the purchase price paid by such holder, the vesting schedule under which such repurchase rights lapse. Part 3.3(a) of the Biosight Disclosure Schedule accurately and completely lists all Biosight Shares that are 102 Biosight Shares.

**(b)** Except for the Biosight Employee Plan, and except as set forth in Part 3.3(b) of the Biosight Disclosure Schedule, Biosight does not have any stock option plan or any other plan, program, agreement or arrangement providing for any equity-based compensation for any Person. Biosight has reserved 527,905 Biosight Ordinary Shares for issuance under the Biosight Employee Plans. Of such reserved Biosight Ordinary Shares, 80,510 Biosight Ordinary Shares have been issued pursuant to the exercise of outstanding options, options to purchase 309,407 Biosight Ordinary Shares have been granted and are currently outstanding (with a weighted average exercise price per share of $9.147) and 137,988 Biosight Ordinary Shares remain available for future issuance pursuant to the Biosight Employee Plan. No other shares of capital stock or other voting securities of Biosight are issued, reserved for issuance or outstanding. Part 3.3(b) of the Biosight Disclosure Schedule sets forth the following information with respect to each Biosight Option outstanding as of the date of this Agreement (A) the name of the holder thereof; (B) the number of Biosight Ordinary Shares issuable thereunder or otherwise subject thereto at the time of grant; (C) the number of Biosight Ordinary Shares issuable thereunder or otherwise subject thereto as of the date of this Agreement; (D) if applicable, the exercise price; (E) the date on which such award was granted; (F) the applicable vesting schedule, including the number of vested and unvested shares; (G) the date on which such award expires; (H) if applicable, whether such Biosight Option is an "incentive stock option" (as defined in the Code) or a non-qualified stock option; and (I) if applicable, whether each such Biosight Option is a 102 Biosight Option or 3(i) Biosight Option, and with respect to the 102 Biosight Options, if any, the date of deposit of the applicable board resolution and option agreement with the 102 Trustee. Biosight has made available to Advaxis accurate and complete copies of the Biosight Employee Plan and forms of all award agreements approved for use thereunder. No vesting of Biosight Options will accelerate in connection with the closing of the Transactions.

**(c)** Except for the outstanding Biosight Options and the warrants of Biosight as set forth on Parts 3.3(a), 3.3(b) or 3.3(c) of the Biosight Disclosure Schedule, there is no (i) outstanding subscription, option, call, warrant or right (whether or not currently exercisable) to acquire any shares of the capital stock or other Securities of Biosight or any of its Subsidiaries; (ii) outstanding security, instrument or obligation that is or may become convertible into or exchangeable for any shares of the capital stock or other Securities of Biosight or any of its Subsidiaries; (iii) stockholder rights plan (or similar plan commonly referred to as a "poison pill") or Contract under which Biosight or any of its Subsidiaries is or may become obligated to sell or otherwise issue any shares of its capital stock or any other Securities; or (iv) condition or circumstance that may give rise to or provide a basis for the assertion of a claim by any Person to the effect that such Person is entitled to acquire or receive any shares of capital stock or other Securities of Biosight or any of its Subsidiaries. There are no outstanding or authorized stock appreciation, phantom stock, profit participation or other similar rights with respect to Biosight or any of its Subsidiaries.

**(d)** All outstanding Biosight Shares, as well as all options, warrants and other Securities of Biosight, have been issued and granted in material compliance with (i) all applicable securities laws and other applicable Legal Requirements and (ii) all requirements set forth in applicable Contracts.

**3.4** Financial Statements; Biosight Reports.

**(a)** Part 3.4(a) of the Biosight Disclosure Schedule includes true and complete copies of (i) BioSight's draft unaudited balance sheet for the year ending on December 31, 2020, and (ii) Biosight's draft unaudited statement of operations for the year ended December 31, 2020 (collectively, the "***Biosight Financial Statements***"). The Biosight Financial Statements (i) were prepared in accordance with GAAP (except as may be indicated in the footnotes to such Biosight Financial Statements and that unaudited financial statements may not have notes thereto and other presentation items that may be required by GAAP and are subject to normal and recurring year-end adjustments that are not reasonably expected to be material in amount) applied on a consistent basis unless otherwise noted therein throughout the periods indicated and (ii) fairly present the financial condition and operating results of Biosight as of the dates and for the periods indicated therein.

**(b)** Each of Biosight and its Subsidiaries maintains a system of internal accounting controls designed to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Biosight and each of its Subsidiaries maintains internal control over financial reporting that provides reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP.

**(c)** Since November 1, 2017, there have been no formal internal investigations regarding financial reporting or accounting policies and practices discussed with, reviewed by or initiated at the direction of the chief executive officer, chief financial officer or general counsel of Biosight, Biosight's Board of Directors or any committee thereof. Since November 1, 2017, neither Biosight nor its independent auditors have identified (i) any significant deficiency or material weakness in the system of internal accounting controls utilized by Biosight and its Subsidiaries, (ii) any fraud, whether or not material, that involves Biosight's management or other employees who have a role in the preparation of financial statements or the internal accounting controls utilized by Biosight or any of its Subsidiaries or (iii) any claim or allegation regarding any of the foregoing.

**3.5** Absence of Changes. Except as set forth on Part 3.5 of the Biosight Disclosure Schedule, since the date of the Biosight Financial Statements, (a) except as contemplated by this Agreement, the business of Biosight and its Subsidiaries has been conducted in all material respects in the Ordinary Course of Business, (b) there has not been any Effect which has had a Biosight Material Adverse Effect, and no Effect exists or has occurred which would reasonably be expected to have, individually or in the aggregate, a Biosight Material Adverse Effect and (c) there has not been any action, event or occurrence that would have required consent of Advaxis pursuant to Section 4.3(b) had such action, event or occurrence taken place after the execution and delivery of this Agreement.

**3.6** Title to Assets. Each of Biosight and its Subsidiaries owns, and has good and valid title to, or, in the case of leased properties and assets, valid leasehold interests in, all tangible properties or assets and equipment used or held for use in its business or operations or purported to be owned by it, including (a) all assets reflected on the Biosight Financial Statements; and (b) all other assets reflected in the books and records of Biosight or any of its Subsidiaries as being owned by Biosight or such Subsidiary. All of said assets are owned by Biosight free and clear of any Encumbrances, except for Permitted Encumbrances.

**3.7** Real Property; Leasehold

**(a)** Neither Biosight nor any of its Subsidiaries owns any real property. Except as would not reasonably be expected to have, individually or in the aggregate, a Biosight Material Adverse Effect, (i) each lease, sublease, license, concession and other agreement under which Biosight or its Subsidiaries lease, sublease, use or occupy the real property leased, subleased, licensed or otherwise occupied by Biosight or any of its Subsidiaries, including all material amendments, modifications, extensions and guaranties relating thereto (each, an "***Biosight Lease***" and such real property, the "***Biosight Leased Real Property***") is a valid and binding obligation on Biosight and such of its Subsidiaries party thereto and, to the Knowledge of Biosight, each other party thereto and is in full force and effect and enforceable in accordance with its terms (except that (A) such enforcement may be subject to the Bankruptcy and Equity Exception and (B) the remedy of specific performance and injunctive and other forms of equitable relief may be subject to equitable defenses and to the discretion of the court before which any proceedings therefor may be brought), (ii) there is no breach or default under any Biosight Lease by Biosight or any of its Subsidiaries or, to the Knowledge of Biosight, any other party thereto, (iii) no event has occurred which, with notice, lapse of time or both, would constitute a default under any Biosight Lease by any of Biosight or its Subsidiaries and (iv) Biosight or one of its Subsidiaries that is either the tenant, subtenant or licensee named under the Biosight Lease has a good and valid leasehold interest in each Biosight Leased Real Property which is subject to a Biosight Lease and is in possession of such Biosight Leased Real Property.

**(b)** There are no pending or, to the Knowledge of Biosight, threatened condemnation or eminent domain proceedings that affect any Biosight Leased Real Property and Biosight has not received any written notice of the intention of any Governmental Authority or other Person to take any Biosight Leased Real Property.

**3.8** Intellectual Property.

**(a)** Part 3.8(a) of the Biosight Disclosure Schedule contains a complete and accurate list of all Biosight IP Rights that are owned or purported to be owned by Biosight or any of its Subsidiaries that are registered or the subject of a pending application for registration with any Governmental Authority (the "***Biosight Registered IP***"). All Biosight Registered IP is valid, subsisting and, to the Knowledge of the Biosight, enforceable, and each item of Biosight Registered IP has been prosecuted in good faith, is in good administrative standing, and the deadlines for maintaining any registration for and prosecuting any application to register Intellectual Property included in the Biosight Registered IP up to and including the Closing Date have been satisfied, and any such deadlines occurring in the period up to and including ninety (90) days after the Closing Date have been identified on Part 3.8(a) of the Biosight Disclosure Schedule. All assignments and other vesting instruments pertaining to any Biosight Registered IP have been timely and properly recorded with the applicable Governmental Authority. The owner of record of each item of Biosight Registered IP is the beneficial and legal owner in fact of such Biosight Registered IP and the entity identified as the current assignee and owner thereof on Part 3.8(a) of the Biosight Disclosure Schedule.

**(b)** Biosight or one of its Subsidiaries is the sole and exclusive owner of all right, title and interest in and to the Biosight Registered IP, and owns or has a license, sublicense or otherwise possesses legally enforceable rights to use all other Biosight IP Rights free and clear of all Encumbrances (other than Permitted Encumbrances). The Biosight IP Rights include all of the material Intellectual Property necessary for Biosight and each of its Subsidiaries to conduct their respective businesses as currently conducted.

**(c)** The operation of the business of Biosight and its Subsidiaries as currently conducted, and the use of any Intellectual Property in connection therewith, do not conflict with, infringe, misappropriate, or otherwise violate the Intellectual Property, of any other Person.

**(d)** As of the date of this Agreement, there are no Legal Proceedings pending or, to the Knowledge of Biosight, threatened in writing with respect to any Biosight IP Rights owned or purported to be owned by Biosight and its Subsidiaries, and neither Biosight nor any of its Subsidiaries is a party to any Legal Proceeding relating to any Biosight IP Rights. Within the past five (5) years (or prior thereto if the same is still pending or subject to appeal or reinstatement), neither Biosight nor any of its Subsidiaries has been sued or charged in writing with or been a defendant in any Legal Proceeding that involves a claim of infringement or misappropriation of any Intellectual Property. None of the Biosight IP Rights that is owned or purported to be owned by Biosight and its Subsidiaries is subject to any pending or outstanding injunction, order, judgment, settlement, consent order, ruling or other disposition of dispute that adversely restricts the use, transfer or registration of, or adversely affects the validity or enforceability of, any such Intellectual Property.

**(e)** No past or present director, officer or employee of Biosight or any of its Subsidiaries owns (or has any claim or any right (whether or not currently exercisable) to any ownership interest in or to) any Biosight IP Rights. Biosight and its Subsidiaries have taken commercially reasonable steps to maintain the secrecy, confidentiality and value of all Trade Secrets included in the Biosight IP Rights. No material Trade Secret has been authorized to be disclosed, or, to the Knowledge of Biosight, has been disclosed to any employees or other Person by Biosight or any of its Subsidiaries, other than as subject to an agreement restricting the disclosure and use of such Trade Secret, and to the Knowledge of Biosight, there is no uncured breach by any employee or other Person under any such agreement.

**(f)** Except as set forth in Part 3.8(f) of the Biosight Disclosure Schedule, to the Knowledge of Biosight, no funding, facilities or personnel of any Governmental Authority or any university, college, research institute or other educational institution has been or is being used in any material respect to create, in whole or in part, any material Biosight IP Rights owned or purported to be owned by Biosight or any of its Subsidiaries.

**(g)** Except with respect to the Contracts listed in Part 3.9(a)(xii) of the Biosight Disclosure Schedule and the Biosight Standard Contracts, neither Biosight nor any of its Subsidiaries is obligated under any Contract to make any payments by way of royalties, fees, or otherwise to any owner or licensor of, or other claimant to, any Biosight IP Rights.

**(h)** To the Knowledge of Biosight, the information technology networks, computer hardware, and software applications owned or used by Biosight or any of its Subsidiaries (the "***Biosight IT Systems***") are free of all viruses, worms, Trojan horses and other material known contaminants and do not contain any bugs, errors, or problems of a material nature that could materially disrupt or have a material adverse impact on the operation of the Biosight IT Systems. The Biosight IT Systems are adequate for the operation of the businesses of Biosight and its Subsidiaries as currently conducted. In the last twelve (12) months, there have been no failures, breakdowns, continued substandard performance or other adverse events affecting any such Biosight IT Systems that have caused or could reasonably be expected to result in a material disruption or interruption in or to the use of such Biosight IT Systems or the conduct of the businesses of Biosight or any of its Subsidiaries. Biosight and each of its Subsidiaries have taken commercially reasonable actions intended to protect the security and integrity of the Biosight IT Systems. Neither Biosight nor any of its Subsidiaries has experienced any information security incident that has compromised the integrity or availability of the Biosight IT Systems, and to the Knowledge of Biosight, there has been no material loss, damage, or unauthorized access, disclosure, use, or breach of security of the Biosight IT Systems or any data stored therein.

**3.9** Agreements, Contracts and Commitments.

**(a)** Except as listed in Part 3.9(a) of the Biosight Disclosure Schedule, as of the date of this Agreement, neither Biosight nor any of its Subsidiaries is a party to or bound by any:

**(i)** Biosight Contract relating to any bonus, deferred compensation, severance, incentive compensation, pension, profit-sharing or retirement plans, or any other employee benefit plans or arrangements;

**(ii)** Biosight Contract relating to the employment of, or the performance of employment-related services by, any Person, including any employee, consultant or independent contractor, not terminable by Biosight or its Subsidiaries on ninety (90) days' notice without liability, except to the extent general principles of wrongful termination law may limit Biosight, its Subsidiaries' or such successor's ability to terminate employees at will;

**(iii)** Biosight Contract relating to any agreement or plan, including any stock option plan, stock appreciation right plan or stock purchase plan, any of the benefits of which will be increased, or the vesting of benefits of which will be accelerated, by the occurrence of any of the Transactions, including the Merger (either alone or in conjunction with any other event, such as termination of employment), or the value of any of the benefits of which will be calculated on the basis of any of the Transactions;

**(iv)** indenture, credit agreement, loan agreement, security agreement, guarantee, note, mortgage or other evidence of indebtedness, in each case providing for indebtedness in excess of $100,000, other than indebtedness solely between or among any of Biosight and any of its wholly owned Subsidiaries;

**(v)** Biosight Contract relating to any agreement, contract or commitment containing any covenant limiting the freedom of Biosight, its Subsidiaries or the Surviving Company to engage in any line of business or compete with any Person;

**(vi)** Biosight Contract that contains a put, call, right of first refusal or similar right pursuant to which Biosight or any of its Subsidiaries would be required to purchase or sell, as applicable, any equity interests of any Person;

**(vii)** material settlement agreement or similar agreement with a Governmental Authority to which Biosight or any of its Subsidiaries is a party that contains material obligations or limitations on Biosight or such Subsidiary's conduct;

**(viii)** Biosight Contract relating to any agreement, contract or commitment relating to capital expenditures and involving obligations after the date of this Agreement in excess of $100,000 and not cancelable without penalty;

**(ix)** Biosight Contract relating to any agreement, contract or commitment currently in force relating to the disposition or acquisition of material assets or any ownership interest in any Entity in excess of $100,000;

**(x)** Biosight Contract relating to (i) any distribution agreement (identifying any that contain exclusivity provisions); (ii) any agreement involving provision of services or products with respect to any pre-clinical or clinical development activities of Biosight (iii) any dealer, distributor, joint marketing, alliance, joint venture, cooperation, development or other agreement currently in force under which Biosight or its Subsidiaries has continuing obligations to develop or market any product, technology or service, or any agreement pursuant to which Biosight or its Subsidiaries has continuing obligations to develop any Intellectual Property that will not be owned, in whole or in part, by Biosight or such Subsidiary; or (iv) any Contract currently in force to license any third party to manufacture or produce any Biosight product, service or technology or any Contract currently in force to sell, distribute or commercialize any Biosight products or service, except, in each case, agreements entered in the Ordinary Course of Business;

**(xi)** Biosight Contract with any Person, including any financial advisor, broker, finder, investment banker or other Person, providing advisory services to Biosight in connection with the transactions set forth in this Agreement, including the Merger;

**(xii)** Biosight Contract pursuant to which any Biosight IP Rights are licensed by or to Biosight or any of its Subsidiaries, other than (A) "shrink wrap" or other licenses for generally commercially available software (including open source software) or hosted services, (B) customer or channel partner Biosight Contracts substantially on Biosight or any of its Subsidiaries' standard forms, (C) Biosight Contracts that authorizes Biosight or any of its Subsidiaries to identify another Person as a customer, vendor, supplier or partner or that authorizes another Person to identify Biosight or any of its Subsidiaries as a customer, vendor, supplier or partner of such Person, (D) Biosight Contracts that provide a limited, non-exclusive license to use the trademarks included in the Biosight IP Rights to promote any products or services of Biosight or its Subsidiaries or to otherwise provide such products or services to others, (E) Biosight Contracts with Biosight's or its Subsidiaries' employees or contractors substantially on Biosight's or its Subsidiaries' standard forms, and (F) non-disclosure agreements (the "***Biosight Standard Contracts***"); or

**(xiii)** other agreement, contract or commitment (i) which involves payment or receipt by Biosight or its Subsidiaries under any such agreement, contract or commitment of $100,000 or more in the aggregate or obligations after the date of this Agreement in excess of $100,000 in the aggregate, or (ii) that may not be terminable with no liability or cost within ninety (90) days;

Each such Contract described in clauses (i) through (xiii) is referred to herein as an "***Biosight Material Contract***".

**(b)** Biosight has delivered to Advaxis accurate and complete (except for applicable redactions thereto) copies of all Biosight Material Contracts, including all amendments thereto. There are no Biosight Material Contracts that are not in written form. Except as would not reasonably be expected to have, individually or in the aggregate, a Biosight Material Adverse Effect, (i) neither Biosight nor any of its Subsidiaries is (and, to the Knowledge of Biosight, no other party is) in default under or breach of any Contract to which Biosight is a party, there are no events or conditions, including with respect to any events or conditions as a result of the COVID-19 pandemic, which constitute, or, after notice or lapse of time or both, will constitute, a default on the part of Biosight or any of its Subsidiaries or, to the Knowledge of Biosight, any counterparty under such Biosight Contract, (ii) each of the Biosight Material Contracts is in full force and effect and is a valid, binding and enforceable obligation of Biosight and its Subsidiaries, except (A) that such enforcement may be subject to the Bankruptcy and Equity Exception, (B) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to equitable defenses and to the discretion of the court before which any proceedings therefor may be brought, and (C) to the extent that any Biosight Material Contract expires in accordance with its terms, and (iii) Biosight and its Subsidiaries have performed all respective material obligations required to be performed by them to date under the Biosight Material Contracts to which they are a party.

**3.10** Liabilities. Neither Biosight nor any of its Subsidiaries has any Liability, except for (a) Liabilities identified as such in the "liabilities" column of the Biosight Financial Statements; (b) normal and recurring current liabilities that have been incurred by Biosight or its Subsidiaries since the date of the Biosight Financial Statements in the Ordinary Course of Business and which are not in excess of $100,000 in the aggregate; (c) Liabilities for performance in the Ordinary Course of Business of executory obligations of Biosight or any of its Subsidiaries under Biosight Contracts in accordance with their written terms (which would not include, for example, any instances of breach or indemnification or any violation of any Legal Requirement or Order); (d) Liabilities incurred in connection with this Agreement; and (e) Liabilities listed in Part 3.10 of the Biosight Disclosure Schedule.

**3.11** Compliance; Permits; Restrictions.

**(a)** Biosight and each of its Subsidiaries are, and since November 1, 2015 have been, in compliance in all material respects with all applicable Legal Requirements, including all Healthcare Laws. No investigation, claim, suit, proceeding, audit or other action by any Governmental Authority is pending or, to the Knowledge of Biosight, threatened against Biosight or any of its Subsidiaries, nor has any Governmental Authority indicated to Biosight in writing an intention to conduct the same. There is no agreement, judgment, injunction, order or decree binding upon Biosight or any of its Subsidiaries which (i) has or would reasonably be expected to have the effect of prohibiting or materially impairing any business practice of Biosight or any of its Subsidiaries, any acquisition of material property by Biosight or any of its Subsidiaries or the conduct of business by Biosight or any of its Subsidiaries as currently conducted, (ii) may have an adverse effect on Biosight's ability to comply with or perform any covenant or obligation under this Agreement, or (iii) may have the effect of preventing, delaying, making illegal or otherwise interfering with the Merger or any of the Transactions.

**(b)** Biosight and its Subsidiaries hold all required Governmental Authorizations which are material to the operation of the business of Biosight (the "***Biosight Permits***") as currently conducted. Part 3.11(b) of the Biosight Disclosure Schedule identifies each Biosight Permit, including the holder of the Biosight Permit, the name of the Biosight Permit, and the date of expiration. Each of Biosight and its Subsidiaries is in material compliance with the terms of the Biosight Permits and the Biosight Permits are in full force and effect. All fees and charges with respect to the Biosight Permits, as of the date hereof, have been paid in full, and all filing, reporting, record keeping, and maintenance obligations required under the applicable Biosight Permits and Healthcare Laws have been completely and timely satisfied. All such reports, records, and filings were complete and accurate in all material respects, or were subsequently updated, changed, corrected, or modified. No action, proceeding, revocation proceeding, amendment procedure, writ, injunction or claim is pending or, to the Knowledge of Biosight, threatened, which seeks to revoke, materially limit, suspend, or materially modify any Biosight Permit. The rights and benefits of each material Biosight Permit will be available to the Surviving Company immediately after the Effective Time on terms substantially identical to those enjoyed by Biosight and its Subsidiaries as of the date of this Agreement and immediately prior to the Effective Time. There have been no occurrences, events, or Legal Proceedings that are pending, under investigation, or to the Knowledge of Biosight, threatened, nor has Biosight received any written notice which has resulted in or would reasonably be expected to result in any material limitation, adverse modification, revocation, withdrawal, cancellation, lapse, integrity review, suspension, or any other adverse action against any Biosight Permit.

**(c)** There are no proceedings pending or, to the Knowledge of Biosight, threatened with respect to an alleged violation by Biosight or any of its Subsidiaries of any Legal Requirements promulgated by any Drug Regulatory Agency. Biosight has not been restrained by any Governmental Authority or other Person in its ability to conduct or have conducted the manufacturing, clinical and pre-clinical investigation, handling, shipping, packaging, labeling, storage, import, export, or distribution of its Biosight Product Candidates.

**(d)** Biosight and each of its Subsidiaries holds all required Governmental Authorizations issuable by any Drug Regulatory Agency necessary for the conduct of the business of Biosight or such Subsidiary as currently conducted, and, to the extent applicable, development, clinical testing, manufacturing, marketing, distribution and importation or exportation, as currently conducted, of any of its products or product candidates (the "***Biosight Product Candidates***") (collectively, the "***Biosight Regulatory Permits***"), and no such Biosight Regulatory Permit has been (i) revoked, withdrawn, suspended, cancelled or terminated or (ii) modified in any adverse manner, other than immaterial adverse modifications. Biosight and each of its Subsidiaries is in compliance in all material respects with the Biosight Regulatory Permits and has not received any written notice or other written communication from any Drug Regulatory Agency regarding (A) any material violation of or failure to comply materially with any term or requirement of any Biosight Regulatory Permit or (B) any revocation, withdrawal, suspension, cancellation, termination or material modification of any Biosight Regulatory Permit. Except for the information and files identified in Part 3.11(d) of the Biosight Disclosure Schedule, Biosight has made available to Advaxis all information requested by Biosight in Biosight's or its Subsidiaries' possession or control relating to the Biosight Product Candidates and the development, clinical testing, manufacturing, importation and exportation of the Biosight Product Candidates, including complete copies of the following (to the extent there are any) (x) adverse event reports; clinical study reports and material study data; inspection reports, notices of adverse findings, warning letters, filings and letters and other written correspondence to and from any Drug Regulatory Agency; and meeting minutes with any Drug Regulatory Agency; and (y) similar reports, material study data, notices, letters, filings, correspondence and meeting minutes with any other Governmental Authority.

**(e)** All material preclinical and clinical investigations conducted or sponsored by or on behalf of and intended to be submitted to a Governmental Authority to support a Governmental Authorization are being and have been conducted in compliance in all material respects with all applicable Healthcare Laws administered or issued by the applicable Governmental Authority, including, as applicable, (i) the FDA regulations for conducting non-clinical laboratory studies contained in Title 21 part 58 of the Code of Federal Regulations, (ii) applicable FDA standards for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials contained in Title 21 parts 50, 54, 56 and 312 of the Code of Federal Regulations and (iii) applicable federal, state and foreign Healthcare Laws restricting the use and disclosure of individually identifiable health information, including HIPAA. Neither Biosight or its Subsidiaries, nor, to the Knowledge of Biosight, any of third party conducting a clinical or preclinical study on their behalf, has received any written notice, correspondence or other written communication from the FDA or any other Governmental Authority or from IRB requiring or threatening the termination, suspension, delay, restriction, rejection, or material modification of any ongoing, completed, or planned clinical or pre-clinical trials conducted by, or on behalf of, Biosight. The study reports, protocols, and statistical analysis plans for all such material preclinical and clinical investigations, accurately, completely, and fairly reflect the results from and plans for such studies. Biosight has no Knowledge of any other studies, the results of which are inconsistent or otherwise call into question the results of the material preclinical and clinical investigations. Biosight does not have any Knowledge of any material facts or circumstances related to the safety or efficacy of the Biosight Product Candidates that would materially and adversely affect its ability to receive or maintain a Governmental Authorization.

**(f)** As of the date of this Agreement, no data generated by or on behalf of Biosight or its Subsidiaries with respect to the Biosight Product Candidates is the subject of any written regulatory action, either pending, or to the Knowledge of Biosight, threatened by any Governmental Authority relating to the truthfulness or scientific integrity of such data.

**(g)** Neither Biosight, any of its Subsidiaries, nor, to the Knowledge of Biosight, any Person providing services on their behalf, is the subject of any pending, or to the Knowledge of Biosight, threatened investigation in respect of its business or the Biosight Product Candidates by the FDA pursuant to its "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or otherwise with respect to any other untrue or false statement or omission. To the Knowledge of Biosight, neither Biosight nor any of its Subsidiaries or Persons proving services on their behalf, has committed any acts, made any statement, or failed to make any statement, in each case in respect of its business or the Biosight Product Candidates that would violate the FDA's "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy, and any amendments thereto. None of Biosight, any of its Subsidiaries, to the Knowledge of Biosight, any of their respective officers, employees or agents, or to the Knowledge of Biosight, any Person providing services on Biosight's or its Subsidiaries' behalf, have been debarred, disqualified, or excluded, or have been convicted of any crime or engaged in any conduct that could result in a debarment, disqualification, or exclusion (i) under 21 U.S.C. Section 335a, (ii) under 42 U.S.C. §1320a-7, (iii) with respect to federal procurement or non-procurement programs, including those produced by the U.S. General Services Administration, (iv) under 21 C.F.R. Parts 312, 511, or 812 or otherwise with respect to the receipt of investigational products, or (v) any similar applicable Legal Requirement. To the Knowledge of Biosight, no debarment, ineligibility, or exclusionary claims, actions, proceedings or investigations in respect of their business or the Biosight Product Candidates are pending or threatened against Biosight, any of its Subsidiaries, any of their respective officers, employees or agents, or any Person providing services on behalf of Biosight or its Subsidiaries.

**(h)** To the Knowledge of Biosight, no Biosight Product Candidate manufactured or distributed by or on behalf of Biosight or its Subsidiaries is (i) adulterated within the meaning of 21 U.S.C. §351 (or any similar Healthcare Law), (ii) misbranded within the meaning of 21 U.S.C. §352 (or any similar Healthcare Law); or (iii) otherwise prohibited from introduction into interstate commerce under applicable Legal Requirements. As of the date of this Agreement, neither the Biosight or its Subsidiaries nor, to the Knowledge of Biosight and with respect to services provided to Biosight, any of their respective contractors, including, but not limited to, contract manufacturers, has received any FDA Form 483, warning letter, untitled letter, cyber letter, reprimand, regulatory letter, adverse inspectional findings, notice of integrity review or investigation, request for corrective or remedial action, deficiency notice, or other similar correspondence or written notice from the FDA or any other regulatory authority alleging or asserting material noncompliance with any applicable Healthcare Laws or Biosight Permits issued to Biosight or its Subsidiaries by the FDA or any other regulatory authority. No manufacturing site owned by Biosight or its Subsidiaries, to the Knowledge of Biosight, any of their respective contract manufacturers, is or has been subject to a shutdown or import or export prohibition imposed by FDA or another regulatory authority.

**(i)** No Biosight Product Candidate has been or has been requested by a regulatory authority or other Person to be Recalled. Neither Biosight, its Subsidiaries, nor, to the Knowledge of Biosight, any regulatory authority or other Person, has sought, is seeking, or, to the Knowledge of Biosight, has or is currently threatening or contemplating any Recall of any such Biosight Product Candidate.

**3.12** Tax Matters.

**(a)** Biosight and each of its Subsidiaries has duly timely filed all Israeli income Tax Returns and other material Tax Returns that they were required to file under applicable Legal Requirements (taking into account any valid applicable extension of time within which to file). All such Tax Returns are true, correct and complete in all material respects and have been prepared in material compliance with all applicable Legal Requirements. No claim has ever been made in writing by a Governmental Authority in a jurisdiction where Biosight or any of its Subsidiaries does not file Tax Returns that any of them is or may be subject to taxation by that jurisdiction, which claim has not been resolved.

**(b)** All material Taxes due and payable by Biosight or any of its Subsidiaries (whether or not shown on any Tax Return), other than Taxes that are being contested in good faith by appropriate proceedings and with respect to which adequate reserves have been made in accordance with GAAP, have been timely paid in full. All material Taxes of Biosight and its Subsidiaries incurred but not yet due and payable (i) for periods covered by the Biosight Financial Statements have been accrued and adequately disclosed on the Biosight Financial Statements in accordance with GAAP and (ii) for periods not covered by the Biosight Financial Statements have been accrued for on the books and records of Biosight or the relevant Subsidiary of Biosight. Since the date of the Biosight Financial Statements, neither Biosight nor any of its Subsidiaries has incurred any Liability for Taxes outside the Ordinary Course of Business.

**(c)** Biosight and each of its Subsidiaries have timely (i) withheld all material Taxes required to have been withheld in connection with any amounts paid or owing to any employee, independent contractor, creditor, stockholder or other third party and (ii) remitted such amounts required to be remitted to the appropriate Governmental Authority.

**(d)** There are no Encumbrances for Taxes upon any of the assets of Biosight or any of its Subsidiaries (other than Permitted Encumbrances for Taxes).

**(e)** No material deficiencies for Taxes with respect to Biosight or any of its Subsidiaries have been claimed, proposed or assessed by any Governmental Authority in writing that have not been fully resolved. There are no pending (or, based on written notice, threatened) audits, assessments or other actions for or relating to any Liability in respect of Taxes of Biosight or any of its Subsidiaries. No issues relating to Taxes of Biosight or any of its Subsidiaries were raised by the relevant Governmental Authority in any completed audit or examination that would reasonably be expected to result in a material amount of Taxes in a later taxable period that would not otherwise be expected to be imposed absent such audit or examination. Biosight has delivered or made available to Biosight complete and accurate copies of all Israeli income Tax Returns and all other material Tax Returns of Biosight and each of its Subsidiaries (and any predecessors of either) for all taxable years remaining subject to assessment under the applicable statute of limitations, and complete and accurate copies of all examination reports and statements of deficiencies assessed against or agreed to by Biosight and each of its Subsidiaries (and any predecessors of either), with respect to Israeli income Taxes and all other material Taxes. Neither Biosight nor any of its Subsidiaries (or any of their predecessors) has waived any statute of limitations in respect of Taxes or agreed to any extension of time with respect to a Tax assessment or deficiency that has not expired, nor has any request been made in writing for any such extension or waiver that is currently pending.

**(f)** Neither Biosight nor any of its Subsidiaries will be required to include any material item of income in, or exclude any material item of deduction from, taxable income for any taxable period (or portion thereof) ending after the Closing Date as a result of any: (i) change in any method of accounting, or use of an impermissible period of accounting, in either case for a taxable period (or portion thereof) ending on or prior to the Closing Date; (ii) ruling by, or written agreement with, a Governmental Authority (including any closing agreement pursuant to Section 7121 of the Code or any similar provision of state, local or foreign income Tax Legal Requirement) issued or executed prior to the Closing; (iii) installment sale or open transaction disposition made prior to the Closing; (iv) prepaid amount received prior to the Closing; (v) intercompany transaction or excess loss accounts described in the Treasury Regulations promulgated under Section 1502 of the Code (or any corresponding or similar provision of state, local or foreign income Legal Requirement) that existed prior to the Closing; or (vi) Section 965 of the Code.

**(g)** Neither Biosight nor any of its Subsidiaries are, or have ever been, a real property corporation (*Igud Mekarke'in*) within the meaning of this term under Section 1 of the Israeli Land Taxation Law (Appreciation and Acquisition), 5723-1963.

**(h)** Neither Biosight nor any of its Subsidiaries is a party to, or bound by, or has any obligation to, any Governmental Authority or other Person any Tax allocation, Tax sharing or similar agreement (including Tax indemnity arrangements), other than commercial contracts entered into in the Ordinary Course of Business with vendors, customers and landlords.

**(i)** Neither Biosight nor any of its Subsidiaries has ever been a member of an affiliated group filing a consolidated, combined, unitary or other group Tax Return (other than a group the common parent of which is Biosight) for U.S. federal, state, local or foreign Tax purposes. Neither Biosight nor any of its Subsidiaries has any Liability for the Taxes of any Person (other than Biosight and its Subsidiaries) under Treasury Regulations Section 1.1502-6 (or any similar provision of state, local, or foreign Legal Requirement), as a transferee or successor, by Contract, or otherwise.

**(j)** Neither Biosight nor any of its Subsidiaries has distributed stock of another Person, or has had its stock distributed by another Person, in a transaction that was purported or intended to be governed in whole or in part by Section 355 of the Code or Section 361 of the Code.

**(k)** Neither Biosight nor any of its Subsidiaries is a partner for Tax purposes with respect to any joint venture, partnership, or, to the Knowledge of Biosight, other arrangement or contract which is treated as a partnership for Tax purposes.

**(l)** Neither Biosight nor any of its Subsidiaries has entered into any transaction identified as a "listed transaction" for purposes of Treasury Regulations Sections 1.6011-4(b). Neither Biosight nor any of its Subsidiaries participates in, or has ever participated in, engages or have ever engaged in any transaction listed in Section 131(g) of the Ordinance and the Income Tax Regulations (Reportable Tax Planning), 5767-2006 promulgated thereunder (or any comparable provision of state, local or foreign law) or is subject to reporting obligations under Sections 131D and 131E of the Ordinance or similar provisions under the Israel Value Added Tax Law of 1975.

**(m)** Neither Biosight nor any of its Subsidiaries has taken any action, or has any knowledge of any fact or circumstance, that could reasonably be expected to prevent the Transactions, including the Merger, from qualifying for the Intended Tax Treatment.

**(n)** Neither Biosight nor any of its Subsidiaries is subject to any restrictions or limitations pursuant to Part E2 of the Ordinance or pursuant to any Tax ruling made with reference to the provisions of Part E2.

**(o)** Biosight is duly registered for the purposes of Israeli value added tax and has complied in all respects with all requirements concerning value added Taxes ("**VAT**"). Biosight (i) has not made any exempt transactions (as defined in the Israel Value Added Tax Law of 1975) and there are no circumstances by reason of which there might not be an entitlement to full credit of all VAT chargeable or paid on inputs, supplies, and other transactions and imports made by it, (ii) has collected and timely remitted to the relevant Governmental Authority all output VAT which it is required to collect and remit under any Legal Requirement; and (iii) has not received a refund or credit for input VAT for which it is not entitled under any Legal Requirement. All the non-Israeli Subsidiaries of Biosight are not required to effect Israeli VAT registration.

**(p)** Biosight has never made any election to be treated or claimed any benefits as "Beneficial Enterprise" (*Mifaal Mutav*) or otherwise nor did it take any position of being a "Preferred Enterprise" (*Mifaal Muadaf*) or "Preferred Technological Enterprise" (*Mifaal Technology Muadaf*) or otherwise under the Law for Encouragement of Capital Investments, 1959.

**(q)** The Biosight Employee Plan has received a favorable determination or approval letter from, or is otherwise approved by, or deemed approved by passage of time without objection by, the ITA under the trustee capital gains route of Section 102 of the Ordinance. All 102 Biosight Shares and 102 Biosight Options which were issued under any equity plan were and are currently in compliance with the applicable requirements of Section 102(b)(2) of the Ordinance and the written requirements and guidance of the ITA, including the filing of the necessary documents with the ITA, the grant of 102 Biosight Options only following the lapse of the required 30 day period from the filing of the Biosight Employee Plan with the ITA, the receipt of the required written consents from the option holders, the appointment of an authorized trustee to hold the 102 Biosight Options and 102 Biosight Shares, the receipt of all required Tax rulings, and the due deposit of such 102 Biosight Options and 102 Biosight Shares with the 102 Trustee pursuant to the terms of Section 102 of the Ordinance, and applicable regulations and rules and the guidance published by the ITA on July 24, 2012 and clarification dated November 6, 2012.

**3.13** Employee and Labor Matters; Benefit Plans.

**(a)** Part 3.13(a) of the Biosight Disclosure Schedule sets forth, with respect to each current employee of Biosight or any of its Subsidiaries, (i) the name of such employee and the date as of which such employee was originally hired by Biosight or any of its Subsidiaries, and whether the employee is on an active or inactive status, (ii) such employee's title, (iii) such employee's monthly compensation as of the date of this Agreement, including base salary, bonus and commission potential, and (iv) whether such employee is not fully available to perform work because of a qualified disability or other leave and, if applicable, the type of leave (e.g., disability, workers compensation, family or other leave protected by applicable Legal Requirements) and the anticipated date of return to full service. Other than their salary, Biosight's employees are not entitled to any payment or benefit that may be reclassified as part of their determining salary for all intents and purposes, including for social contributions and severance pay. No Biosight employee is entitled (whether by virtue of any law, Contract or otherwise) to any benefits, entitlement or compensation that is not detailed in Part 3.13(a) of the Biosight Disclosure Schedule.

**(b)** Part 3.13(b) of the Biosight Disclosure Schedule sets forth a true and complete list of all present contractors of Biosight who were entitled to an average monthly compensation of more than $10,000 since January 1st, 2021 in consideration for their services, and includes each such contractor's name, engaging entity, date of commencement, and rate of all regular compensation and benefits, bonus or any other compensation payable to such contractor. Except as set forth in Part 3.13(b) of the Biosight Disclosure Schedule, all current and former contractors of Biosight are (or were, as applicable) rightly classified as independent contractors and Biosight has not engaged any consultants, sub-contractors, sales agents or freelancers who, according to any applicable Legal Requirement, would be entitled to the rights of an employee vis-à-vis Biosight.

**(c)** Neither Biosight nor any of its Subsidiaries is a party to, bound by, negotiating or required to negotiate any collective bargaining agreement or other agreement with a labor union or other labor organization. To the Knowledge of Biosight, no employees of Biosight or any of its Subsidiaries are represented by any labor union or other labor organization. To the Knowledge of Biosight, there are no activities or proceedings of any labor union or other labor organization to organize any employees of Biosight or any of its Subsidiaries and no demand for recognition or certification as the exclusive bargaining representative of any employees has been made by or on behalf of any labor union or other labor organization. There are no pending or, to the Knowledge of Biosight, threatened, and, since November 1, 2017, there have been no, strikes, lockouts, union organization activities (including, but not limited to, union organization campaigns or requests for representation), pickets, slowdowns, stoppages, material grievances or collective labor disputes or similar activity in respect of the business of Biosight or its Subsidiaries that may, individually or in the aggregate, interfere in any material respect with the respective business activities of Biosight or any of its Subsidiaries. Biosight and each of its Subsidiaries is not engaged in and, since November 1, 2017, have not engaged in any unfair labor practice that has resulted or could reasonably be expected to result, individually or in the aggregate, in any material liability to Biosight or any of its Subsidiaries. There is no material unfair labor practice charge against Biosight or any of its Subsidiaries pending or, to the Knowledge of Biosight, threatened before the National Labor Relations Board or any similar Governmental Authority that could reasonably be expected to result in any material liability to Biosight or any of its Subsidiaries.

**(d)** Biosight and each of its Subsidiaries is, and, since November 1, 2017, has been, in compliance in all material respects with all applicable Legal Requirements respecting labor, employment, fair employment practices (including equal employment opportunity laws), terms and conditions of employment, classification of employees, workers' compensation, occupational safety and health, immigration, affirmative action, harassment (including sexual harassment), employee and data privacy, plant closings, wages and work and rest hours. There is no pending or, to the Knowledge of Biosight, threatened charge, complaint, arbitration, audit or investigation brought by or on behalf of, or otherwise involving, any current or former employee, any Person alleged to be a current or former employee, any applicant for employment, or any class of the foregoing, or any Governmental Authority, that involve the labor or employment relations and practices of Biosight or any of its Subsidiaries that could reasonably be expected to result, individually or in the aggregate, in any material liability to Biosight or any of its Subsidiaries.

**(e)** To the Knowledge of Biosight, no senior executive or other key employee of Biosight or any of its Subsidiaries is party to any confidentiality, non-competition, non-solicitation, proprietary rights or other such agreement that would materially restrict the performance of such Person's employment duties with Biosight or its Subsidiaries or the ability of Biosight and/or any of its Subsidiaries to conduct its or their business.

**(f)** Neither Biosight nor any of its Subsidiaries has incurred any material liability or obligation under the Worker Adjustment and Retraining Notification Act or any similar state or local Legal Requirement that remains unsatisfied.

**(g)** All material payments due from Biosight and any of its Subsidiaries on account of wages or other compensation, and employee pension, health and welfare insurance and other benefits, have been timely paid as and when they have become due and owing.

**(h)** To the Knowledge of Biosight, in the last five (5) years, no allegations of sexual harassment have been made to Biosight against any individual in his or her capacity as director or an employee of Biosight at a level of Senior Vice President or above.

**(i)** Biosight has delivered to Advaxis true and complete copies of the Biosight Employee Plan and form of agreement evidencing each Biosight Option, and has also delivered any other stock option or other equity or equity-related award agreements to the extent there are material variations from the applicable form of agreement, specifically identifying the Person(s) to whom such material variant forms apply. With respect to Biosight Options granted pursuant to the Biosight Employee Plan, (i) each Biosight Option intended to qualify as a 102 Biosight Option or 3(i) Biosight Option so qualifies, (ii) each grant of a Biosight Option was duly authorized no later than the date on which the grant of such Biosight Option was by its terms to be effective by all necessary corporate action, including, as applicable, approval by the Board of Directors of Biosight (or a duly constituted and authorized committee thereof) and any required stockholder approval by the necessary number of votes or written consents, and the award agreement governing such grant (if any) was duly executed and delivered by each party thereto, and (iii) each Biosight Option grant was made in accordance with the terms of the Biosight Employee Plan and all other Legal Requirements.

**(j)** Part 3.13(j) of the Biosight Disclosure Schedule sets forth an accurate and complete list of each material Biosight Benefit Plan. "***Biosight Benefit Plan***" shall mean each benefit or compensation plan, program, policy, practice, contract, agreement or other arrangement, covering current or former employees, directors or independent contractors of Biosight or any of its Subsidiaries, employment, consulting, retirement, pension, disability coverage, severance, termination or change in control agreements, deferred compensation, vacation, sick, stock option, stock purchase, stock appreciation rights, stock-based or other equity-based (including the Biosight Employee Plan), incentive, bonus, supplemental retirement, profit-sharing, insurance, medical, welfare, fringe or other benefits or remuneration of any kind, whether or not in writing and whether or not funded, in each case, which is sponsored, maintained or contributed to by Biosight or any of its Subsidiaries, or to which Biosight or any of its Subsidiaries is obligated to contribute.

**(k)** With respect to each Biosight Benefit Plan listed on Part 3.13(k) of the Biosight Disclosure Schedule, Biosight has made available to Advaxis, to the extent applicable, true, correct and complete copies of (A) the Biosight Benefit Plan document, including any amendments thereto, and all related trust documents, insurance contracts or other funding vehicles, (B) a written description of such Biosight Benefit Plan if such plan is not set forth in a written document, (C) the most recently prepared actuarial report, (D) the most recent summary plan description together with the summary or summaries of all material modifications thereto, (E) the most recent Internal Revenue Service determination or opinion letter, (F) the two most recent annual reports (Form 5500 or 990 series and all schedules and financial statements attached thereto or any similar form under the applicable local law), and (G) all material correspondence to or from the IRS, the United States or Department of Labor or any other Governmental Authority received in the last three years with respect to any Biosight Benefit Plan.

**(l)** There are no pending, or to the Knowledge of Biosight, threatened claims (other than routine claims for benefits) by, on behalf of or against or in connection with any Biosight Benefit Plan or any trust related thereto which could reasonably be expected to result in any material liability to Biosight or any of its Subsidiaries, and no audit or other proceeding by a Governmental Authority is pending, or to the Knowledge of Biosight, threatened with respect to any Biosight Benefit Plan.

**(m)** Except as required by applicable Legal Requirements, no Biosight Benefit Plan provides retiree or post-employment medical, disability, life insurance or other welfare benefits to any Person, and none of Biosight or any of its Subsidiaries has any obligation to provide such benefits.

**(n)** Except as set forth on Part 3.13(n) of the Biosight Disclosure Schedule, neither the execution and delivery of this Agreement, shareholder or other approval of this Agreement nor the consummation of the Merger could, either alone or in combination with another event, (i) entitle any employee, director, officer or independent contractor of Biosight or any of its Subsidiaries to severance pay or any material increase in severance pay, (ii) accelerate the time of payment or vesting, or materially increase the amount of compensation due to any such employee, director, officer or independent contractor, (iii) directly or indirectly cause Biosight to transfer or set aside any assets to fund any material benefits under any Biosight Benefit Plan, (iv) otherwise give rise to any material liability under any Biosight Benefit Plan.

**(o)** Solely with respect to Biosight's employees who reside or work in Israel ("***Israeli Employees***"): (i) Biosight does not have or is not subject to, and no Israeli Employee of Biosight benefits from, any extension order (*tzavei harchava*) (other than extension orders applicable to all employers in Israel); (ii) Biosight's obligations to provide severance pay, vacation and contributions to any Biosight Benefit Plan (including pension plans, managers' insurance policy, study fund and loss of earning insurance) to its Israeli Employees pursuant to applicable Legal Requirements and any other source have been fully funded or, if not required to be fully funded, are accrued on Biosight's financial statements; (iii) without derogating from the generality of the above, arrangement set out in Section 14 of the Israeli Severance Pay Law - 1963 (the "***Section 14 Arrangement***") applies to all Israeli Employees as of their start date of employment with Biosight or any of its Subsidiaries based on their entire determining salary; and (iv) Biosight is in compliance with all Legal Requirements and Biosight Contracts relating to employment, employment practices, wages, bonuses, commissions and other compensation matters and terms and conditions of employment related to its Israeli Employees, including The Advance Notice of Discharge and Resignation Law (5761 2001), The Notice to the Employee and Job Candidate Law (Employment Conditions and Candidate Screening and Selection), 5762-2002, The Prevention of Sexual Harassment Law (5758 1998), the Hours of Work and Rest Law, 1951, the Annual Leave Law, 1951, the Salary Protection Law, 1958, Law for Increased Enforcement of Labor Laws, 2011 and The Employment of Employee by Manpower Contractors Law (5756 1996). To the Knowledge of Biosight, Biosight has not engaged any Israeli Employees whose employment would require special approvals from any Governmental Authority. Except for matters that have not resulted in and would not, individually or in the aggregate, result in material liabilities to Biosight (A) all amounts that Biosight is legally or contractually required either (x) to deduct from its Israeli Employees' salaries or to transfer to such Israeli Employees' pension or provident, life insurance, incapacity insurance, continuing education fund or other similar funds or (y) to withhold from its Israeli Employees' salaries and benefits and to pay to any Governmental Authority as required by any Legal Requirement or otherwise have, in each case, been duly deducted, transferred, withheld and paid (other than routine payments, deductions or withholdings to be timely made in the normal course of business and consistent with past practice), and (B) Biosight does not have any outstanding obligations to make any such deduction, transfer, withholding or payment (other than such that has not yet become due).

**3.14** Environmental Matters. Biosight and each of its Subsidiaries is in material compliance with all applicable Environmental Laws, which compliance includes the possession by Biosight of all permits and other Governmental Authorizations required under applicable Environmental Laws and compliance with the terms and conditions thereof. Neither Biosight nor any of its Subsidiaries has received since November 1, 2017 any written notice or other communication (in writing or otherwise), whether from a Governmental Authority, citizens group, employee or otherwise, that alleges that Biosight or any of its Subsidiaries is not in material compliance with any Environmental Law, and, to the Knowledge of Biosight, there are no circumstances that may prevent or interfere with Biosight's or any of its Subsidiaries' material compliance with any Environmental Law in the future. To the Knowledge of Biosight (i) no current or prior owner of any property leased or controlled by Biosight or any of its Subsidiaries has received since November 1, 2017 any written notice or other communication relating to property owned or leased at any time by Biosight or any of its Subsidiaries, whether from a Governmental Authority, citizens group, employee or otherwise, that alleges that such current or prior owner or Biosight or any of its Subsidiaries is not in material compliance with or has violated in any material respect any Environmental Law relating to such property and (ii) neither it nor any of its Subsidiaries has any material liability under any Environmental Law.

**3.15** Insurance.

**(a)** Each of Biosight and its Subsidiaries maintains insurance coverage with reputable insurers in such amounts and covering such risks as Biosight reasonably believes, based on past experience, is adequate for the businesses and operations of Biosight and its Subsidiaries (taking into account the cost and availability of such insurance). Neither Biosight nor any of its Subsidiaries has received any written notice of any pending or threatened cancellation (other than in connection with ordinary renewals) or material premium increase (other than premium increases in the ordinary course) with respect to any such material insurance policy, and each Subsidiary of Biosight is in compliance with all conditions contained therein, except for such noncompliance as has not had and would not reasonably be expected to have, individually or in the aggregate, a Biosight Material Adverse Effect. All such material insurance policies are in full force and effect will not be affected by, or terminated or lapse by reason of, this Agreement or the consummation of the Merger. There is no material claim pending under any of Biosight's insurance policies as to which coverage has been denied by the underwriters of such policies.

**(b)** Biosight has delivered to Advaxis accurate and complete copies of the existing policies (primary and excess) of directors' and officers' liability insurance maintained by Biosight and each of its Subsidiaries as of the date of this Agreement (the "***Existing Biosight D&O Policies***"). Part 3.15(b) of the Biosight Disclosure Schedule accurately sets forth the most recent annual premiums paid by Biosight and each of its Subsidiaries with respect to the Existing Biosight D&O Policies.

**3.16** Legal Proceedings; Orders.

**(a)** There are no Legal Proceedings pending or, to the Knowledge of Biosight, threatened in writing against Biosight or any of its Subsidiaries.

**(b)** Neither Biosight nor any of its Subsidiaries is a party to or subject to the provisions of any Order specifically imposed upon Biosight or any of its Subsidiaries.

**3.17** Authority; Binding Nature of Agreement.

**(a)** Biosight has all requisite corporate power and authority to execute and deliver this Agreement, to perform its obligations hereunder and, subject to the Biosight Shareholder Approval, to consummate the Transactions. The execution, delivery and performance of this Agreement and the consummation of the Transactions have been duly and validly authorized by all necessary corporate action, and no other corporate proceedings on the part of Biosight are necessary for it to authorize this Agreement or to consummate the Transactions, except for, in any such case, the adoption of this Agreement by the Biosight Shareholder Approval. This Agreement has been duly and validly executed and delivered by Biosight and, assuming due authorization, execution and delivery by the other Parties, is a legal, valid and binding obligation of Biosight, enforceable against Biosight in accordance with its terms, subject to the Bankruptcy and Equity Exception.

**(b)** The Board of Directors of Biosight, at a meeting duly called and held, has (i) determined that this Agreement and the Transactions are fair to and in the best interests of Biosight and its shareholders, and (ii) approved, adopted and declared advisable this Agreement and the Transactions.

**(c)** The Biosight Shareholder Written Consent is the only vote or consent of the holders of any class or series of Securities of Biosight necessary in connection with the consummation of the Transactions, including the Merger.

**3.18** Takeover Statutes.

**(a)** Biosight has taken all action necessary to exempt or exclude this Agreement and the Transactions, including the Merger, from all Takeover Statutes. Accordingly, no Takeover Statute applies to this Agreement or the Transactions, including the Merger, with respect to Biosight.

**(b)** Biosight is not party to a rights agreement, "poison pill" or similar agreement or plan.

**3.19** Non-Contravention; Consents. Subject to compliance with the HSR Act and any Foreign Competition Law, obtaining the Biosight Shareholder Approval for the Transactions and the filing of the Certificate of Merger in accordance with the ICL, neither (x) the execution, delivery or performance of this Agreement by Biosight, nor (y) the consummation of the Merger or any of the other Transactions, will directly or indirectly (with or without notice or lapse of time):

**(a)** contravene, conflict with or result in a violation of (i) any of the provisions of the Constituent Documents of Biosight or any of its Subsidiaries, or (ii) any resolution adopted by the stockholders, the Board of Directors or any committee of the Board of Directors of Biosight;

**(b)** contravene, conflict with or result in a material violation of, or give any Governmental Authority or other Person the right to challenge the Merger or any of the other Transactions or to exercise any remedy or obtain any relief under, any Legal Requirement or any Order to which Biosight or its Subsidiaries, or any of the assets owned or used by Biosight or its Subsidiaries, is subject;

**(c)** contravene, conflict with or result in a material violation of any of the terms or requirements of, or give any Governmental Authority the right to revoke, withdraw, suspend, cancel, terminate or modify, any Governmental Authorization that is held by Biosight or its Subsidiaries or that otherwise relates to the business of Biosight or its Subsidiaries or to any of the assets owned or used by Biosight or its Subsidiaries;

**(d)** contravene, conflict with or result in a violation or breach of, or result in a default under, any provision of any Biosight Contract, or give any Person the right to (i) declare a default or exercise any remedy under any Biosight Contract; (ii) a rebate, chargeback, penalty or change in delivery schedule under any such Biosight Contract; (iii) accelerate the maturity or performance of any Biosight Contract; or (iv) cancel, terminate or modify any term of any Biosight Contract, except, in the case of any Biosight Material Contract, any non-material breach, default, penalty or modification and, in the case of all other Biosight Contracts, any breach, default, penalty or modification that would not result in a Biosight Material Adverse Effect or default;

**(e)** result in the imposition or creation of any Encumbrance upon or with respect to any asset owned or used by Biosight or its Subsidiaries (except for minor liens that will not, in any case or in the aggregate, materially detract from the value of the assets subject thereto or materially impair the operations of Biosight); or

**(f)** result in, or increase the likelihood of, the transfer of any material asset of Biosight or its Subsidiaries to any Person.

Except (i) for any Consent set forth on Part 3.19 of the Biosight Disclosure Schedule under any Biosight Contract, (ii) the Biosight Shareholder Approval, (iii) the filing of the Certificate of Merger in accordance with the ICL, (iv) any required filings under the HSR Act and any Foreign Competition Law and (v) such consents, waivers, approvals, orders, authorizations, registrations, declarations and filings as may be required under applicable federal and state securities laws, neither Biosight nor any of its Subsidiaries was, is or will be required to make any filing with or give any notice to, or to obtain any Consent from, any Person in connection with (x) the execution, delivery or performance of this Agreement or (y) the consummation of the Transactions, including the Merger.

**3.20** Bank Accounts; Receivables.

**(a)** Part 3.20(a) of the Biosight Disclosure Schedule provides accurate information with respect to each account maintained by or for the benefit of Biosight or any of its Subsidiaries at any bank or other financial institution, including the name of the bank or financial institution, the account number, the balance as of June 30, 2021 and the names of all individuals authorized to draw on or make withdrawals from such accounts.

**(b)** All existing accounts receivable of Biosight or any of its Subsidiaries (including those accounts receivable reflected on the Biosight Financial Statements that have not yet been collected and those accounts receivable that have arisen since the date of the Biosight Financial Statements and have not yet been collected) (i) represent valid obligations of customers of Biosight or any of its Subsidiaries arising from bona fide transactions entered into in the Ordinary Course of Business, and (ii) are current and are expected to be collected in full when due, without any counterclaim or set off, net of applicable reserves for bad debts on the Biosight Financial Statements.

**3.21** Brokers and Finders. No Person is entitled to any brokerage, financial advisory, finder's or similar fee or commission payable by any Party in connection with the Transactions, including the Merger, based upon arrangements made by or on behalf of the Board of Directors of Biosight (or any committee thereof), Biosight or any of its Subsidiaries.

**3.22** [RESERVED]

**3.23** Governmental Grants.

**(a)** Except as set forth in Part 3.23(a) of the Biosight Disclosure Schedule, neither Biosight nor any of its Subsidiaries has developed any Intellectual Property, to which Biosight has any rights, through the application of any financing made available by any Governmental Grants through the assistance or use of the facilities of a university, college, other educational institution, research center, hospitals, medical centers or other similar institutions, and none of Biosight's Intellectual Property or Biosight's knowhow licensed to Biosight or any of its Subsidiaries by any third party other than commercial off-the-shelf products available to the general public for licensing and open source licenses, is subject to any assignment, grant-back, license, march-in or other right, or prohibitions or restrictions of any Governmental Authority, including as a result of any grants.

**(b)** Except as set forth on Part 3.23(b) of the Biosight Disclosure Schedule, Biosight has not entered into, applied for, requested, accepted, been notified that it has been approved for, elected to participate in or received or become subject to or bound by any requirement or obligation relating to, any Governmental Grant, or amended or terminated, or waived any right or remedy related to, any Governmental Grant, including: (i) Governmental Grants from the IIA, (ii) "Approved Enterprise" or similar status granted by the Israeli Investment Center, (iii) Governmental Grants from the Israeli Fund for the Promotion of Marketing and (iv) Governmental Grants from the ITA, the State of Israel, the BIRD Foundation, and other bi- or multi-national grant programs for the financing of research and development or other similar funds, the European Union and the Fund for Encouragement of Marketing Activities of the Israeli government.

**(c)** Biosight has delivered to Advaxis accurate and complete copies of (i) all applications and material correspondence submitted by or on behalf of Biosight to the applicable Governmental Authority in connection with a Governmental Grant or application therefore, or accepted or received by Biosight, and (ii) all certificates of approval and letters of approval (and supplements thereto) granted to Biosight by any Governmental Authority in connection with a Governmental Grant or application therefor or accepted or received by Biosight, and any undertakings binding upon Biosight in connection with any such Governmental Grant and (iii) any other material documents or information regarding any Governmental Grant including complete information regarding the amount of any Governmental Grant and any accrued interest or other financial liabilities connected thereto. Except for undertakings set forth in letters of approvals, provided under any applicable law, there are no undertakings which Biosight has given in connection with any Governmental Grant accepted or received by Biosight.

**(d)** Biosight has been and is in compliance with all the terms, conditions, requirements of all Governmental Grants (including any reporting requirements) and any applicable law in connection thereto, and has duly fulfilled in all respects all conditions, undertakings and other obligations relating thereto. In any application in respect of Governmental Grant submitted by or on behalf of Biosight, Biosight has disclosed all material information required by such application in an accurate and complete manner.

**(e)** No event has occurred, and no circumstance or condition resulting from an action or omission to act of Biosight exists, that would reasonably be expected to give rise to (i) the annulment, revocation, withdrawal, suspension, cancellation, recapture or modification of any Governmental Grant or any benefit available in connection with any Governmental Grant, (ii) the imposition of any limitation on any Governmental Grant or any benefit available in connection with any Governmental Grant or (iii) a requirement that Biosight return or refund any benefits provided under any Governmental Grant, an acceleration or increase of royalty payments obligation, requirement for past royalties, or obligation to pay additional payments in respect to any Governmental Grant other than prospective on-going royalty payments in connection with the Governmental Grants.

**(f)** No claim or challenge has been made against Biosight by any Governmental Authority with respect to Biosight's entitlement to any Governmental Grant or the compliance of Biosight with the terms, conditions, obligations or laws relating to the Governmental Grants. Biosight has not been and is not under an audit by any Governmental Authority regarding any Governmental Grant.

**(g)** Except as set forth on Part 3.23(g) of the Biosight Disclosure Schedule, no Governmental Authority has awarded any participation or provided any support to Biosight or is or may become entitled to receive any royalties or other payments from Biosight with respect to any Governmental Grant.

**(h)** Except as set forth in Part 3.23(h) of the Biosight Disclosure Schedule, the consummation of the Transactions (i) will not adversely affect the ability of Biosight to obtain the benefit of any Governmental Grant for the remaining duration thereof or require any recapture of any previously claimed incentive, and (ii) will not result in (A) the failure of Biosight to materially comply with any of the terms, conditions, requirements and criteria of any Governmental Grant, law, regulations, ordinances or guidelines or, (B) any claim by any Governmental Authority or other Person that Biosight is required to return or refund, or that any Governmental Authority is entitled to recapture, any benefit provided under any Governmental Grant, or that Biosight is required to pay any amount to any Governmental Authority with respect to any Governmental Grant or other Person due to the Transactions.

**(i)** Except as set forth on Part 3.23(i) of the Biosight Disclosure Schedule, no consent of or notification to any Governmental Authority is required to be obtained prior to the consummation of the Closing in order to comply with applicable Legal Requirements or the terms of the Governmental Grants.

**(j)** Part 3.23(j) of the Biosight Disclosure Schedule sets forth, with respect to each Governmental Grant: (i) the total amount of the benefits received by Biosight under such Governmental Grant and the total amount of the benefits available for future use by Biosight under such Governmental Grant, if any, (ii) the time period in which Biosight received, or will be entitled to receive, benefits under such Governmental Grant, (iii) a general description of any research and development program for which such Governmental Grant was approved and Biosight's Intellectual Property or Biosight's product that was developed, in whole or in part, in connection with such Governmental Grant, (iv) any royalty or other repayment schedule applicable to such Governmental Grant, (v) the type of revenues from which royalty or other payments are required to be made under such Governmental Grant, and (vi) the total amount of any payments made by Biosight prior to the date of this Agreement with respect to such Governmental Grant.

**3.24** Disclosure. The information supplied by Biosight and each of its Subsidiaries for inclusion in the Proxy Statement/Prospectus/Information Statement (including any Biosight Financial Statements) will not, as of the date of the Proxy Statement/Prospectus/Information Statement or as of the date such information is prepared or presented, (i) contain any statement that is inaccurate or misleading with respect to any material facts or (ii) omit to state any material fact necessary in order to make such information, in the light of the circumstances under which such information is provided, not false or misleading.

**3.25** No Other Representations and Warranties. Except for the representations and warranties contained in this Section 3 neither Biosight nor any other Person acting on behalf of Biosight makes any other express or implied representation or warranty. In particular, and without limiting the generality of the foregoing, except for the representations and warranties contained in this Section 3, neither Biosight nor any other Person makes or has made any express or implied representation or warranty to Biosight or any of its representatives with respect to (a) any financial projection, forecast, estimate, budget or prospect information relating to Biosight, any of its Subsidiaries or their respective businesses or (b) any oral, written, video, electronic or other information presented to Biosight or any of its authorized representatives in the course of their due diligence investigation of Biosight, the negotiation of this Agreement or the course of the Transactions (including with respect to the accuracy and completeness thereof). Neither Biosight nor any other Person will have or be subject to any liability to Biosight or any other Person resulting from the distribution to Biosight, or Biosight's use of, any such information, including any information, documents, projections, forecasts or other material made available to Biosight or any of its authorized representatives in management presentations or otherwise in expectation of the Transactions, unless and to the extent any such information is included in the representations and warranties contained in this Section 3.

SECTION 4. Certain Covenants of the Parties

**4.1** Access and Investigation.

**(a)** During the period from the date of this Agreement to the earlier of the termination of this Agreement pursuant to Section 9.1 and the Effective Time (the "***Interim Period***"), upon reasonable notice, each Party shall, and shall cause such Party's Representatives to (a) provide the other Party and such other Party's Representatives with reasonable access during normal business hours to such Party's and its Subsidiaries' properties, books, records, Contracts and personnel, (b) furnish all other information (financial or otherwise) with respect to such Party as the other Party may reasonably request, including reports regarding the use of Advaxis' cash funds and usage prior to the Effective Time, and (c) permit the other Party's Representatives to meet, upon reasonable notice and during normal business hours, with the chief financial officer and other officers and managers of such Party responsible for such Party's financial statements and the internal controls of such Party to discuss such matters as the other Party may deem necessary or appropriate in order to enable the other Party to satisfy its obligations under the Sarbanes-Oxley Act and the rules and regulations relating thereto. Without limiting the generality of any of the foregoing, during the Interim Period, each Party shall promptly make available to the other Party copies of:

**(i)** any written materials or communications sent by or on behalf of a Party to its stockholders;

**(ii)** any material notice, document or other communication sent by or on behalf of a Party to any party to any Advaxis Material Contract or Biosight Material Contract, as applicable, or sent to a Party by any party to any Advaxis Material Contract or Biosight Material Contract, as applicable (other than any communication that relates solely to routine commercial transactions between such Party and the other party to any such Advaxis Material Contract or Biosight Material Contract, as applicable, and that is of the type sent in the Ordinary Course of Business and consistent with past practices);

**(iii)** any non-privileged notice, document or other communication sent by or on behalf of, or sent to, a Party relating to any pending or threatened Legal Proceeding involving or affecting such Party; and

**(iv)** any material notice, report or other document received by a Party from any Governmental Authority.

**(b)** Notwithstanding the foregoing, none of Advaxis or Biosight shall be required to provide access to, disclose information to or assist or cooperate with the other Party, in each case if such access, disclosure, assistance or cooperation (i) would, as reasonably determined based on the advice of outside counsel, jeopardize any attorney-client privilege with respect to such information, or (ii) would contravene any applicable Legal Requirement; *provided*, that Advaxis and Merger Sub shall use reasonable best efforts to make appropriate substitute disclosure arrangements under circumstances in which such restrictions apply and to provide such information as to the applicable matter as can be conveyed.

**(c)** All information furnished pursuant to this Section 4.1 shall be subject to the confidentiality agreement, dated as of August 5, 2020, by and between Advaxis and Biosight (the "***Confidentiality Agreement***").

**4.2** Operation of Advaxis' Business.

**(a)** During the Interim Period, except as set forth on Part 4.2(a) of the Advaxis Disclosure Schedule, Advaxis shall, and shall cause its Subsidiaries to, (i) conduct their respective businesses and operations (A) in the Ordinary Course of Business but, with the goal of not expanding any of Advaxis' operations, programs or activities, and (B) in compliance with all applicable Legal Requirements and the requirements of all Contracts that constitute Advaxis Material Contracts, and (ii) not take any action which would reasonably be expected to adversely affect its ability to consummate the Merger or the other Transactions.

**(b)** Except (i) as expressly contemplated or permitted by this Agreement, (ii) as set forth in Part 4.2(a) of the Advaxis Disclosure Schedule, or (iii) with the prior written consent of Biosight, at all times during the period commencing with the execution and delivery of this Agreement and continuing until the earlier to occur of the termination of this Agreement pursuant to Section 9 and the Effective Time, Advaxis shall not, nor shall it cause or permit any of its Subsidiaries to, do any of the following:

**(i)** declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of capital stock; or repurchase, redeem or otherwise reacquire any shares of capital stock or other Securities (except for shares of Advaxis Common Stock from terminated employees of Advaxis);

**(ii)** amend its Constituent Documents, except as related to the Transactions (including the Reverse Split);

**(iii)** (A) effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except as related to the Transactions, (B) acquire the assets or Securities of any other Person, or (C) adopt or implement a plan of complete or partial liquidation or resolution providing for or authorizing such liquidation or a dissolution, restructuring or other reorganization of Advaxis or any of its Subsidiaries;

**(iv)** sell, issue (other than any capital stock issued as part of an exercise of an option or with respect to 14,005,202 private placement warrants issued on April 14, 2021 for shares of capital stock not yet authorized) or grant, or authorize the issuance of, or make any commitments to do any of the foregoing, other than as contemplated by the Transactions (A) any capital stock or other security; (B) any option, warrant or right to acquire any capital stock or any other security; or (C) any instrument convertible into or exchangeable for any capital stock or other security;

**(v)** form any Subsidiary or enter into any joint venture, partnership or similar arrangement, or acquire any equity interest or other interest in any other Entity;

**(vi)** (A) make any loans, advances or capital contributions to, or investments in, any other Person, (B) create, incur, guarantee, assume or otherwise become liable for any indebtedness, issuances of debt securities, guarantees, indemnities, loans or advances not in existence as of the date of this Agreement, or (C) make or commit to make any capital expenditure, other than in the Ordinary Course of Business;

**(vii)** sell, lease, license, subject to an Encumbrance, encumber or otherwise surrender, relinquish or dispose of any assets, property or rights owned or held by Advaxis or any of its Subsidiaries;

**(viii)** except as required under applicable Legal Requirements or the terms of any Advaxis Benefit Plan existing as of the date hereof (A) increase in any manner the compensation, bonus, pension, welfare, fringe or other benefits, severance or termination pay of any of the current or former directors, officers, employees or independent contractor of Advaxis or its Subsidiaries, (B) become a party to, establish, amend, commence participation in, terminate or commit itself to the adoption of any stock option plan or other stock-based compensation plan, or any compensation, severance, pension, retirement, profit-sharing, welfare benefit, or other employee benefit plan or agreement with or for the benefit of any current or former directors, officers, employees or independent contractors of Advaxis or its Subsidiaries (or newly hired employees), including under the applicable Advaxis Benefit Plans, (C) accelerate the vesting of or lapsing of restrictions with respect to any stock-based compensation or other long-term incentive compensation under any Advaxis Benefit Plan, (D) grant any new awards under any Advaxis Benefit Plan, (E) amend or modify any outstanding award under any Advaxis Benefit Plan, (F) enter into, amend or terminate any collective bargaining agreement or other agreement with a labor union, works council or similar organization, (G) forgive any loans, or issue any loans (other than routine travel advances issued in the Ordinary Course of Business) to any of its or its Subsidiaries' directors, officers, independent contractors or employees, or (H) hire or engage any new employee or independent contractor;

**(ix)** enter into any material transaction outside the Ordinary Course of Business;

**(x)** except as required by applicable Legal Requirements, make, change or revoke any material Tax election, file any material amendment to any Tax Return, adopt or change any accounting method in respect of Taxes, change any annual Tax accounting period, enter into any Tax allocation agreement, Tax sharing agreement or Tax indemnity agreement, other than commercial contracts entered into in the Ordinary Course of Business with vendors, customers or landlords, enter into any closing agreement with respect to any Tax, settle or compromise any claim, notice, audit report or assessment in respect of material Taxes; apply for or enter into any ruling from any Governmental Authority with respect to Taxes, surrender any right to claim a material Tax refund, or consent to any extension or waiver of the statute of limitations period applicable to any material Tax claim or assessment;

**(xi)** change any method of accounting or accounting principles or practices by Advaxis or any of its Subsidiaries, except for any such change required by a change in Legal Requirement or by a Governmental Authority;

**(xii)** (A) modify or amend in any material respect, transfer, novate, assign or terminate, waive any rights under, or settle or compromise any material claim, liability or obligation under, any Advaxis Material Contract, (B) enter into any successor agreement to an expiring Advaxis Material Contract that changes the terms of the expiring Advaxis Material Contract in a way that is materially adverse to Advaxis or any of its Subsidiaries or (C) enter into any new Contract that would have been considered a Advaxis Material Contract if it were entered into at or prior to the date hereof;

**(xiii)** sell, assign, transfer, license, sublicense or otherwise dispose of any material Advaxis IP Rights (other than non-exclusive licenses in the Ordinary Course of Business);

**(xiv)** initiate or settle any material Legal Proceeding; or

**(xv)** agree, resolve or commit to do any of the foregoing.

**4.3** Operation of Biosight's Business.

**(a)** During the Interim Period, except as set forth on Part 4.3(a) of the Biosight Disclosure Schedule, (i) Biosight shall, and shall cause each of its Subsidiaries to, conduct its respective business and operations (A) in the Ordinary Course of Business, and (B) in compliance with all applicable Legal Requirements and the requirements of all Contracts that constitute Biosight Material Contracts, and (ii) not take any action which would reasonably be expected to adversely affect its ability to consummate the Merger or the other Transactions.

**(b)** Except (i) as expressly contemplated or permitted by this Agreement, (ii) as set forth on Part 4.3(b) of the Biosight Disclosure Schedule, or (iii) with the prior written consent of Advaxis, at all times during the period commencing with the execution and delivery of this Agreement and continuing until the earlier to occur of the termination of this Agreement pursuant to Section 9 and the Effective Time, Biosight shall not, nor shall it cause or permit any of its Subsidiaries to, do any of the following:

**(i)** declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of capital stock; or repurchase, redeem or otherwise reacquire any shares of capital stock or other Securities (except for shares of Biosight Shares from terminated employees of Biosight);

**(ii)** amend its Constituent Documents, except as related to the Transactions;

**(iii)** (A) effect or be a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except as related to the Transactions, (B) acquire the assets or Securities of any other Person, or (C) adopt or implement a plan of complete or partial liquidation or resolution providing for or authorizing such liquidation or a dissolution, restructuring or other reorganization of Biosight or any of its Subsidiaries;

**(iv)** sell, issue (other than any capital stock issued as part of an exercise of an option) or grant, or authorize the issuance of, or make any commitments to do any of the foregoing, other than as contemplated by the Transactions (A) any capital stock or other security; (B) any option, warrant or right to acquire any capital stock or any other security; or (C) any instrument convertible into or exchangeable for any capital stock or other security;

**(v)** form any Subsidiary or enter into any joint venture, partnership or similar arrangement, or acquire any equity interest or other interest in any other Entity;

**(vi)** (A) make any loans, advances or capital contributions to, or investments in, any other Person, (B) create, incur, guarantee, assume or otherwise become liable for any indebtedness, issuances of debt securities, guarantees, indemnities, loans or advances not in existence as of the date of this Agreement, or (C) make or commit to make any capital expenditure, other than in the Ordinary Course of Business;

**(vii)** sell, lease, license, subject to an Encumbrance, encumber or otherwise surrender, relinquish or dispose of any assets, property or rights owned or held by Biosight or any of its Subsidiaries;

**(viii)** except as required under applicable Legal Requirements or the terms of any Biosight Benefit Plan existing as of the date hereof (A) increase in any manner the compensation, bonus, pension, welfare, fringe or other benefits, severance or termination pay of any of the current or former directors, officers, employees or independent contractor of Biosight or its Subsidiaries, (B) become a party to, establish, amend, commence participation in, terminate or commit itself to the adoption of any stock option plan or other stock-based compensation plan, or any compensation, severance, pension, retirement, profit-sharing, welfare benefit, or other employee benefit plan or agreement with or for the benefit of any current or former directors, officers, employees or independent contractors of Biosight or its Subsidiaries (or newly hired employees), including under the applicable Biosight Benefit Plans, (C) accelerate the vesting of or lapsing of restrictions with respect to any stock-based compensation or other long-term incentive compensation under any Biosight Benefit Plan, (D) grant any new awards under any Biosight Benefit Plan, (E) amend or modify any outstanding award under any Biosight Benefit Plan, (F) enter into, amend or terminate any collective bargaining agreement or other agreement with a labor union, works council or similar organization, (G) forgive any loans, or issue any loans (other than routine travel advances issued in the Ordinary Course of Business) to any of its or its Subsidiaries' directors, officers, independent contractors or employees, or (H) hire or engage any new employee or independent contractor;

**(ix)** enter into any material transaction outside the Ordinary Course of Business;

**(x)** except as required by applicable Legal Requirements, make, change or revoke any material Tax election, file any material amendment to any Tax Return, adopt or change any accounting method in respect of Taxes, change any annual Tax accounting period, enter into any Tax allocation agreement, Tax sharing agreement or Tax indemnity agreement, other than commercial contracts entered into in the Ordinary Course of Business with vendors, customers or landlords, enter into any closing agreement with respect to any Tax, settle or compromise any claim, notice, audit report or assessment in respect of material Taxes; apply for or enter into any ruling from any Governmental Authority with respect to Taxes, surrender any right to claim a material Tax refund, or consent to any extension or waiver of the statute of limitations period applicable to any material Tax claim or assessment;

**(xi)** change any method of accounting or accounting principles or practices by Biosight or any of its Subsidiaries, except for any such change required by a change in Legal Requirement or by a Governmental Authority;

**(xii)** (A) modify or amend in any material respect, transfer, novate, assign or terminate, waive any rights under, or settle or compromise any material claim, liability or obligation under, any Biosight Material Contract, (B) enter into any successor agreement to an expiring Biosight Material Contract that changes the terms of the expiring Biosight Material Contract in a way that is materially adverse to Biosight or any of its Subsidiaries or (C) enter into any new Contract that would have been considered a Biosight Material Contract if it were entered into at or prior to the date hereof;

**(xiii)** sell, assign, transfer, license, sublicense or otherwise dispose of any material Biosight IP Rights (other than non-exclusive licenses in the Ordinary Course of Business);

**(xiv)** initiate or settle any material Legal Proceeding; or

**(xv)** agree, resolve or commit to do any of the foregoing.

**4.4** Advaxis No Solicitation.

**(a)** Advaxis agrees that neither it nor any of its Subsidiaries shall, nor shall it nor any of its Subsidiaries authorize or permit any of the officers, directors, employees, investment bankers, attorneys, accountants, Representatives, consultants or other agents retained by it or any of its Subsidiaries to, directly or indirectly: (i) solicit, initiate, encourage, induce or knowingly facilitate the communication, making, submission or announcement of any Acquisition Proposal or take any action that could reasonably be expected to lead to an Acquisition Proposal; (ii) furnish to any Person any information or data with respect to, or cooperate in any way that would otherwise reasonably be expected to lead to, any proposal or inquiry that constitutes, or would reasonably be expected to lead to, any Acquisition Proposal; (iii) enter into, continue or otherwise engage in any discussions or negotiations with any Person with respect to any Acquisition Proposal or any proposal or inquiry that would reasonably be expected to lead to any Acquisition Proposal; (iv) submit to the stockholders of Advaxis for their approval or adoption any Acquisition Proposal; (v) approve, declare advisable, adopt or recommend, or publicly propose to approve, declare advisable, adopt or recommend, or allow Advaxis or any of its Subsidiary to execute or enter into, any binding or non-binding letter of intent, agreement in principle, memorandum of understanding, merger agreement, acquisition agreement, option agreement, joint venture agreement, partnership agreement or other agreement contemplating or otherwise in connection with, or that is intended to or would reasonably be expected to lead to, any Acquisition Proposal; (vi) grant any waiver or release under any confidentiality, standstill or similar agreement (other than to Biosight); or (vii) agree or publicly announce an intention to take any of the foregoing actions.

**(b)** Notwithstanding anything contained in Section 4.4(a), from the date of this Agreement and continuing until Advaxis' receipt of the Advaxis Stockholder Approval, if neither Advaxis nor any of its Representatives breached the covenants in Section 4.4(a), Advaxis and the Board of Directors of Advaxis may, directly or indirectly through one or more of its Representatives (including the Advaxis Financial Advisor), in response to a bona fide written Acquisition Proposal that was first received after the date hereof:

**(i)** furnish information regarding Advaxis and its Subsidiaries to the Person making such Acquisition Proposal and its Representatives pursuant to and in accordance with an Acceptable Confidentiality Agreement; *provided*, that all such information provided to such Person has previously been provided to Biosight or is provided to Biosight at least three (3) Business Days prior to furnishing such information to such Person; and

**(ii)** enter into discussions or negotiations with such Person or its Representatives;

*provided*, in each case, that (A) the Board of Directors of Advaxis determines in good faith, after consultation with its outside legal counsel and a reputable financial advisor, that (1) such Acquisition Proposal is reasonably likely to result in a Superior Offer and (2) the failure to furnish such information or enter into such discussions or negotiations with respect to such Acquisition Proposal would constitute a breach of its fiduciary duties under applicable Legal Requirements; and (B) at least three (3) Business Days prior to furnishing any such information to, or entering into discussions or negotiations with, such Person, Advaxis gives Biosight written notice of the identity of such Person and of such Party's intention to furnish information to, or enter into discussions with, such Person.

**(c)** If Advaxis or any Representative of Advaxis receives an Acquisition Proposal at any time during the Interim Period, then Advaxis shall promptly (and in no event later than 24 hours after becoming aware of such Acquisition Proposal) advise Biosight orally and in writing of such Acquisition Proposal (including the identity of the Person making or submitting such Acquisition Proposal, and the terms thereof). Advaxis shall keep Biosight informed in all material respects with respect to the status and terms of any such Acquisition Proposal and any modification or proposed modification thereto. In addition to the foregoing, Advaxis shall provide Biosight with at least three (3) Business Days' written notice of a meeting of its Board of Directors (or any committee thereof) at which its Board of Directors (or any committee thereof) is reasonably expected to consider an Acquisition Proposal it has received.

**(d)** Neither the Board of Directors of Advaxis nor any committee thereof shall, directly or indirectly, effect a Change in Advaxis Board Recommendation. Notwithstanding the foregoing, at any time prior to receipt of the Advaxis Stockholder Approval, if neither Advaxis nor any of its Representatives breached the covenants in Section 4.4, the Board of Directors of Advaxis may, effect a Change in Advaxis Board Recommendation if: (i) an unsolicited, bona fide, written Acquisition Proposal that did not otherwise result directly or indirectly from a breach of the provisions of this Section 4.4 is made to Advaxis and is not withdrawn; (ii) Advaxis' Board of Directors reasonably determines in good faith, after having taken into account the advice of an independent reputable financial advisor and the advice of Advaxis' outside legal counsel, that such Acquisition Proposal constitutes a Superior Offer; (iii) Advaxis' Board of Directors reasonably determines in good faith, after having taken into account the advice of Advaxis' outside legal counsel, that, in light of such Superior Offer, making a Change in Advaxis Board Recommendation is required in order for Advaxis' Board of Directors to comply with its fiduciary duties to Advaxis' stockholders under applicable Delaware Legal Requirements; (iv) prior to effecting such Change in Advaxis Board Recommendation, Advaxis' Board of Directors shall have given Biosight at least five (5) Business Days' prior written notice: (A) that it has received a Superior Offer that did not result directly or indirectly from a breach of the provisions of this Section 4.4; (B) that it intends to make a Change in Advaxis Board Recommendation; and (C) specifying the material terms and conditions of such Superior Offer, including the identity of the Person making such offer (and attaching the most current and complete version of any written agreement or other document relating thereto) (it being understood and agreed that any change to the consideration payable in connection with such Superior Offer or any other material modification thereto shall require a new five (5) Business Days' advance written notice by Advaxis (except that the three day period referred to above shall be reduced to two days)); (v) during any such three (3) Business Day notice period(s), Advaxis engages (to the extent requested by Biosight) in good faith negotiations with Biosight to amend this Agreement in such a manner that such Superior Offer would no longer constitute a Superior Offer; and (vi) at the time of any Change in Advaxis Board Recommendation, the Advaxis Board of Directors reasonably determines in good faith, after taking into account the advice of an independent reputable financial advisor and the advice of Advaxis' outside legal counsel, that the failure to make a Change in Advaxis Board Recommendation would still constitute a breach of the fiduciary duties of Advaxis' Board of Directors to the Advaxis' stockholders under applicable Delaware Legal Requirements in light of such Superior Offer (taking into account any changes to the terms of this Agreement proposed by Biosight as a result of the negotiations required by clause "(v)" or otherwise).

**(e)** Advaxis shall, and shall cause its Subsidiaries and shall use reasonable best efforts to cause its and their respective Representatives to, immediately cease and cause to be terminated any existing activities, discussions or negotiations with any Persons or their Representatives conducted prior to the date of this Agreement with respect to any Acquisition Proposal and will request the prompt return or destruction of any confidential information previously furnished to such Persons in connection therewith and immediately terminate the access of each such Person and its Representatives to any data room maintained by or on behalf of Advaxis or any of its Subsidiaries. Neither Advaxis nor any of its Subsidiaries shall modify, amend or terminate, or waive, release, fail to enforce or assign any provisions of, any confidentiality agreement (other than any standstill provision therein) to which it is a party relating to any Acquisition Proposal and shall enforce, to the fullest extent permitted under applicable Legal Requirements, the provisions of any such agreement (other than any standstill provision therein). Without limiting the foregoing, any violation of the restrictions set forth in this Section 4.4 by any Representative of Advaxis or any of its Subsidiaries shall be deemed to be a breach of this Section 4.4 by Advaxis.

**4.5** Biosight No Solicitation.

**(a)** Biosight agrees that neither it nor any of its Subsidiaries shall, nor shall it nor any of its Subsidiaries authorize or permit any of the officers, directors, employees, investment bankers, attorneys, accountants, Representatives, consultants or other agents retained by it or any of its Subsidiaries to, directly or indirectly, (i) solicit, initiate, encourage, induce or knowingly facilitate the communication, making, submission or announcement of any Acquisition Proposal or take any action that could reasonably be expected to lead to an Acquisition Proposal; (ii) furnish to any Person any information or data with respect to, or cooperate in any way that would otherwise reasonably be expected to lead to, any proposal or inquiry that constitutes, or would reasonably be expected to lead to, any Acquisition Proposal; (iii) enter into, continue or otherwise engage in any discussions or negotiations with any Person with respect to any Acquisition Proposal or any proposal or inquiry that would reasonably be expected to lead to any Acquisition Proposal; (iv) submit to the stockholders of Biosight for their approval or adoption any Acquisition Proposal; (v) approve, declare advisable, adopt or recommend, or publicly propose to approve, declare advisable, adopt or recommend, or allow Biosight or any of its Subsidiary to execute or enter into, any binding or non-binding letter of intent, agreement in principle, memorandum of understanding, merger agreement, acquisition agreement, option agreement, joint venture agreement, partnership agreement or other agreement contemplating or otherwise in connection with, or that is intended to or would reasonably be expected to lead to, any Acquisition Proposal; (vi) grant any waiver or release under any confidentiality, standstill or similar agreement (other than to Advaxis); or (vii) agree or publicly announce an intention to take any of the foregoing actions.

**(b)** Notwithstanding anything contained in Section 4.5(a), from the date of this Agreement and continuing until Biosight's receipt of the Biosight Shareholder Approval, if neither Biosight nor any of its Representatives breached the covenants in Section 4.5(a), Biosight and the Board of Directors of Biosight may, directly or indirectly through one or more of its Representatives, in response to a bona fide written Acquisition Proposal that was first received after the date hereof:

**(i)** furnish information regarding Biosight and its Subsidiaries to the Person making such Acquisition Proposal and its Representatives pursuant to and in accordance with an Acceptable Confidentiality Agreement; *provided*, that all such information provided to such Person has previously been provided to Advaxis or is provided to Advaxis at least three (3) Business Days prior to furnishing such information to such Person; and

**(ii)** enter into discussions or negotiations with such Person or its Representatives;

*provided*, in each case, that (A) the Board of Directors of Biosight determines in good faith, after consultation with its outside legal counsel and a reputable financial advisor, that (1) such Acquisition Proposal is reasonably likely to result in a Superior Offer and (2) the failure to furnish such information or enter into such discussions or negotiations with respect to such Acquisition Proposal would constitute a breach of its fiduciary duties under applicable Legal Requirements; and (B) at least three (3) Business Days prior to furnishing any such information to, or entering into discussions or negotiations with, such Person, Biosight gives Advaxis written notice of the identity of such Person and of such Party's intention to furnish information to, or enter into discussions with, such Person.

**(c)** If Biosight or any Representative of Biosight receives an Acquisition Proposal at any time during the Interim Period, then Biosight shall promptly (and in no event later than 24 hours after becoming aware of such Acquisition Proposal) advise Advaxis orally and in writing of such Acquisition Proposal (including the identity of the Person making or submitting such Acquisition Proposal, and the terms thereof). Biosight shall keep Advaxis informed in all material respects with respect to the status and terms of any such Acquisition Proposal and any modification or proposed modification thereto. In addition to the foregoing, Biosight shall provide Advaxis with at least three (3) Business Days' written notice of a meeting of its Board of Directors (or any committee thereof) at which its Board of Directors (or any committee thereof) is reasonably expected to consider an Acquisition Proposal it has received.

**(d)** Neither the Board of Directors of Biosight nor any committee thereof shall, directly or indirectly, effect a Change in Biosight Board Recommendation. Notwithstanding the foregoing, at any time prior to receipt of the Biosight Shareholder Approval, if neither Biosight nor any of its Representatives breached the covenants in Section 4.5, the Board of Directors of Biosight may, effect a Change in Biosight Board Recommendation if: (i) an unsolicited, bona fide, written Acquisition Proposal that did not otherwise result directly or indirectly from a breach of the provisions of this Section 4.5 is made to Biosight and is not withdrawn; (ii) Biosight's Board of Directors reasonably determines in good faith, after having taken into account the advice of an independent reputable financial advisor and the advice of Biosight's outside legal counsel, that such Acquisition Proposal constitutes a Superior Offer; (iii) Biosight's Board of Directors reasonably determines in good faith, after having taken into account the advice of Biosight's outside legal counsel, that, in light of such Superior Offer, making a Change in Biosight Board Recommendation is required in order for Biosight's Board of Directors to comply with its fiduciary duties to Biosight's stockholders under applicable law; (iv) prior to effecting such Change in Biosight Board Recommendation, Biosight's Board of Directors shall have given Advaxis at least five (5) Business Days' prior written notice: (A) that it has received a Superior Offer that did not result directly or indirectly from a breach of the provisions of this Section 4.5; (B) that it intends to make a Change in Biosight Board Recommendation; and (C) specifying the material terms and conditions of such Superior Offer, including the identity of the Person making such offer (and attaching the most current and complete version of any written agreement or other document relating thereto) (it being understood and agreed that any change to the consideration payable in connection with such Superior Offer or any other material modification thereto shall require a new five (5) Business Days' advance written notice by Biosight (except that the three day period referred to above shall be reduced to two days)); (v) during any such three (3) Business Day notice period(s), Biosight engages (to the extent requested by Advaxis) in good faith negotiations with Advaxis to amend this Agreement in such a manner that such Superior Offer would no longer constitute a Superior Offer; and (vi) at the time of any Change in Biosight Board Recommendation, the Biosight Board of Directors reasonably determines in good faith, after taking into account the advice of an independent reputable financial advisor and the advice of Biosight's outside legal counsel, that the failure to make a Change in Biosight Board Recommendation would still constitute a breach of the fiduciary duties of Biosight's Board of Directors to the Biosight's stockholders under applicable law in light of such Superior Offer (taking into account any changes to the terms of this Agreement proposed by Biosight as a result of the negotiations required by clause "(v)" or otherwise).

**(e)** Biosight shall, and shall cause its Subsidiaries and shall use reasonable best efforts to cause its and their respective Representatives to, immediately cease and cause to be terminated any existing activities, discussions or negotiations with any Persons or their Representatives conducted prior to the date of this Agreement with respect to any Acquisition Proposal and will request the prompt return or destruction of any confidential information previously furnished to such Persons in connection therewith and immediately terminate the access of each such Person and its Representatives to any data room maintained by or on behalf of Biosight or any of its Subsidiaries. Neither Biosight nor any of its Subsidiaries shall modify, amend or terminate, or waive, release, fail to enforce or assign any provisions of, any confidentiality agreement (other than any standstill provision therein) to which it is a party relating to any Acquisition Proposal and shall enforce, to the fullest extent permitted under applicable Legal Requirements, the provisions of any such agreement (other than any standstill provision therein). Without limiting the foregoing, any violation of the restrictions set forth in this Section 4.5 by any Representative of Biosight or any of its Subsidiaries shall be deemed to be a breach of this Section 4.5 by Biosight.

**(f)** Solely for purposes of this Section 4.5 it is understood and agreed that, in the absence of compelling legal authority to the contrary, Biosight, the Biosight Board of Directors and Biosight's outside legal counsel shall be entitled to rely on and deem applicable to Biosight and the Biosight Board of Directors the Legal Requirements applicable to corporations incorporated in Delaware for purposes of making the conclusions contemplated by this Section 4.5 (and providing advice with respect thereto) relating to the fiduciary obligations of such Person for purposes of this Agreement, and that references to the "fiduciary duties" of the Biosight Board of Directors and other terms of similar import shall, for purposes of this Agreement, include reference to such Delaware Legal Requirement, and shall assume that Israeli law follows Delaware Legal Requirements with respect thereto. The immediately preceding sentence is intended only to govern the contractual rights of the parties to this Agreement; it being understood and agreed that nothing in this Agreement is intended to modify any fiduciary duties of the Biosight Board of Directors under applicable Legal Requirements or give rise to any breach or violation of this Agreement on the part of Biosight by reason of the fact that the Biosight Board of Directors has complied with the Legal Requirements of the State of Israel, rather than the Delaware Legal Requirements, governing the duties owed by a director of a company formed under the Legal Requirements of the State of Israel to such company, its shareholders or any other Person.

**4.6** No Control. Nothing contained in this Agreement shall give Advaxis or Biosight, directly or indirectly, the right to control or direct the other Party's operations prior to the Effective Time. Prior to the Effective Time, each Party will exercise, consistent with the terms and conditions of this Agreement, complete control and supervision over its and its Subsidiaries' respective operations.

SECTION 5. Additional Agreements of the Parties

**5.1** Registration Statement; Proxy Statement/Prospectus/Information Statement.

**(a)** As promptly as practicable and, in any event, no later than forty-five (45) calendar days following the date of this Agreement, Advaxis and Biosight shall prepare and cause to be filed with the SEC the Proxy Statement/Prospectus/Information Statement and Advaxis shall prepare and cause to be filed with the SEC the Form S-4 Registration Statement, in which the Proxy Statement/Prospectus/Information Statement will be included as a prospectus. The Form S-4 Registration Statement and the Proxy Statement/Prospectus/Information Statement shall comply as to form in all material respects with the applicable provisions of the Securities Act and the Exchange Act. Advaxis covenants and agrees that the Proxy Statement/Prospectus/Information Statement, including any pro forma financial statements included therein (and the letter to stockholders, notice of meeting and form of proxy included therewith), will not, at the time that the Proxy Statement/Prospectus/Information Statement or any amendment or supplement thereto is filed with the SEC or is first mailed to the stockholders of Advaxis, at the time of the Advaxis Stockholders' Meeting and at the Effective Time, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements made therein, in light of the circumstances under which they were made, not misleading. Biosight covenants and agrees that the information provided by Biosight or its Affiliates to Advaxis for inclusion in the Form S-4 Registration Statement and/or Proxy Statement/Prospectus/Information Statement will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make such information not misleading. Notwithstanding the foregoing, Advaxis makes no covenant, representation or warranty with respect to statements made in the Proxy Statement/Prospectus/Information Statement (and the letter to stockholders, notice of meeting and form of proxy included therewith), if any, based on information furnished in writing by Biosight or any of Biosight's Representatives specifically for inclusion therein. Each of Advaxis and Biosight shall furnish all information concerning such Person and its Affiliates to the other, including financial statements and descriptions of its business and financial condition, and provide such other assistance, as may be reasonably requested in connection with the preparation, filing and distribution of the Form S-4 Registration Statement and Proxy Statement/Prospectus/Information Statement, including causing the timely cooperation of its independent public accountants in connection with the preparation and filing of the Form S-4 Registration Statement and Proxy Statement/Prospectus/Information Statement, including by causing such accountants to provide a consent to the inclusion of such accountant's reports in respect of the financial statements of the applicable party in the Form S-4 Registration Statement and/or Proxy Statement/Prospectus/Information Statement (as applicable) and to the reference to such accountant firm as an "expert" therein, and the Form S-4 Registration Statement and Proxy Statement/Prospectus/Information Statement shall include all information reasonably requested by such other party to be included therein. All filings by Advaxis with the SEC in connection with the Transactions and all mailings to the Advaxis' stockholders in connection with the Transactions shall be subject to the prior review and comment by Biosight. Each of the Parties shall use commercially reasonable efforts to cause the Form S-4 Registration Statement and the Proxy Statement/Prospectus/Information Statement to comply with the applicable rules and regulations promulgated by the SEC, to respond promptly to any comments of the SEC or its staff and to have the Form S-4 Registration Statement declared effective under the Securities Act as promptly as practicable after it is filed with the SEC and keep the Form S-4 Registration Statement effective for so long as necessary to consummate the Transactions. Each of the Parties shall use commercially reasonable efforts to cause the Proxy Statement/Prospectus/Information Statement to be mailed to Advaxis' stockholders as promptly as practicable after the Form S-4 Registration Statement is declared effective under the Securities Act. In the event there is any tax opinion, comfort letter or other opinion required to be provided in connection with the Form S-4 Registration Statement and/or the Proxy Statement/Prospectus/Information Statement, notwithstanding anything to the contrary, neither this provision nor any other provision in this Agreement shall require counsel to Biosight or its tax advisors to provide an opinion that the Transactions (including the Merger) qualify for the Intended Tax Treatment; provided, however, that in the event such a tax opinion is required by the SEC, each Party shall use reasonable best efforts to execute and deliver customary tax representation letters to the applicable tax advisor (or advisors) in form and substance reasonably satisfactory to the applicable tax advisor (or advisors) delivering such opinion and the Party (or Parties) delivering such tax representation letter(s).

**(b)** Each of Advaxis and Biosight shall, as promptly as practicable after receipt thereof, provide the other Parties copies of any written comments and advise the other Parties of any oral comments, with respect to the Proxy Statement/Prospectus/Information Statement received from the SEC. Advaxis shall provide Biosight with a reasonable opportunity to review and comment on any amendment or supplement to the Form S-4 Registration Statement and any communications prior to filing such with the SEC and will promptly provide Biosight with a copy of all such filings and communications made with the SEC.

**(c)** Advaxis and Biosight shall promptly make all necessary filings with respect to the Merger and the issuance of the Advaxis Common Stock under the Securities Act, the Exchange Act, applicable state blue sky laws and the rules and regulations thereunder. Each Party will advise the other Parties, promptly after it receives notice thereof, of the time when the Form S-4 Registration Statement has become effective, the issuance of any stop order, the suspension of the qualification of Advaxis Common Stock issuable in connection with the Merger for offering or sale in any jurisdiction, or any request by the SEC for amendment of the Form S-4 Registration Statement and Proxy Statement/Prospectus/Information Statement.

**(d)** If at any time prior to the Effective Time, (i) any event or change occurs with respect to the Parties or any of their respective Affiliates, officers or directors, which should, in Advaxis' reasonable discretion, be set forth in an amendment of, or supplement to, the Form S-4 Registration or the Proxy Statement/Prospectus/Information Statement or (ii) any information relating to the Parties, or any of their respective Affiliates, officers or directors, should be discovered by any of the Parties which should be set forth in an amendment or supplement to the Form S-4 Registration Statement or the Proxy Statement/Prospectus/Information Statement so that any such document would not include any misstatement of a material fact or omit to state any material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, the Parties shall file as promptly as practicable with the SEC a mutually acceptable amendment of, or supplement to, the Form S-4 Registration Statement or the Proxy Statement/Prospectus/Information Statement and, to the extent required by applicable Legal Requirements, disseminate the information contained in such amendment or supplement to the stockholders of the Parties.

**5.2** Advaxis Stockholders' Meeting.

**(a)** Promptly after the Form S-4 Registration Statement is declared effective, Advaxis shall, in consultation with Biosight, take all action necessary to (i) establish a record date for, duly call and give notice of a meeting of the stockholders of Advaxis (the "***Advaxis Stockholders' Meeting***") for the purpose of obtaining the Advaxis Stockholder Approval, (ii) cause the Proxy Statement/Prospectus/Information Statement (and all other proxy materials for the Advaxis Stockholders' Meeting) to be mailed to its stockholders and (iii) duly convene and hold the Advaxis Stockholders' Meeting. Advaxis' obligation to call, convene and hold the Advaxis Stockholders' Meeting shall not be affected by a Change in Advaxis Board Recommendation, unless the Agreement is terminated pursuant to Section 9.1. Advaxis will use its reasonable best efforts to solicit from its stockholders proxies in favor of the adoption of this Agreement and the approval of the Transactions, including the Merger, and the Reverse Split, and will take all other action necessary or advisable to obtain the Advaxis Stockholder Approval. Notwithstanding anything to the contrary contained in this Agreement, Advaxis may adjourn or postpone the Advaxis Stockholders' Meeting (i) after consultation with Biosight, to the extent necessary to ensure that any necessary supplement or amendment to the information provided to Advaxis' stockholders (as determined by Advaxis in good faith and upon the advice of outside counsel) is provided to Advaxis' stockholders a reasonable time in advance of the Advaxis Stockholders' Meeting (or at any adjournment or postponement thereof), or (ii) if as of the time for which the Advaxis Stockholders' Meeting (or any adjournment or postponement thereof) is scheduled there are insufficient shares of Advaxis Common Stock represented in person or by proxy to constitute a quorum necessary to conduct the business of the Advaxis Stockholders' Meeting or to adopt this Agreement and approve the Transactions, including the Merger. The Proxy Statement/Prospectus/Information shall include the Advaxis Board Recommendation.

**(b)** To the extent reasonably necessary to comply with applicable listing criteria of the Exchange or otherwise to permit the issuance of the Merger Consideration hereunder, Advaxis will submit to the holders of Advaxis Common Stock at the Advaxis Stockholders' Meeting a proposal to approve a reverse stock split of Advaxis Common Stock whereby each share of Advaxis Common Stock issued and outstanding immediately prior to the filing of such amendment to the certificate of incorporation of Advaxis shall be converted into and become a number of fully paid and nonassessable shares of Advaxis Common Stock, with such reverse stock split ratio in the range mutually agreed to by Advaxis and Biosight (the "***Reverse Split***").

**(c)** Neither the Board of Directors of Advaxis nor any committee thereof shall (i) withhold, withdraw or qualify (or amend or modify in a manner adverse to Biosight) or publicly propose to withdraw or qualify (or amend or modify in a manner adverse to Biosight), the Advaxis Board Recommendation, (ii) take any public action or make any public statement in connection with the Advaxis Stockholders' Meeting inconsistent with such Advaxis Board Recommendation, (iii) recommend, adopt, endorse or approve, or propose publicly to recommend, adopt, endorse or approve, any Acquisition Proposal, or (iv) waive any rights under or amend the Rights Agreement, except as contemplated by Section 2.3(f), redeem any rights under the Rights Agreement or otherwise cause the Rights Agreement to be inapplicable or neutralized with respect to any Acquisition Proposal (any of the actions described in clauses (i), (ii), (iii) or (iv), a "***Change in Advaxis Board Recommendation***").

**5.3** Biosight Shareholder Approval.

**(a)** Promptly after the S-4 Registration Statement shall have been declared effective under the Securities Act, Biosight shall take all actions necessary in accordance with the ICL and its Constituent Documents to duly call, give notice of, convene and hold as promptly as practicable a special meeting of Biosight Shareholders (the "***Biosight Shareholders' Meeting***") to seek the Biosight Shareholder Approval, including mailing any applicable materials to its shareholders as promptly as reasonably practicable. Alternatively, in accordance with the ICL and its Constituent Documents, Biosight may seek the Biosight Shareholder Approval by written consent (the "***Biosight Shareholder Written Consent***"). Biosight's obligation to call, convene and hold the Biosight Shareholders' Meeting shall not be affected by a Change in Biosight Board Recommendation, unless the Agreement is terminated pursuant to Section 9.1. Biosight will use its reasonable best efforts to solicit from its shareholders proxies or the Biosight Shareholder Written Consent in favor of the adoption of this Agreement and the approval of the Transactions, including the Merger, and will take all other action necessary or advisable to obtain the Biosight Shareholder Approval. Notwithstanding anything to the contrary contained in this Agreement, Biosight may adjourn or postpone the Biosight Shareholders' Meeting to the extent necessary to ensure that any necessary supplement or amendment to the information provided to Biosight Shareholders (as determined by Biosight in good faith and upon the advice of outside counsel) is provided to the Biosight Shareholders a reasonable time in advance of the Biosight Shareholders' Meeting (or at any adjournment or postponement thereof), or if as of the time for which the Biosight Shareholders' Meeting (or any adjournment or postponement thereof) is scheduled insufficient Biosight Shares are represented in person or by proxy to constitute a quorum necessary to conduct the business of the Biosight Shareholders' Meeting or to adopt this Agreement and approve the Transactions, including the Merger.

**(b)** The Board of Directors of Biosight shall recommend that Biosight Shareholders vote in favor of the adoption of this Agreement and the approval of the Transactions, including the Merger, at the Biosight Shareholders' Meeting (or any adjournment or postponement thereof) or by the Biosight Shareholder Written Consent (the ***"Biosight Board Recommendation"***).

**(c)** Neither the Board of Directors of Biosight nor any committee thereof shall (i) withhold, withdraw or qualify (or amend or modify in a manner adverse to Advaxis) or publicly propose to withdraw or qualify (or amend or modify in a manner adverse to Advaxis), the Biosight Board Recommendation, (ii) take any public action or make any public statement in connection with the Biosight Shareholders' Meeting inconsistent with such Biosight Board Recommendation; or (iii) recommend, adopt, endorse or approve, or propose publicly to recommend, adopt, endorse or approve, any Acquisition Proposal (any of the actions described in clauses (i), (ii) or (iii), a "***Change in Biosight Board Recommendation***").

**5.4** Merger Proposal; Certificate of Merger.

**(a)** Subject to the ICL, as promptly as practicable following the date hereof, Biosight and Merger Sub, as applicable, shall take the following actions within the timeframes set forth herein; *provided*, *however*, that any such actions or the timeframe for taking such action shall be subject to any amendment in the applicable provisions of the ICL (and in case of an amendment thereto, such amendment shall automatically apply so as to amend this Section 5.4(a) accordingly): (i) Biosight and Merger Sub shall cause a merger proposal (in the Hebrew language) (the "***Merger Proposal***") to be prepared and executed in accordance with Section 316 of the ICL; (ii) Biosight and Merger Sub shall deliver the executed Merger Proposal to the Companies Registrar within three (3) days from the calling of the Biosight Shareholders' Meeting; (iii) Biosight and Merger Sub, as applicable, shall cause a copy of the Merger Proposal to be delivered to its secured creditors, if any, no later than three (3) days after the date on which the Merger Proposal is delivered to the Companies Registrar; (iv) promptly after Biosight and Merger Sub, as applicable, shall have complied with the preceding sentence and with clauses (i) and (ii) of this Section 5.4(a), but in any event no more than three (3) days following the date on which such notice was sent to the creditors, Biosight and Merger Sub, as applicable, shall inform the Companies Registrar, in accordance with Section 317(b) of the ICL, that notice was given to their respective creditors, if any, under Section 318 of the ICL; (v) each of Biosight and, if applicable, Merger Sub, shall: (A) publish a notice to its creditors, stating that a Merger Proposal was submitted to the Companies Registrar and that the creditors may review the Merger Proposal at the office of the Companies Registrar, Biosight's registered office or Merger Sub's registered offices, as applicable, and at such other locations as Biosight or Merger Sub, as applicable, may determine, in (x) two (2) daily Hebrew newspapers, on the day that the Merger Proposal is submitted to the Companies Registrar, and (y) in a popular newspaper in New York as may be required by applicable Legal Requirements, within three (3) Business Days from the date of submitting the Merger Proposal to the Companies Registrar; and (B) if applicable, within four (4) Business Days from the date of submitting the Merger Proposal to the Companies Registrar, send a notice by registered mail to all of the "Substantial Creditors" (as such term is defined in the Israeli Companies Regulations (Merger) 5760-2000 promulgated under the ICL) that Biosight or Merger Sub, as applicable, is aware of, in which it shall state that a Merger Proposal was submitted to the Companies Registrar and that the creditors may review the Merger Proposal at such additional locations, if such locations were determined in the notice referred to in the immediately preceding clause (A); (vi) not later than three (3) days after the date on which the Biosight Shareholder Approval is received, Biosight shall (in accordance with Section 317(b) of ICL and the regulations thereunder) inform the Companies Registrar of such approval; and (vii) subject to the satisfaction or waiver of the last of the conditions set forth in Sections 6, 7 and 8 to be satisfied or (to the extent permitted) waived (other than any such conditions that by their nature are to be satisfied at the Closing, but subject to the satisfaction or (to the extent permitted) waiver of such conditions at the Closing), in accordance with the customary practice of the Companies Registrar, Biosight and Merger Sub shall provide the Companies Registrar with the Merger Notices and request that the Companies Registrar declare the Merger effective and issue the Certificate of Merger upon such date as Biosight and Merger Sub shall advise the Companies Registrar. For the avoidance of doubt, and notwithstanding any provision of this Agreement to the contrary, it is the intention of the Parties that the Merger shall be declared effective and the Certificate of Merger shall be issued on the same day that the Merger Notices are provided. For purposes of this Section 5.4(a), "***Business Day***" shall have the meaning set forth in the Israeli Companies Regulations (Merger) 5760-2000 promulgated under the ICL.

**(b)** The sole stockholder of Merger Sub has approved the Merger. No later than three (3) days after the date of such approval, Merger Sub shall (in accordance with Section 317(b) of the ICL and the regulations thereunder) inform the Companies Registrar of such approval.

**5.5** Required Approvals.

**(a)** Each Party shall use reasonable best efforts to take, or cause to be taken, all actions and to do, or cause to be done, all things necessary, proper or advisable under applicable Legal Requirements to consummate the Transactions, including obtaining as promptly as reasonably practicable any necessary Consents of, and actions or inaction by, and making as promptly as practicable all necessary filings, submissions and declarations with, any Governmental Authority, or other third party as mutually agreed and as necessary in connection with the consummation of the Transactions. In furtherance and not in limitation of the foregoing, each of Advaxis and Biosight shall (i) make or cause to be made the filings, submissions and declarations required of such party under the HSR Act and any Foreign Competition Law, including but not limited to the Israeli Economic Competition Law 1988 (the "***Israeli Competition Law***"), with respect to the Transactions as promptly as practicable after the date of this Agreement (and in any event, in the case of the HSR Act, within seven (7) Business Days after the date of this Agreement), (ii) comply at the earliest practicable date with any request under the HSR Act or the Israeli Competition Law for additional information, documents or other materials received by such Party from the U.S. Federal Trade Commission, the Antitrust Division of the U.S. Department of Justice, Israeli Competition Authority, the Israeli Competition Commissioner, the Israeli Competition Tribunal or by any other Governmental Authority (including under any Foreign Competition Laws) in respect of such filings, submissions and declarations or the Transactions and (iii) act in good faith and reasonably cooperate with the other Party in connection with any such filings, submissions and declarations and in connection with resolving, and use reasonable best efforts to resolve, any investigation or other inquiry of any such agency or other Governmental Authority under any of the HSR Act, the Israeli Competition Law or other Foreign Competition Laws, the Sherman Act, the Clayton Act and any other Legal Requirements or Orders that are designed to prohibit, restrict or regulate actions having the purpose or effect of monopolization or restraint of trade (collectively, the "***Antitrust Laws***") with respect to any such filings, submissions and declarations or any of the Transactions. To the extent not prohibited by applicable Legal Requirement, Advaxis, on the one hand, will provide Biosight, and Biosight, on the other hand, will provide Advaxis, with copies of any material correspondence, filing or communication between such Party or any of its Representatives, on the one hand, and any Governmental Authority or members of their respective staffs, on the other hand, with respect to this Agreement and the Transactions. Prior to submitting or making any such correspondence, filing or communication to any such Governmental Authority or members of their respective staffs, the Parties shall, to the extent permitted by applicable Legal Requirement, first provide the other Party with a copy of such correspondence, filing or communication in draft form and give such other Party a reasonable opportunity to discuss its content before it is submitted or filed with the relevant Governmental Authorities, and shall consider and take account of all reasonable comments timely made by the other Party with respect thereto. To the extent permitted by applicable Legal Requirement, each of the Parties shall ensure that the other Party is given the opportunity to attend any meetings with or other appearances before any Governmental Authority with respect to the Transactions; provided further, and for the avoidance of doubt, neither Party shall have an obligation to agree to any structural, operational or behavioral remedy or to litigate in connection with the consummation of the Transactions.

**(b)** In furtherance and not in limitation of the foregoing, Biosight shall file final written notice with the Israeli National Authority for Technological Innovation (also known as the Israeli Innovation Authority and formerly known as the Office of the Chief Scientist of the Israeli Ministry of Economy and Industry) (the "***IIA***") pursuant to the Israeli Encouragement of Research, Development and Technological Innovation in the Industry Law, 5744 1984, and the rules and regulations related thereto in connection with the Merger. Advaxis shall execute an undertaking towards the IIA, in the standard form as required by the IIA, attached hereto as Exhibit E (the "***IIA Undertaking***").

**5.6** Indemnification of Advaxis' Officers and Directors.

**(a)** From the Effective Time through the sixth ($6^{th}$) anniversary of the date on which the Effective Time occurs, Advaxis shall indemnify and hold harmless each person who is now, or has been at any time prior to the date hereof, or who becomes prior to the Effective Time, a director, manager or officer of Advaxis (the "***Advaxis D&O Indemnified Parties***"), against all claims, losses, liabilities, damages, judgments, fines and reasonable fees, costs and expenses, including attorneys' fees and disbursements (collectively, "***Costs***"), incurred in connection with any claim, action, suit, proceeding or investigation, whether civil, criminal, administrative or investigative, arising out of or pertaining to the fact that the Advaxis D&O Indemnified Party is or was a director or officer of Advaxis, whether asserted or claimed prior to, at or after the Effective Time, to the fullest extent that Advaxis would have been required under its Constituent Documents in effect on the date of this Agreement. Each Advaxis D&O Indemnified Party will be entitled to advancement of expenses incurred in the defense of any such claim, action, suit, proceeding or investigation from Advaxis, upon receipt by Advaxis from the Advaxis D&O Indemnified Party of a request therefor; *provided*, that any person to whom expenses are advanced provides an undertaking, as applicable, to repay such advances if it is ultimately determined that such person is not entitled to indemnification.

**(b)** The Constituent Documents of Advaxis shall contain provisions no less favorable with respect to indemnification, advancement of expenses and exculpation of present and former directors, managers and officers of Advaxis than are presently set forth in the Constituent Documents of Advaxis, which provisions shall not be amended, modified or repealed for a period of six (6) years from the Effective Time in a manner that would adversely affect the rights thereunder of individuals who, at or prior to the Effective Time, were directors, managers or officers of Advaxis.

**(c)** At or prior to the Effective Time, Advaxis shall purchase, and for a period of six (6) years following the Effective Time, Advaxis shall continue in effect, a directors' and officers' liability "tail" insurance policy or policies covering the Advaxis D&O Indemnified Parties for events occurring at or prior to the Effective Time, that is substantially equivalent to and in any event not less favorable in the aggregate than the existing policies of Advaxis as of the date of this Agreement; *provided*, that Advaxis shall not pay for such "tail" policy more than 300% of the current annual premium paid by Advaxis for such insurance policy.

**(d)** In the event Advaxis or any of its successors or assigns (i) consolidates with or merges into any other person and shall not be the continuing or surviving company or entity of such consolidation or merger, or (ii) transfers all or substantially all of its properties and assets to any person, then, and in each such case, proper provision shall be made so that the successors and assigns of Advaxis shall succeed to the obligations set forth in this Section 5.6.

**5.7** Indemnification of Biosight's Officers and Directors.

**(a)** From the Effective Time through the sixth ($6^{th}$) anniversary of the date on which the Effective Time occurs, the Surviving Company shall indemnify and hold harmless each person who is now, or has been at any time prior to the date hereof, or who becomes prior to the Effective Time, a director, manager or officer of Biosight (the "***Biosight D&O Indemnified Parties***"), against all Costs incurred in connection with any claim, action, suit, proceeding or investigation, whether civil, criminal, administrative or investigative, arising out of or pertaining to the fact that the Biosight D&O Indemnified Party is or was a director or officer of the Surviving Company, whether asserted or claimed prior to, at or after the Effective Time, to the fullest extent that the Surviving Company would have been required under its Constituent Documents in effect on the date of this Agreement. Each Biosight D&O Indemnified Party will be entitled to advancement of expenses incurred in the defense of any such claim, action, suit, proceeding or investigation from the Surviving Company upon receipt by the Surviving Company from the Biosight D&O Indemnified Party of a request therefor; *provided*, that any person to whom expenses are advanced provides an undertaking, as applicable, to repay such advances if it is ultimately determined that such person is not entitled to indemnification.

**(b)** Advaxis shall cause the Constituent Documents of the Surviving Company to contain provisions no less favorable with respect to indemnification, advancement of expenses and exculpation of present and former directors, managers and officers of Biosight than are presently set forth in the Constituent Documents of Biosight, which provisions shall not be amended, modified or repealed for a period of six (6) years from the Effective Time in a manner that would adversely affect the rights thereunder of individuals who, at or prior to the Effective Time, were directors, managers or officers of Biosight.

**(c)** At or prior to the Effective Time, Biosight shall purchase, and for a period of six (6) years following the Effective Time, the Surviving Company shall continue in effect, a directors' and officers' liability "tail" insurance policy or policies covering the Biosight D&O Indemnified Parties for events occurring at or prior to the Effective Time, that is substantially equivalent to and in any event not less favorable in the aggregate than the existing policies of Biosight as of the date of this Agreement; *provided*, that Biosight or the Surviving Company (as applicable) shall not pay for such "tail" policy more than 300% of the current annual premium paid by Biosight for such insurance policy.

**(d)** In the event the Surviving Company or any of its successors or assigns (i) consolidates with or merges into any other person and shall not be the continuing or surviving company or entity of such consolidation or merger, or (ii) transfers all or substantially all of its properties and assets to any person, then, and in each such case, proper provision shall be made so that the successors and assigns of the Surviving Company shall succeed to the obligations set forth in this Section 5.7.

**5.8** Further Assurances. Without limiting any covenant contained in Section 4 or Section 5, which covenants shall control to the extent of any conflict with the succeeding provisions of this Section 5.8, each of Advaxis, Merger Sub and Biosight shall use commercially reasonable efforts, consistent with the terms of this Agreement, to take, or cause to be taken, all actions, and to do, or cause to be done, all things necessary, proper or advisable to consummate the Merger and the other Transactions. Without limiting the generality of the foregoing, each Party to this Agreement: (a) shall use commercially reasonable efforts to make all filings and other submissions (if any) and give all notices (if any) required to be made and given by such Party in connection with the Transactions; (b) shall use commercially reasonable efforts to obtain each Consent reasonably required to be obtained (pursuant to any applicable Legal Requirement or Contract, or otherwise) by such Party in connection with the Transactions or for such Contract to remain in full force and effect; (c) shall use commercially reasonable efforts to lift any injunction prohibiting, or any other legal bar to, the Transactions; (d) shall use commercially reasonable efforts to satisfy the conditions to Closing set forth in this Agreement and (e) execute or deliver any additional instruments necessary to consummate the Merger and the other Transactions, and to fully carry out the purposes of, this Agreement.

**5.9** Public Announcement. Advaxis and Biosight have agreed upon the initial joint press release with respect to the execution of this Agreement, and will issue such press release promptly following the execution of this Agreement. From and after the date of this Agreement until the earlier of the Effective Time or the date, if any, on which this Agreement is terminated pursuant to Section 9.1, so long as this Agreement is in effect, neither Advaxis nor Biosight, nor any of their respective Affiliates, shall issue or cause the publication of any press release or any public announcement with respect to the Transactions or this Agreement without the prior consent of the other Party (such consent not to be unreasonably withheld, conditioned or delayed), unless such Party determines, after consultation with outside counsel, that it is required by applicable Legal Requirements or by any listing agreement with or the listing rules of a national securities exchange or trading market to issue or cause the publication of any press release or any public announcement with respect to the Transactions or this Agreement, in which event such Party shall endeavor, on a basis reasonable under the circumstances, to provide a meaningful opportunity to the other Party to review and comment upon such press release or public announcement in advance and shall give due consideration to all reasonable additions, deletions or changes suggested thereto. Notwithstanding the foregoing, the restrictions set forth in this Section 5.9 shall not apply to any release or announcement made or proposed to be made in connection with and related to: (a) a Change in Advaxis Board Recommendation or (b) a Change in Biosight Board Recommendation, in each case to the extent made in accordance with the provisions of this Agreement.

**5.10** Listing.

**(a)** Following the date of this Agreement, Advaxis shall use its reasonable best efforts to (i) regain compliance with Nasdaq Listing Rule 5550(a)(2) (the "***Listing Rule***"), including appealing any determination by the Listing Qualifications Department of The Nasdaq Stock Market LLC that Advaxis is not in compliance with the Listing Rule, (ii) otherwise remain in compliance with Nasdaq Listing Rules, and (iii) ensure that the shares of Advaxis Common Stock to be issued in the Merger shall be approved for listing (subject to official notice of issuance) on the NASDAQ Capital Market as of the Effective Time. Advaxis shall promptly provide Biosight with true, correct and complete copies of any and all correspondences with and to the Exchange. Any responses by Advaxis with respect to any communication by the Exchange shall be provided to the Exchange only after providing Biosight with reasonable opportunity to provide advice and input in respect of such response.

**(b)** Advaxis shall promptly, and in any event within five (5) Business Days after the filing of the Form S-4 Registration Statement, contact the Exchange to determine the requirements for the shares of Advaxis Common Stock to be listed on the Exchange at and after the Effective Time. Advaxis shall use its reasonable best efforts to (a) cause the shares of Advaxis Common Stock to be approved, at or prior to the Effective Time, for listing (subject only to notice of issuance) on the Exchange at and after the Effective Time, including paying any required fees and timely submitting any listing application and listing agreement, if any, required by the Exchange, and (b) change the trading symbol of Advaxis to a symbol chosen by Biosight, effective at, or as soon as practicable after, the Effective Time; *provided* that any required fees payable in connection with any such listing application and listing agreement shall be split evenly between Advaxis and Biosight up to a maximum aggregate amount of $50,000 payable by each such Party, with any fees above such amount to be borne solely by Advaxis.

**5.11** U.S. Tax Matters.

**(a)** Each of Advaxis, Merger Sub and Biosight and their respective Affiliates shall use their respective commercially reasonable efforts to cause the Merger to qualify for, and agree not to, and not to permit or cause any Affiliate or any Subsidiary to, knowingly take or cause to be taken, or knowingly fail to take any action or cause to be failed to be taken, any action which would reasonably be expected to prevent either the Merger or the Transactions from qualifying for the Intended Tax Treatment.

**(b)** The parties hereto hereby adopt this Agreement as a "plan of reorganization" within the meaning of Treasury Regulations Sections 1.368-2(g) and 1.368-3(a). The Parties shall not file any Tax Return, or take any position in any audit, claim, investigation, inquiry or other proceeding in respect of Taxes that is inconsistent with the Intended Tax Treatment, unless otherwise required pursuant to a final "determination" within the meaning of Section 1313(a) of the Code or any analogous provision of applicable state, local or foreign Legal Requirements. Each of the parties agrees to use reasonable best efforts to promptly notify all other parties of any challenge to the Intended Tax Treatment by any Governmental Authority.

**(c)** Notwithstanding anything to the contrary contained herein, Advaxis and Biosight each shall pay fifty percent (50%) of all transfer, documentary, sales, use, stamp, registration, value added or other similar Taxes incurred in connection with the Merger. The party responsible under applicable Legal Requirements shall file any necessary Tax Returns with respect to all such Taxes, and, if required by applicable Legal Requirements, each of Biosight, Advaxis and their respective Affiliates shall join in the execution of any such Tax Returns.

**5.12** Legends. Advaxis shall be entitled to place appropriate legends on the certificates evidencing any shares of Advaxis Common Stock to be received in the Merger by Biosight Shareholders who may be considered "affiliates" of Advaxis for purposes of Rules 144 and 145 under the Securities Act reflecting the restrictions set forth in Rules 144 and 145 and to issue appropriate stop transfer instructions to the transfer agent for Advaxis Common Stock.

**5.13** Cooperation. Each Party shall cooperate reasonably with the other Party and shall provide the other Party with such assistance as may be reasonably requested for the purpose of facilitating the performance by each Party of its respective obligations under this Agreement and to enable the Surviving Company to continue to meet its obligations following the Closing.

**5.14** Directors and Officers.

**(a)** Advaxis and Biosight shall obtain and deliver to the other Party at or prior to the Effective Time the resignation of each officer and director of Advaxis and Biosight, as applicable, who is not continuing as an officer or director of Advaxis or the Surviving Company, as applicable, following the Effective Time. Advaxis shall use reasonable best efforts to take all actions necessary so that, effective as of immediately following the Effective Time, the Board of Directors of Advaxis shall consist of nine (9) directors consisting of (i) six (6) directors designated by Biosight prior to the Closing, and (ii) three (3) directors designated by Advaxis, who shall be Dr. David Sidransky (Chairman of the Board), Ken Berlin, and one director designated by Advaxis prior to the Closing, each to hold office from and after the Effective Time until the earliest of the appointment of his or her respective successor, his or her resignation or his or her proper removal, which Board of Directors designations shall otherwise comply with the applicable listing requirements of NASDAQ. Dr. David Sidransky shall serve on the Board of Directors of Advaxis for a period of up to six (6) months from the Effective Time.

**(b)** Following the Effective Time, Ken Berlin shall continue to serve as Chief Executive Officer of Advaxis. Notwithstanding anything to the contrary herein: (i) nothing in this Section 5.14(b) shall confer on any Person any right or guarantee of continued employment (or compensation or severance with respect thereto) with Advaxis or any Subsidiary thereof following the Closing; and (ii) for the avoidance of doubt, and without limiting Section 10.7, no Person shall be a third-party beneficiary of this Section 5.14(b).

**5.15** Section 16 Matters. Prior to the Effective Time, Advaxis shall take all such steps as may be required (to the extent permitted under applicable Legal Requirements) to cause any acquisitions of Advaxis Common Stock and any options to purchase Advaxis Common Stock resulting from the Transactions, including the Merger, by each individual who is reasonably expected to become subject to the reporting requirements of Section 16(a) of the Exchange Act with respect to Advaxis, to be exempt under Rule 16b-3 promulgated under the Exchange Act.

**5.16** Treatment of Advaxis Warrants. If any holder of an Advaxis Warrant issued in connection with Advaxis' September 2018 offering properly exercises such holder's right to receive a cash payment in connection with the Transactions pursuant to the terms and conditions of the underlying agreement governing such Advaxis Warrant, Advaxis shall promptly pay such cash payment to such holder, in each case in such amount as determined in accordance with, and pursuant to the procedures set forth in, such agreement governing such Advaxis Warrant.

**5.17** Advaxis Certificate of Incorporation Amendment. Immediately prior to the Effective Time, Advaxis shall file with the Secretary of State of the State of Delaware, an amendment to the certificate of incorporation of Advaxis (the "***Advaxis Certificate of Incorporation Amendment***") to effect (i) an increase to the number of authorized shares of Advaxis Common Stock, if necessary, (ii) a change of the name of Advaxis to **"**Biosight, Inc." or any other name designated by Biosight, (iii) the Reverse Split (if approved by the Advaxis stockholders at the applicable special meeting), and (iv) any other changes as are mutually agreeable to Advaxis and Biosight.

**5.18** Notice of Certain Events. Each of the Parties shall promptly notify the other Parties after receiving or becoming aware of (a) any notice or other communication from any Person alleging that the Consent of such Person is or may be required in connection with the Transactions, (b) any Effect that would have an Advaxis Material Adverse Effect, in the case of Advaxis, or a Biosight Material Adverse Effect, in the case of Biosight, (c) any Legal Proceeding commenced or, to its knowledge, threatened against, relating to or otherwise involving Advaxis or any of its Subsidiaries or Biosight or any of its Subsidiaries, as the case may be, and (d) any Effect that has occurred that would reasonably be expected to result in any of the conditions set forth in Section 6, Section 7 and Section 8 not being satisfied; *provided*, *however*, that the delivery of any notice pursuant to this Section 5.18 shall not limit or otherwise affect the remedies available hereunder to the Party receiving such notice; *provided*, *further*, that, notwithstanding the foregoing, a failure to comply with this Section 5.18 shall not constitute the failure of any condition set forth in Section 6, Section 7 and Section 8 to be satisfied unless the underlying change or event would independently result in the failure of a condition set forth in Section 6, Section 7 and Section 8 to be satisfied.

**5.19** Advaxis Consent as Sole Stockholder of Merger Sub. Advaxis shall deliver to Biosight within two (2) Business Days of the date of this Agreement evidence of its approval, as the sole stockholder of Merger Sub, of the adoption of this Agreement and of the Transactions, including the Merger.

**5.20** Stockholder Litigation. Each of Advaxis and Biosight shall promptly notify the other Party following receipt of any claim, threat or the filing of any litigation by any stockholder of such Party against such Party and/or its directors or executive officers ("***Shareholder Litigation***"). Each of Advaxis and Biosight shall give the other Party the opportunity to participate in (at such Party's sole cost and expense), and each of Advaxis and Biosight shall reasonably cooperate with respect to, the defense or settlement of any Shareholder Litigation, and neither Party shall settle or offer to settle any such litigation without the prior written consent of the other Party.

**5.21** ESPP. As soon as practicable following the date of this Agreement, the Board of Directors of Advaxis or the appropriate committee of the Board of Directors of Advaxis shall take all reasonable actions, including adopting any necessary resolutions, to (i) terminate the ESPP as of immediately prior to the Closing Date, (ii) ensure that no offering period under the ESPP shall be commenced on or after the date of this Agreement, (iii) if the Closing shall occur prior to the end of the offering period in existence under the ESPP on the date of this Agreement, cause a new exercise date to be set under the ESPP, which date shall be the Business Day immediately prior to the anticipated Closing Date, (iv) prohibit participants in the ESPP from altering their payroll deductions from those in effect on the date of this Agreement (other than to discontinue their participation in the ESPP in accordance with the terms and conditions of the ESPP) and (v) provide that the amount of the accumulated contributions of each participant under the ESPP as of immediately prior to the Effective Time shall, to the extent not used to purchase shares of Advaxis Common Stock in accordance with the terms and conditions of the ESPP (as amended pursuant to this Section 5.21), be refunded to such participant as promptly as practicable following the Effective Time (without interest).

**5.22** Tax Rulings.

**(a)** As soon as practicable after the date of this Agreement, Biosight shall instruct its Israeli counsel, advisors and/or accountants to prepare and file with the ITA, in full coordination with Advaxis' advisors, an application for a ruling as part of the 104(h) ruling referred to in Section 5.22(b), confirming that: (i) Advaxis and anyone on its behalf shall be exempt from withholding tax in relation to payments made under this Agreement to the 102 Trustee in relation to any 102 Biosight Options, 3(i) Biosight Options and 102 Biosight Shares; (ii) the assumption of 102 Biosight Options and 3(i) Biosight Options or exchange of 102 Biosight Shares for 102 Advaxis Shares will not constitute a violation of the requirements of Section 102 or a taxable event and tax continuity will apply to the 102 Advaxis Options, 3(i) Advaxis Options and 102 Advaxis Shares issued in exchange for 102 Biosight Options, 3(i) Biosight Options and 102 Biosight Shares, respectively; (which ruling may be subject to customary conditions regularly associated with such a ruling and which may include additional issues which are raised by the ITA in light of the factual background of the ruling request) (the "***Option Tax Ruling***"). Biosight shall include in the request for the Option Tax Ruling a request to exempt Advaxis, the Surviving Company, the Exchange Agent and their respective agents from any withholding obligation with respect to the assumption of the 102 Biosight Options and 3(i) Biosight Options and issuance of 102 Advaxis Shares to the 102 Trustee. Each of Biosight and Advaxis shall cause its respective Israeli counsel, advisors and accountants to coordinate all activities, and to cooperate with each other, with respect to the preparation and filing of such application and with respect to any written or oral submission that may be necessary, proper or advisable in order to obtain the Option Tax Ruling. Subject to the terms and conditions hereof, Biosight shall use reasonable best efforts to promptly take, or cause to be taken, all action and to do, or cause to be done, all things necessary under applicable Legal Requirements to obtain the Option Tax Ruling, as promptly as practicable. If the Option Tax Ruling is not granted prior to the Closing, Biosight shall seek to obtain prior to the Closing an interim Tax ruling confirming, among other things, that Advaxis and any Person acting on its behalf (including the Exchange Agent) shall be exempt from Israeli withholding tax in relation to assumption of the 102 Biosight Options and 3(i) Biosight Options and issuance of 102 Advaxis Shares to the 102 Trustee (the "***Interim Option Tax Ruling***"). To the extent that prior to the Closing an Interim Option Tax Ruling shall have been obtained, then all references herein to the Option Tax Ruling shall be deemed to refer to such Interim Option Tax Ruling, until such time that a final definitive Option Tax Ruling is obtained. The final text of the Option Tax Ruling and the Interim Option Tax Ruling, including appendices thereof, shall in all circumstances be subject to the prior written confirmation of Advaxis and its counsel, which consent shall not unreasonably be withheld, delayed or conditioned. Biosight shall provide Advaxis and Advaxis' counsel with an update of any meeting or discussion with the ITA within two (2) Business Days of such meeting or discussion. To the extent that the Israeli Income Tax Ruling substitutes the need for the Option Tax Ruling and the Interim Option Tax Ruling, then any reference to the Option Tax Ruling and the Interim Option Tax Ruling shall be deemed to read the Israeli Income Tax Ruling with the necessary changes. Advaxis shall take the necessary steps to assume the Biosight Employee Plan as necessary to assume the 102 Biosight Options and 3(i) Biosight Options and issuance of 102 Advaxis Shares to the 102 Trustee in connection with the Merger.

**(b)** Israeli Income Tax Ruling. As soon as practicable after the date of this Agreement, but no later than fourteen (14) days, Biosight shall prepare and file with the ITA an application for a Tax ruling pursuant to the provisions of Section 104(h) to the Ordinance on behalf of the Biosight Shareholders who elect to become a party to such a Tax ruling (each, an "***Electing Holder***"), which application shall be filed only after allowing Advaxis and its Israeli counsel to review, comment on and approve such application in advance of its submission to the ITA, deferring any obligation to pay capital gains tax on the exchange of the Biosight Shares in the Merger (the "***Israeli Income Tax Ruling***"); provided that (i) neither the Israeli Interim Income Tax Ruling nor the Israeli Income Tax Ruling shall impose any restrictions or obligations on Advaxis or any of its subsidiaries or the Surviving Company, without Advaxis' prior written consent, (ii) the final wording of such rulings shall be approved in advance by Advaxis or its Israeli counsel, and (iii) any Costs associated with the application for such rulings shall be paid by reducing from the Merger Consideration payable to, or otherwise funded by, the Electing Holders. Subject to the terms and conditions hereof, the Parties shall use their reasonable best efforts to promptly take, or cause to be taken, all actions and to do, or cause to be done, all things necessary, proper or advisable under applicable Legal Requirements to obtain the Israeli Income Tax Ruling as promptly as practicable. Biosight shall provide Advaxis and Advaxis' counsel with a notice regarding any meeting or discussion with the ITA within three (3) Business Days prior to such meeting or discussion and, if requested, shall allow Advaxis' counsel to participate in such meeting or discussion. The Parties hereby agree, that to the extent so required under the relevant Israeli Income Tax Ruling, the Merger Consideration distributable to Biosight Shareholders at the Closing in accordance with this Agreement shall be deposited with a Paying Agent or trustee, who shall act as a paying, escrow agent or trustee, subject to the terms of the Israeli Income Tax Ruling and a customary paying agent agreement shall be executed prior to the Closing by and between the Paying Agent, Advaxis and Biosight.

**(c)** Each Party shall, and shall instruct its Representatives to cooperate with the other parties and their respective counsels and representatives, with respect to the preparation and filing of such applications and in the preparation of any written or oral submissions that may be necessary, proper or advisable to obtain the Israeli Income Tax Ruling or the Option Tax Ruling. For the avoidance of doubt, the Parties shall not, and shall cause its Representatives not to, make any application to the ITA with respect to any matter relating to the subject matter of the Israeli Income Tax Ruling or the Option Tax Ruling without the consent of other Parties (such consent not to be unreasonably withheld, conditioned or delayed), and Biosight will inform Advaxis of the content of any discussions and meetings relating thereto with the ITA.

**5.23** Takeover Statutes. If any Takeover Statute is or may become applicable to the Transactions, each of Advaxis, the Board of Directors of Advaxis, Biosight and the Board of Directors of Biosight, as applicable, shall grant such approvals and take such actions as are necessary so that the Transactions may be consummated as promptly as practicable on the terms contemplated by this Agreement and otherwise act to eliminate or minimize the effects of such statute or regulation on the Transactions.

SECTION 6. Conditions Precedent to Obligations of Each Party

The obligations of each Party to effect the Merger and otherwise consummate the Transactions to be consummated at the Closing are subject to the satisfaction or, to the extent permitted by applicable Legal Requirements, the written waiver by each of the Parties, at or prior to the Closing, of each of the following conditions:

**6.1** Effectiveness of Registration Statement. The Form S-4 Registration Statement shall have become effective in accordance with the provisions of the Securities Act, and shall not be subject to any stop order or proceeding (or threatened proceeding by the SEC) seeking a stop order with respect to the Form S-4 Registration Statement that has not been withdrawn.

**6.2** No Restraints. No Legal Requirement shall have been adopted or promulgated after the date of this Agreement, and no temporary restraining order, preliminary or permanent injunction or other Order shall have been issued and remain in effect, by a Governmental Authority of competent jurisdiction having the effect of making the Merger illegal or otherwise prohibiting consummation of the Transactions.

**6.3** Advaxis Stockholder Approval. The Advaxis Stockholder Approval shall have been duly obtained.

**6.4** Biosight Shareholder Approval. The Biosight Shareholder Approval shall have been duly obtained.

**6.5** Regulatory Matters. Any waiting period (and any extension thereof) applicable to the Merger under the HSR Act shall have been terminated or shall have expired or the necessary approval or clearance shall have been obtained. Any other applicable waiting periods (or any extension thereof), consents, waivers, filings or approvals under any applicable Legal Requirements required to consummate the Transactions shall have expired, been terminated, been made or been obtained.

SECTION 7. Additional Conditions Precedent to Obligations of Advaxis and Merger Sub

The obligations of Advaxis and Merger Sub to effect the Merger and otherwise consummate the Transactions to be consummated at the Closing are subject to the satisfaction or, to the extent permitted by applicable Legal Requirements, the written waiver by Advaxis, at or prior to the Closing, of each of the following conditions:

**7.1** Accuracy of Representations. Each of the Biosight Fundamental Representations shall be true and correct as of the date of this Agreement and as of the Closing Date as though made on and as of the Closing Date (except to the extent in either case that such representations and warranties speak as of another date). The representations and warranties of Biosight set forth in this Agreement (except for the Biosight Fundamental Representations), made as if none of such representations and warranties contained any qualifications or limitations as to "materiality" or Biosight Material Adverse Effect, shall be true and correct as of the date of this Agreement and as of the Closing Date as though made on and as of the Closing Date (except to the extent in either case that such representations and warranties speak as of another date), except where the failure of such representations and warranties to be true and correct as so made does not constitute a Biosight Material Adverse Effect.

**7.2** Performance of Covenants. Each of the covenants and obligations in this Agreement that Biosight is required to comply with or to perform at or prior to the Closing shall have been complied with and performed by Biosight in all material respects.

**7.3** Agreements and Other Documents. Advaxis shall have received a certificate duly executed by the Chief Executive Officer and Chief Financial Officer of Biosight confirming that the conditions set forth in Sections 7.1, 7.2 and 7.4 have been duly satisfied.

**7.4** No Biosight Material Adverse Effect. Since the date of this Agreement, there shall not have occurred any Biosight Material Adverse Effect that is continuing.

SECTION 8. Additional Conditions Precedent to Obligation of Biosight

The obligations of Biosight to effect the Merger and otherwise consummate the Transactions to be consummated at the Closing are subject to the satisfaction or, to the extent permitted by applicable Legal Requirements, the written waiver by Biosight, at or prior to the Closing, of each of the following conditions:

**8.1** Accuracy of Representations. Each of the Advaxis Fundamental Representations shall be true and correct as of the date of this Agreement and as of the Closing Date as though made on and as of the Closing Date (except to the extent in either case that such representations and warranties speak as of another date). The representations and warranties of Advaxis set forth in this Agreement (except for the Advaxis Fundamental Representations), made as if none of such representations and warranties contained any qualifications or limitations as to "materiality" or Advaxis Material Adverse Effect, shall be true and correct as of the date of this Agreement and as of the Closing Date as though made on and as of the Closing Date (except to the extent in either case that such representations and warranties speak as of another date), except where the failure of such representations and warranties to be true and correct as so made does not constitute an Advaxis Material Adverse Effect.

**8.2** Performance of Covenants. All of the covenants and obligations in this Agreement that either Advaxis or Merger Sub is required to comply with or to perform at or prior to the Closing shall have been complied with and performed in all material respects.

**8.3** Agreements and Other Documents. Biosight shall have received the following documents, each of which shall be in full force and effect as of immediately prior to the Closing:

**(a)** a certificate duly executed by the Chief Executive Officer and Chief Financial Officer of Advaxis confirming that the conditions set forth in Sections 8.1, 8.2 and Section 8.4 have been duly satisfied;

**(b)** written resignations in forms satisfactory to Biosight, dated as of the Closing Date and effective as of the Closing executed by the officers and directors of Advaxis who are not to continue as officers or directors of Advaxis pursuant to Section 5.14 hereof;

**(c)** a duly executed copy of the IIA Undertaking; and

**(d)** a certificate duly executed by the Chief Executive Officer and Chief Financial Officer of Advaxis setting forth the number of outstanding Securities of Advaxis and each component thereof (broken down by outstanding shares, options and other Securities) and indicating if such Securities are not vested (and is not expected to be vested as a result of the Merger).

**8.4** No Advaxis Material Adverse Effect. Since the date of this Agreement, there shall not have occurred any Advaxis Material Adverse Effect that is continuing.

**8.5** Israeli Tax Rulings. Biosight shall have obtained the Option Tax Ruling and the Israeli Income Tax Ruling or the Israeli Interim Income Tax Ruling and, if necessary, the Parties shall have entered into a customary paying agent agreement for the implementation of the Option Tax Ruling and the Israeli Income Tax Ruling and/or the Israeli Interim Income Tax Ruling.

**8.6** Listing. NASDAQ shall not have rejected Advaxis' appeal to its determination by the Listing Qualifications Department of The Nasdaq Stock Market LLC that Advaxis is not in compliance with the Listing Rule, and the shares of Advaxis Common Stock to be issued in the Merger shall be approved for listing (subject to official notice of issuance) on the NASDAQ Capital Market as of the Effective Time.

SECTION 9. Termination

**9.1** Termination. This Agreement may be terminated prior to the Effective Time (whether before or after the Advaxis Stockholder Approval or Biosight Shareholder Approval is obtained (except as otherwise set forth below)):

**(a)** by mutual written consent of Advaxis and Biosight;

**(b)** by either Advaxis or Biosight if:

**(i)** the Merger shall not have been consummated by December 31, 2021 (subject to possible extension as provided in this Section 9.1(b), the "***End Date***"); *provided*, that, in the event that the SEC has not declared effective under the Securities Act the Form S-4 Registration Statement by the date which is sixty (60) days prior to the End Date, then either Biosight or Advaxis shall be entitled to extend the End Date for an additional sixty (60) days;

**(ii)** any restraint (other than a temporary restraining order, preliminary injunction or similar non-permanent Order) having any of the effects set forth in Section 6.2 shall be in effect and shall have become final and non-appealable;

**(iii)** the Biosight Shareholder Approval shall not have been obtained at the Biosight Shareholders' Meeting or any adjournments or postponements thereof;

**(iv)** the Advaxis Stockholder Approval shall not have been obtained at the Advaxis Stockholders' Meeting or any adjournments or postponements thereof;

*provided*, *however*, that the right to terminate this Agreement pursuant to this Section 9.1(b) shall not be available to any Party whose failure to fulfill any obligation under this Agreement has been the primary cause of, or directly resulted in, the failure of any such condition;

**(c)** by Biosight if:

**(i)** Advaxis shall have breached or failed to perform any of its representations, warranties or covenants contained in this Agreement, which breach or failure to perform (A) is incapable of being cured by Advaxis prior to the End Date or is not cured by the earlier of (x) thirty (30) days following written notice to Advaxis by Biosight of such breach or (y) the End Date and (B) would result in a failure of any condition set forth in Section 8.1 or Section 8.2;

**(ii)** Advaxis or any of its Subsidiaries or their respective Representatives shall have Willfully Breached any of their respective obligations under Section 4.4;

**(iii)** The Board of Directors of Advaxis shall (A) fail to include the Advaxis Board Recommendation in the Proxy Statement/Prospectus/Information Statement, (B) effect a Change in Advaxis Board Recommendation, (C) make any public recommendation in connection with a tender offer or exchange offer that is subject to Regulation 14D under the Exchange Act other than a recommendation in a Solicitation/Recommendation Statement on Schedule 14D-9 against such tender offer or exchange offer, (D) if an Acquisition Proposal shall have been publicly announced or disclosed, fail to recommend against such Acquisition Proposal or fail to reaffirm the Advaxis Board Recommendation on or prior to the earlier of ten (10) Business Days after such Acquisition Proposal shall have been publicly announced or disclosed or five (5) Business Days prior to the Advaxis Stockholders' Meeting, or (E) fail to hold the Advaxis Stockholders' Meeting within sixty (60) days after the Form S-4 Registration Statement is declared effective under the Securities Act (other than to the extent that the Form S-4 Registration Statement is subject to any stop order or proceeding (or threatened proceeding by the SEC) seeking a stop order with respect to the Form S-4 Registration Statement, in which case such sixty (60) day period shall be tolled for the earlier of sixty (60) days or so long as such stop order remains in effect or proceeding or threatened proceeding remains pending);

**(iv)** Advaxis shall have Willfully Breached this Agreement;

**(d)** by Advaxis if:

**(i)** Biosight shall have breached or failed to perform any of its representations, warranties or covenants contained in this Agreement, which breach or failure to perform (A) is incapable of being cured by Biosight prior to the End Date or is not cured by the earlier of (x) thirty (30) days following written notice to Biosight by Advaxis of such breach or (y) the End Date and (B) would result in a failure of any condition set forth in Section 7.1 or Section 7.2;

**(ii)** Biosight or its Representatives shall have Willfully Breached any of their respective obligations under Section 4.5;

**(iii)** the Board of Directors of Biosight shall effect a Change in Biosight Board Recommendation; or

**(iv)** Biosight shall have Willfully Breached this Agreement.

**9.2** Notice of Termination; Effect of Termination. The Party terminating this Agreement pursuant to Section 9.1 (other than pursuant to Section 9.1(a)) shall deliver prompt written notice thereof to the other Parties setting forth in reasonable detail the provision of Section 9.1 pursuant to which this Agreement is being terminated and the facts and circumstances forming the basis for such termination pursuant to such provision. In the event of the termination of this Agreement as provided in Section 9.1, this Agreement shall be of no further force or effect; *provided*, *however*, that (i) this Section 9.2, Section 9.3, and Section 10 shall survive the termination of this Agreement and shall remain in full force and effect, and (ii) the termination of this Agreement shall not relieve any Party for its fraud or from any liability for any Willful Breach of this Agreement.

**9.3** Expenses; Termination Fees.

**(a)** Except as set forth in this Section 9.3 and Section 5.10(b), all fees and expenses incurred in connection with this Agreement and the Transactions shall be paid by the Party incurring such expenses, whether or not the Merger is consummated; *provided*, *however*, that Advaxis and Biosight shall share equally all filing fees and expenses, other than attorneys' and accountants' fees and expenses, incurred in relation to the filings by the Parties under any filing requirement under the HSR Act and any Foreign Competition Law applicable to this Agreement and the Transactions.

**(b)** If:

**(i)** this Agreement is terminated pursuant to (A) Section 9.1(c)(ii), (B) Section 9.1(c)(iii) or (C) Section 9.1(b)(i), Section 9.1(b)(iv) or Section 9.1(c)(i) if Biosight could have terminated pursuant to Section 9.1(c)(ii) or Section 9.1(c)(iii); or

**(ii)** (A) this Agreement is terminated pursuant to Section 9.1(b)(i), Section 9.1(b)(iv) or Section 9.1(c)(i), (B) (1) in the case of a termination pursuant to Section 9.1(b)(i) or Section 9.1(c)(i), an Acquisition Proposal shall have been made to the Board of Directors of Advaxis or becomes publicly known, prior to the date of such termination, or (2) in the case of a termination pursuant to Section 9.1(b)(iv), an Acquisition Proposal shall have been made to the Board of Directors of Advaxis or becomes publicly known, prior to the date of the Advaxis Stockholders' Meeting, and (C) within twelve (12) months of such termination, Advaxis enters into a definitive agreement with any third party to consummate, or consummates, an Acquisition Proposal; then Advaxis shall pay to Biosight, by wire transfer of immediately available funds, an amount equal to $7,500,000 (the "***Termination Fee***") (x) in the case of termination pursuant to clause (i) above, within two (2) Business Days of the date of termination and (y) in the case of termination pursuant to clause (ii) above, within two (2) Business Days of the date of the first to occur of (I) the execution of a definitive agreement relating to an Acquisition Proposal and (II) consummation of a transaction relating to an Acquisition Proposal.

**(c)** If this Agreement is terminated pursuant to Section 9.1(c)(iv), then Advaxis shall pay to Biosight, by wire transfer of immediately available funds, an amount equal to $7,500,000 (the "***Advaxis Breach Termination Fee***") within two (2) Business Days of the date of termination.

**(d)** If:

**(i)** this Agreement is terminated pursuant to (A) Section 9.1(d)(ii), (B) or Section 9.1(d)(iii), or (C) Section 9.1(b)(i), Section 9.1(b)(iii) or Section 9.1(d)(i) if Advaxis could have terminated pursuant to Section 9.1(d)(ii) or Section 9.1(d)(iii); or

**(ii)** (A) this Agreement is terminated pursuant to Section 9.1(b)(i), Section 9.1(b)(iii) or Section 9.1(d)(i), (B) (1) in the case of a termination pursuant to Section 9.1(b)(i) or Section 9.1(d)(i), an Acquisition Proposal shall have been made to the Board of Directors of Biosight or becomes publicly known, prior to the date of such termination, or (2) in the case of a termination pursuant to Section 9.1(b)(iii), an Acquisition Proposal shall have been made to the Board of Directors of Biosight or becomes publicly known, prior to the date of the Biosight Shareholders' Meeting, and (C) within twelve (12) months of such termination, Biosight enters into a definitive agreement with any third party to consummate, or consummates, an Acquisition Proposal,

**(e)** then Biosight shall pay to Advaxis, by wire transfer of immediately available funds, an amount equal to the Termination Fee (x) in the case of termination pursuant to clause (d)(i) above, within two (2) Business Days of the date of termination and (y) in the case of termination pursuant to clause (d)(ii) above, within two (2) Business Days of the date of the first to occur of (I) the execution of a definitive agreement relating to an Acquisition Proposal and (II) consummation of a transaction relating to an Acquisition Proposal.

**(f)** If this Agreement is terminated pursuant to Section 9.1(d)(iv), then Biosight shall pay to Advaxis, by wire transfer of immediately available funds, an amount equal to $7,500,000 (the "***Biosight Breach Termination Fee***") within five (5) Business Days of the date of termination.

**(g)** For the avoidance of doubt, the Parties acknowledge that if this Agreement is terminated (i) by Biosight or Advaxis pursuant to Section 9.1(b)(i) solely due to a failure of the condition in Section 8.6 and all other conditions set forth in Section 6 and Section 8 are waived or satisfied, or (ii) by Biosight pursuant to Section 9.1(c)(i) solely due to a breach of Section 5.10(a) and all other conditions set forth in Section 6 and Section 8 are waived or satisfied, and with respect to (i) and (ii) above (A) Biosight could not have terminated pursuant to Section 9.1(c)(ii) or Section 9.1(c)(iii) with respect to Advaxis' obligation to pay the Termination Fee and Advaxis could not have terminated pursuant to Section 9.1(d)(ii) or Section 9.1(d)(iii) with respect to Biosight's obligation to pay the Termination Fee; and (B) the circumstances set forth in Section 9.3(b)(ii) (with respect to Advaxis' obligation to pay the Termination Fee) or Section 9.3(d)(ii) (with respect to Biosight's obligation to pay the Termination Fee) do not exist, then neither party shall be entitled to Termination Fee and Biosight shall be entitled to the Expense Reimbursement (as described below). Notwithstanding the foregoing, nothing herein shall limit the Parties' remedies in the event of an Intentional Breach (as defined below).

**(h)** Each of the Parties acknowledges that the agreements contained in this Section 9.3 are an integral part of this Agreement, and that the Termination Fee, the Advaxis Breach Termination Fee or the Biosight Breach Termination Fee is not a penalty, but rather is a reasonable amount that will compensate Biosight or Advaxis, as applicable, in the circumstances in which such payment is payable for the efforts and resources expended and opportunities foregone while negotiating this Agreement and in reliance on this Agreement and on the expectation of the consummation of the Transactions. In addition, if any Party fails to pay in a timely manner any amount due pursuant to Section 9.3(a), Section 9.3(b), Section 9.3(c), Section 9.3(d) or Section 9.3(e), as applicable, then (i) such Party shall reimburse the other Party for all costs and expenses (including disbursements and fees of counsel) incurred in the collection of such overdue amount, including in connection with any related Legal Proceedings commenced and (ii) such Party shall pay to the other Party interest on the amount payable pursuant to Section 9.3(a), Section 9.3(b), Section 9.3(c), Section 9.3(d) or Section 9.3(e) from and including the date payment of such amount was due to but excluding the date of actual payment at the prime rate set forth in The Wall Street Journal in effect on the date such payment was required to be made plus 2%. Notwithstanding anything to the contrary in this Agreement, upon payment of the Termination Fee pursuant to this Section 9.3, neither the paying party nor any of its Subsidiaries or any of their respective former, current or future officers, directors, partners, stockholders, managers, members, Affiliates or agents shall have any further liability or obligation relating to or arising out of this Agreement or the Transactions, except in the event of material willful or intentional breach of, or fraud in connection with, this Agreement (collectivelly, an "***Intentional Breach***"); provided, however, that any Termination Fee, Advaxis Breach Termination Fee or Biosight Breach Termination Fee, as applicable, received by either Party shall reduce the amount of any damages payable by the other party, if any, in respect of any such material willful or intentional breach or such fraud.

**(i)** Unless Biosight receives the Termination Fee or the Biosight Breach Termination Fee, pursuant to the terms and conditions of the above provisions of this Section 9.3, if this Agreement is validly terminated by either Biosight or Advaxis pursuant to Section 9.1 due to failure of the condition set forth in Section 8.6, then Advaxis shall pay (or cause to be paid) to Biosight an amount equal to the Biosight Expenses (as defined below) within two (2) Business Days after receipt by Advaxis of evidence of the Biosight Expenses by wire transfer of immediately available funds to an account designated by Biosight in writing (the "***Expense Reimbursement***"). The term "***Biosight Expenses***" shall include any and all reasonable and documented out-of-pocket expenses (including, all fees and expenses of counsel, accountants, investment bankers, experts and consultants to Biosight) incurred, paid or otherwise payable by Biosight or on its behalf in connection with or related to the authorization, preparation, documentation, negotiation, execution, consummation (including due diligence) and performance of this Agreement and the Transactions, including the preparation, printing, filing and mailing, as the case may be, of the Proxy Statement/Prospectus/Information Statement, the Form S-4 Registration Statement, other filing fees and any amendments or supplements thereto and all other matters related to the Transactions; *provided*, that such expenses shall not exceed $2,000,000.

SECTION 10. Miscellaneous Provisions

**10.1** Non-Survival of Representations and Warranties. None of the representations, warranties, covenants and other agreements in this Agreement or in any instrument delivered pursuant to this Agreement, including any rights arising out of any breach of such representations, warranties, covenants and other agreements, shall survive the Effective Time, except for those covenants and agreements contained herein and therein (including Section 5.8) that by their terms apply or are to be performed in whole or in part after the Effective Time and this Section 10.

**10.2** Amendment. This Agreement may be amended with the approval of the respective Boards of Directors of Biosight, Merger Sub and Advaxis at any time (whether before or after the Advaxis Stockholder Approval or Biosight Shareholder Approval is obtained); *provided*, *however*, that after any such adoption and approval of this Agreement by a Party's stockholders, no amendment shall be made which by Legal Requirement requires further approval of the stockholders of such Party without the further approval of such stockholders. This Agreement may not be amended except by an instrument in writing signed on behalf of each of Biosight, Merger Sub and Advaxis.

**10.3** Waiver.

**(a)** No failure on the part of any Party to exercise any power, right, privilege or remedy under this Agreement, and no delay on the part of any Party in exercising any power, right, privilege or remedy under this Agreement, shall operate as a waiver of such power, right, privilege or remedy; and no single or partial exercise of any such power, right, privilege or remedy shall preclude any other or further exercise thereof or of any other power, right, privilege or remedy.

**(b)** No Party shall be deemed to have waived any claim arising out of this Agreement, or any power, right, privilege or remedy under this Agreement, unless the waiver of such claim, power, right, privilege or remedy is expressly set forth in a written instrument duly executed and delivered on behalf of such Party; and any such waiver shall not be applicable or have any effect except in the specific instance in which it is given.

**10.4** Entire Agreement; Counterparts. This Agreement (including the Schedules, Annexes and Exhibits hereto) and the other agreements and instruments referred to in this Agreement constitute the entire agreement and supersede all prior agreements and understandings, both written and oral, among or between any of the Parties with respect to the subject matter hereof and thereof; *provided*, *however*, that the Confidentiality Agreement shall not be superseded and shall remain in full force and effect in accordance with its terms. This Agreement may be executed and delivered (including by e-mail of a .pdf, .tif, .jpeg or similar attachment ("***Electronic Delivery***")) in two (2) or more counterparts, and by the different Parties hereto in separate counterparts, each of which when executed and delivered shall be deemed to be an original but all of which taken together shall constitute one and the same agreement. Any such counterpart, to the extent delivered using Electronic Delivery shall be treated in all manner and respects as an original executed counterpart and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. No Party shall raise the use of Electronic Delivery to deliver a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of Electronic Delivery as a defense to the formation of a contract, and each such Party forever waives any such defense, except to the extent that such defense relates to lack of authenticity.

**10.5** Applicable Law; Jurisdiction; Waiver of Jury Trial.

**(a)** This Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware, without giving effect to conflicts of laws principles (whether of the State of Delaware or otherwise) that would result in the application of the Legal Requirements of any other state; *provided* that notwithstanding the foregoing, the Merger, the Option Tax Ruling (if any), the Israeli Income Tax Ruling and any tax withholding under Israeli law in connection with the Merger and any consideration provided thereunder shall be governed by and construed in accordance with the laws of Israel.

**(b)** Each of the Parties hereto hereby irrevocably and unconditionally submits, for itself and its property, to the exclusive jurisdiction of the Court of Chancery of the State of Delaware or, to the extent such court does not have subject matter jurisdiction, the United States District Court for the District of Delaware, in any Legal Proceeding arising out of or relating to this Agreement or the agreements delivered in connection herewith or the Transactions contemplated hereby or thereby or for recognition or enforcement of any judgment relating thereto, and each of the Parties hereby irrevocably and unconditionally (i) agrees not to commence any such Legal Proceeding except in the Court of Chancery of the State of Delaware or, to the extent such court does not have subject matter jurisdiction, the United States District Court for the District of Delaware, (ii) agrees that any claim in respect of any such Legal Proceeding may be heard and determined in the Court of Chancery of the State of Delaware or, to the extent such court does not have subject matter jurisdiction, the United States District Court for the District of Delaware, (iii) waives, to the fullest extent it may legally and effectively do so, any objection that it may now or hereafter have to the laying of venue of any such Legal Proceeding in such courts and (iv) waives, to the fullest extent permitted by applicable Legal Requirements, the defense of an inconvenient forum to the maintenance of such Legal Proceeding in such courts. Each of the Parties hereto (A) agrees that a final judgment in any such Legal Proceeding shall be conclusive and may be enforced in other jurisdictions (including Israel) by suit on the judgment or in any other manner provided by applicable Legal Requirements and (B) waives any objection to the recognition and enforcement by a court in other jurisdictions (including Israel) of any such final judgment.

**(c)** EACH PARTY ACKNOWLEDGES AND AGREES THAT ANY CONTROVERSY THAT MAY ARISE PURSUANT TO THIS AGREEMENT IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES, AND THEREFORE EACH PARTY HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT THAT SUCH PARTY MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LEGAL PROCEEDING (WHETHER FOR BREACH OF CONTRACT, TORTIOUS CONDUCT OR OTHERWISE) DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT, THE MERGER, OR THE OTHER AGREEMENTS TO BE ENTERED INTO IN CONNECTION HEREWITH, AND THE TRANSACTIONS CONTEMPLATED HEREBY AND THEREBY. EACH PARTY ACKNOWLEDGES AND AGREES THAT (i) NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER; (ii) IT UNDERSTANDS AND HAS CONSIDERED THE IMPLICATIONS OF THIS WAIVER; (iii) IT MAKES THIS WAIVER VOLUNTARILY; AND (iv) IT HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 10.5(C).

**10.6** Attorneys' Fees. In any action at law or suit in equity to enforce this Agreement or the rights of any of the parties under this Agreement, the prevailing Party in such action or suit shall be entitled to recover its reasonable sum out-of-pocket attorneys' fees and all other reasonable costs and expenses incurred in such action or suit.

**10.7** Assignability; No Third Party Beneficiaries. This Agreement shall be binding upon, and shall be enforceable by and inure solely to the benefit of, the parties hereto and their respective successors and assigns; *provided*, *however*, that neither this Agreement nor any of a Party's rights or obligations hereunder may be assigned or delegated by such Party without the prior written consent of the other Party, and any attempted assignment or delegation of this Agreement or any of such rights or obligations by such Party without the other Party's prior written consent shall be void and of no effect. Nothing in this Agreement, express or implied, is intended to or shall confer upon any Person, including the Persons described or identified in Section 5.14, other than the parties hereto, the Advaxis D&O Indemnified Parties and the Biosight D&O Indemnified Parties to the extent of their respective rights pursuant to Section 5.6, any right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

**10.8** Notices. All notices and other communications hereunder shall be in writing and shall be deemed duly given on the date of delivery if delivered personally, by email (which is confirmed), or sent by a nationally recognized overnight courier service (providing proof of delivery). All notices hereunder shall be delivered as set forth below or pursuant to such other instructions as may be designated in writing by the Party to receive such notice:

if to Advaxis or Merger Sub:

Advaxis, Inc.
9 Deer Park Drive, Suite K-1
Monmouth Junction, NJ 08852
E-Mail: berlin@advaxis.com
Attention: Ken Berlin

with a copy (which shall not constitute notice) to:

Morgan Lewis & Bockius LLP
502 Carnegie Center
Princeton, NJ 08540
E-Mail: david.schwartz@morganlewis.com
Attention: David C. Schwartz

with a copy (which shall not constitute notice) to:

Herzog Fox & Neeman
Asia House, 4 Weizmann St.
Tel Aviv 6423904, Israel
E-Mail: HerbstR@herzoglaw.co.il
Attention: Rafael Herbst

if to Biosight:

Biosight LTD.
3 Hayarden St., Airport City
P.O.B 1083
Lod 7019802
Israel
E-Mail: ruth@biosight-pharma.com
Attention: Ruth Ben Yakar

with a copy (which shall not constitute notice) to:

White & Case LLP
3000 El Camino Real, 2 Palo Alto Square, Suite 900
Palo Alto, CA 94306-2109
Telephone No.: +1 650 213 0315
E-Mail: tsealman@whitecase.com
Attention: Tali Sealman

with a copy (which shall not constitute notice) to:

White & Case LLP
1221 Avenue of the Americas
New York, NY 10020-1095
Telephone No.: +1 212 819 8754
E-Mail: cdiamond@whitecase.com
Attention: Colin Diamond

with a copy (which shall not constitute notice) to:

Horn & Co. Law Offices
Amot Investments Tower, 24th Floor
2 Weizmann St., Tel-Aviv, 6423902, Israel
Telephone No.: +972-3-637 8200
E-Mail: yhorn@hornlaw.co.il
Attention: Adv. Yuval Horn

**10.9** Severability. If any term or other provision of this Agreement is invalid, illegal or incapable of being enforced by any Legal Requirement or public policy, all other terms and provisions of this Agreement shall nevertheless remain in full force and effect. Notwithstanding the foregoing, upon such determination that any term or other provision is invalid, illegal or incapable of being enforced, the Parties shall negotiate in good faith to modify this Agreement so as to effect the original intent of the Parties as closely as possible in an acceptable manner in order that the Transactions are consummated as originally contemplated to the greatest extent possible.

**10.10** Other Remedies; Specific Performance. Except as otherwise provided herein, any and all remedies herein expressly conferred upon a Party will be deemed cumulative with and not exclusive of any other remedy conferred hereby, or by law or equity upon such Party, and the exercise by a Party of any one remedy will not preclude the exercise of any other remedy. The Parties hereto agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that the Parties shall be entitled to an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions hereof in any court of the United States or any state having jurisdiction, this being in addition to any other remedy to which they are entitled at law or in equity, and each of the Parties hereto waives any bond, surety or other security that might be required of any other Party with respect thereto.

**10.11** Construction. When a reference is made in this Agreement to Sections, Exhibits or Schedules, such reference shall be to a Section of or Exhibit or Schedule to this Agreement unless otherwise indicated. The table of contents and headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement. Whenever the words "include," "includes" or "including" are used in this Agreement, they shall be deemed to be followed by the words "without limitation". The words "made available" or "delivered" shall be deemed to mean that such information was included in Advaxis' electronic data room or Biosight's electronic data room, as applicable, at least five (5) Business Days prior to the date of this Agreement or solely with respect to the Advaxis SEC Reports, filed with and publicly available on the SEC's Electronic Data Gathering Analysis and Retrieval system at least five (5) Business Days prior to the date of this Agreement. The definitions contained in this Agreement are applicable to the singular as well as the plural forms of such terms and the masculine gender shall include the feminine and neuter genders. The Parties have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as drafted jointly by the Parties and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any provisions of this Agreement. The words "hereby," "herein," "hereof," "hereunder" and words of similar import refer to this Agreement as a whole (including any Exhibits hereto and Schedules delivered herewith) and not merely to the specific section, paragraph or clause in which such word appears. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. Except as otherwise expressly provided herein, all references to "Dollars" or "$" shall be deemed references to the lawful money of the United States of America. Any reference in this Agreement to a date or time shall be deemed to be such date or time in the City of New York, New York, U.S.A., unless otherwise specified. Any reference to a number of days shall refer to calendar days unless Business Days are specified. Whenever the last day for the exercise of any privilege or the discharge of any duty hereunder shall fall upon a Saturday, Sunday, or any date on which banks in New York, New York or Tel Aviv, Israel are authorized or obligated by Legal Requirement to be closed, the Party having such privilege or duty may exercise such privilege or discharge such duty on the next succeeding day which is a regular Business Day. References to any statute, rule or regulation are to the statute, rule or regulation as amended, modified, supplemented or replaced from time to time (and, in the case of statutes, include any rules and regulations promulgated under said statutes) and to any section of any statute, rule or regulation including any successor to said section. All terms defined in this Agreement have the defined meanings when used in any certificate or other document made or delivered pursuant hereto, unless otherwise defined therein. When reference is made herein to a Person, such reference shall be deemed to include all direct and indirect Subsidiaries of such Person unless otherwise indicated or the context otherwise requires. The terms "or", "any" and "either" are not exclusive. The word "extent" in the phrase "to the extent" shall mean the degree to which a subject or other thing extends, and such phrase shall not mean simply "if". The word "will" shall be construed to have the same meaning and effect as the word "shall".

**[***Remainder of page intentionally left blank***]**

**In Witness Whereof**, the parties have caused this Agreement to be executed as of the date first above written.

**ADVAXIS, INC.**

By: */s/ Kenneth A. Berlin*
Name: Kenneth A. Berlin
Title: President and Chief Executive Officer,
Interim Chief Financial Officer

**ADVAXIS LTD.**

By: */s/ Kenneth A. Berlin*
Name: Kenneth A. Berlin
Title: Sole Director

**BIOSIGHT LTD.**

By: */s/ Dr. Ruth Ben Yakar*
Name: Dr. Ruth Ben Yakar
Title: Chief Executive Officer

**SCHEDULE A**

**PERSONS EXECUTING BIOSIGHT SUPPORT AGREEMENTS**

1. Dr. Ruth Ben Yakar
2. Dr. Pini Orbach
3. Aaron Sasson
4. Dr. Gary Gordon
5. Dr. Briggs Morison
6. Roy Golan

**SCHEDULE B**

**PERSONS EXECUTING ADVAXIS SUPPORT AGREEMENTS**

1. Ken Berlin
2. Andres Gutierrez
3. Igor Gitelman
4. Dr. David Sidransky
5. Dr. James Patton
6. Dr. Samir N Khleif
7. Richard Berman
8. Dr. Roni A Appel

Exhibit A

CERTAIN DEFINITIONS

For purposes of the Agreement (including this Exhibit A):

"***3(i) Biosight Options***" shall mean Biosight Options granted and subject to tax under Section 3(i) of the Ordinance.

"***102 Advaxis Options***" shall have the meaning set forth in Section 1.5(c).

"***102 Advaxis Shares***" shall mean shares of Advaxis Common Stock issued under the assumed Biosight Employee Plan and subject to tax pursuant to the Interim Option Tax Ruling and Option Tax Ruling and Section 102(b)(2) or 102(b)(3) of the Ordinance.

"***102 Biosight Options***" shall have the meaning set forth in Section 1.5(c).

"***102 Biosight Shares***" shall have the meaning set forth in Section 1.7(b).

"***102 Trustee***" shall mean IBI Capital Compensation and Trusts (2004) Ltd. appointed by Biosight to serve as trustee of the Biosight Employee Plan and the awards granted thereunder pursuant to Section 102 of the Ordinance.

"***Acceptable Confidentiality Agreement***" means an agreement with Advaxis or Biosight, as applicable, that is either (i) in effect as of the execution and delivery of this Agreement; or (ii) executed, delivered and effective after the execution and delivery of this Agreement, in either case containing provisions that require any counterparty thereto (and any of its Affiliates and representatives named therein) that receive material non-public information of, or with respect to, Advaxis or Biosight, as applicable, to keep such information confidential; *provided*, *however*, that, in each case, the confidentiality and use provisions contained therein are no less restrictive in the aggregate to such counterparty (and any of its Affiliates and Representatives as provided therein) than the terms of the Confidentiality Agreement (it being understood that such agreement need not contain any "standstill" or similar provisions or otherwise prohibit the making of any Acquisition Proposal).

"***Acquisition Proposal***" shall mean with respect to Advaxis or Biosight, any inquiry, proposal or offer from any Person, other than from the other party to the Agreement, relating to any (i) direct or indirect acquisition (whether in a single transaction or a series of related transactions) of assets of such party equal to 15% or more of the consolidated assets of such party and its Subsidiaries, or to which 15% or more of the revenues or earnings of such party and its Subsidiaries on a consolidated basis are attributable for the most recent fiscal year in which audited financial statements are then available, (ii) direct or indirect acquisition or issuance (whether in a single transaction or a series of related transactions) of 15% or more of any class of equity or voting securities of such party, (iii) tender offer or exchange offer that, if consummated, would result in such Person Beneficially Owning 15% or more of any class of equity or voting securities of such party, or (iv) merger, consolidation, share exchange, business combination, joint venture, reorganization, recapitalization, liquidation, dissolution or similar transaction or series of related transactions involving such party or any of its Subsidiaries, under which (A) such Person would, directly or indirectly, acquire assets equal to 15% or more of the consolidated assets of such party and its Subsidiaries, or to which 15% or more of the revenues or earnings of such party and its Subsidiaries on a consolidated basis are attributable for the most recent fiscal year in which audited financial statements are then available, or (B) the stockholders or equityholders of such third party Person immediately after giving effect to such transaction(s) would Beneficially Own 15% or more of any class of equity or voting securities of such party or the surviving or resulting entity in such transaction(s), provided, however, that the transactions set forth on Part 1-A of the Advaxis Disclosure Schedule shall not constitute Acquisition Proposal.

"***Advaxis***" shall have the meaning set forth in the Preamble.

"***Advaxis Benefit Plan***" shall have the meaning set forth in Section 2.13(j).

"***Advaxis Board Recommendation***" shall have the meaning set forth in Section 2.17(b).

"***Advaxis Breach Termination Fee***" shall have the meaning set forth in Section 9.3(c).

"***Advaxis Certificate of Incorporation Amendment***" shall have the meaning set forth in Section 5.17.

"***Advaxis Common Stock***" shall mean the Common Stock, $0.001 par value per share, of Advaxis.

"***Advaxis Contract***" shall mean any Contract (a) to which Advaxis or any of its Subsidiaries is a party; (b) by which Advaxis or any of its Subsidiaries or any Advaxis IP Rights or any other asset of Advaxis or any of its Subsidiaries is or may become bound or under which Advaxis has, or may become subject to, any obligation; or (c) under which Advaxis or any of its Subsidiaries has or may acquire any right or interest.

"***Advaxis D&O Indemnified Parties***" shall have the meaning set forth in Section 5.6(a).

"***Advaxis Disclosure Schedule***" shall have the meaning set forth in Section 2.

"***Advaxis Equity Plans***" shall have the meaning set forth in Section 2.3(b).

"***Advaxis Financial Advisor***" shall mean LifeSci Capital LLC.

"***Advaxis Financial Statements***" shall have the meaning set forth in Section 2.4(a).

"***Advaxis Fundamental Representations***" shall mean the representations and warranties of Advaxis and Merger Sub set forth in Sections 2.1, 2.3(a), 2.17, 2.18 and 2.21.

"***Advaxis IP Rights***" shall mean all Intellectual Property which is owned or purported to be owned by Advaxis or any of its Subsidiaries, or used or held for use in their respective businesses.

"***Advaxis IT Systems***" shall have the meaning set forth in Section 2.8(h).

"***Advaxis Lease***" shall have the meaning set forth in Section 2.7(a).

"***Advaxis Leased Real Property***" shall have the meaning set forth in Section 2.7(a).

"***Advaxis Material Adverse Effect***" shall mean, with respect to Advaxis, a fact, circumstance, condition, development, change, event, occurrence or effect (an "***Effect***") that, individually or in the aggregate, has, or would reasonably be expected have, a material adverse effect on (a) the business, condition (financial or otherwise), capitalization, assets, liabilities, contracts, cash, operations or financial performance of Advaxis and its Subsidiaries as a whole; or (b) would reasonably be expected to prevent, materially impair or materially delay the ability of Advaxis to perform its obligations under this Agreement or to consummate the Transactions, including the Merger, other than, in the case of clause (a) above, (i) Effects in general economic or political conditions or the securities market in general, or changes in or affecting the industries in which Advaxis and its Subsidiaries operate; (ii) any failure by Advaxis to meet internal projections or forecasts or third party revenue or earnings predictions for any period ending (or for which revenues or earnings are released) on or after the date of this Agreement or any change in the price or trading volume of Advaxis Common Stock (it being understood, however, that any Effect causing or contributing to any such failure to meet projections or predictions or any change in stock price or trading volume may constitute an Advaxis Material Adverse Effect and may be taken into account in determining whether an Advaxis Material Adverse Effect has occurred); (iii) the execution, delivery, announcement or performance of the obligations under this Agreement or the announcement, pendency or anticipated consummation of the Merger; (iv) the resignation or termination of any officer or director; (v) any natural disaster, any epidemic, pandemic or disease outbreak (including the COVID-19 virus) or other public health emergencies (as declared by the World Health Organization or the Health and Human Services Secretary of the United States) or any acts of terrorism, sabotage, military action or war or any escalation or worsening thereof, but solely to the extent Advaxis can prove that such Effect was caused directly as a result of such natural disaster, epidemic, pandemic, disease outbreak or other health emergency; or (vi) any changes (after the date of this Agreement) in GAAP or applicable Legal Requirements; *provided*, that any Effect referred to in clauses (i), (v), and (vi) may be taken into account in determining whether there has been, or would reasonably be expected to be, an Advaxis Material Adverse Effect to the extent such Effect has a disproportionate effect on Advaxis and its Subsidiaries, taken as a whole, relative to other similarly sized participants in the businesses, industries and geographic locations in which Advaxis and its Subsidiaries operate.

"***Advaxis Material Contract***" shall have the meaning set forth in Section 2.9.

"***Advaxis Options***" shall mean options or other rights to purchase shares of Advaxis Common Stock issued or granted by Advaxis.

"***Advaxis Permits***" shall have the meaning set forth in Section 2.11(b).

"***Advaxis Preferred Stock***" shall have the meaning set forth in Section 2.3(a).

"***Advaxis Product Candidates***" shall have the meaning set forth in Section 2.11(d).

"***Advaxis Registered IP***" shall have the meaning set forth in Section 2.8(a).

"***Advaxis Regulatory Permits***" shall have the meaning set forth in Section 2.11(d).

"***Advaxis RSU***" shall mean a restricted stock unit issued by Advaxis pursuant to an Advaxis Equity Plan that vests solely on the basis of time, pursuant to which the holder has a right to receive shares of Advaxis Common Stock or cash after the vesting or lapse of restrictions applicable to such restricted stock unit.

"***Advaxis SEC Reports***" shall mean all material forms, certifications, reports, statements and documents required to be filed or furnished by Advaxis with the SEC pursuant to the Securities Act and the Exchange Act since January 1, 2019.

"***Advaxis Standard Contracts***" shall have the meaning set forth in Section 2.9(a)(xiii).

"***Advaxis Stock Issuance***" shall have the meaning set forth in the Recitals.

"***Advaxis Stockholder Approval***" shall have the meaning set forth in Section 2.17(c).

"***Advaxis Stockholders' Meeting***" shall have the meaning set forth in Section 5.2(a).

"***Advaxis Support Agreements***" shall have the meaning set forth in the Recitals.

"***Advaxis Unaudited Interim Balance Sheet***" shall mean the unaudited consolidated balance sheet of Advaxis included in Advaxis' Report on Form 10-Q filed with the SEC for the period ended January 31, 2021.

"***Advaxis Warrants***" shall have the meaning set forth in Section 2.3(c).

"***Affiliates***" shall have the meaning for such term as used in Rule 145 under the Securities Act.

"***Agreement***" shall have the meaning set forth in the Preamble.

"***Antitrust Laws***" shall have the meaning set forth in Section 5.5(a).

"***Bankruptcy and Equity Exception***" shall mean any bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar Legal Requirements of general applicability relating to or affecting creditors' rights, to general equity principles (whether considered in a proceeding in equity or at law).

"***Biosight***" shall have the meaning set forth in the Preamble.

"***Biosight Benefit Plan***" shall have the meaning set forth in Section 3.13(j).

"***Biosight Board Recommendation***" shall have the meaning set forth in Section 5.3(b).

"***Biosight Breach Termination Fee***" shall have the meaning set forth in Section 9.3(f).

"***Biosight Contract***" shall mean any Contract (a) to which Biosight or any of its Subsidiaries is a Party; (b) by which Biosight or any Subsidiary of Biosight or any Biosight IP Rights or any other asset of Biosight or its Subsidiaries is or may become bound or under which Biosight or any Subsidiary of Biosight has, or may become subject to, any obligation; or (c) under which Biosight or Subsidiary of Biosight has or may acquire any right or interest.

"***Biosight D&O Indemnified Parties***" shall have the meaning set forth in Section 5.7(a).

"***Biosight Disclosure Schedule***" shall have the meaning set forth in Section 3.

"***Biosight Employee Plan***" shall mean the Biosight Ltd. 2009 Israeli Share Option Plan, including any exhibit and appendix thereto (including without limitation, US Appendix to the Share Option Plan).

"***Biosight Expenses***" shall have the meaning set forth in Section 9.3(i).

"***Biosight Financial Statements***" shall have the meaning set forth in Section 3.4(a).

"***Biosight Fundamental Representations***" shall mean the representations and warranties of Biosight set forth in Sections 3.1, 3.3(a), 3.17, 3.18 and 3.21.

"***Biosight IP Rights***" shall mean all Intellectual Property which is owned or purported to be owned by Biosight or any of its Subsidiaries, or used or held for use in their respective businesses.

"***Biosight IT Systems***" shall have the meaning set forth in Section 3.8(h).

"***Biosight Lease***" shall have the meaning set forth in Section 3.7(a).

"***Biosight Leased Real Property***" shall have the meaning set forth in Section 3.7(a).

"***Biosight Material Adverse Effect***" shall mean, with respect to Biosight, an Effect that, individually or in the aggregate, has, or would reasonably be expected have, a material adverse effect on (a) the business, condition (financial or otherwise), capitalization, assets, operations or financial performance of Biosight and its Subsidiaries as a whole; or (b) would reasonably be expected to prevent, materially impair or materially delay the ability of Biosight to perform its obligations under this Agreement or to consummate the Transactions, including the Merger, other than, in the case of clause (a) above, (i) Effects in general economic or political conditions or the securities market in general, or changes in or affecting the industries in which Biosight and its Subsidiaries operate; (ii) any failure by Biosight to meet internal projections or; (iii) the execution, delivery, announcement or performance of the obligations under this Agreement or the announcement, pendency or anticipated consummation of the Merger; (iv) the resignation or termination of any officer or director; (v) any natural disaster, any epidemic, pandemic or disease outbreak (including the COVID-19 virus) or other public health emergencies (as declared by the World Health Organization or the Health and Human Services Secretary of the United States) or any acts of terrorism, sabotage, military action or war or any escalation or worsening thereof, but solely to the extent Biosight can prove that such Effect was caused directly as a result of such natural disaster, epidemic, pandemic, disease outbreak or other health emergency; or (vi) any changes (after the date of this Agreement) in GAAP or applicable Legal Requirements; *provided*, that any Effect referred to in clauses (i), (v), and (vi) may be taken into account in determining whether there has been, or would reasonably be expected to be, a Biosight Material Adverse Effect to the extent such Effect has a disproportionate effect on Biosight and its Subsidiaries, taken as a whole, relative to other similarly sized participants in the businesses, industries and geographic locations in which Biosight and its Subsidiaries operate.

"***Biosight Material Contract***" shall have the meaning set forth in Section 3.9(a).

"***Biosight Options***" shall mean options or other rights to purchase shares of Biosight Shares issued or granted by Biosight.

"***Biosight Ordinary Shares***" shall mean the ordinary shares, par or nominal value NIS 0.01 per share, of Biosight.

"***Biosight Permits***" shall have the meaning set forth in Section 3.11(b).

"***Biosight Preferred Shares***" shall mean, collectively, the Ordinary A-1 shares, Ordinary A-2 shares, Ordinary A-3 shares, Preferred B shares, Preferred B-1 shares and Preferred C shares, in each case, par or nominal value NIS 0.01 per share, of Biosight.

"***Biosight Product Candidates***" shall have the meaning set forth in Section 3.11(d).

"***Biosight Registered IP***" shall have the meaning set forth in Section 3.8(a).

"***Biosight Regulatory Permits***" shall have the meaning set forth in Section 3.11(d).

"***Biosight Share Certificate***" shall have the meaning set forth in Section 1.6.

"***Biosight Shareholder***" shall mean each shareholder of Biosight, and "***Biosight Shareholders***" shall mean all shareholders of Biosight, in each case as determined immediately prior to the Effective Time.

"***Biosight Shareholder Approval***" shall mean the approval by the shareholders of Biosight of the Transactions in accordance with Biosight's Constituent Documents and any applicable Legal Requirements.

"***Biosight Shareholder Written Consent***" shall have the meaning set forth in Section 5.3(a).

"***Biosight Shareholders' Meeting***" shall have the meaning set forth in Section 5.3(a).

"***Biosight Shares***" shall mean, depending on the context, the Biosight Ordinary Shares and/or the Biosight Preferred Shares.

"***Biosight Standard Contracts***" shall have the meaning set forth in Section 3.9(a)(xii).

"***Biosight Support Agreements***" shall have the meaning set forth in the Recitals.

"***Board of Directors***" shall mean the board of directors of any specified Person.

"***Business Day***" shall mean a day, other than Friday, Saturday, Sunday or other day on which commercial banks in New York, New York or Tel Aviv, Israel are authorized or required by applicable Legal Requirements to close.

"***CARES Act***" shall mean the federal Coronavirus Aid, Relief, and Economic Security Act, and applicable rules and regulations.

"***Certificate of Merger***" shall have the meaning set forth in Section 1.3.

"***Change in Advaxis Board Recommendation***" shall have the meaning set forth in Section 5.2(c).

"***Change in Biosight Board Recommendation***" shall have the meaning set forth in Section 5.3(c).

"***Clayton Act***" shall mean the Clayton Act of 1914, as amended.

"***Closing***" shall have the meaning set forth in Section 1.3.

"***Closing Date***" shall have the meaning set forth in Section 1.3.

"***Code***" shall mean the Internal Revenue Code of 1986, as amended.

"***Companies Registrar***" shall have the meaning set forth in Section 1.3.

"***Confidentiality Agreement***" shall have the meaning set forth in Section 4.1(c).

"***Consent***" shall mean any approval, consent, ratification, permission, waiver or authorization (including any Governmental Authorization).

"***Constituent Documents***" shall mean with respect to any entity, its certificate or articles of association or incorporation, bylaws and any similar charter or other organizational documents of such entity.

"***Contract***" shall, with respect to any Person, mean any written agreement, contract, subcontract, lease (whether real or personal property), mortgage, understanding, arrangement, instrument, note, option, warranty, purchase order, license, sublicense, insurance policy, benefit plan or legally binding commitment or undertaking of any nature to which such Person is a party or by which such Person or any of its assets are bound or affected under applicable Legal Requirement.

"***Costs***" shall have the meaning set forth in Section 5.6(a).

"***Drug Regulatory Agency***" shall have the meaning set forth in Section 2.11(c).

"***Effective Time***" shall have the meaning set forth in Section 1.3.

"***Electing Holder***" shall have the meaning set forth in Section 5.22(b).

"***Electronic Delivery***" shall have the meaning set forth in Section 10.4.

"***Encumbrance***" shall mean any lien, pledge, hypothecation, charge, mortgage, security interest, encumbrance, claim, infringement, interference, option, right of first refusal, preemptive right, community property interest or restriction of any nature (including any restriction on the voting of any security, any restriction on the transfer of any security or other asset, any restriction on the receipt of any income derived from any asset, any restriction on the use of any asset and any restriction on the possession, exercise or transfer of any other attribute of ownership of any asset).

"***End Date***" shall have the meaning set forth in Section 9.1(b)(i).

"***Entity***" shall mean any corporation (including any non-profit corporation), partnership (including any general partnership, limited partnership or limited liability partnership), joint venture, estate, trust, company (including any company limited by shares, limited liability company or joint stock company), firm, society or other enterprise, association, organization or entity, and each of its successors.

"***Environmental Law***" shall mean any federal, state, local or foreign Legal Requirement relating to pollution or protection of human health or the environment (including ambient air, surface water, ground water, land surface or subsurface strata), including any law or regulation relating to emissions, discharges, releases or threatened releases of Hazardous Materials, or otherwise relating to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials.

"***ERISA***" shall mean the Employee Retirement Income Security Act of 1974, as amend

"***ESPP***" shall mean the Advaxis 2018 Employee Stock Purchase Plan.

"***Exchange***" shall mean the NASDAQ Capital Market.

"***Exchange Act***" shall mean the Securities Exchange Act of 1934, as amended.

"***Exchange Agent***" shall have the meaning set forth in Section 1.7(a).

"***Exchange Fund***" shall have the meaning set forth in Section 1.7(a).

"***Exchange Ratio***" shall have the meaning set forth in Section 1.5(a)(ii).

"***Existing Advaxis D&O Policies***" shall have the meaning set forth in Section 2.15(b).

"***Existing Biosight D&O Policies***" shall have the meaning set forth in Section 3.15(b).

"***Expense Reimbursement***" shall have the meaning set forth in Section 9.3(i).

"***FDA***" shall have the meaning set forth in Section 2.11(c).

"***FDCA***" shall have the meaning set forth in Section 2.11(a).

"***Foreign Competition Law***" shall mean any Legal Requirements of any Governmental Authorities in the area of trade and competition, other than any such U.S. and Israeli Governmental Authorities.

"***Form S-4 Registration Statement***" shall mean the registration statement on Form S-4 to be filed with the SEC by Advaxis registering the public offering and sale of Advaxis Common Stock to some or all holders of Biosight Shares in the Merger, including all shares of Advaxis Common Stock to be issued in exchange for all other shares of Biosight Shares in the Merger, as said registration statement may be amended prior to the time it is declared effective by the SEC.

"***GAAP***" shall have the meaning set forth in Section 2.4(a).

"***Governmental Authority***" shall mean any supranational, national, state, municipal or local government (including any subdivision, court, administrative agency or commission or other authority thereof) or any other supranational, governmental, intergovernmental, quasi-governmental authority, body, department or organization, including the SEC and European Union, any self-regulatory organization (including the Exchange), or any regulatory body appointed by any of the foregoing, in each case, in any jurisdiction.

"***Governmental Authorization***" shall mean any (a) permit, license, certificate, franchise, permission, variance, exceptions, orders, clearance, registration, qualification or authorization issued, granted, given or otherwise made available by or under the authority of any Governmental Authority or pursuant to any Legal Requirement; or (b) right under any Contract with any Governmental Authority.

"***Governmental Grant***" shall mean any grant, funding, incentive, subsidy, award, participation, exemption, status, cost sharing arrangement, reimbursement arrangement or other benefit, relief, support or privilege (including approval to participate in a program or framework without receiving financial support), including any application therefor, whether pending, approved, provided or made available by or on behalf of or under the authority of the IIA or any related authorities or programs, the Israeli Investment Center, the ITA, the State of Israel, and any bi-, multi-national, regional or similar program, framework or foundation (including, for example, BIRD), the European Union, the Fund for Encouragement of Marketing Activities of the Israeli Government or any other Governmental Authority.

"***Hazardous Materials***" shall mean any pollutant, chemical, substance and any toxic, infectious, carcinogenic, reactive, corrosive, ignitable or flammable chemical, or chemical compound, or hazardous substance, material or waste, whether solid, liquid or gas, that is subject to regulation, control or remediation under any Environmental Law, including crude oil or any fraction thereof, and petroleum products or by-products.

"***Healthcare Laws***" shall have the meaning set forth in Section 2.11(a).

"***HSR Act***" shall mean the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

"***ICL***" shall have the meaning set forth in the Recitals.

"***IIA***" shall have the meaning set forth in Section 5.5(b).

"***IIA Undertaking***" shall have the meaning set forth in Section 5.5(b).

"***Intellectual Property***" shall mean all rights, title and interest in or relating to intellectual property throughout the world, whether protected, created or arising under the laws of the United States or any other jurisdiction, including: (a) all patents, patent applications, including provisional applications, statutory invention registrations, invention disclosures and inventions, (b) all trademarks, service marks, trade names, domain names, URLs, social media accounts, trade dress, logos and other source identifiers, together with the goodwill associated with any of the foregoing, including registrations and applications for registration, renewals and extensions thereof, (c) all copyrights, copyrightable subject matter and works of authorship, whether registered or unregistered or published or unpublished, including registrations and applications for registration thereof, (d) all rights in software, moral rights, and rights of publicity and privacy, (e) all know-how, trade secrets and other proprietary and/or confidential information, including formulae, customer lists, supplier lists, pricing and cost information, business and marketing plans and proposals, technology (including patented, patentable and unpatented inventions and unpatentable proprietary or confidential information, systems or procedures), discoveries and improvements, technical data and information, techniques, research and development, inventions (including conceptions and/or reductions to practice), designs, specifications, concepts, drawings, procedures, processes, models, algorithms, formulations, recipes, ideas, manuals and systems, databases and data, whether or not patentable or copyrightable (collectively, "***Trade Secrets***"), (f) all applications, registrations, provisions, continuations, continuations-in-part, divisionals, re-examinations, re-issues, renewals, extensions, foreign counterparts, reversions, and similar rights with respect to the foregoing, (g) all causes of action, claims damages and other remedies for past, current, and future infringement, misappropriation, and similar violations of any of the foregoing, and (h) all embodiments and fixations thereof and related documentation and media describing or relating to any of the foregoing.

"***Intended Tax Treatment***" shall have the meaning set forth in Section 1.9.

"***Intentional Breach***" shall have the meaning set forth in Section 9.3(h).

"***Interim Option Tax Ruling***" shall have the meaning set forth in Section 5.22(a).

"***Interim Period***" shall have the meaning set forth in Section 4.1(a).

"***IRB***" shall have the meaning set forth in Section 2.11(e).

"***IRS***" shall mean the United States Internal Revenue Service.

"***Israeli Competition Law***" shall have the meaning set forth in Section 5.5(a).

"***Israeli Employees***" shall have the meaning set forth in Section 3.13(o).

"***Israeli Income Tax Ruling***" shall have the meaning set forth in Section 5.22(b).

"***Israeli Interim Income Tax Ruling***" shall mean an interim approval confirming, among other matters, that Advaxis and anyone acting on its behalf shall be exempt from Israeli withholding Tax in relation to any payments or transfers of the Merger Consideration to the Paying Agent or an Electing Holder.

"***ITA***" means the Israel Tax Authority.

"***Knowledge***" shall mean, (A) in the case of Advaxis, the actual knowledge, following reasonable inquiry of direct reports, of individuals listed in Part 1-K of the Advaxis Disclosure Schedule, and (B) in the case of Biosight, the actual knowledge, following reasonable inquiry of direct reports, of individuals listed in Part 1-K of the Biosight Disclosure Schedule.

"***Legal Proceeding***" shall mean any action, suit, litigation, arbitration, proceeding (including any civil, criminal, administrative, investigative or appellate proceeding), hearing, inquiry, audit, examination or investigation commenced, brought, conducted or heard by or before, or otherwise involving, any court or other Governmental Authority or any arbitrator or arbitration panel.

"***Legal Requirement***" shall mean any federal, state, foreign, material local or municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, edict, decree, rule, regulation, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Authority (or under the authority of the NASDAQ Stock Market or the Financial Industry Regulatory Authority).

"***Liability***" shall have the meaning set forth in Section 2.10.

"***Listing Rule***" shall have the meaning set forth in Section 5.10(a).

"***Merger***" shall have the meaning set forth in the Recitals.

"***Merger Consideration***" shall have the meaning set forth in Section 1.5(a)(ii).

"***Merger Notice***" shall have the meaning set forth in Section 1.3.

"***Merger Proposal***" shall have the meaning set forth in Section 5.4(a).

"***Merger Sub***" shall have the meaning set forth in the Preamble.

"***Multiemployer Plan***" shall have the meaning set forth in Section 2.13(l).

"***Option Tax Ruling***" shall have the meaning set forth in Section 5.22(a).

"***Order***" shall mean any charge, order, writ, injunction, judgment, decree, ruling, determination, directive, award or settlement, whether civil, criminal or administrative and whether formal or informal.

"***Ordinance***" shall mean the Israeli Income Tax Ordinance New Version, 1961, as amended, and the rules and regulations promulgated thereunder.

"***Ordinary Course of Business***" shall mean, in the case of each of Biosight and Advaxis and for all periods, such actions taken in the ordinary course of its normal operations and consistent with its past practices, and for periods following the date of this Agreement consistent with its operating plans delivered to the other Party.

"***Party***" or "***Parties***" shall have the meanings set forth in the Preamble.

"***Paying Agent***" shall have the meaning set forth in Section 1.7(f).

"***Payor***" shall have the meaning set forth in Section 1.7(e).

"***Permitted Encumbrance***" shall mean (i) any lien for current Taxes not yet due and payable or for Taxes that are being contested in good faith through appropriate proceedings and for which adequate reserves have been made on the Advaxis Unaudited Interim Balance Sheet or Biosight's audited consolidated balance sheets as of December 31, 2020, as applicable; (ii) minor liens that have arisen in the Ordinary Course of Business and that do not (in any case or in the aggregate) materially detract from the value of the assets subject thereto or materially impair the operations of Advaxis or any of its Subsidiaries or Biosight or any of its Subsidiaries, as applicable; (iii) liens listed in Part 1-P of the Advaxis Disclosure Schedule or Part 1-P of the Biosight Disclosure Schedule, as applicable, (iv) statutory liens to secure obligations to landlords, lessors or renters under leases or rental agreements to the extent no payment or performance under any such lease or rental agreement is in arrears or is otherwise due; (v) deposits or pledges made in connection with, or to secure payment of, workers' compensation, unemployment insurance or similar programs mandated by Legal Requirement; (vi) statutory liens securing payments not yet due or which are being contested in good faith, including liens of carriers, warehousemen, mechanics, materialmen, suppliers and repairmen and (vii) in the case of Intellectual Property, non-exclusive licenses granted in the Ordinary Course of Business.

"***Person***" shall mean any individual, Entity or Governmental Authority.

"***PHSA***" shall have the meaning set forth in Section 2.11(a).

"***Proxy Statement/Prospectus/Information Statement***" shall mean the proxy statement/prospectus/information statement to be sent to Biosight Shareholders in connection with the approval of this Agreement and the Merger (at the Biosight Shareholders' Meeting or by signing the Biosight Shareholder Written Consent) and to Advaxis' stockholders in connection with the Advaxis Stockholders' Meeting.

"***Recall***" shall have the meaning set forth in Section 2.11(i).

"***Representatives***" shall mean directors, officers, other employees, agents, attorneys, accountants, advisors and representatives.

"***Reverse Split***" shall have the meaning set forth in Section 5.2(b).

"***Rights Agreement***" shall mean the Rights Agreement, dated September 29, 2020, by and between Advaxis and Continental Stock Transfer and Trust Company.

"***Sarbanes-Oxley Act***" shall mean the Sarbanes-Oxley Act of 2002, as it may be amended from time to time.

"***SEC***" shall mean the United States Securities and Exchange Commission.

"***Section 14 Arrangement***" shall have the meaning set forth in Section 3.13(o).

"***Securities***" shall mean, with respect to any Person, any series of common stock or preferred stock, any ordinary shares or preferred shares and any other equity securities or capital stock of such Person, however described and whether voting or non-voting, including options to purchase capital stock or warrants to purchase capital stock or any other instrument convertible into capital stock.

"***Securities Act***" shall mean the Securities Act of 1933, as amended.

"***Shareholder Litigation***" shall have the meaning set forth in Section 5.20.

"***Sherman Act***" shall mean the Sherman Antitrust Act of 1890, as amended.

"***Subsidiary***" shall mean, with respect to any Party, any corporation, partnership, trust, limited liability company or other non-corporate business enterprise in which such party (or another Subsidiary of such party) owns or controls, directly or indirectly, securities or other ownership interests representing (a) more that 50% of the voting power of all outstanding stock or ownership interests of such entity or (b) the right to receive more than 50% of the net assets of such entity available for distribution to the holders of outstanding stock or ownership interests upon a liquidation or dissolution of such entity. For the avoidance of doubt, Merger Sub is a Subsidiary of Advaxis.

"***Superior Offer***" with respect to Biosight or Advaxis shall mean an unsolicited bona fide written Acquisition Proposal that was first received after the date hereof that (i) did not result from, and is not otherwise attributable to, a direct or indirect breach of (or in violation of) Section 4.4 or Section 4.5, as applicable, and (ii) the Board of Directors of such party (Advaxis or Biosight, as applicable) determines, in good faith, after consultation with its outside legal counsel and its financial advisors, if any, (A) is reasonably likely to be consummated in accordance with its terms (if accepted) without unreasonable delay, taking into account all legal, regulatory and financing aspects (including certainty of closing, any termination or break-up fees and, to the extent third party financing is required, that such financing is then fully committed on customary terms and conditions) of such Acquisition Proposal, the Person making the proposal, as well as any written offer by the other Party to amend the terms of this Agreement, and other aspects of the Acquisition Proposal that the Board of Directors of such party (Advaxis or Biosight, as applicable) deems relevant, and (B) if consummated, would result in a transaction more favorable from a financial point of view: (x) in the case of Advaxis, to the holders of Advaxis Common Stock (solely in their capacity as such) than the Transactions and (y) in the case of Biosight, to the shareholders of Biosight (solely in their capacity as such) than the Transactions; *provided*, *however*, that, for the purposes of this definition of "Superior Offer," the term "Acquisition Proposal" shall have the meaning assigned to such term herein, except that references to "15%" in such definition shall be deemed to be references to "50%" and in the case of Biosight, the term "Acquisition Proposal" shall include any other transaction that results in the shareholders of Biosight being the majority holders of a publicly traded company.

"***Surviving Company***" shall have the meaning set forth in Section 1.1.

"***Takeover Statute***" shall have the meaning set forth in Section 2.18(a).

"***Tax***" shall mean any federal, state, local, foreign or other tax, assessment, charge, duty, fee, levy or other governmental charge imposed by a Governmental Authority, including any income tax, franchise tax, capital gains tax, gross receipts tax, value-added tax, surtax, estimated tax, unemployment tax, national health insurance tax, excise tax, ad valorem tax, transfer tax, stamp tax, sales tax, use tax, property tax, business tax, withholding tax, payroll tax, customs duty, alternative or add-on minimum or other tax, assessment, charge, duty, fee, levy or other governmental charge of any kind whatsoever imposed by a Governmental Authority, and including any fine, penalty, addition to tax or interest, whether disputed or not.

"***Tax Return***" shall mean any return (including any information return), report, statement, declaration, estimate, schedule, notice, notification, form, election, certificate or other document or information, and any amendment or supplement to any of the foregoing, filed with or submitted to, or required to be filed with or submitted to, any Governmental Authority in connection with the determination, assessment, collection or payment of any Tax or in connection with the administration, implementation or enforcement of or compliance with any Legal Requirement relating to any Tax.

"***Termination Fee***" shall have the meaning set forth in Section 9.3(b)(ii).

"***Transactions***" shall have the meaning set forth in the Recitals.

"***Treasury Regulations***" shall mean the United States Treasury regulations promulgated under the Code.

"***VAT***" shall have the meaning set forth in Section 3.12(o).

"***Valid Tax Certificate***" shall mean a valid certificate, ruling or any other written instructions regarding Tax withholding, issued by the ITA in form and substance reasonably satisfactory to Advaxis and the Paying Agent, that is applicable to payments to be made to any Person, in cash or in kind, pursuant to this Agreement stating that no withholding, or reduced withholding, of Israeli Tax is required with respect to such payment or providing other instructions regarding such withholding. For the avoidance of doubt, the Israeli Income Tax Ruling, the Israeli Interim Income Tax Ruling, the Option Tax Ruling and the Interim Option Tax Ruling (each, if obtained), are regarded as Valid Tax Certificates.

"***Willful Breach***" shall mean with respect to any breaches or failures to perform any of the covenants or other agreements contained in this Agreement, a material breach that is a consequence of an act or failure to act undertaken by the breaching party with actual or constructive knowledge (which shall be deemed to include knowledge of facts that a Person acting reasonably should have, based on reasonable due inquiry) that such party's act or failure to act would, or would reasonably be expected to, result in or constitute a breach of this Agreement. The term "***Willfully Breached***" shall be construed accordingly.

"***Withholding Drop Date***" shall have the meaning set forth in Section 1.7(f).

Exhibit B

FORM OF BIOSIGHT SUPPORT AGREEMENT

(attached)

Exhibit C

FORM OF ADVAXIS SUPPORT AGREEMENT

(attached)

Exhibit D

FORM OF LETTER OF TRANSMITTAL

(attached)

Exhibit E

FORM OF IAA UNDERTAKING

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To: The National Technological Innovation Authority ("**Innovation Authority**")

Relating to projects that have been financed by or are currently being financed by the Innovation Authority (or have been financed by the Office of the Chief Scientist of the Ministry of Economy and Industry - hereinafter referred to as the "**OCS**") project title 24956, OCS file number 4500 and to projects of the Company (as this term is defined below) that may be financed by the Innovation Authority in the future (the "**Projects**").

UNDERTAKING

We, the undersigned, of Advaxis, Inc. a company incorporated, organized and existing under the laws of Delaware and whose registered office is at 9 Deer Park Drive, Suite K-1 Monmouth Junction, NJ 08852, USA ("**Advaxis**"), have entered into an Agreement and Plan of Merger and Reorganization dated as of July 4, 2021 with Biosight Ltd. (the "**Company**") and Advaxis Ltd., an Israeli company and a wholly-owned subsidiary of Advaxis.

Recognizing that the Company's research and development or technological innovation Projects are currently, have been or will be financially supported by the Innovation Authority or the OCS under and subject to the provisions of The Encouragement of Research, Development and Technological Innovation in the Industry Law 5744-1984 (the "**Innovation Law**") and the applicable regulations, rules, procedures and benefit plans;

Recognizing that the Innovation Law places strict constraints on the transfer of know-how and/or production rights, making all such transfers subject to the absolute discretion of the Innovation Authority's research committee (the "**Research Committee**"), acting in accordance with the aims of the Innovation Law and requiring that any such transfer receive the prior written approval of the Research Committee;

**Hereby declare and undertake:**

1. To observe strictly all the requirements of the Innovation Law and the provisions of the applicable regulations, rules, procedures and benefit plans, as applied to the Company and as directed by the Research Committee, in particular those requirements relating to the prohibitions on the transfer of know-how and/or production rights.

2. As a shareholder of the Company, to make all reasonable efforts that the Company shall observe strictly all the requirements of the Innovation Law and the provisions of the applicable regulations, rules, procedures and benefit plans, as applied to the Company and as directed by the Research Committee, in particular those requirements relating to the prohibitions on the transfer of know-how and/or production rights.

Date

Name (block letters) and signature of Authorized Company Representative and Company Seal

LifeSci Capital LLC
250 West 55th Street, Suite 3401
New York, NY 10019

July 2, 2021

CONFIDENTIAL

The Board of Directors
Advaxis, Inc.
9 Deer Park Drive, Suite K-1
Monmouth Junction, NJ 08852

The Board of Directors:

You have requested our opinion as to the fairness, from a financial point of view, to the holders of the outstanding shares of common stock, par value $0.001 per share (the "Shares") (other than Excluded Shares, as defined below), of Advaxis, Inc., a Delaware corporation (the "Company") of the Exchange Ratio (as defined below) proposed to be paid by the Company pursuant to the Agreement and Plan of Merger and Reorganization proposed to be entered into (the "Agreement") by and among Biosight Ltd., a company organized under the laws of the State of Israel ("Parent"), Advaxis Ltd., a company organized under the laws of the State of Israel and wholly owned subsidiary of the Company ("Merger Sub"). The Agreement provides that Merger Sub will be merged with and into Parent (the "Merger" and, collectively with the other transactions contemplated by the Agreement, the "Transaction"), as a result of which Parent will become a wholly owned subsidiary of the Company and each issued and outstanding ordinary share, par or nominal value NIS 0.01 per share, of Parent (the "Ordinary Shares") and Parent Preferred Share (as defined in the Agreement, and together with the Ordinary Shares, the "Parent Shares") immediately prior to the effective time of the Merger (other than shares of Parent owned by (i) Parent subsidiaries, the Company or Merger Sub, or by any of their respective subsidiaries immediately prior to the Effective Time shall remain outstanding, (ii) the 102 Biosight Shares (as defined in the Agreement) and (iii) any Parent Share that is a dormant share (the shares referred to in clauses (i), (ii) and (iii), "Excluded Shares")) will be converted into the right to receive 118.2009 (the "Exchange Ratio") Company Shares. The terms and conditions of the Transaction are more fully set forth in the Agreement.

We have acted as financial advisor to the Board of Directors of the Company in connection with the Transaction. We will receive a fee for our services in connection with the Transaction, a portion of which is payable upon the rendering of this opinion and a substantial portion of which is contingent upon the consummation of the Transaction. In addition, the Company has agreed to reimburse certain of our expenses arising, and indemnify us against certain liabilities that may arise, out of our engagement.

We are a securities firm engaged directly and through affiliates and related persons in a number of investment banking, financial advisory and merchant banking activities. In the past two years, we or our affiliates have been engaged to provide certain financial advisory or other services to the Company from time to time, including ordinary course strategic advisory engagements and investor relations consulting services, and we have received and may in the future receive compensation from the Company for such services. In the past two years, we or our affiliates have been engaged to provide certain services to Parent from time to time, including ordinary course investor relations and executive recruitment consulting services, and we have received and may in the future receive compensation from Parent for such services. We may provide investment banking and other services to or with respect to the Company or Parent or their respective affiliates in the future, for which we may receive compensation. Certain (i) of our and our affiliates' directors, officers, members and employees, or family members of such persons, (ii) of our affiliates or related investment funds and (iii) investment funds or other persons in which any of the foregoing may have financial interests or with which they may co-invest, may at any time acquire, hold, sell or trade, in debt, equity and other securities or financial instruments (including derivatives, bank loans or other obligations) of, or investments in, the Company or any of its affiliates, or any other party that may be involved in the Transaction.

In connection with this opinion, we have reviewed, among other things: (i) a draft of the Agreement dated July 1, 2021 (the "Draft Agreement"); (ii) certain available research analyst reports for the Company; (iii) certain other communications from the Company and Parent; (iv) certain internal information relating to the business, operations, earnings, cash flow, assets, liabilities and prospects of the Company, including certain financial forecasts, analyses and projections relating to the Company prepared by management of the Company and furnished to us by the Company for purposes of our analysis (the "Company Forecasts") (collectively, the "Company Internal Data"); and (v) certain internal information relating to the business, operations, earnings, cash flow, assets, liabilities and prospects of Parent, including certain financial forecasts, analyses and projections relating to Parent prepared by management of Parent and furnished to us by the Company for purposes of our analysis (the "Parent Forecasts") (collectively, the "Parent Internal Data"). We have participated in discussions with members of the senior management and representatives of the Company and Parent regarding their assessment of the Company Internal Data and the Parent Internal Data, as appropriate, and the strategic rationale for the Transaction. In addition, we reviewed publicly available financial and stock market data, including valuation multiples, for the Company and Parent and compared that data with similar data for certain other companies, the securities of which are publicly traded, in lines of business that we deemed relevant. We also conducted such other financial studies and analyses and took into account such other information as we deemed appropriate.

We have assumed, without independent verification or any responsibility therefor, the accuracy and completeness of the financial, legal, regulatory, tax, accounting and other information supplied to, discussed with, or reviewed by us for purposes of this opinion and have, with your consent, relied upon such information as being complete and accurate. In that regard, we have assumed, at your direction, that the Company Internal Data (including, without limitation, the Company Forecasts) have been reasonably prepared on bases reflecting the best currently available estimates and judgments of the management of the Company as to the matters covered thereby and, that the Parent Internal Data (including, without limitation, the Parent Forecasts) have been reasonably prepared on bases reflecting the best currently available estimates and judgments of the management of Parent as to the matters covered thereby, and we have relied, at your direction, on the Company Internal Data, the Parent Internal Data for purposes of our analysis and this opinion. We express no view or opinion as to the Internal Data or the assumptions on which it is based. In addition, at your direction, we have not made any independent evaluation or appraisal of any of the assets or liabilities (contingent, derivative, off-balance-sheet or otherwise) of the Company or Parent, nor have we been furnished with any such evaluation or appraisal, and we have not been asked to conduct, and did not conduct, a physical inspection of the properties or assets of the Company or Parent. We have assumed, at your direction, that the final executed Agreement will not differ in any respect material to our analysis or this opinion from the Draft Agreement reviewed by us. We have also assumed, at your direction, that the Transaction will be consummated on the terms set forth in the Agreement and in accordance with all applicable laws and other relevant documents or requirements, without delay or the waiver, modification or amendment of any term, condition or agreement, the effect of which would be material to our analysis or this opinion and that, in the course of obtaining the necessary governmental, regulatory and other approvals, consents, releases and waivers for the Transaction, no delay, limitation, restriction, condition or other change, including any divestiture requirements or amendments or modifications, will be imposed, the effect of which would be material to our analysis or this opinion. We have further assumed, at your direction, that the Merger will qualify for U.S. federal income tax purposes as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended. We have not evaluated and do not express any opinion as to the solvency or fair value of the Company or Parent, or the ability of the Company or Parent to pay their respective obligations when they come due, or as to the impact of the Transaction on such matters, under any state, federal or other laws relating to bankruptcy, insolvency or similar matters. We are not legal, regulatory, tax or accounting advisors, and we express no opinion as to any legal, regulatory, tax or accounting matters.

We express no view as to, and our opinion does not address, the Company's underlying business decision to proceed with or effect the Transaction, or the relative merits of the Transaction as compared to any alternative business strategies or transactions that might be available to the Company or in which the Company might engage. This opinion is limited to and addresses only the fairness, from a financial point of view, as of the date hereof, to the holders of the Shares (other than Excluded Shares) of the Exchange Ratio provided for pursuant to the Agreement. We have not been asked to, nor do we express any view on, and our opinion does not address, any other term or aspect of the Agreement or the Transaction, including, without limitation, the structure or form of the Transaction, or any other agreements or arrangements contemplated by the Agreement or entered into in connection with or otherwise contemplated by the Transaction, including, without limitation, the fairness of the Transaction or any other term or aspect of the Transaction to, or any consideration to be received in connection therewith by, or the impact of the Transaction on, the holders of any other class of securities, creditors or other constituencies of the Company or any other party. In addition, we express no view or opinion as to the fairness (financial or otherwise) of the amount, nature or any other aspect of any compensation to be paid or payable to any of the officers, directors or employees of the Company or any party, or class of such persons in connection with the Transaction, whether relative to the Exchange Ratio provided for pursuant to the Agreement or otherwise. Our opinion is necessarily based on financial, economic, monetary, currency, market and other conditions and circumstances as in effect on, and the information made available to us as of, the date hereof, and we do not have any obligation or responsibility to update, revise or reaffirm this opinion based on circumstances, developments or events occurring after the date hereof. Our opinion does not constitute a recommendation to any stockholder of the Company or any other person as to how such stockholder or other person should vote with respect to the Merger or otherwise act with respect to the Transaction or any other matter.

Our financial advisory services and the opinion expressed herein are provided solely for the information and assistance of the Board of Directors of the Company (in their capacity as directors and not in any other capacity) in connection with and for purposes of its consideration of the Transaction. This opinion may not be disclosed, quoted, referred to or communicated (in whole or in part) to, and may not be relied upon by, any other person, nor shall any public references to us or this opinion be made at any time, in any manner or for any purpose whatsoever except with our prior written consent. The issuance of this opinion was approved by the LifeSci Capital LLC Fairness Opinion Committee.

Based upon and subject to the foregoing, including the various assumptions made, procedures followed, matters considered, and qualifications and limitations set forth herein, we are of the opinion, as of the date hereof, that the Exchange Ratio provided for pursuant to the Agreement is fair, from a financial point of view, to the holders of Shares other than Excluded Shares.

Very truly yours,

LIFESCI CAPITAL LLC

LifeSci Capital LLC (Member: FINRA/SIPC)
250 West 55th Street, Suite 3401, New York, New York 10019

**Annex C**

## SUPPORT AGREEMENT

This Support Agreement (this "Agreement"), dated as of July 4, 2021, is entered into by and among Advaxis, Inc., a Delaware corporation ("Advaxis"), Biosight Ltd., a company organized under the laws of the State of Israel ("Biosight") and the director or executive officer of Advaxis included on the signature page hereto ("Stockholder"). Defined terms used but not defined herein shall have the meaning ascribed to such terms in the Merger Agreement (as defined below).

## RECITALS

WHEREAS, concurrently herewith, Advaxis, Advaxis Ltd., a company organized under the laws of the State of Israel and a wholly owned Subsidiary of Advaxis ("Merger Sub"), and Biosight are entering into that certain Agreement and Plan of Merger and Reorganization, dated as of the date hereof (as amended, supplemented, restated or otherwise modified from time to time, the "Merger Agreement"), pursuant to which (and subject to the terms and conditions set forth therein) Merger Sub will merger with and into Biosight, with Biosight being the surviving entity (the "Merger Transaction");

WHEREAS, in connection with the Merger Transaction and pursuant to the terms of the Merger Agreement, Advaxis will duly convene and hold a meeting of its stockholders (the "Advaxis Stockholders' Meeting") for the purposes of obtaining approval of the Merger Transaction (among other things) by the stockholders of Advaxis;

WHEREAS, as of the date hereof, the Stockholder is the record and "beneficial owner" (within the meaning of Rule 13d-3 under the Securities Exchange Act of 1934, as amended (together with the rules and regulations promulgated thereunder, the "Exchange Act")) of [_____] issued and outstanding shares of Advaxis Common Stock (the "Current Shares" and together with any shares of Advaxis Common Stock or any other equity securities of Advaxis acquired (including the acquisition of the right to vote or beneficial ownership) or purchased by, or issued (including as a result of a share split, share dividend, merger, reorganization, recapitalization, reclassification, combination, exchange of shares or other similar event) to, the Stockholder after the date hereof, the "Owned Shares"); and

WHEREAS, as a condition and inducement to the willingness of Biosight to enter into the Merger Agreement and commence the Transactions, Biosight, Advaxis and the Stockholder are entering into this Agreement for the Stockholder to take certain actions as described herein.

**AGREEMENT**

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants and agreements herein contained, and intending to be legally bound hereby, Biosight, Advaxis and the Stockholder hereby agree as follows:

1. Agreement to Vote Common Stock in Support of the Merger Transaction. From the date hereof until the Termination Date (as defined below), the Stockholder, in its capacity as a stockholder of Advaxis, hereby irrevocably and unconditionally agrees that at any meeting of the stockholders of Advaxis, however called (including, for the avoidance of doubt, the Advaxis Stockholders' Meeting), or at any adjournment or postponement thereof, and in any action by written consent of the stockholders of Advaxis distributed by the Board of Directors of Advaxis, or otherwise undertaken as contemplated by the Merger Agreement or the Transactions, or in any other circumstance in which the vote, consent or other approval of the stockholders of Advaxis is sought, the Stockholder shall, and shall cause any other holder of record of any of the Owned Shares to:

(i) when such meeting is held, appear at such meeting or otherwise cause the Owned Shares to be counted as present thereat for the purpose of establishing a quorum;

(ii) vote (or execute and return an action by written consent), or cause to be voted at such meeting (or validly execute and return and cause such consent to be granted with respect to), all of the Owned Shares in favor of, and to adopt and approve, the Merger Agreement and the consummation of the Merger Transaction and the other Transactions (including, the Advaxis Certificate of Incorporation Amendment, the Reverse Split and the Advaxis Stock Issuance);

(iii) vote (or execute and return an action by written consent), or cause to be voted at such meeting, or validly execute and return and cause such consent to be granted with respect to, all of the Owned Shares against any action that would reasonably be expected to (a) impede, frustrate, interfere with, delay, postpone, prevent, nullify or adversely affect the Transactions, including the Merger Transaction, (b) result in a breach of any covenant, representation or warranty or other obligation or agreement of the Stockholder contained in this Agreement or (c) to the Stockholder's knowledge, result in a breach of any covenant, representation or warranty or other obligation or agreement of Advaxis contained in the Merger Agreement; and

(iv) vote (or execute and return an action by written consent), or cause to be voted at such meeting (or validly execute and return and cause such consent to be granted with respect to), all of the Owned Shares against (a) any Acquisition Proposal or any proposal relating to an Acquisition Proposal (for the avoidance of doubt, in each case, other than with respect to the Transactions) or any proposal made in opposition to, in competition with, or inconsistent with, the Merger Agreement or the Merger or any other Transactions, or (b) any merger agreement, merger, consolidation, combination, sale of substantial assets, reorganization, recapitalization, dissolution, liquidation or winding up of or by Advaxis (other than the Merger Agreement or the Transactions).

During the period commencing on the date hereof and ending on the Termination Date, the Stockholder hereby agrees that it shall not commit, agree, or publicly propose any intention to take any action inconsistent with the foregoing.

2. No Transfer. From the date hereof until the Termination Date, the Stockholder shall not Transfer (as defined below) any Owned Shares, in each case except pursuant to a Permitted Transfer (as defined below). For purposes of this Section 2, the following terms shall have the meanings as defined below:

(i) "Permitted Transfer" means any Transfer of shares of Advaxis Common Stock or Biosight Shares, as applicable, (A) to (x) any officer or director of Advaxis or Biosight, or (y) any Affiliates or family members of the officers or directors of Advaxis or Biosight; (B) by gift to a member of the individual's immediate family or to a trust, the beneficiary of which is a member of the individual's immediate family or an Affiliate of such Person, or to a charitable organization; (C) by virtue of laws of descent and distribution upon death of the individual; (D) pursuant to a qualified domestic relations order, divorce settlement, divorce decree or separation agreement; (E) to a nominee or custodian of a Person to whom a Transfer would be permitted under clauses (A) through (D) above; (F) in connection with any bona fide mortgage, encumbrance or pledge to a financial institution in connection with any bona fide loan or debt transaction or enforcement thereunder, including foreclosure thereof; (G) in connection with any legal, regulatory or other order; (H) to Advaxis or Biosight; or (I) in connection with the exercise of stock options, including through a "net" or "cashless" exercise; provided, however, that in the case of clauses (A) through (F) such transferees must enter into a written agreement with Biosight agreeing to be bound by the transfer restrictions set forth in this Agreement; provided, further, that in the case of clause (I), the remaining shares issued upon the exercise of stock options shall be subject to the transfer restrictions set forth in this Agreement.

(ii) "Transfer" shall mean, with respect to any Person, (A) the sale or assignment of, offer to sell, contract or agreement to sell, hypothecate, pledge, grant of any option to purchase or otherwise dispose of or agreement to dispose of, directly or indirectly, or establishment or increase of a put equivalent position or liquidation with respect to or decrease of a call equivalent position within the meaning of Section 16 of the Exchange Act, in each case with respect to any security owned, including ownership of record or the power to vote (including, without limitation, by proxy or power of attorney), by such Person; (B) the entry into any swap or other arrangement that transfers to another Person, in whole or in part, any of the economic consequences of ownership of any security owned by such Person, whether any such transaction is to be settled by delivery of such securities, in cash or otherwise; or (C) the public announcement of any intention to effect any transaction specified in clause (A) or (B).

3. No Inconsistent Agreements. From the date hereof until the Termination Date, the Stockholder hereby covenants and agrees that the Stockholder shall not (i) enter into any voting agreement or voting trust with respect to any of the Owned Shares that is inconsistent with the Stockholder's obligations pursuant to this Agreement, (ii) grant a proxy or power of attorney with respect to any of the Owned Shares that is inconsistent with the Stockholder's obligations pursuant to this Agreement, or (iii) enter into any agreement or undertaking that is otherwise inconsistent with, or would restrict, limit or interfere with, or prohibit or prevent it from satisfying, its obligations pursuant to this Agreement.

4. Binding Effect of Merger Agreement. The Stockholder hereby acknowledges that it has read the Merger Agreement and this Agreement and has had the opportunity to consult with its tax and legal advisors. The Stockholder shall be bound by and comply with Sections 4.4 (*Advaxis No Solicitation*) (other than Section 4.4(a)(vi), Section 4.4(b) and Section 4.4(d) thereof) and 5.9 (*Publicity*) of the Merger Agreement (and any relevant definitions contained in any such Sections) as if (i) the Stockholder was an original signatory to the Merger Agreement with respect to such provisions and (ii) each reference to "Advaxis" contained in Section 4.4 of the Merger Agreement (other than Section 4.4(a)(iv) thereof or for purposes of the definition of Acquisition Proposal) also referred to the Stockholder.

5. Termination. This Agreement shall terminate upon the earliest of (i) the Effective Time, (ii) the valid termination of the Merger Agreement in accordance with Section 9 thereof, and (iii) the time this Agreement is terminated upon the mutual written agreement of Biosight and the Stockholder (the earliest of such applicable date, the "Termination Date"). Upon such termination of this Agreement, all obligations of the parties under this Agreement will terminate, without any liability or other obligation on the part of any party hereto to any Person in respect hereof or the transactions contemplated hereby, and no party hereto shall have any claim against another (and no Person shall have any rights against such party), whether under contract, tort or otherwise, pursuant to this Agreement; provided, however, that the termination of this Agreement shall not relieve any party hereto from liability arising in respect of material willful or intentional breach of, or fraud in connection with, this Agreement. This Section 5 shall survive the termination of this Agreement.

6. Representations and Warranties of the Stockholder. The Stockholder hereby represents and warrants to Biosight as follows:

(a) The Stockholder is the record and a beneficial (within the meaning of Rule 13d-3 under the Exchange Act) owner of, and has good and valid title to, the Owned Shares, free and clear of any Encumbrances, other than any applicable restrictions on transfer under applicable securities laws. As of the date of this Agreement, the only equity securities in Advaxis owned of record or beneficially by the Stockholder are the Current Shares. The Stockholder does not hold or own any rights to acquire (directly or indirectly) any equity securities of Advaxis or any securities convertible into, or which can be exchanged for, equity securities of Advaxis.

(b) The Stockholder, except as provided in this Agreement, has full voting power, full power of disposition and full power to issue instructions with respect to, and agree to all, the matters set forth herein, in each case, with respect to the Owned Shares, and has not entered into any agreement or undertaking that is otherwise inconsistent with, or would interfere with, or prohibit or prevent it from satisfying, its obligations pursuant to this Agreement.

(c) The Stockholder has full legal capacity and all requisite power and authority to, and has taken all action necessary in order to, execute, deliver and perform its obligations under this Agreement and to consummate the transactions to be performed by it hereunder. This Agreement has been duly executed and delivered by the Stockholder, and, assuming due authorization, execution and delivery by the other parties to this Agreement, constitutes a valid and binding agreement of the Stockholder enforceable against the Stockholder in accordance with its terms, subject to applicable bankruptcy, insolvency, fraudulent conveyance, reorganization, moratorium and similar laws affecting creditors' rights generally and subject, as to enforceability, to general principles of equity.

(d) The Stockholder has not (i) entered into any voting agreement or voting trust with respect to any of the Owned Shares that is still in effect and that is inconsistent with the Stockholder's obligations pursuant to this Agreement (including Section 1 hereof), (ii) granted a proxy or power of attorney with respect to any of the Owned Shares that is still in effect and that is inconsistent with the Stockholder's obligations pursuant to this Agreement (including Section 1 hereof), or (iii) entered into any agreement or undertaking that is otherwise inconsistent with, or would restrict, limit or interfere with, or prohibit or prevent it from satisfying, its obligations pursuant to this Agreement (including Section 1 hereof).

(e) The execution and delivery of this Agreement by the Stockholder does not, and the performance by the Stockholder of his or her obligations hereunder will not, require any consent or approval that has not been given or other action that has not been taken by any Person (including under any Contract binding upon the Stockholder or the Owned Shares), in each case, to the extent such consent, approval or other action would prevent, enjoin or materially delay the performance by the Stockholder of his or her obligations under this Agreement.

(f) There are no Legal Proceedings pending against the Stockholder, or to the knowledge of the Stockholder threatened against the Stockholder, before (or, in the case of threatened Legal Proceedings, that would be before) any Governmental Authority, which in any manner challenges or seeks to prevent, enjoin or materially delay the performance by the Stockholder of his or her obligations under this Agreement.

(g) The Stockholder is a sophisticated holder with respect to the Owned Shares and has adequate information concerning the Transactions, including the transactions contemplated hereby, and concerning the business and financial condition of Advaxis and Biosight to make an informed decision regarding the matters referred to herein and has independently, without reliance upon Advaxis, Biosight, any of their Affiliates or any of the respective Representatives of the foregoing, and based on such information as the Stockholder has deemed appropriate, made the Stockholder's own analysis and decision to enter into this Agreement. The Stockholder has received and reviewed a copy of this Agreement and the Merger Agreement, has had an opportunity to obtain the advice of counsel prior to executing this Agreement and fully understands and accepts all of the provisions hereof and of the Merger Agreement, including that the consummation of the Merger is subject to the conditions set forth in the Merger Agreement, and as such there can be no assurance that the Merger will be consummated.

Except for the representations and warranties made by the Stockholder in this Section 6, neither the Stockholder nor any other Person makes any express or implied representation or warranty to Biosight in connection with this Agreement or the transactions contemplated by this Agreement, and the Stockholder expressly disclaims any such other representations or warranties.

7. No Challenges. From the date hereof until the Termination Date, the Stockholder agrees not to commence, join in, facilitate, assist or encourage, and agrees to take all actions within its power necessary to opt out of any class in any class action with respect to, any claim, derivative or otherwise, against Advaxis, Merger Sub, Biosight or any of their respective successors or directors (except in any case arising out of the fraud of such parties) (a) challenging the validity of, or seeking to enjoin the operation of, any provision of this Agreement or (b) alleging a breach of any fiduciary duty of any person in connection with the evaluation, negotiation or entry into the Merger Agreement. Notwithstanding the foregoing, nothing herein shall be deemed to prohibit the Stockholder from enforcing the Stockholder's rights under this Agreement and the other agreements entered into by the Stockholder in connection herewith, or otherwise in connection with the Merger Transaction or the other Transactions.

8. No Agreement as Director or Officer. Notwithstanding any provision of this Agreement to the contrary, the Stockholder is signing this Agreement solely in its capacity as a stockholder of Advaxis. The Stockholder makes no agreement or understanding in this Agreement in the Stockholder's capacity as a director, officer or employee of Advaxis (if the Stockholder holds such office or position) or in the Stockholder's capacity as a trustee or fiduciary of any employee benefit plan or trust. Nothing in this Agreement will be construed to prohibit, limit or restrict the Stockholder from exercising his or her fiduciary duties as an officer or director to Advaxis or its equityholders.

9. Amendment and Modification. This Agreement may not be amended, modified or supplemented in any manner, whether by course of conduct or otherwise, except by an instrument in writing signed by Biosight, Advaxis and the Stockholder.

10. Waiver. No failure or delay by any party hereto exercising any right, power or privilege hereunder shall operate as a waiver thereof nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege. The rights and remedies of the parties hereto hereunder are cumulative and are not exclusive of any rights or remedies which they would otherwise have hereunder. Any agreement on the part of a party hereto to any such waiver shall be valid only if set forth in a written instrument executed and delivered by such party.

11. Entire Agreement. This Agreement and the Merger Agreement constitute the entire agreement, and supersede all prior agreements and understandings, both written and oral, between the parties hereto with respect to the subject matter hereof and thereof.

12. Governing Law. This Agreement and any disputes relating hereto shall be governed by, and construed in accordance with, the laws of the State of Delaware (without giving effect to choice of law or conflict of law principles thereof or of any other jurisdiction that would cause the application of any laws of any jurisdiction other than the State of Delaware). Each of the parties hereto hereby irrevocably and unconditionally submits, for itself and its property, to the exclusive jurisdiction of the Court of Chancery of the State of Delaware or, to the extent such court does not have subject matter jurisdiction, the United States District Court for the District of Delaware, in any Legal Proceeding arising out of or relating to this Agreement or the agreements delivered in connection herewith or the transactions contemplated hereby or thereby or for recognition or enforcement of any judgment relating thereto, and each of the parties hereto hereby irrevocably and unconditionally (i) agrees not to commence any such Legal Proceeding except in the Court of Chancery of the State of Delaware or, to the extent such court does not have subject matter jurisdiction, the United States District Court for the District of Delaware, (ii) agrees that any claim in respect of any such Legal Proceeding may be heard and determined in the Court of Chancery of the State of Delaware or, to the extent such court does not have subject matter jurisdiction, the United States District Court for the District of Delaware, (iii) waives, to the fullest extent it may legally and effectively do so any objection that it may now or hereafter have to the laying of venue of any such Legal Proceeding in such courts and (iv) waives, to the fullest extent permitted by applicable Legal Requirements, the defense of an inconvenient forum to the maintenance of such Legal Proceeding in such courts. Each of the parties hereto (A) agrees that a final judgment in any such Legal Proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by applicable Legal Requirements and (B) waives any objection to the recognition and enforcement by a court in other jurisdictions of any such final judgment. EACH PARTY HERETO ACKNOWLEDGES AND AGREES THAT ANY CONTROVERSY THAT MAY ARISE PURSUANT TO THIS AGREEMENT IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES, AND THEREFORE EACH PARTY HERETO HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT THAT SUCH PARTY MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LEGAL PROCEEDING (WHETHER FOR BREACH OF CONTRACT, TORTIOUS CONDUCT OR OTHERWISE) DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE OTHER AGREEMENTS TO BE ENTERED INTO IN CONNECTION HEREWITH, AND THE TRANSACTIONS CONTEMPLATED HEREBYAND THEREBY. EACH PARTY HERETO ACKNOWLEDGES AND AGREES THAT (i) NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HERETO HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER; (ii) IT UNDERSTANDS AND HAS CONSIDERED THE IMPLICATIONS OF THISWAIVER; (iii) IT MAKES THIS WAIVER VOLUNTARILY; AND (iv) IT HAS BEENINDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 12.

13. Assignment; Successors. Neither this Agreement nor any of the rights, interests or obligations hereunder shall be assigned by any of the parties hereto in whole or in part (whether by operation of law or otherwise) without the prior written consent of the other parties, and any such assignment without such consent shall be null and void. This Agreement shall be binding upon, inure to the benefit of and be enforceable by the parties hereto and their respective successors and permitted assigns.

14. Further Assurances. The Stockholder shall execute and deliver, or cause to be executed and delivered, such additional documents, and will use commercially reasonable efforts to take, or cause to be taken, all such further actions and do, or cause to be done, all things reasonably necessary to consummate the transactions contemplated by this Agreement, on the terms and subject to the conditions set forth therein and herein, as applicable.

15. Specific Performance. The parties hereto agree that irreparable damage for which monetary damages, even if available, would not be an adequate remedy, would occur in the event that the parties hereto do not perform the provisions of this Agreement in accordance with its specified terms or otherwise breach or threaten to breach such provisions. The parties hereto acknowledge and agree that the parties hereto shall be entitled, in addition to any other remedy to which they are entitled at law or in equity, to an injunction, specific performance and other equitable relief to prevent breaches or threatened breaches of this Agreement and to enforce specifically the terms and provisions hereof. Without limiting the foregoing, each of the parties hereto agrees that it will not oppose the granting of an injunction, specific performance and other equitable relief on the basis that (a) there is adequate remedy at law or (b) an award of specific performance is not an appropriate remedy for any reason at law or in equity. Any party hereto seeking an order or injunction to prevent breaches or threatened breaches and to enforce specifically the terms and provisions of this Agreement shall not be required to provide any bond or other security in connection with any such order or injunction.

16. Severability. If any provision of this Agreement is held invalid or unenforceable by any court of competent jurisdiction, the other provisions of this Agreement will remain in full force and effect. Any provision of this Agreement held invalid or unenforceable only in part or degree will remain in full force and effect to the extent not held invalid or unenforceable.

17. Disclosure. Advaxis and Biosight shall be permitted to publish and disclose in all documents and schedules filed with the SEC, and any press release or other disclosure document that Biosight determines to be necessary or desirable in connection with the Merger Transaction and the other Transactions, the Stockholder’s identity and ownership of Owned Shares and the nature of the Stockholder’s commitments, arrangements and understandings under this Agreement and, if deemed reasonably appropriate by Advaxis or Biosight, a copy of this Agreement.

18. Construction. Section 10.11 (*Construction*) of the Merger Agreement is incorporated herein by reference and shall apply to this Agreement *mutatis mutandis*.

19. Notices. All notices and other communications hereunder shall be in writing and shall be deemed duly given on the date of delivery if delivered personally, by email (which is confirmed), or sent by a nationally recognized overnight courier service (providing proof of delivery). All notices hereunder shall be delivered as set forth below or pursuant to such other instructions as may be designated in writing by the party to receive such notice:

if to Advaxis:

Advaxis, Inc.
9 Deer Park Drive, Suite K-1
Monmouth Junction, NJ 08852
E-Mail: berlin@advaxis.com
Attention: Ken Berlin

with a copy (which shall not constitute notice) to:

Morgan Lewis & Bockius LLP
502 Carnegie Center
Princeton, NJ 08540
E-Mail: david.schwartz@morganlewis.com
Attention: David C. Schwartz

with a copy (which shall not constitute notice) to:

Herzog Fox & Neeman
Asia House, 4 Weizmann St.
Tel Aviv 6423904, Israel
E-Mail: HerbstR@herzoglaw.co.il
Attention: Rafael Herbst

if to Biosight:

Biosight LTD.
3 Hayarden St., Airport City
P.O.B 1083
Lod 7019802
Israel
E-Mail: ruth@biosight-pharma.com
Attention: Ruth Ben Yakar

with a copy (which shall not constitute notice) to:

White & Case LLP
3000 El Camino Real, 2 Palo Alto Square, Suite 900
Palo Alto, CA 94306-2109
Telephone No.: +1 650 213 0315
E-Mail: tsealman@whitecase.com
Attention: Tali Sealman

with a copy (which shall not constitute notice) to:

White & Case LLP
1221 Avenue of the Americas
New York, NY 10020-1095
Telephone No.: +1 212 819 8754
E-Mail: cdiamond@whitecase.com
Attention: Colin Diamond

with a copy (which shall not constitute notice) to:

Horn & Co. Law Offices
Amot Investments Tower, 24th Floor
2 Weizmann St., Tel-Aviv, 6423902, Israel
Telephone No.: +972-3-637 8200
E-Mail: yhorn@hornlaw.co.il
Attention: Adv. Yuval Horn

if to the Stockholder: to the Stockholder's address set forth below the Stockholder's signature block.

20. Counterparts. This Agreement may be executed and delivered (including by email transmission, ".pdf," or other electronic transmission) in one or more counterparts, and by the different parties in separate counterparts, each of which when executed shall be deemed to be an original but all of which taken together shall constitute one and the same agreement.

***[Signature Page Follows]***

IN WITNESS WHEREOF, each of the parties hereto have caused this Agreement to be executed (where applicable, by their respective officers or other authorized persons thereunto duly authorized) as of the date first written above.

**Stockholder**

By: _____

Name:

Address for Notices:

[*Signature Page to Support Agreement*]

IN WITNESS WHEREOF, each of the parties hereto have caused this Agreement to be executed (where applicable, by their respective officers or other authorized persons thereunto duly authorized) as of the date first written above.

**Advaxis, Inc.**

By: _____
Name: Kenneth A. Berlin
Title: President, Chief Executive Officer and
Interim Chief Financial Officer

[*Signature Page to Support Agreement*]

IN WITNESS WHEREOF, each of the parties hereto have caused this Agreement to be executed (where applicable, by their respective officers or other authorized persons thereunto duly authorized) as of the date first written above.

**Biosight Ltd.**

By: _____
Name: Ruth Ben Yakar
Title: Chief Executive Officer

[*Signature Page to Support Agreement*]

**Annex D**

## SUPPORT AGREEMENT

This Support Agreement (this "Agreement"), dated as of July 4, 2021, is entered into by and among Advaxis, Inc., a Delaware corporation ("Advaxis"), Biosight Ltd., a company organized under the laws of the State of Israel ("Biosight") and the director or executive officer of Biosight included on the signature page hereto ("Securityholder"). Defined terms used but not defined herein shall have the meaning ascribed to such terms in the Merger Agreement (as defined below).

## RECITALS

WHEREAS, concurrently herewith, Advaxis, Advaxis Ltd., a company organized under the laws of the State of Israel and a wholly owned Subsidiary of Advaxis ("Merger Sub"), and Biosight are entering into that certain Agreement and Plan of Merger and Reorganization, dated as of the date hereof (as amended, supplemented, restated or otherwise modified from time to time, the "Merger Agreement"), pursuant to which (and subject to the terms and conditions set forth therein) Merger Sub will merge with and into Biosight, with Biosight being the surviving entity (the "Merger Transaction");

WHEREAS, in connection with the Merger Transaction and pursuant to the terms of the Merger Agreement, Biosight will duly convene and hold a meeting of its shareholders (the "Biosight Shareholders' Meeting") for the purposes of obtaining approval of the Merger Transaction (among other things) by the shareholders of Biosight;

WHEREAS, as of the date hereof, the Securityholder is the direct or indirect (through its controlled Affiliates) record and "beneficial owner" (within the meaning of Rule 13d-3 under the Securities Exchange Act of 1934, as amended (together with the rules and regulations promulgated thereunder, the "Exchange Act")) of [_____] issued and outstanding Biosight Shares (the "Current Shares" and together with any Biosight Shares or any other equity securities of Biosight acquired (including the acquisition of the right to vote or beneficial ownership) or purchased by, or issued (including as a result of a share split, share dividend, merger, reorganization, recapitalization, reclassification, combination, exchange of shares or other similar event) to, the Securityholder directly or indirectly (through its controlled Affiliates) after the date hereof, the "Owned Shares"); and

WHEREAS, as a condition and inducement to the willingness of Advaxis to enter into the Merger Agreement and commence the Transactions, Biosight, Advaxis and the Securityholder are entering into this Agreement for the Securityholder to take certain actions as described herein.

**AGREEMENT**

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants and agreements herein contained, and intending to be legally bound hereby, Biosight, Advaxis and the Securityholder hereby agree as follows:

1. Agreement to Vote Common Stock in Support of the Merger Transaction. From the date hereof until the Termination Date (as defined below), the Securityholder, in his or her capacity as a direct or indirect (through its controlled Affiliates) equityholder of Biosight, hereby irrevocably and unconditionally agrees that at any meeting of the shareholders of Biosight, however called (including, for the avoidance of doubt, the Biosight Shareholders' Meeting), or at any adjournment or postponement thereof, and in any action by written consent of the shareholders of Biosight distributed by the Board of Directors of Biosight, or otherwise undertaken as contemplated by the Merger Agreement or the Transactions, or in any other circumstance in which the vote, consent or other approval of the shareholders of Biosight is sought, the Securityholder shall and/or, as applicable, shall cause any other holder of record of any of the Owned Shares to:

(i) when such meeting is held, appear at such meeting or otherwise cause the Owned Shares to be counted as present thereat for the purpose of establishing a quorum;

(ii) vote (or execute and return an action by written consent), or cause to be voted at such meeting (or validly execute and return and cause such consent to be granted with respect to), all of the Owned Shares in favor of, and to adopt and approve, the Merger Agreement and the consummation of the Merger Transaction and the other Transactions;

(iii) vote (or execute and return an action by written consent), or cause to be voted at such meeting, or validly execute and return and cause such consent to be granted with respect to, all of the Owned Shares against any action that would reasonably be expected to (a) impede, frustrate, interfere with, delay, postpone, prevent, nullify or adversely affect the Transactions, including the Merger Transaction, (b) result in a breach of any covenant, representation or warranty or other obligation or agreement of the Securityholder contained in this Agreement or (c) to the Securityholder's knowledge, result in a breach of any covenant, representation or warranty or other obligation or agreement of Biosight contained in the Merger Agreement; and

(iv) vote (or execute and return an action by written consent), or cause to be voted at such meeting (or validly execute and return and cause such consent to be granted with respect to), all of the Owned Shares against (a) any Acquisition Proposal or any proposal relating to an Acquisition Proposal (for the avoidance of doubt, in each case, other than with respect to the Transactions) or any proposal made in opposition to, in competition with, or inconsistent with, the Merger Agreement or the Merger or any other Transactions, or (b) any merger agreement, merger, consolidation, combination, sale of substantial assets, reorganization, recapitalization, dissolution, liquidation or winding up of or by Biosight (other than the Merger Agreement or the Transactions).

During the period commencing on the date hereof and ending on the Termination Date, the Securityholder hereby agrees that it shall not commit, agree, or publicly propose any intention to take any action inconsistent with the foregoing.

2. No Transfer. From the date hereof until the Termination Date, the Securityholder shall not Transfer (as defined below) any Owned Shares, in each case except pursuant to a Permitted Transfer (as defined below). For purposes of this Section 2, the following terms shall have the meanings as defined below:

(i) "Permitted Transfer" means any Transfer of shares of Advaxis Common Stock or Biosight Shares, as applicable, (A) to (x) any officer or director of Advaxis or Biosight, or (y) any Affiliates or family members of the officers or directors of Advaxis or Biosight; (B) by gift to a member of the individual's immediate family or to a trust, the beneficiary of which is a member of the individual's immediate family or an Affiliate of such Person, or to a charitable organization; (C) by virtue of laws of descent and distribution upon death of the individual; (D) pursuant to a qualified domestic relations order, divorce settlement, divorce decree or separation agreement; (E) to a nominee or custodian of a Person to whom a Transfer would be permitted under clauses (A) through (D) above; (F) in connection with any bona fide mortgage, encumbrance or pledge to a financial institution in connection with any bona fide loan or debt transaction or enforcement thereunder, including foreclosure thereof; (G) in connection with any legal, regulatory or other order; (H) to Advaxis or Biosight; or (I) in connection with the exercise of stock options, including through a "net" or "cashless" exercise; provided, however, that in the case of clauses (A) through (F) such transferees must enter into a written agreement with Advaxis agreeing to be bound by the transfer restrictions set forth in this Agreement; provided, further, that in the case of clause (I), the remaining shares issued upon the exercise of stock options shall be subject to the transfer restrictions set forth in this Agreement.

(ii) "Transfer" shall mean, with respect to any Person, (A) the sale or assignment of, offer to sell, contract or agreement to sell, hypothecate, pledge, grant of any option to purchase or otherwise dispose of or agreement to dispose of, directly or indirectly, or establishment or increase of a put equivalent position or liquidation with respect to or decrease of a call equivalent position within the meaning of Section 16 of the Exchange Act, in each case with respect to any security owned, including ownership of record or the power to vote (including, without limitation, by proxy or power of attorney), by such Person; (B) the entry into any swap or other arrangement that transfers to another Person, in whole or in part, any of the economic consequences of ownership of any security owned by such Person, whether any such transaction is to be settled by delivery of such securities, in cash or otherwise; or (C) the public announcement of any intention to effect any transaction specified in clause (A) or (B).

3. No Inconsistent Agreements. Except pursuant to or under the terms and conditions of the Biosight Employee Plan, from the date hereof until the Termination Date, the Securityholder hereby covenants and agrees that the Securityholder shall not (i) enter into any voting agreement or voting trust with respect to any of the Owned Shares that is inconsistent with the Securityholder's obligations pursuant to this Agreement, (ii) grant a proxy or power of attorney with respect to any of the Owned Shares that is inconsistent with the Securityholder's obligations pursuant to this Agreement, or (iii) enter into any agreement or undertaking that is otherwise inconsistent with, or would restrict, limit or interfere with, or prohibit or prevent it from satisfying, its obligations pursuant to this Agreement.

4. Binding Effect of Merger Agreement. The Securityholder hereby acknowledges that it has read the Merger Agreement and this Agreement and has had the opportunity to consult with its tax and legal advisors. The Securityholder shall be bound by and comply with Sections 4.5 (*Biosight No Solicitation*) (other than Section 4.5(a)(vi), Section 4.5(b) and Section 4.5(d) thereof) and 5.9 (*Publicity*) of the Merger Agreement (and any relevant definitions contained in any such Sections) as if (i) the Securityholder was an original signatory to the Merger Agreement with respect to such provisions and (ii) each reference to "Biosight" contained in Section 4.5 of the Merger Agreement (other than Section 4.5(a)(iv) thereof or for purposes of the definition of Acquisition Proposal) also referred to the Securityholder.

5. Termination. This Agreement shall terminate upon the earliest of (i) the Effective Time, (ii) the valid termination of the Merger Agreement in accordance with Section 9 thereof, and (iii) the time this Agreement is terminated upon the mutual written agreement of Advaxis and the Securityholder (the earliest of such applicable date, the "Termination Date"). Upon such termination of this Agreement, all obligations of the parties under this Agreement will terminate, without any liability or other obligation on the part of any party hereto to any Person in respect hereof or the transactions contemplated hereby, and no party hereto shall have any claim against another (and no Person shall have any rights against such party), whether under contract, tort or otherwise, pursuant to this Agreement; provided, however, that the termination of this Agreement shall not relieve any party hereto from liability arising in respect of material willful or intentional breach of, or fraud in connection with, this Agreement. This Section 5 shall survive the termination of this Agreement.

6. Representations and Warranties of the Securityholder. The Securityholder hereby represents and warrants to Advaxis as follows, in each case, subject to the terms and conditions of the Biosight Employee Plan, including, without limitation, all terms and conditions relating to the voting of any Biosight Shares acquired by any Person pursuant to the exercise of options granted under the Biosight Employee Plan:

(a) The Securityholder is the direct or indirect (through its controlled Affiliates) record and a beneficial (within the meaning of Rule 13d-3 under the Exchange Act) owner of, and directly or indirectly (through its controlled Affiliates) has good and valid title to, the Owned Shares, free and clear of any Encumbrances, other than any applicable restrictions on transfer under applicable securities laws. As of the date of this Agreement, and except for any Biosight Options and/or any Biosight warrants, the only equity securities in Biosight owned, directly or indirectly (through its controlled Affiliates), of record or beneficially by the Securityholder are the Current Shares. The Securityholder does not hold or own any rights to acquire (directly or indirectly) any equity securities of Biosight or any securities convertible into, or which can be exchanged for, equity securities of Biosight, except, in each case, for any Biosight Options and/or any Biosight warrants.

(b) The Securityholder, except as provided in this Agreement, has, either directly or indirectly (through its controlled Affiliates) full voting power, full power of disposition and full power to issue instructions with respect to, and agree to all, the matters set forth herein, in each case, with respect to the Owned Shares, and has not entered into any agreement or undertaking that is otherwise inconsistent with, or would interfere with, or prohibit or prevent it from satisfying, its obligations pursuant to this Agreement.

(c) The Securityholder has full legal capacity and all requisite power and authority to, and has taken all action necessary in order to, execute, deliver and perform its obligations under this Agreement and to consummate the transactions to be performed by it hereunder. This Agreement has been duly executed and delivered by the Securityholder, and, assuming due authorization, execution and delivery by the other parties to this Agreement, constitutes a valid and binding agreement of the Securityholder enforceable against the Securityholder in accordance with its terms, subject to applicable bankruptcy, insolvency, fraudulent conveyance, reorganization, moratorium and similar laws affecting creditors' rights generally and subject, as to enforceability, to general principles of equity.

(d) The Securityholder has not (i) entered into any voting agreement or voting trust with respect to any of the Owned Shares that is still in effect and that is inconsistent with the Securityholder's obligations pursuant to this Agreement (including Section 1 hereof), (ii) granted a proxy or power of attorney with respect to any of the Owned Shares that is still in effect and that is inconsistent with the Securityholder's obligations pursuant to this Agreement (including Section 1 hereof), or (iii) entered into any agreement or undertaking that is otherwise inconsistent with, or would restrict, limit or interfere with, or prohibit or prevent it from satisfying, its obligations pursuant to this Agreement (including Section 1 hereof).

(e) The execution and delivery of this Agreement by the Securityholder does not, and the performance by the Securityholder of his or her obligations hereunder will not, require any consent or approval that has not been given or other action that has not been taken by any Person (including under any Contract binding upon the Securityholder or the Owned Shares), in each case, to the extent such consent, approval or other action would prevent, enjoin or materially delay the performance by the Securityholder of his or her obligations under this Agreement.

(f) There are no Legal Proceedings pending against the Securityholder, or to the knowledge of the Securityholder threatened against the Securityholder, before (or, in the case of threatened Legal Proceedings, that would be before) any Governmental Authority, which in any manner challenges or seeks to prevent, enjoin or materially delay the performance by the Securityholder of his or her obligations under this Agreement.

(g) The Securityholder is a sophisticated holder (directly or indirectly (through its controlled Affiliates)) with respect to the Owned Shares and has adequate information concerning the Transactions, including the transactions contemplated hereby, and concerning the business and financial condition of Advaxis and Biosight to make an informed decision regarding the matters referred to herein and has independently, without reliance upon Advaxis, Biosight, any of their Affiliates or any of the respective Representatives of the foregoing, and based on such information as the Securityholder has deemed appropriate, made the Securityholder's own analysis and decision to enter into this Agreement. The Securityholder has received and reviewed a copy of this Agreement and the Merger Agreement, has had an opportunity to obtain the advice of counsel prior to executing this Agreement and fully understands and accepts all of the provisions hereof and of the Merger Agreement, including that the consummation of the Merger is subject to the conditions set forth in the Merger Agreement, and as such there can be no assurance that the Merger will be consummated.

Except for the representations and warranties made by the Securityholder in this Section 6, neither the Securityholder nor any other Person makes any express or implied representation or warranty to Advaxis in connection with this Agreement or the transactions contemplated by this Agreement, and the Securityholder expressly disclaims any such other representations or warranties.

7. No Challenges. From the date hereof until the Termination Date, the Securityholder agrees not to commence, join in, facilitate, assist or encourage, and agrees to take all actions within its power necessary to opt out of any class in any class action with respect to, any claim, derivative or otherwise, against Advaxis, Merger Sub, Biosight or any of their respective successors or directors (except in any case arising out of the fraud of such parties) (a) challenging the validity of, or seeking to enjoin the operation of, any provision of this Agreement or (b) alleging a breach of any fiduciary duty of any person in connection with the evaluation, negotiation or entry into the Merger Agreement. Notwithstanding the foregoing, nothing herein shall be deemed to prohibit the Securityholder from enforcing the Securityholder's rights under this Agreement and the other agreements entered into by the Securityholder in connection herewith, or otherwise in connection with the Merger Transaction or the other Transactions.

8. No Agreement as Director or Officer. Notwithstanding any provision of this Agreement to the contrary, the Securityholder is signing this Agreement solely in his or her capacity as a direct or indirect (through its controlled Affiliates) equityholder of Biosight. The Securityholder makes no agreement or understanding in this Agreement in the Securityholder's capacity as a director, officer or employee of Biosight (if the Securityholder holds such office or position) or in the Securityholder's capacity as a trustee or fiduciary of any employee benefit plan or trust. Nothing in this Agreement will be construed to prohibit, limit or restrict the Securityholder from exercising his or her fiduciary duties as an officer or director to Biosight or its equityholders.

9. Amendment and Modification. This Agreement may not be amended, modified or supplemented in any manner, whether by course of conduct or otherwise, except by an instrument in writing signed by Biosight, Advaxis and the Securityholder.

10. Waiver. No failure or delay by any party hereto exercising any right, power or privilege hereunder shall operate as a waiver thereof nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege. The rights and remedies of the parties hereto hereunder are cumulative and are not exclusive of any rights or remedies which they would otherwise have hereunder. Any agreement on the part of a party hereto to any such waiver shall be valid only if set forth in a written instrument executed and delivered by such party.

11. Entire Agreement. This Agreement and the Merger Agreement constitute the entire agreement, and supersede all prior agreements and understandings, both written and oral, between the parties hereto with respect to the subject matter hereof and thereof.

12. Governing Law. This Agreement and any disputes relating hereto shall be governed by, and construed in accordance with, the laws of the State of Delaware (without giving effect to choice of law or conflict of law principles thereof or of any other jurisdiction that would cause the application of any laws of any jurisdiction other than the State of Delaware). Each of the parties hereto hereby irrevocably and unconditionally submits, for itself and its property, to the exclusive jurisdiction of the Court of Chancery of the State of Delaware or, to the extent such court does not have subject matter jurisdiction, the United States District Court for the District of Delaware, in any Legal Proceeding arising out of or relating to this Agreement or the agreements delivered in connection herewith or the transactions contemplated hereby or thereby or for recognition or enforcement of any judgment relating thereto, and each of the parties hereto hereby irrevocably and unconditionally (i) agrees not to commence any such Legal Proceeding except in the Court of Chancery of the State of Delaware or, to the extent such court does not have subject matter jurisdiction, the United States District Court for the District of Delaware, (ii) agrees that any claim in respect of any such Legal Proceeding may be heard and determined in the Court of Chancery of the State of Delaware or, to the extent such court does not have subject matter jurisdiction, the United States District Court for the District of Delaware, (iii) waives, to the fullest extent it may legally and effectively do so any objection that it may now or hereafter have to the laying of venue of any such Legal Proceeding in such courts and (iv) waives, to the fullest extent permitted by applicable Legal Requirements, the defense of an inconvenient forum to the maintenance of such Legal Proceeding in such courts. Each of the parties hereto (A) agrees that a final judgment in any such Legal Proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by applicable Legal Requirements and (B) waives any objection to the recognition and enforcement by a court in other jurisdictions of any such final judgment. EACH PARTY HERETO ACKNOWLEDGES AND AGREES THAT ANY CONTROVERSY THAT MAY ARISE PURSUANT TO THIS AGREEMENT IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES, AND THEREFORE EACH PARTY HERETO HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT THAT SUCH PARTY MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LEGAL PROCEEDING (WHETHER FOR BREACH OF CONTRACT, TORTIOUS CONDUCT OR OTHERWISE) DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE OTHER AGREEMENTS TO BE ENTERED INTO IN CONNECTION HEREWITH, AND THE TRANSACTIONS CONTEMPLATED HEREBYAND THEREBY. EACH PARTY HERETO ACKNOWLEDGES AND AGREES THAT (i) NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HERETO HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER; (ii) IT UNDERSTANDS AND HAS CONSIDERED THE IMPLICATIONS OF THISWAIVER; (iii) IT MAKES THIS WAIVER VOLUNTARILY; AND (iv) IT HAS BEENINDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 12.

13. Assignment; Successors. Neither this Agreement nor any of the rights, interests or obligations hereunder shall be assigned by any of the parties hereto in whole or in part (whether by operation of law or otherwise) without the prior written consent of the other parties, and any such assignment without such consent shall be null and void. This Agreement shall be binding upon, inure to the benefit of and be enforceable by the parties hereto and their respective successors and permitted assigns.

14. Further Assurances. The Securityholder shall execute and deliver, or cause to be executed and delivered, such additional documents, and will use commercially reasonable efforts to take, or cause to be taken, all such further actions and do, or cause to be done, all things reasonably necessary to consummate the transactions contemplated by this Agreement, on the terms and subject to the conditions set forth therein and herein, as applicable.

15. Specific Performance. The parties hereto agree that irreparable damage for which monetary damages, even if available, would not be an adequate remedy, would occur in the event that the parties hereto do not perform the provisions of this Agreement in accordance with its specified terms or otherwise breach or threaten to breach such provisions. The parties hereto acknowledge and agree that the parties hereto shall be entitled, in addition to any other remedy to which they are entitled at law or in equity, to an injunction, specific performance and other equitable relief to prevent breaches or threatened breaches of this Agreement and to enforce specifically the terms and provisions hereof. Without limiting the foregoing, each of the parties hereto agrees that it will not oppose the granting of an injunction, specific performance and other equitable relief on the basis that (a) there is adequate remedy at law or (b) an award of specific performance is not an appropriate remedy for any reason at law or in equity. Any party hereto seeking an order or injunction to prevent breaches or threatened breaches and to enforce specifically the terms and provisions of this Agreement shall not be required to provide any bond or other security in connection with any such order or injunction.

16. Severability. If any provision of this Agreement is held invalid or unenforceable by any court of competent jurisdiction, the other provisions of this Agreement will remain in full force and effect. Any provision of this Agreement held invalid or unenforceable only in part or degree will remain in full force and effect to the extent not held invalid or unenforceable.

17. Disclosure. Advaxis and Biosight shall be permitted to publish and disclose in all documents and schedules filed with the SEC, and any press release or other disclosure document that Advaxis determines to be necessary or desirable in connection with the Merger Transaction and the other Transactions, the Securityholder's identity and ownership of Owned Shares and the nature of the Securityholder's commitments, arrangements and understandings under this Agreement and, if deemed reasonably appropriate by Advaxis or Biosight, a copy of this Agreement.

18. Construction. Section 10.11 (*Construction*) of the Merger Agreement is incorporated herein by reference and shall apply to this Agreement *mutatis mutandis*.

19. Notices. All notices and other communications hereunder shall be in writing and shall be deemed duly given on the date of delivery if delivered personally, by email (which is confirmed), or sent by a nationally recognized overnight courier service (providing proof of delivery). All notices hereunder shall be delivered as set forth below or pursuant to such other instructions as may be designated in writing by the party to receive such notice:

if to Advaxis:

Advaxis, Inc.
9 Deer Park Drive, Suite K-1
Monmouth Junction, NJ 08852
E-Mail: berlin@advaxis.com
Attention: Ken Berlin

with a copy (which shall not constitute notice) to:

Morgan Lewis & Bockius LLP
502 Carnegie Center
Princeton, NJ 08540
E-Mail: david.schwartz@morganlewis.com
Attention: David C. Schwartz

with a copy (which shall not constitute notice) to:

Herzog Fox & Neeman
Asia House, 4 Weizmann St.
Tel Aviv 6423904, Israel
E-Mail: HerbstR@herzoglaw.co.il
Attention: Rafael Herbst

if to Biosight:

Biosight LTD.
3 Hayarden St., Airport City
P.O.B 1083
Lod 7019802
Israel
E-Mail: ruth@biosight-pharma.com
Attention: Ruth Ben Yakar

with a copy (which shall not constitute notice) to:

White & Case LLP
3000 El Camino Real, 2 Palo Alto Square, Suite 900
Palo Alto, CA 94306-2109
Telephone No.: +1 650 213 0315
E-Mail: tsealman@whitecase.com
Attention: Tali Sealman

with a copy (which shall not constitute notice) to:

White & Case LLP
1221 Avenue of the Americas
New York, NY 10020-1095
Telephone No.: +1 212 819 8754
E-Mail: cdiamond@whitecase.com
Attention: Colin Diamond

with a copy (which shall not constitute notice) to:

Horn & Co. Law Offices
Amot Investments Tower, 24th Floor
2 Weizmann St., Tel-Aviv, 6423902, Israel
Telephone No.: +972-3-637 8200
E-Mail: yhorn@hornlaw.co.il
Attention: Adv. Yuval Horn

if to the Securityholder: to the Securityholder's address set forth below the Securityholder's signature block.

20. Counterparts. This Agreement may be executed and delivered (including by email transmission, ".pdf," or other electronic transmission) in one or more counterparts, and by the different parties in separate counterparts, each of which when executed shall be deemed to be an original but all of which taken together shall constitute one and the same agreement.

***[Signature Page Follows]***

IN WITNESS WHEREOF, each of the parties hereto have caused this Agreement to be executed (where applicable, by their respective officers or other authorized persons thereunto duly authorized) as of the date first written above.

**Securityholder**

By: _____

Name:

Address for Notices:

[*Signature Page to Support Agreement*]

IN WITNESS WHEREOF, each of the parties hereto have caused this Agreement to be executed (where applicable, by their respective officers or other authorized persons thereunto duly authorized) as of the date first written above.

**Advaxis, Inc.**

By: _____
Name: Kenneth A. Berlin
Title: President, Chief Executive Officer and
Interim Chief Financial Officer

[*Signature Page to Support Agreement*]

IN WITNESS WHEREOF, each of the parties hereto have caused this Agreement to be executed (where applicable, by their respective officers or other authorized persons thereunto duly authorized) as of the date first written above.

**Biosight Ltd.**

By: _____
Name: Dr. Ruth Ben Yakar
Title: Chief Executive Officer

[*Signature Page to Support Agreement*]

**Annex E**

**SECOND AMENDED AND RESTATED**
**CERTIFICATE OF INCORPORATION**
**OF**
**ADVAXIS, INC.**

**FIRST:** The name of this corporation is Biosight Therapeutics, Inc. (the "**Corporation**").

**SECOND:** The address of the registered office of the Corporation in the State of Delaware is 1209 Orange Street, in the City of Wilmington, County of New Castle 19801. The name of its registered agent at such address is National Registered Agents, Inc.

**THIRD:** The nature of the business or purposes to be conducted or promoted is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware (the "**General Corporation Law**").

**FOURTH:** Effective immediately upon the filing of this Second Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware (such time, the "**Effective Time**"), every [___] ([___]) shares of common stock, par value $0.001 per share ("**Common Stock**"), then issued and outstanding or held by the Corporation in treasury stock immediately prior to the Effective Time shall, automatically and without any action on the part of the respective holders thereof, be combined and converted into one (1) share of Common Stock (the "**Reverse Stock Split**"), subject to the treatment of fractional interests as described below. Notwithstanding the immediately preceding sentence, no fractional shares will be issued in connection with the combination effected by the preceding sentence. Stockholders of record who would otherwise be entitled to receive fractional shares in connection with such combination will instead be entitled to receive, in lieu of such fractional shares, an amount in cash equal to the product of (i) the closing sales price of the Common Stock as reported on The Nasdaq Global Select Market as of the Effective Time, multiplied by (ii) the number of shares of Common Stock held by the stockholder immediately prior to the Effective Time that would otherwise have been exchanged for such fractional shares. The Reverse Stock Split shall occur whether or not the certificates representing such shares of Common Stock are surrendered to the Company or its transfer agent. The Reverse Stock Split shall be effected on a record holder-by-record holder basis, such that any fractional shares of Common Stock resulting from the Reverse Stock Split and held by a single record holder shall be aggregated.

Following the Reverse Stock Split, the total number of shares of all classes of stock which the Corporation shall have authority to issue is One Hundred and Seventy Five Million (175,000,000) shares of which (i) One Hundred and Seventy Million (170,000,000) shares shall be designated as Common Stock, and (ii) 5,000,000 shares shall be "blank check" preferred stock and have a par value of $0.001 per share.

**FIFTH:** Subject to any additional vote required by this Second Amended and Restated Certificate of Incorporation or the Bylaws, in furtherance and not in limitation of the powers conferred by statute, the Board of Directors is expressly authorized to make, repeal, alter, amend and rescind any or all of the Bylaws.

**SIXTH:** Subject to any additional vote required by this Second Amended and Restated Certificate of Incorporation, the number of directors of the Corporation shall be determined in the manner set forth in the Bylaws.

**SEVENTH:** Elections of directors need not be by written ballot unless the Bylaws shall so provide.

**EIGHTH:** Meetings of shareholders may be held within or without the State of Delaware, as the Bylaws may provide. The books of the Corporation may be kept outside the State of Delaware at such place or places as may be designated from time to time by the Board of Directors or in the Bylaws.

**NINTH:** To the fullest extent permitted by law, a director of the Corporation shall not be personally liable to the Corporation or its shareholders for monetary damages for breach of fiduciary duty as a director. If the General Corporation Law or any other law of the State of Delaware is amended after approval by the shareholders of this Article Ninth to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law as so amended.

Any repeal or modification of the foregoing provisions of this Article Ninth by the shareholders of the Corporation shall not adversely affect any right or protection of a director of the Corporation existing at the time of, or increase the liability of any director of the Corporation with respect to any acts or omissions of such director occurring prior to, such repeal or modification.

**TENTH:** To the fullest extent permitted by applicable law, the Corporation is authorized to provide indemnification of (and advancement of expenses to) directors, officers and agents of the Corporation (and any other persons to which General Corporation Law permits the Corporation to provide indemnification) through Bylaw provisions, agreements with such agents or other persons, vote of shareholders or disinterested directors or otherwise, in excess of the indemnification and advancement otherwise permitted by Section 145 of the General Corporation Law.

Any amendment, repeal or modification of the foregoing provisions of this Article Tenth shall not (a) adversely affect any right or protection of any director, officer or other agent of the Corporation existing at the time of such amendment, repeal or modification or (b) increase the liability of any director of the Corporation with respect to any acts or omissions of such director, officer or agent occurring prior to, such amendment, repeal or modification.

**Annex F**

**SECOND AMENDED AND RESTATED**
**CERTIFICATE OF INCORPORATION**
**OF**
**ADVAXIS, INC.**

**FIRST:** The name of this corporation is Biosight Therapeutics, Inc. (the "**Corporation**").

**SECOND:** The address of the registered office of the Corporation in the State of Delaware is 1209 Orange Street, in the City of Wilmington, County of New Castle 19801. The name of its registered agent at such address is National Registered Agents, Inc.

**THIRD:** The nature of the business or purposes to be conducted or promoted is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware (the "**General Corporation Law**").

**FOURTH:** Effective immediately upon the filing of this Second Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware (such time, the "**Effective Time**"), every [___] ([___]) shares of common stock, par value $0.001 per share ("**Common Stock**"), then issued and outstanding or held by the Corporation in treasury stock immediately prior to the Effective Time shall, automatically and without any action on the part of the respective holders thereof, be combined and converted into one (1) share of Common Stock (the "**Reverse Stock Split**"), subject to the treatment of fractional interests as described below. Notwithstanding the immediately preceding sentence, no fractional shares will be issued in connection with the combination effected by the preceding sentence. Stockholders of record who would otherwise be entitled to receive fractional shares in connection with such combination will instead be entitled to receive, in lieu of such fractional shares, an amount in cash equal to the product of (i) the closing sales price of the Common Stock as reported on The Nasdaq Global Select Market as of the Effective Time, multiplied by (ii) the number of shares of Common Stock held by the stockholder immediately prior to the Effective Time that would otherwise have been exchanged for such fractional shares. The Reverse Stock Split shall occur whether or not the certificates representing such shares of Common Stock are surrendered to the Company or its transfer agent. The Reverse Stock Split shall be effected on a record holder-by-record holder basis, such that any fractional shares of Common Stock resulting from the Reverse Stock Split and held by a single record holder shall be aggregated.

Following the Reverse Stock Split, the total number of shares of all classes of stock which the Corporation shall have authority to issue is One Hundred and Seventy Five Million (175,000,000) shares of which (i) One Hundred and Seventy Million (170,000,000) shares shall be designated as Common Stock, and (ii) 5,000,000 shares shall be "blank check" preferred stock and have a par value of $0.001 per share.

**FIFTH:** Subject to any additional vote required by this Second Amended and Restated Certificate of Incorporation or the Bylaws, in furtherance and not in limitation of the powers conferred by statute, the Board of Directors is expressly authorized to make, repeal, alter, amend and rescind any or all of the Bylaws.

**SIXTH:** Subject to any additional vote required by this Second Amended and Restated Certificate of Incorporation, the number of directors of the Corporation shall be determined in the manner set forth in the Bylaws.

**SEVENTH:** Elections of directors need not be by written ballot unless the Bylaws shall so provide.

**EIGHTH:** Meetings of shareholders may be held within or without the State of Delaware, as the Bylaws may provide. The books of the Corporation may be kept outside the State of Delaware at such place or places as may be designated from time to time by the Board of Directors or in the Bylaws.

**NINTH:** To the fullest extent permitted by law, a director of the Corporation shall not be personally liable to the Corporation or its shareholders for monetary damages for breach of fiduciary duty as a director. If the General Corporation Law or any other law of the State of Delaware is amended after approval by the shareholders of this Article Ninth to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law as so amended.

Any repeal or modification of the foregoing provisions of this Article Ninth by the shareholders of the Corporation shall not adversely affect any right or protection of a director of the Corporation existing at the time of, or increase the liability of any director of the Corporation with respect to any acts or omissions of such director occurring prior to, such repeal or modification.

**TENTH:** To the fullest extent permitted by applicable law, the Corporation is authorized to provide indemnification of (and advancement of expenses to) directors, officers and agents of the Corporation (and any other persons to which General Corporation Law permits the Corporation to provide indemnification) through Bylaw provisions, agreements with such agents or other persons, vote of shareholders or disinterested directors or otherwise, in excess of the indemnification and advancement otherwise permitted by Section 145 of the General Corporation Law.

Any amendment, repeal or modification of the foregoing provisions of this Article Tenth shall not (a) adversely affect any right or protection of any director, officer or other agent of the Corporation existing at the time of such amendment, repeal or modification or (b) increase the liability of any director of the Corporation with respect to any acts or omissions of such director, officer or agent occurring prior to, such amendment, repeal or modification.

**PART II**
**INFORMATION NOT REQUIRED IN PROXY STATEMENT/PROSPECTUS**

**Item 20.** ***Indemnification of Directors and Officers***

Subsection (a) of Section 145 of the Delaware General Corporation Law ("DGCL") empowers a corporation to indemnify any person who was or is a party or who is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful.

Subsection (b) of Section 145 empowers a corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person acted in any of the capacities set forth above, against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses that the Court of Chancery or such other court shall deem proper.

Section 145 further provides that to the extent a director or officer of a corporation has been successful on the merits or otherwise in the defense of any action, suit or proceeding referred to in subsections (a) and (b) of Section 145, or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith; that indemnification provided for by Section 145 shall not be deemed exclusive of any other rights to which the indemnified party may be entitled; and the indemnification provided for by Section 145 shall, unless otherwise provided when authorized or ratified, continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of such person's heirs, executors and administrators. Section 145 also empowers the corporation to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of his or her status as such, whether or not the corporation would have the power to indemnify such person against such liabilities under Section 145.

Section 102(b)(7) of the DGCL provides that a corporation's certificate of incorporation may contain a provision eliminating or limiting the personal liability of a director to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, provided that such provision shall not eliminate or limit the liability of a director (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL, or (iv) for any transaction from which the director derived an improper personal benefit.

Advaxis' certificate of incorporation contains provisions that eliminate, to the maximum extent permitted by the DGCL, the personal liability of directors and executive officers for monetary damages for breach of their fiduciary duties as a director or officer. Advaxis' certificate of incorporation and bylaws provide that Advaxis shall indemnify its directors and officers and may indemnify its employees and other agents to the fullest extent permitted by the DGCL. However, the DGCL prohibits Advaxis from limiting the liability of directors for (i) any breach of a director's duty of loyalty to Advaxis or to Advaxis' stockholders, (ii) acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law, (iii) unlawful payment of dividends or unlawful stock repurchases or redemptions, and (iv) any transaction from which a director derived an improper personal benefit.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of Advaxis' directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Advaxis' certificate of incorporation does not eliminate a director's duty of care and, in appropriate circumstances, equitable remedies, such as injunctive or other forms of non-monetary relief, remain available under Delaware law. It also does not affect a director's responsibilities under any other laws, such as the federal securities laws or other state or federal laws. Under Advaxis' bylaws, Advaxis will also be empowered to enter into indemnification agreements with its directors, officers, employees and other agents and to purchase insurance on behalf of any person whom Advaxis is required or permitted to indemnify.

Advaxis entered into indemnification agreements with certain of its directors and executive officers, in addition to the indemnification provided for in its certificate of incorporation and bylaws, and intends to enter into indemnification agreements with any new directors and executive officers in the future. These agreements provide for the indemnification of such persons for all reasonable expenses and liabilities incurred in connection with any action or proceeding brought against them by reason of the fact that they are or were serving in such capacity. Advaxis believes that these certificate of incorporation and bylaws provisions and indemnification agreements are necessary to attract and retain qualified persons as directors, officers and employees.

Advaxis has purchased and intends to maintain insurance on behalf of any person who is or was a director or officer of Advaxis against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions.

The limitation of liability and indemnification provisions in Advaxis' certificate of incorporation and bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit Advaxis and its stockholders. A stockholder's investment may be harmed to the extent Advaxis pays the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended (the "Securities Act"), may be permitted to Advaxis' directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, Advaxis has been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. There is no pending litigation or proceeding naming any of Advaxis' directors or officers as to which indemnification is being sought, nor is Advaxis aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

Under the Merger Agreement, from the closing of the merger through the sixth anniversary of the closing, Advaxis and the surviving corporation agree that all rights to indemnification, exculpation or advancement of expenses now existing in favor of, and all limitations on the personal liability of, each present and former director or officer, of Advaxis or Biosight provided for in the respective organizational documents of Advaxis and Biosight in effect as of July 4, 2021, the date of the Merger Agreement, shall continue to be honored and in full force and effect.

Under the Merger Agreement, the certificate of incorporation and bylaws of the surviving corporation in the merger will contain provisions no less favorable with respect to indemnification, advancement of expenses and exculpation of present and former directors and officers of Advaxis than are presently set forth in Advaxis' amended and restated certificate of incorporation and amended and restated bylaws, which provisions shall not be amended, modified or repealed for a period of six years' time from the closing of the merger in a manner that would materially and adversely affect the rights thereunder of individuals who, at or prior to the closing, were officers or directors of Advaxis.

The Merger Agreement also provides that Advaxis shall purchase an insurance policy in effect for six years from the closing, providing at least the same coverage as the current directors' and officers' liability insurance policies maintained by Advaxis and containing terms and conditions that are not materially less favorable to current and former officers and directors of Advaxis.

**Item 21.** ***Exhibits and Financial Statement Schedules***

A list of exhibits filed with this registration statement on Form S-4 is set forth on the Exhibit Index and is incorporated herein by reference.

**Item 22.** ***Undertakings***

(a) The undersigned registrant hereby undertakes as follows:

(1) That prior to any public reoffering of the securities registered hereunder through use of a prospectus which is a part of this registration statement, by any person or party who is deemed to be an underwriter within the meaning of Rule 145(c), the issuer undertakes that such reoffering prospectus will contain the information called for by the applicable registration form with respect to reofferings by persons who may be deemed underwriters, in addition to the information called for by the other items of the applicable form.

(2) That every prospectus (i) that is filed pursuant to paragraph (b) immediately preceding, or (ii) that purports to meet the requirements of Section 10(a)(3) of the Securities Act and is used in connection with an offering of securities subject to Rule 415, will be filed as a part of an amendment to the registration statement and will not be used until such amendment is effective, and that, for purposes of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To respond to requests for information that is incorporated by reference into this proxy statement/prospectus/information statement pursuant to Item 4, 10(b), 11, or 13 of Form S-4, within one business day of receipt of such request, and to send the incorporated documents by first class mail or other equally prompt means. This includes information contained in documents filed subsequent to the effective date of the registration statement through the date of responding to the request.

(4) To supply by means of a post-effective amendment all information concerning a transaction, and the company being acquired involved therein, that was not the subject of and included in the registration statement when it became effective.

(b) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

**EXHIBIT INDEX**

| Exhibit Number | Description of Exhibits |
|---|---|
| 2.1 | Agreement and Plan of Merger and Reorganization, by and among the Company, Merger Sub, and Biosight, dated as of July 4, 2021. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on July 6, 2021. |
| 2.2 | Form of Support Agreement, dated as of July 4, 2021, by and between the Company, Biosight and each director and executive officer of the Company or Biosight. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on July 6, 2021. |
| 3.1 | Amended and Restated Certificate of Incorporation. Incorporated by reference to Annex C to DEF 14A Proxy Statement filed with the SEC on May 15, 2006. |
| 3.2 | Certificate of Designations of Preferences, Rights and Limitations of Series A Preferred Stock of the registrant, dated September 24, 2009. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on September 25, 2009. |
| 3.3 | Certificate of Designations of Preferences, Rights and Limitations of Series B Preferred Stock of the registrant, dated July 19, 2010. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on July 20, 2010. |
| 3.4 | Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on August 16, 2012. Incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the SEC on August 17, 2012. |
| 3.5 | Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on July 11, 2013 (reverse stock split). Incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the SEC on July 15, 2013. |
| 3.6 | Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on July 12, 2013 (reverse stock split). Incorporated by reference to Exhibit 3.2 to Current Report on Form 8-K filed with the SEC on July 15, 2013. |
| 3.7 | Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on July 9, 2014. Incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the SEC on July 10, 2014. |
| 3.8 | Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on March 10, 2016. Incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the SEC on March 11, 2016. |
| 3.9 | Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on March 21, 2018. Incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the SEC on March 21, 2018. |
| 3.10 | Certificate of Designation of Series C Junior Participating Preferred Stock of Advaxis, Inc. Incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the SEC on September 29, 2020. |
| 3.11* | Form of the Second Amendment to the Amended and Restated Certificate of Incorporation of Advaxis Inc (as included as Annexes E and F to this proxy statement/prospectus/information statement). |
| 3.12 | Second Amended and Restated Bylaws. Incorporated by reference to Exhibit 3.2 to Current Report on Form 8-K filed with the SEC on March 5, 2021. |
| 3.13 | Amendment No. 1 to the Second Amended and Restated By-Laws of Advaxis, Inc. Incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the SEC on September 20, 2021. |

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| 4.1 | Form of Common Stock certificate. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on October 23, 2007. |
| 4.2 | Form of Warrant Agency Agreement, dated as of September 11, 2018 between Advaxis, Inc. and Continental Stock Transfer and Trust Company (and Form of Warrant contained therein). Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on September 11, 2018. |
| 4.3 | Form of Common Stock Warrant dated September 11, 2018 (included in Exhibit 4.2). |
| 4.4 | Rights Agreement, dated as of September 29, 2020, by and between Advaxis, Inc. and Continental Stock Transfer and Trust Company, as rights agent. Incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on September 29, 2020. |
| 5.1* | Opinion of Morgan, Lewis & Bockius, LLP. |
| 10.1 | License Agreement, between the Trustees of the University of Pennsylvania and the registrant dated as of June 17, 2002, as Amended and Restated on February 13, 2007. Incorporated by reference to Exhibit 10.11 to Annual Report on Form 10-KSB filed with the SEC on February 13, 2007. |
| 10.2 | Amended and Restated 2009 Stock Option Plan of the registrant. Incorporated by reference to Annex A to DEF 14A Proxy Statement filed with the SEC on April 30, 2010. |
| 10.3 | Second Amendment to the Amended and Restated Patent License Agreement between the registrant and the Trustees of the University of Pennsylvania dated as of May 10, 2010. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on June 3, 2010. |
| 10.4 | 2011 Omnibus Incentive Plan of registrant. Incorporated by reference to Annex A to DEF 14A Proxy Statement filed with the SEC on August 29, 2011. |
| 10.5 | Amendment No. 1, dated as of March 26, 2007, to the License Agreement, between the Trustees of the University of Pennsylvania and Advaxis, Inc. dated as of June 17, 2002, as amended and restated on February 13, 2007. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on June 14, 2012. |
| 10.6 | Amendment No. 3, dated as of December 12, 2011, to the License Agreement, between the Trustees of the University of Pennsylvania and Advaxis, Inc. dated as of June 17, 2002, as amended and restated on February 13, 2007. Incorporated by reference to Exhibit 10.5 to Quarterly Report on Form 10-Q filed with the SEC on June 14, 2012. |
| 10.7 | Amendment No. 1 to 2011 Omnibus Incentive Plan of registrant. Incorporated by reference to Annex B to DEF 14A Proxy Statement filed with the SEC on July 19, 2012. |
| 10.8 | Indemnification Agreement. Incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed with the SEC on August 20, 2013. |
| 10.9 ‡ | Employment Agreement between Advaxis, Inc. and Robert Petit, dated September 26, 2013. Incorporated by reference to Exhibit 10.70 to Registration Statement on Form S-1/A (File No. 333-188637) filed with the SEC on September 27, 2013. |
| 10.10 | Exclusive License and Technology Transfer Agreement by and between Advaxis, Inc. and Global BioPharma, Inc., dated December 9, 2013. Incorporated by reference to Exhibit 10.79 to Annual Report on Form 10-K/A filed with the SEC on February 6, 2014. |

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| 10.11‡ | Amendment No. 1, dated as of December 19, 2013, to the Employment Agreement by and between Advaxis, Inc. and Robert G. Petit. Incorporated by reference to Exhibit 10.82 to Annual Report on Form 10-K/A filed with the SEC on February 6, 2014. |
| 10.12 | Distribution and Supply Agreement, dated as of January 20, 2014, by and between Advaxis, Inc. and Biocon, Limited. Incorporated by reference to Exhibit 10.7 to Quarterly Report on Form 10-Q filed with the SEC on March 17, 2014. |
| 10.13 | Exclusive License Agreement, dated March 19, 2014, by and between Advaxis, Inc. and Aratana Therapeutics, Inc. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on June 10, 2014. |
| 10.14‡ | Amendment No. 2, dated as of June 5, 2014, to the Employment Agreement by and between Advaxis, Inc. and Robert G. Petit. Incorporated by reference to Exhibit 10.6 to Quarterly Report on Form 10-Q filed with the SEC on June 10, 2014. |
| 10.15 | Clinical Trial Collaboration Agreement, dated July 21, 2014, by and between Advaxis, Inc. and MedImmune, LLC. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on September 9, 2014. |
| 10.16 | 5th Amendment to the Amended & Restated License Agreement, dated July 25, 2014, by and between Advaxis, Inc. and University of Pennsylvania. Incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed with the SEC on September 9, 2014. |
| 10.17 | Amendment No. 2 to the Advaxis, Inc. 2011 Omnibus Incentive Plan, effective July 9, 2014. Incorporated by reference to Annex A to Current Report on Schedule 14A filed with the SEC on May 20, 2014. |
| 10.18 | Amended and Restated 2011 Omnibus Incentive Plan, dated September 8, 2014. Incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-Q filed with the SEC on September 9, 2014. |
| 10.19 | Master Services Agreement for Technical Transfer and Clinical Supply, dated February 5, 2014, by and between Advaxis, Inc. and SynCo Bio Partners B.V. Incorporated by reference to Exhibit 10.1 to Current Report to Form 8-K filed with the SEC on February 11, 2014. |
| 10.20 | Clinical Trial Collaboration and Supply Agreement by and between Advaxis, Inc. and Merck & Co. dated August 22, 2014. Incorporated by reference to Exhibit 10.101 to Annual Report on Form 10-K filed with the SEC on January 6, 2015. |
| 10.21‡ | Amendment No. 3, dated as of April 17, 2015, to the Employment Agreement by and between Advaxis, Inc. and Robert G. Petit. Incorporated by reference to Exhibit 10.6 to Quarterly Report on Form 10-Q filed with the SEC on June 15, 2015. |
| 10.22 | Co-Development and Commercialization Agreement between Advaxis, Inc. and Específicos Stendhal SA de CV dated February 3, 2016. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on February 26, 2016. |
| 10.23‡ | Separation Agreement and General Release, dated July 6, 2017, between Advaxis, Inc. and Daniel J. O'Connor. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on July 7, 2017. |
| 10.24 | 2015 Incentive Plan of registrant. Incorporated by reference to Annex A to DEF 14A Proxy Statement filed with the SEC on April 7, 2015. |

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| 10.25 | Amendment to the Advaxis, Inc. 2015 Incentive Plan. Incorporated by reference to Exhibit B to DEF 14A Proxy Statement filed with the SEC on February 11, 2016. |
| 10.26 | Amendment to the Advaxis, Inc. 2015 Incentive Plan. Incorporated by reference to Exhibit A to DEF 14A Proxy Statement filed with the SEC on February 10, 2017. |
| 10.27 | Amendment to the Advaxis, Inc. 2015 Incentive Plan. Incorporated by reference to Exhibit A to DEF 14A Proxy Statement filed with the SEC on March 20, 2020. |
| 10.28 | Amendment to the Advaxis, Inc. 2015 Incentive Plan, dated as of February 11, 2021. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on June 4, 2021. |
| 10.29‡ | Employment Agreement between Advaxis, Inc. and Molly Henderson, dated June 6, 2018. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on June 6, 2018. |
| 10.30 | 2018 Employee Stock Purchase Plan. Incorporated by reference to Exhibit B to the DEF14A Proxy Statement filed with the SEC on February 6, 2018. |
| 10.31 | Sales Agreement, dated May 8, 2020, by and between Advaxis, Inc. and A.G.P./Alliance Global Partners. Incorporated by reference to Exhibit 1.1 to Current Report on Form 8-K filed with the SEC on May 8, 2020. |
| 10.32 | Purchase Agreement, dated July 30, 2020, by and between Advaxis, Inc. and Lincoln Park Capital Fund, LLC. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on August 3, 2020. |
| 10.33‡ | Employment Agreement between Advaxis, Inc. and Kenneth A. Berlin, dated April 23, 2018. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on April 23, 2018. |
| 10.34‡ | Employment Agreement between Advaxis, Inc. and Kenneth A. Berlin, dated April 23, 2018. Incorporated by reference to Exhibit 10.33 to Amendment No. 1 to Annual Report on Form 10-K/A filed with the SEC on February 26, 2021. |
| 10.35 | Lease Agreement, dated March 25, 2021, by and between the Company and Princeton Corporate Plaza, LLC. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on March 30, 2021. |
| 10.36 | Lease Termination and Surrender Agreement, dated March 26, 2021, by and between the Company and 300 CR LLC. Incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the SEC on March 30, 2021. |
| 10.37 | Securities Purchase Agreement dated April 12, 2021, by and among Advaxis, Inc. and the purchasers identified on the signature pages thereto. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on April 12, 2021. |
| 10.38 | Form of Investor Agreement. Incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the SEC on April 12, 2021. |
| 10.39 | Agreement of Plan of Merger and Reorganization, by and among the Company, Merger Sub, and Biosight, dated as of July 4, 2021, incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on July 4, 2021. |
| 10.40 | Form of Support Agreement, dated as of July 4, 2021, by and between the Company, Biosight and each director and executive officer of the Company or Biosight, incorporated by reference to Exhibit 1.2 to the Company's Current Report on Form 8-K filed with the SEC on July 6, 2021. |
| 10.41* | Master Agreement for Clinical Trials Management Services, dated as of May 3, 2018 and effective as of November 20, 2017, by and between Biosight Ltd. And ICON plc (f/k/a Pharmaceutical Research Associates, Inc.). |
| 10.42* | Amendment No. 1 to Master Agreement for Clinical Trials Management Services, effective as of November 20, 2020, by and between Biosight Ltd. And ICON plc (f/k/a Pharmaceutical Research Associates, Inc.). |
| 10.43*# | Master Services Agreement with Albany Molecular Research Inc., dated as of June 16, 2017, by and between Biosight Ltd. And Albany Molecular Research Inc. |
| 10.44*# | Independent Research Funding Agreement, dated as of July 15, 2020, by and between Biosight Ltd. And GFM (Groupe Franchophone des Myélodysplasies). |
| 10.45*# | Master Agreement, dated as of August 8, 2021, by and between Biosight Ltd. And Sterling Wisconsin, LLC. |
| 10.46* | Separation Agreement, dated on about October 7, 2021, by and among Biosight Ltd., RAM Technologies (RBY 2012) Ltd. And Dr. Ruth Ben Yakar. |
| 21.1* | List of subsidiaries of Advaxis, Inc. |
| 23.1* | Consent of Marcum LLP, an Independent Registered Public Accounting Firm. |
| 23.2* | Consent of Kesselman & Kesselman, Certified Public Accountants (Isr.), a member firm of PricewaterhouseCoopers International Limited. |
| 23.3* | Consent of Morgan, Lewis & Bockius LLP (included in Exhibit 5.1 hereto). |
| 23.4* | Consent of Cello Health Bioconsulting. |

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| 99.1 | Opportunity Assessment for BST-236, dated October 7, 2021. |
| 101.INS** | XBRL Instance Document |
| 101.SCH** | XBRL Taxonomy Extension Schema Document |
| 101.CAL** | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF** | XBRL Taxonomy Extension Definitions Linkbase Document |
| 101.LAB** | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE** | XBRL Taxonomy Extension Presentation Linkbase Document |

* Filed herewith.
** To be filed by amendment.
*** Furnished herewith.
‡ Denotes management contract or compensatory plan or arrangement.
# Certain of the exhibits and schedules to this exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5). The Registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request.

## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Monmouth Junction, State of New Jersey, on October 13, 2021.

**Advaxis, Inc.**

By: */s/ Kenneth A. Berlin*
Name: Kenneth A. Berlin
Title: President and Chief Executive Officer
Interim Chief Financial Officer

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Kenneth A. Berlin, Andres Gutierrez and Igor Gitelman, and each or any one of them, as his true and lawful attorney-in-fact and agent, each with full power of substitution and resubstitution, for him or her and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

| Signature | Title | Date |
|---|---|---|
| */s/ Kenneth A. Berlin*<br>Kenneth A. Berlin | President and Chief Executive Officer,<br>Interim Chief Financial Officer and Director | October 13, 2021 |
| */s/ Andres Gutierrez, M.D., Ph.D.*<br>Andres Gutierrez, M.D., Ph.D. | Chief Medical Officer and Executive Vice President | October 13, 2021 |
| */s/ Igor Gitelman*<br>Igor Gitelman | Chief Accounting Officer, VP of Finance | October 13, 2021 |
| */s/ David Sidranksy*<br>David Sidranksy | Chairman of the Board | October 13, 2021 |
| */s/ Dr. James S. Patton*<br>Dr. James S. Patton | Vice Chairman of the Board | October 13, 2021 |
| */s/ Roni A. Appel*<br>Roni A. Appel | Director | October 13, 2021 |
| */s/ Richard J. Berman*<br>Richard J. Berman | Director | October 13, 2021 |
| */s/ Dr. Samir Khleif*<br>Samir Khleif | Director | October 13, 2021 |

**Exhibit 5.1**

Morgan Lewis

October 13, 2021

Advaxis, Inc.
9 Deer Park Drive, Suite K-1
Monmouth Junction, New Jersey 08852

Registration Statement on Form S-4
(Registration No. 333-259065)

Ladies and Gentlemen:

We have acted as special counsel to Advaxis, Inc., a Delaware corporation (the "Company"), in connection with the Registration Statement on Form S-4, as amended (the "Registration Statement") of the Company, filed with the Securities and Exchange Commission pursuant to the Securities Act of 1933, as amended (the "Act"), and the rules and regulations thereunder (the "Rules"). You have asked us to furnish our opinion as to the legality of the securities being registered under the Registration Statement. The Registration Statement relates to the registration under the Act of 44,205,068 shares (the "Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock"), issuable pursuant to the Agreement and Plan of Merger and Reorganization, dated as of July 4, 2021 (the "Merger Agreement"), by and among the Company, Advaxis Ltd. and Biosight, Ltd.

In connection with the furnishing of this opinion, we have examined originals, or copies certified or otherwise identified to our satisfaction, of the following documents (collectively, the "Documents"):

1. the Registration Statement;

2. the Merger Agreement; and

3. the form of the Second Amendment to the Amended and Restated Certificate of Incorporation of the Company, filed as Exhibit 3.11 to the Registration Statement (the "Amended and Restated Certificate of Incorporation").

In addition, we have examined (i) such corporate records of the Company that we have considered appropriate, including a copy of the certificate of incorporation, as amended, and bylaws, as amended, of the Company, certified by the Company as in effect on the date of this letter and copies of resolutions of the board of directors of the Company relating to the issuance of the Shares, certified by the Company and (ii)such other certificates, agreements and documents that we deemed relevant and necessary as a basis for the opinion expressed below. We have also relied upon the factual matters contained in the representations and warranties of the Company made in the documents and upon certificates of public officials and the officers of the Company.

**Morgan, Lewis & Bockius** LLP

101 Park Avenue
New York, NY 10178-0060
United States

T +1.212.309.6000
F +1.212.309.6001

In our examination of the documents referred to above, we have assumed, without independent investigation, the genuineness of all signatures, the legal capacity of all individuals who have executed any of the documents reviewed by us, the authenticity of all documents submitted to us as originals, the conformity to the originals of all documents submitted to us as certified, photostatic, reproduced or conformed copies of valid existing agreements or other documents, the authenticity of all the latter documents and that the statements regarding matters of fact in the certificates, records, agreements, instruments and documents that we have examined are accurate and complete. We have also assumed that the Second Amendment to the Amended and Restated Certificate of Incorporation will be properly filed in the Secretary of State of the State of Delaware prior to the issuance of the Shares.

Based upon the above, and subject to the stated assumptions, exceptions and qualifications, we are of the opinion that the Shares have been duly authorized by all necessary corporate action on the part of the Company and, when issued, delivered and paid for as contemplated in the Registration Statement, the Shares will be validly issued, fully paid and non-assessable.

The opinion expressed above is limited to the General Corporation Law of the State of Delaware. Our opinion is rendered only with respect to the laws, and the rules, regulations and orders under those laws, that are currently in effect.

We hereby consent to use of this opinion as an exhibit to the Registration Statement and to the use of our name under the heading “Legal Matters” contained in the prospectus included in the Registration Statement. In giving this consent, we do not thereby admit that we come within the category of persons whose consent is required by the Act or the Rules.

Very truly yours,

*/s/ Morgan, Lewis & Bockius LLP*
Morgan, Lewis & Bockius LLP

Horn & Co. Final, May 3, 2018

**MASTER AGREEMENT FOR**
**CLINICAL TRIALS MANAGEMENT SERVICES**

This Master Agreement for Clinical Trials Management Services (the "Agreement") is made and entered into on May 3,2018 and effective as of November 20,2017, (the "Effective Date"), by and between **Biosight Ltd.,** an Israeli corporation, with offices at 1 Hayarden St., Airport City, P.O.B 1083 Lod 7019802, Israel (hereinafter referred to as "Sponsor") and **Pharmaceutical Research Associates, Inc**., a Commonwealth of Virginia corporation, together with its Affiliates, with offices at 4130 ParkLake Avenue, Suite 400, Raleigh, NC 27612 (hereinafter referred to as "PRA"), each hereinafter referred as "Party" and both hereinafter referred as "Parties".

PRA is engaged in the business of providing services related to the design, implementation and management of clinical development programs for the pharmaceutical, biotechnology and medical device industries; and

Sponsor desires to engage PRA to perform such services in connection with certain pharmaceutical products under development by or under control of Sponsor;

**THEREFORE**, in consideration of the premises and mutual promises and undertakings herein, the receipt and sufficiency of which are hereby acknowledged, the Parties intending to be legally bound do hereby agree as follows:

**1.0 DEFINITIONS**

a. Affiliates: With respect to either Party, an Affiliate is any entity that is controlled by, controls, or is under common control with the party named above including joint venture partnerships where the Party has at least 50% of the voting power,

b. Amendment: A written specification of changes to a Task Order that is agreed to by the Parties and authorized by signature of each Party's authorized representative(s), in a format substantially similar to Exhibit B attached hereto.

c. Applicable Anti-Bribery Laws: Any bribery, fraud, kickback, or other similar anti-corruption law or regulation of any relevant country, including the UK Bribery Act 2010 and the US Foreign Corrupt Practices Act of 1977,

d. Audit: A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analyzed and accurately reported according to the Protocol, standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s) (GCP 1.6),

e. Budget for Services: A component of a Task Order that outlines the estimated cost of the Services based upon the Project Specifications.

f. Inspection: The act by a regulatory authority (ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority (ies) to be related to the clinical trial and that may be located at the site of the trial, at the Sponsor's and/or contract research organization's (CRO's) facilities, or at other establishments deemed appropriate by the regulatory authority (ies) (GCP 1.29).

g. Institutional Review Board ("IRB"): Any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of human subjects. The term has the same meaning as the phrase institutional review committee, independent ethics committee or ethics committee.

h. Early Development Services: A Study performed at a facility or external investigative site for Phase I to Phase IIa clinical trials as designated in a Task Order.

i. GCP or Good Clinical Practice: The standard defined in the ICH Harmonised Tripartite Guideline For Good Clinical Practice E6(R1) Current Step 4 version dated 10 June 1996 (including the Post Step 4 corrections) together with, for Services performed in the European Union, such other Good Clinical Practice requirements as are specified in Directive 2001/20/EC of the European Parliament and the Council of 4 April 2001 relating to medicinal products for human use and in guidance published by the European Commission pursuant to such Directive; and for Services performed in other jurisdictions, any analogous laws and/or regulations. All, as may be updated or amended from time to time.

j. Institution: Any public or private entity or agency or medical or dental facility where clinical trials are conducted.

k. Investigator(s): Except where defined otherwise in a Task Order for Early Development Services, a third party responsible for the conduct of the clinical trial at a Trial Site. If a trial is conducted by a team of individuals at a Trial Site, the Investigator is the responsible leader of the team and may be called the principal investigator.

l. Key Personnel: The key PRA personnel assigned to the Services including the Project Manager and others as agreed to by the Parties.

m. Milestone: An event associated with a specific date, for which a payment will be due, as set out in the Payment Schedule of any Task Order.

n. Pass-Through Budget: A component of a Task Order that outlines the estimated costs of pass-through expenses for goods and services incurred by PRA on behalf of Sponsor, in connection with the performance of the Services.

o. Payment Schedule: A component of a Task Order that describes the timing of payments due to be made for Services delivered and pass-through expenses incurred,

p. PRA Project Manager: The PRA representative assigned to lead the PRA project team, act as the principal liaison between PRA and Sponsor, and provide general oversight in the delivery of Services with regard to a specific Task Order.

q. Project Schedule: A component of a Task Order that outlines the project milestones, estimated timelines and completion date for the Services based upon the Project Specifications,

r. Project Specifications: A component of a Task Order that outlines the specific Services to be provided, assumptions used in preparing the Budget for Services, Pass-Through Budget and Project Schedule, and assignment of project-related responsibilities between the Parties.

s. Services: The services to be provided by PRA and Subcontractors (if applicable) under this Agreement as specifically outlined in a Task Order or otherwise authorized by Sponsor.

t. Study: A clinical trial performed at one or more investigative sites under the supervision of one or more Investigator(s) pursuant to a study Protocol.

u. Subcontractor: An individual or company engaged to conduct some elements of a Task Order, including without limitation, clinical laboratories, patient recruitment services, interactive voice recognition systems and other services. Investigators are not included as subcontractors.

v. Task Order: A written specification of Services to be performed by PRA under this Agreement, including the Project Specifications, Project Schedule, Contact Information, Budget for Services, Pass-Through Budget, and Payment Schedule.

w. Trial Site(s): Except where defined otherwise in a Task Order for Early Development Services, a third party location where trial-related activities are actually conducted following Sponsor's written approval of such Trial Site and the terms of operation therein.

**2.0 SERVICES**

PRA, itself or through one of its Affiliates or Subcontractors (if applicable), will perform the Services in accordance with: (i) the Protocol, (ii) the terms and conditions of this Agreement and the associated Task Order, (ii) PRA's standard operating procedures, which will be available for review upon written request of Sponsor, or when applicable and agreed under the Task Order, Sponsor's standard operating procedures (iii) all applicable laws, rules and regulations including GCP, (iv) the standards and practices that are generally accepted in the industry and exercised by other entities engaged in performing similar services; and (v) the written instructions of Sponsor, from time to time. PRA shall use commercially reasonable efforts, skills and resources to diligently and competently perform the Services described in any Task Order issued hereunder and to meet all obligations and deadlines described in such Task Orders. The Parties will agree in advance on all Services to be provided and the performance of those Services will be authorized in writing through the execution of a Task Order. Unless otherwise agreed to by the Parties in writing, PRA will not begin work on any Services without an executed Task Order authorizing the Services. During the term of this Agreement PRA shall provide Sponsor with periodically written progress reports, as shall be further agreed between the Parties. PRA representatives conducting and/or supervising the Services shall be available during the term of this Agreement for meetings from time to time, as agreed under the Task Orders, during regular business hours for updates with Sponsor representatives.

**2.1 Task Orders**

PRA will provide Services as specified in one or more Task Orders, which will be prepared in a format substantially similar to the Form of Task Order, attached hereto, as appropriate. Each Task Order may include detailed information, as applicable, with respect to a specific project, including Project Specifications, Project Schedule, Budget for Services, Pass-Through Budget, and Payment Schedule. Task Orders will become effective when signed by an authorized representative of both Parties.

**2.2 Amendments**

Any changes to a Task Order, including but not limited to changes to the Project Specifications, Project Schedule, Budget for Services or Pass-Through Budget, will be agreed upon by the Parties and documented in an Amendment to the Task Order in a form substantially similar to that attached hereto as Exhibit B. Sponsor agrees that PRA will not perform any out-of-scope work described in an Amendment until it is approved in writing by both Parties.

a. Amendment Process. Some changes in costs associated with clinical research are not within the control of PRA and PRA will not be responsible for any such changes. Upon identification by either Party of changes to the project assumptions or other changes to the Project Specifications, the Parties will negotiate in good faith an Amendment to accommodate increases or decreases to the Project Budget, Project Schedule, and Payment Schedule that are reasonably associated with any such adjustments. Amendments will be documented in accordance with the terms of this Section 2.2. Such changes may include, but are not limited to, any of the following (in all cases, to the extent that such delays are indeed not within the control of PRA):

i. delays in receiving from Sponsor technical information or Sponsor's acceptance of documents submitted by PRA in a timely manner in the performance of its duties under this Agreement or any Task Order, or any other delay on the part of Sponsor;

ii. delay in receipt of regulatory approval from a regulatory agency, IRB, or Ethics Committee;

iii. delay in performance by a Subcontractor not selected by PRA;

iv. delay in shipment of study drug, clinical samples, and/or clinical supplies;

v. delay due to changes in standard of care, clinical landscape, regulation, or changes in medical practice affecting participating sites;

vi. delay by reason of force majeure as defined herein;

vii. Sponsor requested changes to the Services or the Protocol;

viii. delays due to questions received by either Party from regulatory agencies or ethics committees regarding submission materials that relate to characteristics of the study drug or Protocol design;

ix. delays due to any changes in applicable law or regulatory environment; or

x. changes for any other reason agreed upon in writing and in advance by Sponsor to be changes outside PRA control,

**2.3 Project Staffing**

In performing the Services, PRA will assign personnel who are adequately trained, qualified and experienced to conduct the work as specified in a Task Order. Sponsor may make reasonable requests for replacement of assigned personnel for cause, such as unsatisfactory performance or interpersonal conflicts. PRA will promptly respond to any such request and make reasonable efforts to correct the situation in order to improve performance, or to provide a replacement, at its own expense, within a mutually agreeable timeframe.

Key Personnel. PRA will assign a PRA Project Manager and other employees whose participation in a project is required for the duration of the project, who will serve as Key Personnel. For clarity, the Key Personnel are the functional team leads as determined in each Task Order. Key Personnel may include, without limitation, Lead Data Managers and Medical Monitors and Lead Biostatisticians. PRA will provide thirty (30) days notice to Sponsor, whenever possible, of any changes to the Key Personnel and PRA will make reasonable efforts to manage the impact in the Study, PRA will provide project-specific training to replacement Key Personnel at its own expense. Notwithstanding the foregoing, the following Key Personnel may not be replaced without the Sponsor's prior written consent: PRA Project Manager ("PM") and Clinical Team Manager ("CTM"), unless in circumstances (i) which are not within the control of PRA (as termination of the employment, sickness, absence, maternity/paternity leave of that employee, etc.,), (ii) promotion of such individual, or (iii) underutilization of such individual in connection with the Project on which such individual is assigned as a PM or CTM, the following procedure shall apply; (a) PRA will make reasonable efforts to manage the impact in the Study; (b) the situation shall be discussed in good faith between the parties to find a reasonable solution; and (c) the transition process (unless such transition process is not possible, e.g.: sickness, absence, etc.), and, in any case, the replacement shall be made in consultation and agreement with Sponsor. Sponsor's agreement shall not be unreasonably withheld.

a. Project Team. PRA will assign non-Key Personnel from one or more of its offices located worldwide, as needed to perform the Services in accordance with the Task Order. Sponsor will receive in advance the CV of the Clinical Research Associates.

From time to time, PRA may assign some elements of the Services to contract employees. PRA agrees that any contract employees used to perform the Services will be adequately qualified, experienced and trained as required to perform the Services in the same manner as PRA qualifies and trains its own employees. PRA will remain responsible for satisfactory performance of all Services performed by contract employees.

In the event that any unauthorized change of PM and CTM (or the procedure above was not followed when applicable), and provided such authorization was not unreasonably withheld, shall directly result in a delay or have any other direct adverse effect to the Project, then, without derogating from any other right or remedy to which Sponsor may be entitled, PRA shall reimburse BioSight for the portion of Services in failure due to such unauthorized replacement.

**2.4 Use of Subcontractors**

Upon and subject to the prior written approval of the Sponsor, PRA may use Subcontractors to conduct some elements of the Services. In the event that Sponsor objects, for reasonable cause, to any such Subcontractors selected and contracted directly by PRA, PRA will replace the Subcontractor within a mutually agreeable timeframe. Sponsor may request that PRA contracts and uses a specific subcontractor, but such engagement will be subject to PRA's written consent to engage such subcontractor. Such written consent will be subject to PRA performing the necessary activities to qualify and approve a subcontractor, and negotiate contractual terms, and will not be withheld unreasonably. PRA will be responsible and retain primary liability for the performance and agrees to manage the performance of all Subcontractors whom have been qualified, approved and contracted by PRA according to PRA SOPs. In the unlikely event that PRA is unable to consent to engage with a Sponsor requested subcontractor, PRA will work with Sponsor to find a mutually acceptable solution for the Services, and to clarify, PRA will not be responsible for the performance of such unapproved subcontractors.

**2.5 Applicable Standards**

The Parties agree that PRA will provide the operational systems, processes and standard operating procedures to be used in performance of the Services unless specified otherwise in the Task Order. All Services will be conducted in accordance with GCP and applicable laws and regulations.

**2.6 Sponsor-Provided Systems**

In the event that Sponsor requires PRA to use Sponsor's information systems and associated processes, Sponsor will be responsible for all costs associated with installation and operation of the systems, including costs for hardware and software licenses, and for training of PRA personnel assigned to the project in the use of Sponsor system(s)

**3.0 PAYMENT**

The Parties agree that the fees and other reimbursements that PRA will receive for performing the Services hereunder will be outlined in each Task Order and are subject to the following terms and conditions.

**3.1 Compensation for Services**

For Services provided, Sponsor will pay PRA in accordance with the terms in this section of the Agreement and each applicable Task Order. The timing and frequency of payments will be governed by the Payment Schedule detailed in each Task Older.

**3.2 Pass-Through Budget**

a. Pass-Through Expenses. In order to provide funding for pass-through expenses, exclusive of investigator grants described below, Sponsor will make an advance payment to PRA in an amount set forth in a Task Order immediately upon execution of the Task Order. PRA will submit to Sponsor monthly invoices for amounts incurred during the relevant billing period. The advance payment will be retained by PRA until the completion of the Services, at which time a reconciliation of expenses will be done to ensure that Sponsor pays for only those expenses actually incurred. The advance payment will then be applied to the final invoice, if unpaid, and any remaining advance payment will be refunded to Sponsor within thirty (30) days from the date of the final reconciliation.

b. Sponsor will reimburse all travel expenses in accordance with PRA's applicable Travel and Expense Policy (to be provided upon request). Each invoice will include, as necessary, a summary of all pass-through expenses. Provided however, that any such expense which exceeds an amount of US$ 500 (per single expense), and was not originally included in the Task Order budget, shall be subject to the advanced written approval of the Sponsor.

**3.3 Investigator Grants and Reconciliation.**

In order to provide for timely payments to Investigators, Sponsor will make an additional advance payment to PRA in an amount set forth in a Task Order immediately upon execution of a Task Order. PRA will submit to Sponsor quarterly invoices in advance for estimated amounts to be paid to Investigators to be incurred in the upcoming quarter to ensure that adequate funds are available to pay such expenses. Sponsor agrees that PRA will not make payments to Investigators without sufficient funds available. The advance payment will be retained by PRA until the completion of the Services, at which time a reconciliation of expenses will be done to ensure that Sponsor pays for only those expenses actually incurred. The advance payment will then be applied to the final invoice, if unpaid, and any remaining advance payment will be refunded to Sponsor within thirty (30) days from the date of the final reconciliation.

**3.4 Invoices**

a. Invoices for Services and pass-through expenses will be submitted in accordance with the Payment Schedule associated with the relevant Task Order and will be prepared monthly, or as frequently as necessary. Any final payments specified in the Task Order will be invoiced upon completion of the project and delivery to Sponsor of any final study databases, reports or other deliverables as specified in the Project Specifications.

b. All invoices under this Agreement will be forwarded to the Sponsor representative designated in the relevant Task Order.

c. All payments under this Agreement will be remitted to the PRA affiliate named in the Task Order, to the address and in the manner set forth in the Payment Schedule of the applicable Task Order.

**3.5 Payment Terms**

Sponsor agrees to pay for Services and pass-through expenses in accordance with the Payment Schedule outlined in each Task Order or associated Amendment. Sponsor will pay for all Services, pass-through expenses and other invoiced items within thirty (30) days of the last day of the calendar month in which the Sponsor had received the respective invoice. If Sponsor notifies PRA in writing of any deficiencies in the Services during such period, Sponsor will pay for the portions of the Services that conform to the Task Order within thirty (30) days of the last day of the calendar month in which the Sponsor had received the respective invoice and PRA will correct any non-conforming Services within thirty (30) days of the notice. Upon final shipment of the corrected Services, PRA will submit the invoice for the corrected Services to Sponsor. All payments will be made in the currency noted in the Payment Schedule of the Task Order. All fees for Services and pass-through expenses are exclusive of VAT (including non- refundable VAT) or similar taxes payable by Sponsor under applicable law, including local taxes, social taxes, charges or remittance fees over the pass-through expenses, which Sponsor will pay when applicable. In the event that value added tax (VAT) must be paid by PRA on pass-through expenses and when such VAT is not recoverable by PRA because such recovery is legally impermissible based on the facts and circumstances of the engagement with the third party suppliers, or when PRA considers that it would not be commercially viable to pursue the recovery, PRA may charge such VAT to Sponsor and if Sponsor has any question about such not recoverable VAT, PRA shall provide information. Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from its activities or receipt of payments under this Agreement. To the extent Sponsor is required to deduct and withhold taxes on any payment to PRA hereunder, after exhausting available legal remedies, it shall pay the amounts of such taxes to the proper governmental authority in a timely manner and promptly transmit to PRA an official lax certificate or other evidence of such withholding sufficient to enable PRA to claim such payment of taxes. PRA shall provide Sponsor any tax forms that may be reasonable necessary in order for Sponsor not to withhold tax or to withhold tax at a reduced rate under applicable law.

**3.6 Currency Management.**

The Parties agree that neither should receive a material benefit or detriment from currency exchange rate fluctuation between the currencies in which costs are incurred, and the currencies used for pricing or invoicing and payment.

a. **Service Fees**: For service fees, the bid currencies will be tracked and managed against the contract currency established in each Task Order. On an annual basis a currency review may occur to assess the impact of currency fluctuation on the value of services using the average rate during the evaluation period as published by Oanda.com on the basis of the date of invoicing. For exchange rate fluctuations of less than 5% no adjustments will be made. Once the Parties have agreed upon the impact of any currency fluctuation PRA will issue an invoice or credit memo as appropriate. The Parties will also discuss at that time whether to amend the value of the Task Order to reflect trends in currency fluctuation.

b. **Expenses**. For pass-through expenses and investigator grants, conversion from the currency in which the payment is made to the contract currency will occur at the time the transaction is processed using daily exchange rates provided by Oanda.com. Due to investigator fee invoices being raised on a forecast of payments to be made a retrospective reconciliation will occur at the end of the project using the actual exchange rates applied.

For Early Development Services, the Study budget will be agreed upon in the currency of the country where the Study will be performed, provided however, if an exchange rate fluctuation mechanism is applicable the mechanism will be set out in the Task Order.

## 4.0 Term and Termination

### 4.1 Term

Unless earlier terminated, this Agreement will remain in effect for an initial term of three (3) years from the Effective Date. In the event of expiration or termination of this Agreement, any outstanding Task Order will continue until completion of the Services described in such Task Order or appropriate termination of the Task Order.

### 4.2 Termination

a. The Sponsor may terminate this Agreement or any Task Order for any reason upon thirty (30) days written notice to PRA.

b. Each Party may terminate this Agreement or any Task Order upon written notice to the other Party in the event of a material breach of this Agreement or any Task Order by the other Party that is not cured within sixty (60) days of receipt of written notice of breach.

c. Each Party may terminate this Agreement or any Task Order immediately upon written notice to the other Party, if the other Party; (i) files a petition for bankruptcy or has an involuntary bankruptcy petition filed against it; (ii) is adjudged as bankrupt; (iii) becomes insolvent; (iv) has a receiver, trustee, conservator or liquidator appointed for all or a substantial part of its assets; (v) ceases to do business; (vi) commences any dissolution, liquidation or winding up; or (vii) makes an assignment of its assets for the benefit of its creditors.

### 4.3 Termination for Other Reasons

If PRA's continued performance of the Services contemplated by this Agreement or any Task Order could constitute a potential or actual violation of legal, regulatory, ethical or scientific standards, then PRA may terminate this Agreement or any Task Order by giving written notice stating the effective date (which may not be less than sixty [60] days from the notice date) of such termination. The Parties shall use all reasonable efforts to rectify the alleged violation prior to the end of such notice period.

### 4.4 Effects of Termination/Expiration

In the event of termination or expiration of this Agreement or any Task Order, Sponsor will pay PRA for Services performed up to the effective date of termination, non-cancellable costs and expenses and any associated wind down costs incurred up to effective date of termination. Within thirty (30) days of either Party's receipt of such notice, the Parties will meet to develop a plan for closing down this Agreement or the applicable Task Order, which will include transferring any remaining tasks or other responsibilities to Sponsor or its designee. In the event of termination or postponement of Early Development Services, additional terms will apply as set forth in the applicable Task Order.

**4.5 Survival**

Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination. In addition, the Sections on Payment, Term and Termination, Representations and Warranties, Debarment Certification, Ownership of Data and Intellectual Property, Confidential Information, Indemnification, and Employees as well as any other sections which by their nature should survive, will survive expiration or termination of this Agreement indefinitely, or for the period of time noted in the specific clause.

**5.0 REPRESENTATIONS AND WARRANTIES**

**5.1 Acknowledgments**

Sponsor acknowledges and agrees that the results of the Services to be provided hereunder are inherently uncertain and that, accordingly, there can be no assurance, representation or warranty by PRA that the drug, compound, device or other material which is the subject of research covered by this Agreement or any Task Order issued hereunder can, either during the term of this Agreement or thereafter, will be successfully developed or, if so developed, will receive the required approval by the United States Food and Drug Administration ("FDA") or other regulatory authority.

**5.2 Mutual Representations**

Each of the Parties represents, warrants and covenants to the other that: (a) it has taken all necessary actions on its part to authorize the execution, delivery and performance of the obligations undertaken in this Agreement, and no other corporate actions are necessary with respect thereto; (b) it is not a party to any agreement or understanding and knows of no law or regulation that would prohibit it from entering into and performing this Agreement; (c) when executed and delivered by it, this Agreement will constitute a legal, valid and binding obligation of it, enforceable against it in accordance with this Agreement's terms; (d) it is duly licensed, incorporated, authorized or qualified to do business and is in good standing in every jurisdiction in which a license, authorization or qualification is required for it to perform its obligations under this Agreement; (e) it will perform its obligations hereunder in accordance with current industry standards, the terms of this Agreement and any Task Order issued hereunder; (f) it will perform its obligations hereunder in accordance with all applicable federal, international, state or local law or regulation, including all Applicable Anti-Bribery Laws in the countries where Services are to be performed; (g) performance of its obligations hereunder will not infringe or violate the rights of any third party including but not limited to property, contractual, employment, trademark, trade secrets, copyright, patent, proprietary information and non-disclosure rights; and (h) it will not enter into any other agreements which would interfere or prevent performance of the obligations described herein.

**5.3 Representations and Warranties of Sponsor**

a. Sponsor represents and warrants that it has the right, title and interest in the drug, compound, device or other material which is the subject of research covered by this Agreement or any Task Order (whether such right, title and interest is held solely by Sponsor or jointly with others) and that it has the legal right, authority and power to perform any clinical trial which is the subject of a Task Order issued hereunder.

b. If Sponsor requires PRA to use MedDRA to code, analyze or report data for a Study, Sponsor represents and warrants that it has a current and valid license agreement with the Maintenance and Support Services Organization ("MSSO") to use MedDRA. Furthermore, if PRA is required to use WHO Drug, WHO Herbal or WHO ART for coding of data, Sponsor warrants and represents that it has a current and valid license agreement with The Uppsala Monitoring Centre for the dictionaries which PRA will be required to use. If Sponsor does not currently have such licenses, it represents and warrants that such licenses will be in place prior to PRA's delivery of data which is coded using these dictionaries. PRA will not be liable to Sponsor for use of data coded without proper licensing, and Sponsor will hold PRA harmless in these occasions.

c. Sponsor further warrants and represents that for any software application, computer system or program that is required to be used by PRA in the performance of Services to which PRA does not hold a license at the commencement of this Agreement or the relevant Task Order, Sponsor will have acquired and will maintain current and valid licenses which are necessary for the use of such applications or programs, and that PRA's use of such applications or programs will not subject PRA to any liability for such use.

d. Any drug material used in a Study that is provided by or on behalf of Sponsor will be manufactured, packaged, labeled, and shipped in accordance with all applicable laws, rules, and regulations, including, without limitation, applicable current Good Manufacturing Practices ("cGMPs") as such cGMPs may be adopted in any nations in which such study drugs are imported or manufactured, as applicable.

**5.4 Representations and Warranties of PRA**

a. PRA represents and warrants that without derogating from the representations set forth in Section 2 above, it has the experience, capability, and resources necessary to perform Services under this Agreement, and that the personnel assigned to perform Services rendered under this Agreement will be capable professionally.

b. PRA further represents and warrants that it will make available to Sponsor or to the responsible regulatory authority relevant records, programs, and data as may be reasonably requested by Sponsor for purposes related to filing and prosecution of Sponsor's related new drug applications.

c. In conformity with any applicable law, including the United States Foreign Corrupt Practices Act ("USFCPA"), PRA and its employees and officers shall not directly or indirectly make any offers, payments, promises to pay, or authorize payment, or offer a gift, promise to give, or authorize the giving of anything of value for the purpose of influencing an act (including a decision not to act) or decision of an official of any government within the territory in which the Agreement is being executed or inducing such a person to use his/her influence to affect any such governmental act or decision in order to assist Sponsor (or its clients) in obtaining, retaining or directing business for the benefit of Sponsor (or its clients) if such action on the part of PRA would be in violation of such applicable law,

**5.5 No Other Warranties**

The Parties' warranties and representations contained in this Agreement are in lieu of all other warranties expressed or implied.

**6.0 DEBARMENT CERTIFICATION**

a. PRA certifies that it has not been debarred under Section 306 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §335a(a) or (b) or any equivalent local law or regulation. In the event that PRA becomes debarred, PRA agrees to notify Sponsor immediately,

b. PRA certifies that it has not and will not use in any capacity the services of any individual, corporation, partnership, or association which has been debarred under Section 306 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C §335a (a) or (b) or any equivalent local law or regulation. In the event that PRA becomes aware of or receives notice of the debarment of any individual, corporation, partnership, or association providing services to PRA, which relate to the Services being provided under this Agreement, PRA agrees to notify Sponsor immediately.

**7.0 INSPECTIONS AND AUDITS**

**7.1 Audit by Sponsor**

During the term of this Agreement, PRA will permit representatives of Sponsor who are not competitors of PRA, to examine, at a reasonable time during normal business hours, upon prior written notice to PRA of at least sixty (60) days for once per 12 month period routine audits and at least three (3) days for cause/emergency audits (which shall not be limited by number of audits): (i) the facilities where the Services are being, will be or have been conducted; (ii) related study documentation; and (iii) any other relevant information necessary for Sponsor to confirm that the Services are being or will be or have been conducted in conformance with applicable standard operating procedures, the specific Task Orders, this Agreement and in compliance with applicable laws and regulations. PRA will promptly provide copies of any materials reasonably requested by Sponsor during such audit. However, Sponsor acknowledges that such audits may not be possible due to reasons outside the reasonable control of PRA. In such cases, PRA will endeavor to arrange such audit on the first available date after the sixty (60) day notice and in any event within 75 days from the notice date.

**7.2 Inspection by Regulatory Authorities**

During the term of this Agreement, each Party will permit regulatory authorities to examine, (i) the facilities where the Services are being conducted; (ii) study documentation; and (iii) any other relevant information, including information that may be designated by one or both of the Parties as confidential, reasonably necessary for regulatory authorities to confirm that the Services are being conducted in compliance with applicable laws and regulations. Each Party will immediately notify the other if any regulatory authority schedules, or without scheduling, begins an inspection that relates to the Services or the Parties' respective obligations hereunder. PRA shall disclose to Sponsor any finding from any regulatory authority that is directly related to the Services herein, and if permitted by the regulatory authority shall promptly provide Sponsor with a copy of the inspection report after the removal of any information of a confidential nature which is not related to the Services or to Sponsor's activities or products, PRA shall reasonably act to contractually obtain, if PRA is responsible for contracting the Trial Sites, the cooperation of investigators and Trial Sites with respect to regulatory review. As part of PRA's quality management procedures, PRA conducts periodical audits of its processes and systems. If such audits identify critical findings that impact the Services and/or Sponsor's activities, PRA agrees to inform Sponsor of such findings.

**7.3 Audits of Trial Site(s) by PRA; Recruitment by Trial Sites**

In connection with PRA's provision of Services as specified in this Agreement and any associated Task Order, PRA may conduct audits of Trial Sites, and will conduct such audits at Sponsor's written request and expense, Based on PRA's observations of any Trial Site, PRA may recommend to Sponsor: i) that enrollment should be suspended at the Trial Site; ii) that a Trial Site's non-compliance needs to be reported to regulatory authorities; and/or (iii) Trial Site's participation in a Study needs to be terminated. Upon such a recommendation, PRA will present to Sponsor a basis for its decision. If Sponsor disagrees with the basis for PRA's recommendation, PRA may in its discretion assign its contract with the Trial Site to Sponsor and Sponsor agrees to accept such assignment and to be responsible for all contractual duties and obligations to the Trial Site. Without derogating from the foregoing, both Parties agree to notify the other Party of instances of continued non-compliance or suspected scientific misconduct by Trial Sites, Investigators or Key Personnel, as it relates to the Services.

7.3 (A). In the event that any Trial Site is recommended by PRA, or PRA accepts a Trial Site suggested by Biosight without raising concerns, and they shall not recruit the expected total number of patients set forth in the respective Task Order (provided no unforeseen events occurred that were outside PRA's control as noted in section 2.2.a), Sponsor shall decide, in consultation and agreement with PRA, the correct course of action, and PRA shall bear the cost of any new or replacement Trial Sites to recruit the original amount of total patients included in the original Task Order, including without limitation, any reasonably identifiable delays caused by such replacement, as discussed and agreed by Sponsor and PRA in good faith.

**8.0 Ownership of Data and Intellectual Property**

All data (including without limitation, written, printed, graphic, video and audio material, and information contained in any computer database or computer readable form) generated or collected by PRA in the course of conducting the Services (the "Data") and related to the Services will be Sponsor's property. Any copyrightable work created in connection with performance of the Services and contained in the Data will be considered work made for hire, whether published or unpublished, and all rights therein will be the property of Sponsor as employer, author and owner of copyright in such work.

The underlying rights to the intellectual property and materials that are the subject of each Task Order, including, without limitation, all intellectual property rights in Sponsor's drug candidates or products, are owned solely by Sponsor. Neither PRA, its Affiliates nor any of their respective Subcontractors will acquire any rights of any kind whatsoever with respect to Sponsor's drug candidates or products as a result of conducting Services hereunder. All rights to any know-how, trade secrets, developments, discoveries, inventions or improvements (whether or not patentable) conceived or reduced to practice in the performance of work conducted under this Agreement by PRA's or its Affiliates' employees, or independent contractors, either solely or jointly with employees, agents, consultants or other representatives of Sponsor (the "Intellectual Property"), will be owned solely by Sponsor. PRA, its Affiliates and their respective employees and Subcontractors will sign and deliver to Sponsor all writings and do all such things as may be necessary or appropriate to vest in Sponsor all right, title and interest in and to such Intellectual Property, PRA will promptly disclose to Sponsor any such Intellectual Property arising under this Agreement. Sponsor may, in its sole discretion, file and prosecute in its name and at its expense, patent applications on any patentable inventions within the Intellectual Property. Upon the request of Sponsor, and at the sole expense of Sponsor, PRA will assist Sponsor in the preparation, filing and prosecution of such patent applications and will execute and deliver any and all instruments necessary to effectuate the ownership of such patent applications and to enable Sponsor to file and prosecute such patent applications in any country.

Notwithstanding the foregoing, Sponsor agrees that PRA possesses or may in the future possess analytical methods, computer technical expertise and software, which do not relate specifically to the Sponsor's products or Intellectual Property, and which have been independently developed by PRA and which will remain the sole and exclusive property of PRA, except to the extent that improvements or modifications include, incorporate or are based upon Sponsor's information, in which case these will belong to Sponsor as set forth above. Improvements or enhancements made to PRA's processes or methods which are independently developed incidental to the provision of Services hereunder and are not directly related to Sponsor's products or Intellectual Property will remain the sole property of PRA. Sponsor may use this information of PRA free of charge for interpretation purposes or regulatory authorities' purposes or for any purposes that are appropriate within the scope of this Agreement, to the extent necessary or desirable to commercialization of Sponsor's products, if applicable. Any improvement on information of Sponsor will remain the sole property of Sponsor.

**8A. Maintenance and Disposition of Computer Files and Study Materials**

PRA shall maintain all materials and all other Data obtained or generated by PRA in the course of providing the Services and will take reasonable and customary precautions, including periodic backup of computer files, to prevent the loss or alteration of Sponsor's study Data, documentation, and correspondence. Upon termination of a Study PRA will send to the Sponsor the electronic Trial Master File.

**9.0 CONFIDENTIAL INFORMATION**

**9.1 Sponsor Confidential Information**

a. Sponsor may disclose confidential information to PRA during the course of this Agreement. All information provided by or on behalf of Sponsor (including the study drug) or Data collected by PRA during the performance of the Services, including the study results and Sponsor's Intellectual Property are deemed to be the confidential information of Sponsor and is hereinafter referred to as "Sponsor Information". PRA will not disclose Sponsor Information to any person other than its employees, agents, Investigators, Trial Sites, regulatory authorities, IRBs (only to the extent required by applicable law) and Subcontractors involved in the Services to whom it needs to disclose such specific information or use any such information for any purpose other than the performance of Services without the prior written consent of Sponsor.

b. PRA will require (and be responsible) that it and its Affiliates' employees, agents, Subcontractors and shall require (and take any reasonable action and collaborate with the Sponsor to require) that the Investigators and Trial Sites involved in the Services will comply with terms substantively similar to the confidentiality provisions of this Agreement, pursuant to a form of confidentiality and non-use agreement approved by Sponsor in advance. PRA will disclose only the Sponsor Information to those of its employees, agents, Investigators, Trial Sites and Subcontractors who reasonably need to know the Sponsor Information. The disclosure to Investigators and Trial Sites shall be pursuant to a form of confidentiality and non-use agreement approved by Sponsor in advance.

c. PRA will exercise due care to prevent the unauthorized disclosure and use of Sponsor Information associated with the Services.

d. This confidentiality, nondisclosure and nonuse provision will not apply to Sponsor Information that PRA can demonstrate by competent evidence:

i. was known by PRA before initiation of the Services or which is independently discovered, after the initiation of the Services, without the aid, application of use of Sponsor Information, as evidenced by written records;

ii. was in the public domain at the initiation of the Services or subsequently became publicly available through no fault or action of PRA, provided however, that Sponsor Information shall not be deemed to be in the public domain merely because any part of the Sponsor Information is embodied in general disclosure or because individual features, components or combinations thereof are now or become known to the public; or

iii. was disclosed to PRA on a non-confidential basis by a third party authorized to disclose it,

e. In no event will either Party be prohibited from disclosing confidential information of the other Party to the extent required by law to be disclosed, provided that the disclosing Party provides the non-disclosing Party with written notice thereof, prior to disclosure, to the extent reasonably practicable, discloses only what is required to be disclosed by law or regulation, and, at the non-disclosing Party's request and expense, cooperates with the non-disclosing Party's efforts to obtain a protective order or other confidential treatment of the confidential information required to be disclosed. Since a breach by PRA of any of the promises or agreements contained herein may result in irreparable and continuing damage to Sponsor for which there may be no adequate remedy at law, Sponsor shall be entitled to seek injunctive relief and/or a decree for specific performance, and such other relief as may be proper (including monetary damages if appropriate). Nothing in this Section shall be construed as derogating from any right or remedy that the Sponsor may be entitled to under applicable law or this Agreement.

**9.2 PRA Confidential Information**

Sponsor agrees that all business processes, contract terms, prices, procedures, policies, methodologies, systems, computer programs, software, applications, databases, proposals and other documentation generally used by PRA and not developed solely for the Sponsor pursuant to the provisions of Section 8.0 above, are the exclusive proprietary and confidential property of PRA (hereinafter "PRA Information") or the third parties from whom PRA has secured the right of use. Sponsor agrees that all PRA Information, along with any improvement, alteration or enhancement made thereto during the course of the Services, will be the exclusive proprietary and confidential property of PRA, and will be subject to the same degree of protection as is required of PRA to protect Sponsor Information.

**9.3 Disposition of Confidential Information**

At the conclusion of a Study, or upon the written request of the Sponsor, PRA will deliver to Sponsor or destroy, as the Sponsor may request in its sole discretion, all Sponsor Information in its possession unless Sponsor directs otherwise. Sponsor may communicate any special request for the disposition of materials in writing to PRA. Sponsor will bear all costs incurred by PRA in complying with any such written instructions furnished by Sponsor (provided that disposal or return costs which exceed, in the aggregate, US$ 250, shall require the prior written approval of tire Sponsor). PRA will provide a written estimate to Sponsor, and Sponsor will provide written approval, of all such costs prior to any action by PRA. PRA shall use all reasonable efforts to destroy all notes, summaries, analyses and reports made by PRA's employees, agents and consultants containing such Sponsor Information. Provided, however, that PRA shall be entitled to retain in confidence under this Agreement one archived copy of Sponsor Information solely for the purpose of administering PRA's obligations under this Agreement and Sponsor Information contained in PRA's electronic back-up files that are created in the normal course of business pursuant to PRA's standard protocol for preserving its electronic records.

**9.4 Data Privacy**

Definitions. For the purpose of this Section 9.4, 'Personal Data', 'Process/Processing', 'Data Controller', 'Data Processor' and 'Data Subject' shall have the same meaning as in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data ("Directive 95/46/EC") as implemented in the law of any EU Member State which is applicable to the provision of the Services or as defined in the law of any other country which is applicable to the provision of the Services (including, as applicable, the Regulation (EU) 2016/679 of the European Parliament and the Council of 27 April 2017 ("GDPR"), the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules, 45 C.F.R. Parts 160-164, and the Health Information Technology for Economic and Clinical Health Act (HITECH), P.L. No. 111-005, Part I, Title XIII, Subpart D, 13401-13409, and state privacy laws) (collectively referred to as the "Applicable Data Privacy Laws").

Compliance. Each Party warrants to the other that it will Process the Personal Data in compliance with all Applicable Data Privacy Laws.

Data Processing Agreement, attached hereto as Exhibit C, shall be incorporated into and an effective part of the Task Order and this Agreement. The Parties will execute the Annexes to the Data Processing Agreement with each Task Order.

Data Processing. Sponsor and PRA acknowledge that Sponsor is the Data Controller and PRA is the Data Processor with respect to the Processing of Personal Data relating to the Services provided under this Agreement. PRA shall Process the Personal Data only in accordance with the written instructions from Sponsor or as may be required or permitted by law (the instructions may be specific instructions or instructions of a general nature as set out in this Agreement, a Task Order, the Protocol, or as otherwise notified by Sponsor to PRA during the term hereof).

Security. PRA shall implement appropriate technical and organizational measures to protect the Personal Data as required by GCP and Applicable Data Privacy Laws.

Data Privacy Requests. PRA shall promptly notify Sponsor in writing if it receives any communication with regard to data privacy relating to the Services from a Data Subject, a privacy authority or other regulatory authority, and provide Sponsor with cooperation and assistance in relation to any such communication from Data Subjects. PRA shall be entitled to charge Sponsor for such assistance, at its usual hourly rate, unless the communication relates to a breach or violation by PRA of its obligations under this Section 9.4. However, PRA and Sponsor recognize that any fees charged to the requesting Party must comply with Applicable Data Privacy Laws.

Security Breaches, If PRA becomes aware of any breach of an Applicable Data Privacy Law at PRA or its sub-processors relating to the Services, then it shall promptly notify Sponsor and, if requested, assist Sponsor with investigating the breach and in meeting any obligations under Applicable Data Privacy Law to notify Data Subjects, regulatory authorities or other required parties, as applicable. PRA shall be entitled to charge Sponsor for such assistance, at its usual hourly rate, unless PRA was solely responsible for such breach.

Data transfers. PRA shall only Process or otherwise transfer Personal Data outside the European Economic Area ("EEA") (member states of the European Union plus, Norway, Iceland & Liechtenstein) as necessary to provide Services under this Agreement, or any Task Order or where otherwise instructed by Sponsor. The Sponsor acknowledges that PRA operates a global IT network with primary servers based in the US. In addition, some of the Services performed for the Sponsor with include cloud-based software systems. Sponsor hereby approves and authorizes PRA to make such transfers. PRA shall work with Sponsor to ensure the lawful export of Personal Data under appropriate cross border transfer mechanisms, which may be structured in a separate agreement between the Parties. In providing Services, it may be necessary to sub-contract certain tasks to one or more third party vendors, including cloud based service providers, whose servers may be located outside the EEA. Transfers of Personal Data to said vendors shall be made on the basis of Data Subject consent and/or through a commitment by the vendor to comply with the appropriate cross border transfer mechanisms.

**10.0 PUBLICITY**

Sponsor may use, refer to and disseminate reprints of scientific, medical and other published articles which disclose the name of PRA consistent with applicable international copyright laws, provided such use does not constitute an endorsement of any commercial product or service by PRA. Neither party will disclose publicly or utilize in any advertising or promotional materials or media the existence of this Agreement or its association with the other, or use of the other party's name or the name of any of the other party's Affiliates, divisions, subsidiaries, products or investigations without the prior written permission of the other party, provided however, that PRA may use the name of Sponsor in its list of customers. Further, either Party may make such public disclosures as it determines, based on advice of counsel, are reasonably necessary to comply with laws or regulations in which case the disclosing Party shall provide the other Party with reasonable advance notice of such required public announcement, and provided further that Sponsor shall be entitled to disclose the existence and terms of this Agreement in the course of due diligence enquiries subject to standard confidentiality undertakings.

**11.0 INDEMNIFICATION**

**11.1 Sponsor's Agreement**

a. Sponsor will indemnify, defend and hold harmless PRA, its Affiliates, and their officers, directors, agents, employees, and independent contractors approved by Sponsor (each an "Indemnitee") against any claim, suit, action, proceeding, arbitration or investigation, pending or threatened by a third party (each a "Claim") against Indemnitees relating to the Services, including but not limited to court costs, reasonable legal fees, awards or settlements.

b. Under no circumstances, however, will Sponsor accept liability on behalf of PRA, or otherwise enter into any settlement agreement that attributes fault or negligence to PRA without prior written consent of PRA, not to be unreasonably withheld. PRA will fully cooperate and aid in any such defense.

c. Sponsor will not indemnify, defend, or hold harmless PRA against any Claim to the extent that such Claim arose as a result of PRA's negligence, recklessness, intentional misconduct, or material breach of this Agreement or any Task Order hereunder. Under such circumstances PRA will repay to Sponsor all reasonable defense costs incurred by Sponsor on its behalf.

**11.2 PRA's Agreement**

PRA will indemnify, defend and hold harmless Sponsor and its employees, officers, and directors against any and all losses, costs, expenses and damages, including but not limited to reasonable attorney's fees, based on a Claim resulting from PRA's negligence, intentional misconduct, or material breach of this Agreement or any Task Order hereunder.

a. Under no circumstances, however, will PRA accept liability, on behalf of Sponsor or enter into any settlement agreement that attributes fault or negligence to Sponsor without prior written consent of Sponsor, not to be unreasonably withheld. Sponsor will fully cooperate and aid in any such defense.

b. PRA will not indemnify, defend or hold harmless Sponsor against any Claim to the extent that such Claim arose as a result of Sponsor's negligence, recklessness, intentional misconduct, or material breach of this Agreement or any Task Order hereunder. Under such circumstances Sponsor will repay to PRA all reasonable defense costs incurred by PRA on its behalf.

**11.3 Indemnification Procedure**

Each indemnified Party shall give the indemnifying Party prompt notice of any Claim for which indemnification is sought hereunder; provided, that the failure to give such notice will not relieve the indemnifying Party of its indemnification obligation under this Section 11 except to the extent, if at all, it is prejudiced thereby. The indemnifying Party shall have the right to control the defense and settlement of a Claim, provided the indemnifying Party shall act reasonably and in good faith with respect to all matters relating to the settlement or disposition of the Claim, and the indemnified Party shall reasonably cooperate in the investigation, defense and settlement of such Claim. In the event that representation of indemnified Party and the indemnifying Party by the same counsel is a conflict of interest for such counsel, the indemnified Party may select its own independent counsel, at the indemnifying Party's expense, without relieving the indemnifying Party of its obligations under this Section 11.

**11.4 Limits of Liability**

Both Parties' liability for direct damages hereunder will not exceed twice the total fees for Services, excluding pass-through expenses and investigator grants, payable by Sponsor to PRA under the applicable Task Order with the exception of the indemnification obligation set forth in Section 11.2 and 11.1 (respectively) above. In no event will either Party be liable to the other for any indirect, incidental, special, or consequential damages or lost profits arising out of this Agreement or Task Order, even if a Party has been advised of the possibility of such damages, provided however, that such limitation shall not apply with respect to damages which result from breach of Sections 8 and the Confidentiality obligations under 9 hereunder.

**11.5 Insurance**

a. Sponsor Insurance. During the term of this Agreement, for as long as Company is conducting clinical trials, and for a period of three (3) years following the termination or completion of such clinical trials, Sponsor shall maintain in full force and effect the following program of insurance:

   i. products liability insurance covering clinical trials activity with limits of not less than Five Million Dollars ($5,000,000); and

   ii. Clinical trials insurance in compliance with local compulsory requirements

PRA may from time to time request evidence confirming such insurance.

b. PRA Insurance. PRA shall at all times during the term of this Agreement and for an extended period of three (3) years, provide and maintain at its own expense, the following types of insurance:

i. Professional Liability: Professional Liability covering all professional acts, errors and omissions in an amount of not less than Five Million Dollars ($5,000,000) per occurrence and in the aggregate.

ii. General Liability: Commercial General Liability insurance against claims for bodily injury and property damage in an amount of not less than One Million Dollars ($1,000,000) per occurrence, Two Million Dollars ($2,000,000) in the aggregate, and Ten Million Dollars ($10,000,000) in excess or umbrella coverage.

iii. Workers Compensation and Employers' Liability: To comply with the statutory requirements of the state(s) in which the Services are performed.

iv. Employer's liability insurance with a limit of not less than one million dollars (US$1,000,000);

c. General Terms

d. Insurance required herein will be underwritten by insurers with A. M. Best ratings of not less than A- (Excellent).

e. Throughout the term, each party will provide the other party with at least thirty (30) days advance written notice of cancellation, non-renewal or material reduction of the insurance required herein.

f. Upon request, each will provide with a valid, current certificate of insurance as evidence of the insurance required herein.

g. Nothing in this Section 11.5 shall be construed as limiting each party's obligations elsewhere under this Agreement. Such insurance may be provided on a claims-made basis (with the exception of workers compensation and employers' liability), however, such insurance shall have a retroactive date prior to the date that any work will be performed pursuant to the Agreement.

**12.0 INDEPENDENT CONTRACTOR RELATIONSHIP**

PRA and Sponsor are independent contractors. Nothing in this Agreement will be construed to create the relationship of partners, joint venturers, or employer and employee between PRA and Sponsor or PRA's employees. Neither Party, nor its employees, or independent contractors will have authority to act on behalf of or bind the other Party in any manner whatsoever unless otherwise authorized in this Agreement or in a separate writing signed by both Parties.

**13.0 EMPLOYEES**

Neither Party, during the term of this Agreement and for twelve months thereafter, will, without the prior written consent of the other Party, directly or indirectly solicit for employment or contract, attempt to employ or contract with or assist any other entity in employing, contracting with or soliciting for employment or contract any employee or executive who is at that time employed/contracted by the other Patty and who had been employed/contracted by the other Party in connection with one or more Task Orders issued hereunder. Provided, however, that the foregoing provision will not prevent either Party from conducting solicitation via a general advertisement for employment that is not specifically directed to any such employee or from employing any such person who responds to such solicitation.

**14.0 NOTICES**

Except as otherwise provided, all communications and notices required under this Agreement will be mailed by email, first class mail or sent via nationally recognized overnight courier to the addresses set forth below, or to such other addresses as the Parties from time to time specify in writing.

| If to Sponsor: | If to PRA: |
|---|---|
| **BioSight Ltd.** | **Pharmaceutical Research Associates, Inc.** |
| 1 Hayarden St., Airport City | 4130 ParkLake Avenue |
| P.O.B 1083 | Suite 400 |
| Lod 7019802, Israel | Raleigh, NC 27612 |
| | Attn: Vice President of Legal Affairs |

**15.0 FORCE MAJEURE**

If the performance of this Agreement by PRA or Sponsor is prevented, restricted, interfered with or delayed (either totally or in part) by reason of any cause beyond the control of the Parties (including, but not limited to, acts of God, explosion, disease, weather, war, insurrection, terrorism, civil strike, riots or extensive power failure), the Party so affected will, upon giving notice to the other Party as soon as is practical, be excused from such performance to the extent of such prevention, restriction, interference or delay, provided that the affected Party will use reasonable efforts to avoid or remove such causes of non-performance and will continue performance whenever such causes are removed.

**16.0 GOVERNING LAW**

This Agreement will be governed in all respects by the laws of England and Wales without regard to its conflict of laws principles.

**17.0 SEVERABILITY**

If any of the provisions or a portion of any provision of this Agreement is held to be unenforceable or invalid by a court of competent jurisdiction, the validity and enforceability of the enforceable portion of any such provision and/or the remaining provisions will not be affected thereby.

**18.0 ASSIGNMENT**

Neither Party may assign this Agreement without the prior written consent of the other party, which consent will not be unreasonably withheld; provided, however, that either party may assign all of its rights and obligations under this Agreement without consent to a successor in interest to substantially all of the business of that party to which the subject matter of this Agreement relates upon delivery to the other Party of notice of such assignment and provided that such assignment shall not adversely affect the non assigning Party.

**19.0 WAIVER**

No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances will be deemed to be construed as a further or continuing waiver of such term, provision or condition or of any other term, provision or condition of this Agreement.

**20.0 ENTIRE AGREEMENT**

This Agreement, including all Exhibits hereto contains the full understanding of the Parties with respect to the Services and supersedes all existing Agreements and all other oral, written or other communications between the Parties concerning the subject matter hereof. This Agreement will not be modified in any way except in writing and signed by a duly authorized representative of Sponsor and an authorized officer of PRA.

**21.0 ENGLISH LANGUAGE**

The Parties hereto confirm that this Agreement as well as any other documents relating hereto, including notices, have been and shall be drawn up in the English language only.

**22.0 COUNTERPARTS**

This Agreement may be executed in several counterparts, each of which will be deemed an original but all of which will constitute one and the same instrument.

**23.0 ARBITRATION**

In the event a dispute relating to this Agreement or any Task Order arises between the Parties, the Parties will use all reasonable efforts to resolve the dispute through direct discussions for a period of thirty (30) business days. The senior management of each Party is committed to respond to any such dispute. Subsequent to such thirty-day period, any dispute, controversy or claim arising out of or relating to this Agreement may be settled by arbitration. If arbitration is being conducted shall be in accordance with the International Chamber of Commerce ("ICC") Arbitration Rules as of present in force and shall be held at London, England in the English language by one arbitrator. The appointing authority shall be the ICC acting in accordance with the Rules adopted by the ICC for this purpose.

The undersigned have executed this Agreement as of the Effective Date.

| **Pharmaceutical Research Associates, Inc.** | | **Biosight Ltd.** | |
|---|---|---|---|
| By | */s/ Michael Wolfgang* | By | */s/ Ruth Ben Yakar* |
| Name | Michael Wolfgang | Name | Ruth Ben Yakar |
| Title | Vice President of Finance | Title | CEO |
| | Date 5/3/2018 | | Date |

**LIST OF EXHIBITS**

Exhibit A: Form of Task Order – Product Registration

Exhibit B: Form of Amendment

Exhibit C: Standard Contractual Clauses

**EXHIBIT A:**

**FORM OF TASK ORDER (Product Registration)**

**Task Order Number: _____**

**Sponsor Project Number: _____**

This Task Order is made and entered into on <Month> <Day>, <Year>, (the "Effective Date"), by and between **BioSight Ltd.,** a corporation of Israel _____ with offices at Hayarden St., Airport City, P.O.B 1083 Lod 7019802, Israel (hereinafter referred to as "Sponsor") and **Pharmaceutical Research Associates, Inc.,** a corporation of the Commonwealth of Virginia, with offices at 4130 ParkLake Avenue, Suite 400, Raleigh, NC 27612 (hereinafter referred to as "PRA").

**WHEREAS**, Sponsor and PRA have entered into that certain Master Agreement for Clinical Trials Management Services dated the <day> of <month>, 200_ (hereinafter referred to as the "Master Agreement"); and

**WHEREAS**, pursuant to the Master Agreement, PRA has agreed to perform certain Services in accordance with Task Orders from time to time entered into by the Parties, as more fully provided in Section 2 of the Master Agreement, and Sponsor and PRA now desire to enter into such a Task Order.

**WHEREAS**, PRA and Sponsor desire that PRA provide certain Services with respect to a _____, (the "Study") for the study of the drug _____ ("Study Drug") as set out in the Protocol titled: _____, which is incorporated herein by reference (the "Protocol").

**NOW, THEREFORE**, in consideration of the mutual covenants contained herein, the parties hereby agree as follows:

1. Project Specifications. PRA will perform the services described in the Project Specifications, attached hereto as Appendix A, in accordance with the Project Schedule, attached hereto as Appendix B and any other documents attached to this Task Order ("Services").

2. Compensation. For performance of these Services, Sponsor will pay to PRA the amounts described in the Budget for Services and Pass-Through Budget set forth in Appendix C, which amounts will be payable pursuant to the Payment Schedule set forth in Appendix D.

3. Term and Termination. The term of this Task Order will commence upon its execution by PRA and Sponsor and will continue until completion of the Services described in Appendix A, provided, however, that either party may terminate this Task Order in accordance with Section 4, Term and Termination, of the Master Agreement.

4. Designated Contact Persons and Key Personnel. The PRA Project Manager and Key Personnel who will oversee the Services in accordance with the Master Agreement are identified in Appendix E, Designated Contact Persons and Key Personnel.

5. Incorporation by Reference; Conflict. The provisions of the Master Agreement are hereby expressly incorporated by reference into and made a part of this Task Order. In the event of a conflict between the terms and conditions of this Task Order and those of the Master Agreement, the terms of the Master Agreement will take precedence and control unless in the event that the Task Order explicitly provides otherwise.

**IN WITNESS WHEREOF**, the parties have hereunto signed this Task Order as of the Effective Date.

| **Pharmaceutical Research Associates, Inc.** | | **BioSight Ltd.** | |
|---|---|---|---|
| By: | | By: | |
| Name: | | Name: | |
| Title: | | Title: | |
| Date: | | Date: | |

**List of Appendices**

| | |
|---|---|
| Appendix A: | Project Specifications |
| Appendix B: | Project Schedule |
| Appendix C: | Budget for Services and Pass-Through Budget |
| Appendix D: | Payment Schedule |
| Appendix E: | Designated Contact Persons and Key Personnel Designation |

**EXHIBIT B**

**FORM OF AMENDMENT**

**AMENDMENT #**

**Task Order #**

**Protocol #**

**THIS AMENDMENT #1** ("Amendment #1"), dated <Month> <Day>, <Year> (the "Effective Date"), by and between **Pharmaceutical Research Associates, Inc.,** together with its affiliates, with offices at 4130 ParkLake Avenue, Suite 400, Raleigh, NC 27612 ("PRA") and **BioSight Ltd.,** a corporation of Israel, with offices at Hayarden St., Airport City, P.O.B 1083 Lod 7019802, Israel ("Sponsor").

***W I T N E S S E T H:***

**WHEREAS**, under the terms of a certain Master Agreement for Clinical Trials Management Services (the "Master Agreement"), dated the ____ day of _____, 201_ by and between the parties, Sponsor agreed to retain PRA, and PRA agreed to be retained by Sponsor, to perform the Services as more particularly described in the Master Agreement pursuant to the terms of Task Orders to be issued from time to time; and

**WHEREAS**, the parties entered into Task Order #___, dated (the "Task Order") for the performance of Services as more pertaining to Sponsor's protocol _____;

**WHEREAS**, the parties hereto have entered into certain additional agreements with respect to modification of the Task Order, and which they desire to memorialize in this Amendment

**NOW, THEREFORE**, in consideration of the premises and of the following mutual promises, covenants and conditions hereinafter set forth, the parties hereto agree as follows:

1. **Project Specifications.** [Use the following if work is to be added to the existing scope of work. If the old scope no longer applies, and a completely new Scope of work is necessary, the old specifications should be stricken and replaced by the new ones.] The Services to be provided by PRA pursuant to the Task Order are hereby amended by inclusion of the Services described in Amendment Appendix ___, "Additional Project Specifications", which is attached hereto and incorporated herein by reference.

2. **Project Schedule.** The Project Schedule, attached to the Task Order as Appendix ___, is hereby stricken and replaced by the Amended Project Schedule, attached hereto as Amendment Appendix ___, "Amended Project Schedule", which is incorporated herein by reference.

3. **Budget and Payment Schedule**, [Each revised Budget should show the following, on one chart; Budget from the original contract, new amounts added or subtracted, and new total budget. This should follow the format of the original contract.] Therefore, the following changes to the Agreement are hereby made:

a. The Budget for Services, attached to the Task Order as Appendix ___, is hereby stricken and replaced by the "Amended Budget", attached hereto as Amendment Appendix __, which is incorporated herein by reference.

b. The Payment Schedule, attached to the Task Order as Appendix ___, is hereby stricken and replaced by the "Amended Payment Schedule", attached hereto as Amendment Appendix ___, which is incorporated herein by reference.

4. **Designated Contact Persons and Key Personnel.** [If there have been changes to the designated people or Key Personnel members, use the following] The staff assigned to the Study has changed, Therefore, the Designated Contact Persons and Key Personnel, attached to the Task Order as Appendix ___, is hereby stricken and replaced by the "Amended Designated Contact Persons and Key Personnel" attached hereto as Amendment Appendix ___, which is incorporated herein by reference.

5. **Ratification of Balance of Task Order**. In all other respects, the terms of the Task Order are hereby ratified and affirmed by each of the parties hereto.

6. **Headings**. The headings in this Amendment # are for convenience of reference only and will not affect its interpretation.

IN WITNESS WHEREOF, the parties hereto, each by a duly authorized representative, have executed this Amendment # as of the Effective Date,

| **PHARMACEUTICAL RESEARCH ASSOCIATES, INC.** | | **BioSight Ltd.** | |
|---|---|---|---|
| By: | | By: | |
| Name: | | Name: | |
| Title: | | Title: | |
| Date: | | Date: | |

List of Appendices:

| | |
|---|---|
| Amendment Appendix A: | Additional Project Specifications |
| Amendment Appendix B: | Amended Project Schedule |
| Amendment Appendix C: | Amended Budget |
| Amendment Appendix D: | Amended Payment Schedule |
| Amendment Appendix E: | Amended Contact Persons and Key Personnel |

**EXHIBIT C**

**European Data Processing Agreement**

This Data Processing Agreement ("DPA") is entered into by and between:

a) Biosight Ltd, having its principal place of business at 1 Hayarden St., Airport City, P.O.B 1083 Lod 7019802, Israel ("**Controller**")

b) Pharm Research Associates (UK) Ltd. having its principal place of business at 500 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD ("**Processor**" or "**PRA**")

each a "**Party**", together the "**Parties**".

BACKGROUND

Under the Agreement for Clinical Trials Management Services concluded by and between the Parties on the date of [insert date] (the "**Agreement**"), Processor agreed to provide Controller with the services as further specified in Annex 1 to this DPA (the "**Services**").

WHEREAS, Controller is a private pharmaceutical development company

WHEREAS, Processor is a pharmaceutical research group of companies.

WHEREAS, in rendering the Services, Processor may from time to time be provided with, or have access to information of Controller's Personal Data or personally identifiable information within the meaning of Applicable Data Protection Law;

WHEREAS, Controller engages PRA as an appointed Processor acting on behalf of Controller;

WHEREAS, this DPA contains the terms and conditions applicable to the collection, processing and use of such Personal Data by PRA as the appointed Processor of Controller with the aim to ensure that the Parties comply with Applicable Data Protection Law;

WHEREAS, if Controller is located outside the European Union ("**EU**")/European Economic Area ("**EEA**") the Parties also wish to adduce adequate safeguards in connection with transfers of Personal Data and therefore additionally agree to enter into the Standard Contractual Clauses for the transfer of Personal Data to Processors established in third countries ("**Standard Contractual Clauses**") pursuant to Commission Decision 2010/87/EC of 5 February 2010 (Part 2).

WHEREAS, Controller also means data exporter and Processor also means data importer.
WHEREAS, for this purpose, the DPA consists of the following parts:

| | |
|---|---|
| Part 1 | Data Processing Agreement to comply with the requirements for the appointed Processor of Personal Data |
| Part 1 - Annex 1 | Details of data processing |
| Part 1 - Annex 2 | Technical and Organisational Security Measures |
| Part 2 | Standard Contractual Clauses (unmodified version) |
| Part 2 – Appendix 1 | Description of data processing operations |
| Part 2 – Appendix 2 | Technical and Organizational Security Measures |

WHEREAS, in the event of inconsistencies between the provisions of this DPA and any other agreements between the Parties, the provisions of this DPA shall prevail with regard to the Parties' data protection obligations. In case of inconsistencies between this DPA and the Standard Contractual Clauses, the Standard Contractual Clauses shall prevail.

**Part 1 - Data Processing Agreement**

1. **Definitions**

For the purposes of this DPA:

| | |
|---|---|
| "**Applicable Data Protection Law**" | shall mean the international and local legislation protecting the fundamental rights and freedoms of individuals and, in particular, their right to privacy with respect to the Processing of Personal Data applicable to Controller and Processor; the term Applicable Data Protection Law shall encompass the GDPR. as of May 25, 2018; |
| "**Controller**" | shall mean the entity that determines as a legal person alone or jointly with others the purposes and means of the Processing of Personal Data; |
| "**General Data Protection Regulation**" or "**GDPR**" | shall mean the Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 on the protection of natural persons with regard to the Processing of Personal Data and on the free movement of such data which will apply as of May 25, 2018; |
| "**Member State**" | shall mean a country belonging to the EU; |
| "**Personal Data**" | shall mean any information relating to an identified or identifiable natural person ("**Data Subject**"); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person; |
| "**Personal Data Breach**" | shall mean a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure, or access to Personal Data transmitted, stored or otherwise Processed; |
| "**Process/Processing**" | shall mean any operation or set of operations which is performed on Personal Data or on sets of Personal Data, whether or not by automated, means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction; |
| "**Processor**" | shall mean PRA who Processes Personal Data on behalf of Controller; |
| "**Special Categories of Data**" | shall mean data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership; genetic data, biometric data Processed for the purpose of uniquely identifying a natural person; data concerning health or data concerning a natural person's sex life or sexual orientation; |

| | |
|---|---|
| "**Standard Contractual Clauses**" | shall mean the Standard Contractual Clauses as adopted by the European Commission and as adapted from time to time. |
| "**Subprocessor**" | shall mean any data processor engaged by Processor who agrees to receive from Processor Personal Data exclusively intended for Processing activities to be carried out on behalf of Controller in accordance with its instructions, the terms of this DPA (including the Standard Contractual Clauses, if applicable) and the terms of the written subcontract; |
| "**Supervisory Authority**" | shall mean an independent public authority which is established by a Member State pursuant to Article 51 of the GDPR; and |
| "**Technical and Organizational Security Measures**" | shall mean those measures aimed at protecting Personal Data against accidental destruction or accidental loss, alteration, unauthorized disclosure or access, in particular where the Processing involves the transmission of data over a network, and against all other unlawful forms of Processing. |

2. **Details of the Processing**

The details of the Processing operation provided by Processor to Controller as appointed Processor (e.g., the subject-matter of the Processing, the nature and purpose of the Processing, the type of Personal Data nod categories of Data Subjects) are specified in Part 1 Annex 1 to this DPA,

3. **Rights and Obligations of Controller**

a. Controller remains the responsible data controller for the Processing of the Personal Data.

b. Controller is entitled to instruct Processor in connection with the Processing of the Personal Data, generally or in the individual case. Instructions may also relate to the correction, deletion, blocking of the Personal Data. Upon request, Controller shall specify its order, instructions and comments more precisely.

4. **Obligations of Processor**

Processor shall:

a. Comply with and act on any written instruction from and on behalf of the Controller regarding the Processing of Personal Data. Such obligation also applies to the transfer of Personal Data to a third country. Processor shall transfer Personal Data to the US via its IT Network. Instructions are provided in the Agreement, this DPA and/or otherwise in documented form.

b. Not Process Personal Data for any other purposes other than to provide the Services to Controller.

c. Immediately notify Controller, where Processor in its opinion believes that an instruction of Controller would result in a violation of Applicable Data Protection Law and request Controller to withdraw, amend or confirm the relevant instruction. Pending the decision on the withdrawal, amendment or confirmation of the relevant instruction, Processor shall be entitled to suspend the implementation of the relevant instruction.

d. Ensure that persons authorized by Processor to Process the Personal Data on behalf of Controller are suitably informed, trained and instructed in respect of Applicable Data Protection Law and have committed themselves in writing to confidentiality or are under an appropriate statutory obligation of confidentiality. Processor will procure that such authorized persons observe any Applicable Data Protection Law beyond their respective employment periods.

e. Implement the Technical and Organizational Security Measures which will meet the requirements of Applicable Data Protection Law as further specified in Annex 2 before Processing the Personal Data and ensure to provide sufficient guarantees to Controller on such Technical and Organizational Security Measures.

f. Assist Controller by appropriate Technical and Organizational Security Measures, insofar as this is possible, for the fulfillment of Controller's obligation to respond to requests for exercising Data Subjects' rights concerning information, access, rectification and erasure, restriction of Processing, notification, data portability, objection and automated decision-making.

g. Take actions requested or instructed by Controller in order to comply with Data Subject's rights under Applicable Data Protection Law. In particular, Processor must provide the information on action taken on such request without undue delay, respectively in a timely manner.

h. Make available to Controller all information necessary to demonstrate compliance with the obligations laid down in this DPA and in Art. 28 GDPR.

i. Allow for and contribute to audits, including inspections conducted by Controller or another auditor mandated by Controller in accordance with the terms of the Agreement as set out therein or as may be otherwise specified.

j. Notify Controller without undue delay:

(i) about any legally binding request for disclosure of the Personal Data by a law enforcement authority, unless otherwise prohibited, such as a prohibition under criminal law to preserve the confidentiality of a law enforcement investigation;

(ii) about any complaints and requests received directly from Data Subjects (e.g., regarding access, rectification, erasure, restriction of Processing, data portability, objection to Processing of data, automated decision-making) without responding to that request, unless it has been otherwise authorized to do so;

(iii) after Processor becomes aware of a Personal Data Breach at Processor or its Subprocessors. In case of such Personal Data Breach, Processor will assist Controller with investigating the Personal Data Breach and Controller's obligation under Applicable Data Protection Law to inform the Data Subjects and the Supervisory Authorities, as applicable, and to document the Personal Data Breach.

k. Assist Controller with any data protection impact assessment and with prior consultation, if any, that relate to the Services provided by Processor to Controller and the Personal Data Processed on behalf of Controller.

5. **Subprocessing**

a. Any subcontract with a third party by which any Services are subcontracted require Controller's prior specific or general written consent and must be concluded in writing, including electronic form.

b. In case of a general written consent from Controller, Processor must inform Controller about any intended changes concerning the addition or replacement of Subprocessors, thereby giving Controller the opportunity to object to such changes,

c. Processor must ensure contractually that with respect to the subcontracted portion of the Services, the Subprocessor has corresponding obligations vis-à-vis Controller, in particular that Subprocessor provides sufficient guarantees to implement appropriate Technical and Organizational Security Measures in such a manner that the Processing will meet the requirements of Applicable Data Protection Law.

d. Where Subprocessor fails to fulfill its data protection obligations, Processor shall remain fully liable to Controller for the performance of the Subprocessor's obligations.

e. Controller shall be entitled to conduct direct audits at Subprocessor and to issue instructions to Subprocessor directly. Controller shall be entitled to request a copy of the subprocessing agreement.

f. Processor shall choose Subprocessor diligently.

6. **Duration and termination**

a. The term of this DPA is identical with the term of the relevant Agreement. Save as otherwise agreed herein, termination rights and requirements shall be the same as set forth in the relevant Agreement.

b. Processor shall, at the choice of Controller, delete or return all Personal Data to Controller after the end of the provision of Services, and shall save one copy as required by EU or equivalent local legislation, in particular the ELI Clinical Trials Regulation 536/2014.

7. **Miscellaneous**

a. A Determination that any provision of the DPA is invalid or unenforceable shall not affect the other provisions of the DPA. In such case the invalid unenforceable provision shall automatically be replaced by a valid and enforceable provision that comes closest to the purpose of the original provision. The same shall apply if the DPA contains an unintended gap.

On behalf of the Controller: Biosight Limited

Name (written out in full): Ruth Ben Yakar

Position: CEO

Address: 1 Hayarden St., Airport City, P.O.B 1083 Lod 701 9802, Israel

Signature: */s/ Ruth Ben Yakar*

Date:

On behalf of the Processor:

Name (written out in full): Chris Gray & Uri-Ben-Or

Position: VP, Operations Finance – Chief Financial Officer

Address: 500 South Oak Way, Green Park, Reading, HG2 GAD

Signature: */s/ Chris Gray - /s/ Uri-Ben-Or*

Date:4 May 2018

**Part 1 – Annex 1 – Details of Data Processing**

**1. The Controller is; Biosight Limited**

Please specify briefly your activities relevant to the transfer:

The Controller is a pharmaceutical company engaged in the discovery, development, manufacturing and sale of therapeutic products and clinical studies.

**2. Tile Processor is: Pharm Research Associates (UK) Limited**

Please specify briefly activities relevant lo the transfer:

The Processor is Contract Research Organization in the business of providing professional and state-of-the-art clinical and medical research services.

**3. Categories of Data Subjects**

The Personal Data transferred concern the following categories of Data Subjects:

Study patient / subject

Investigator / Investigator site staff

**4. Type of Personal Data**

The Personal Data Processed by Processor on behalf of Controller concern the following categories of Personal Data:

- health information
- date of birth, where applicable
- management of (Serious) Adverse Events
- CVs - clinical experience and qualifications
- financial disclosure/transparency requirements

**5. Special Categories of Data (if appropriate)**

The Personal Data Processed by Processor on behalf of Controller concern the following Special Categories of Data:

Key-coded/pseudonymised health related data of patients.

**6. Processing Operations**

The personal data transferred will be subject to the following basic processing activities (please specify)

Processing of personal data associated with the management of, and scientific analysis for clinical trials and samples.

**Part 1 - Annex 2 - Technical and Organizational Security Measures**

Description of the Technical and Organizational Security Measures implemented by Processor in accordance with Applicable Data Protection Law:

This Annex describes the Technical and Organizational Security Measures and procedures that Processor shall, as a minimum, maintain to protect the security of Personal Data created, collected, received, or otherwise obtained.

Access Control of Processing Areas

Processor implements suitable measures in order to prevent unauthorized persons from gaining access to the data processing equipment where the Personal Data is Processed. This is accomplished by;

- establishing security areas;
- securing the data processing equipment;
- establishing access authorizations for staff and third parties, including the respective documentation;
- access to data centres is logged and monitored; and
- data centres are protected by appropriate security measures.

Access Control to Data Processing Systems

Processor implements suitable measures to prevent its data processing systems from being used by unauthorized persons. This is accomplished by:

- identification of the terminal and/or the terminal user to the Processor systems;
- automatic time-out of user terminal if left idle, identification and password required to reopen;
- automatic turn-off of the user ID when several erroneous passwords are entered, log file of events (monitoring of break-in-attempts);
- issuing and safeguarding of access/identification codes;
- staff policies and training in respect of each staff access rights to Personal Data (if any), informing staff about their obligations; and
- utilisation of audit trail.

Access Control to Use Specific Areas of Data Processing Systems

Processor commits that the persons entitled to use its data processing system are only able to access the data within the scope and to the extent covered by its access permission (authorization) and that Personal Data cannot be read, copied or modified or removed without authorization. This shall be accomplished by:

- staff policies and training in respect of each staff member’s access rights to the Personal Data;
- allocation of individual user accounts;
- utilisation of audit trail;
- release of data to only authorized persons; and
- control of files, controlled and documented destruction of data

Availability Control

Processor implements suitable measures to ensure that Personal Data are protected from accidental destruction or loss. This is accomplished by;

- infrastructure redundancy; and
- data redundancy via data backup;

Transmission Control

Processor implements suitable measures to prevent the Personal Data from being read, copied, altered or deleted by unauthorized parties during the transmission thereof or during the transport of the data media. This is accomplished by:

- use of appropriate firewall and encryption technologies; and
- as far as possible, all data transmissions are logged and monitored

Input Control

Processor implements suitable measures to ensure that it is possible to check and establish whether and by whom Personal Data have been input into data processing systems or removed. This is accomplished by:

- an authorization policy for the input of data, as well as for the reading, alteration and deletion of stored data (role based access management rules);
- authentication of the authorized personnel;
- utilization of user codes (passwords);
- all users who have access to Personal Data shall reset their passwords as specified in the relevant password policy; and
- areas housing the computer hardware and related equipment are capable of being locked.

Processor System Administrators

Processor implements suitable measures to monitor its system administrators and to ensure that they act in accordance with instructions received. This is accomplished by;

- individual appointment of system administrators;
- adoption of suitable measures to register system administrators' access logs and keep them secure, accurate and unmodified for a reasonable period; and
- keeping an updated list with system administrators' identification details (e.g. name, surname, function or organizational area) and tasks assigned.

Separation of Processing for Different Purposes

Processor implements suitable measures to ensure that data collected for different purposes and different clients can be Processed separately. This is accomplished by:

- access to data is separated through application security for the appropriate users; and
- modules within Processor's database separate which data is used for which purpose, i.e. by functionality and function;

**Part2 - Standard Contractual Clauses**

For the purposes of Article 26(2) of Directive 95/46/EC for the transfer of personal data to processors established in third countries which do not ensure an adequate level of data protection

**Clause 1 Definitions**

For the purpose of the Clauses:

(a) “personal data”, “special categories of data”, “process/processing”, ‘‘controller”, “processor”, “data subject” and “supervisory authority” shall have the same meaning as in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data;

(b) “the data exporter” means the controller who transfers the personal data;

(c) “the data importer” means the processor who agrees to receive from the data exporter personal data intended for processing on his behalf after the transfer in accordance with his instructions and the terms of the Clauses and who is not subject to a third country’s system ensuring adequate protection within the meaning of Article 25(1) of Directive 95/46/EC;

(d) “the sub-processor” means any processor engaged by the data importer or by any other sub-processor of the data importer who agrees to receive from the data importer or from any other sub-processor of the data importer personal data exclusively intended for processing activities to be carried out on behalf of the data exporter after the transfer in accordance with his instructions, the terms of the Clauses and the Lerma of the written subcontract;

(e) “the applicable data protection law” means the legislation protecting the fundamental rights and freedoms of individuals and, in particular, their right to privacy with respect to the processing of personal data applicable to a data controller in the Member Stale in which the data exporter is established;

(f) ‘‘technical and organisational security measures” means those measures aimed at protecting personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, in particular where the processing involves the transmission of data over a network, and against all other unlawful forms of processing.

**Clause 2 Details of the transfer**

The details of the transfer and in particular the special categories of personal data where applicable are specified in Appendix I which forms an integral part of the Clauses.

**Clause 3 Third-party beneficiary clause**

1. The data subject can enforce against the data exporter this Clause, Clause 4(b) to (i), Clause 5(a) to (c), and (g) to (j), Clause 6(1) and (2), Clause 7, Clause 8(2), and Clauses 9 to 12 as third-party beneficiary.

2. The data subject can enforce against the data importer this Clause, Clause 5(a) to (e) and (g), Clause 6, Clause 7, Clause 8(2), and Clauses 9 to 12, in cases where the data exporter has factually disappeared or has censed to exist in law unless any successor entity has assumed the entire legal obligations of the data exporter by contract or by operation of law, as a result of which it takes on the rights and obligations of the data exporter, in which case the data subject can enforce them against such entity.

3. The data subject can enforce against the sub-processor this Clause, Clause 5(a) to (e) and (g), Clause 6, Clause 7, Clause 8(2), and Clauses 9 to 12, in cases where both the data exporter and the data importer have factually disappeared or ceased to exist in law or have become insolvent, unless any successor entity has assumed the entire legal obligations of the data exporter by contract or by operation of law as a result of which it takes on the rights and obligations of the data exporter, in which case the data subject can enforce them against such entity. Such third-party liability of the sub-processor shall be limited to its own processing operations under the Clauses.

4. The parties do not object to a data subject being represented by an association or other body of the data subject so expressly wishes and if permitted by national law.

**Clause 4 Obligations of the data exporter**

The data exporter agrees and warrants:

(a) that the processing, including the transfer itself, of the personal data has been and will continue to be carried out in accordance with the relevant provisions of the applicable data protection law (and, where applicable, has been notified to the relevant authorities of the Member State where the data exporter is established) and does not violate the relevant provisions of that State;

(b) that it has instructed and throughout the duration of the personal data processing services will instruct the data importer to process the personal data transferred only on the data exporter's behalf and in accordance with the applicable data protection law and the Clauses;

(c) that the data importer will provide sufficient guarantees in respect of the technical and organisational security measures specified in Appendix 2 to this contract;

(d) that after assessment of the requirements of the applicable data protection law, the security measures are appropriate to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, in particular where the processing involves the transmission of data over a network, and against all other unlawful forms of processing, and that these measures ensure a level of security appropriate to the risks presented by the processing and the nature of the data to be protected having regard to the state of the art and the cost of their implementation;

(e) that it will ensure compliance with the security measures;

(f) that, if the transfer involves special categories of data, the data subject has been informed or will be informed before, or as icon as possible after, the transfer that its data could be transmitted to a third country not providing adequate protection within the meaning of Directive 95/46/EC;

(g) to forward any notification received from the data importer or any sub-processor pursuant to Clause 5(b) and Clause 8(3) to the data protection supervisory authority if the data exporter decides to continue the transfer or to lift the suspension;

(h) to make available to the data subjects upon request a copy of the Clauses, with the exception of Appendix 2, and a summary description of the security measures, as well as a copy of any contract for subprocessing services which has to be mode in accordance with the Clauses, unless the Clauses or the contract contain commercial information, in which case it may remove such commercial information;

(i) that, in the event of subprocessing, the processing activity is carried out in accordance with Clause 11 by a sub-processor providing at least the same level of protection for the personal data and the rights of data subject as the data importer under the Clauses; and

(j) that it will ensure compliance with Clause 4(a) to (i).

**Clause 5 Obligations of the data Importer**

The data importer agrees and warrants:

(a) to process the personal data only on behalf of the data exporter and in compliance with its instructions and the Clauses; if it cannot provide such compliance for whatever reasons, it agrees to inform promptly the data exporter of its inability to comply, in which case the data exporter is entitled to suspend the transfer of data and/or terminate the contract;

(b) that it has no reason to believe that the legislation applicable to it prevents it from fulfilling the instructions received from the data exporter and its obligations under the contract and that in the event of a change in this Legislation which is likely to have a substantial adverse effect on the warranties and obligations provided by the Clauses, it will promptly notify the change to the data exporter as soon as it is aware, in which case the data exporter is entitled to suspend the transfer of data and/or terminate the contract;

(c) that it has implemented the technical and organisational security measures specified in Appendix 2 before processing the personal data transferred;

(d) that it will promptly notify the data exporter about:

(i) any legally binding request for disclosure of the personal data by a law enforcement authority unless otherwise prohibited, such as a prohibition under criminal law to preserve the confidentiality of a law enforcement investigation,

(ii) any accidental or unauthorised access, and

(iii) any request received directly from the data subjects without responding to that request, unless it has been otherwise authorised to do so;

(e) to deal promptly and properly with all inquiries from the data exporter relating to its processing of the personal data subject to the transfer and to abide by the advice of the supervisory authority with regard to the processing of the data transferred:

(f) at the request of the data exporter to submit its data processing facilities for audit of the processing activities covered by the Clauses which shall be carried out by the data exporter or an inspection body composed of independent members and in possession of the required professional qualifications bound by a duty of confidentiality, selected by the data exporter, where applicable, in agreement with the supervisory authority;

(g) to make available to the data subject upon request a copy of the Clauses, or any existing contract for subprocessing, unless the Clauses or contract contain commercial information, in which case it may remove such commercial information, with the exception of Appendix 2 which shall be replaced by a summary description of the security measures in those cases where the data subject is unable to obtain a copy from the data exporter.

(h) that, in the event of subprocessing, it has previously informed the data exporter and obtained its prior written consent;

(i) that the processing services by the sub-processor will be carried out in accordance with Clause 11;

(j) to send promptly a copy of any sub-processor agreement it concludes under the Clauses to the data exporter.

**Clause 6 Liability**

1. The parties agree that any data subject, who has suffered damage as a result of any breach of the obligations referred to in Clause 3 or in Clause 11 by any party or sub-processor is entitled to receive compensation from the data exporter for the damage suffered.

2. If a data subject is not able to bring a claim for compensation in accordance with paragraph 1 against the data exporter, arising out of a breach by the data importer or his sub-processor of any of their obligations referred to in Clause 3 or in Clause 11. because foe data exporter has factually disappeared or ceased to exist in law or has become insolvent, the data importer agrees that the data subject may issue a claim against the data importer as if it were the data exporter, unless any successor entity has assumed the entire legal obligations of the data exporter by contract or by operation of law, in which case the data subject can enforce its rights against such entity.

   The data importer may not rely on a breach by a sub-processor of its obligations in order to avoid its own liabilities.

3. If a data subject is not able to bring a claim against the data exporter or the data importer referred to in paragraphs 1 and 2, arising out of a breach by the sub-processor of any of their obligations referred to in Clause 3 or in Clause 11 because both the data exporter and the data importer have factually disappeared or ceased to exist in law or have become insolvent, the sub-processor agrees that the data subject may issue a claim against the data sub-processor with regard to its own processing operations under the Clauses as if it were the data exporter or the data importer, unless any successor entity has assumed the entire legal obligations of the data exporter or data importer by contract or by operation of law, in which case the data subject can enforce its rights against such entity. The liability of the sub-processor shall be limited to its own processing operations under the Clauses.

**Clause 7 Mediation and jurisdiction**

1. The data importer agrees that if the data subject invokes against it third-party beneficiary rights and/or claims compensation for damages under the Clauses, the data importer will accept the decision of the data subject:

   (a) to refer the dispute to mediation, by an independent person or, where applicable, by the supervisory authority;

   (b) to refer the dispute to the courts in the Member State in which the data exporter is established.

2. The parties agree that the choice made by the data subject will not prejudice its substantive or procedural rights to seek remedies in accordance with other provisions of national or international law.

**Clause 8 Cooperation with supervisory authorities**

1. The data exporter agrees to deposit a copy of this contract with the supervisory authority if it so requests of if such deposit is required under the applicable data protection law.

2. The parties agree that (the supervisory authority has the right to conduct an audit of the data importer, and of any sub-processor, which has the same scope and is subject to the same conditions as would apply to an audit of the data exporter under the applicable data protection law.

3. The data importer shall promptly inform the data exporter about the existence of legislation applicable to it or any sub-processor preventing the conduct of an audit of the data importer, or any sub-processor, pursuant to paragraph 2. In such a case the data exporter shall be entitled to take the measures foreseen in Clause 5 (b).

**Clause 9 Governing Law**

The Clauses shall be governed by the law of the Member State in which the data exporter is established.

**Clause 10 Variation of the contract**

The parties undertake not to vary or modify the Clauses. This does not preclude the parties from adding clauses on business related issues where required as long as they do not contradict the Clause.

**Clause 11 Subprocessing**

1. The data importer shall not subcontract any of its processing operations performed on behalf of the data exporter under the Clauses without the prior written consent of the data exporter, Where the data importer subcontracts its obligations under the Clauses, with the consent of the data exporter, it shall do so only by way of a written agreement with the sub-processor which imposes the same obligations on the sub-processor as arc imposed on the data importer under the Clauses. Where the sub-processor fails to fulfil its data protection obligations under such written agreement the data importer shall remain fully liable to the data exporter for the performance of the sub-processor's obligations under such agreement.

2. The prior written contract between the data importer and the sub-processor shall also provide for a third-party beneficiary clause as laid down in Clause 3 for cases where the data subject is not able to bring the claim for compensation referred to in paragraph 1 of Clause 6 against the data exporter or the data importer because they have factually disappeared or have ceased to exist in law or have become insolvent and no successor entity has assumed the entire legal obligations of the data exporter or data importer by contract or by operation of law. Such third-party liability of the sub-processor shall be limited to its own processing operations under the Clauses,

3. The provisions relating to data protection aspects for subprocessing of the contract referred to in paragraph 1 shall be governed by the law of the Member State in which the data exporter is established.

4. The data exporter shall keep a list of subprocessing agreements concluded under the Clauses and notified by the data importer pursuant to Clause 5(j), which shall be updated at least once a year. The list shall be available to the data exporter's data protection supervisory authority.

**Clause 12 Obligation after the termination of personal data processing services**

1. The parties agree that on the termination of the provision of data processing services, the data importer and the sub-processor shall, at the choice of the data exporter, return all the personal data transferred and the copies thereof to the data exporter or shall destroy all the personal data and certify to the data exporter that it has done so, unless legislation imposed upon the data importer prevents it from returning or destroying all or part of the personal data transferred. In that case, the data importer warrants that it will guarantee the confidentiality of the personal data transferred and will not actively process the personal data transferred anymore.

2. The data importer and the sub-processor warrant that upon request of the data exporter and/or of the supervisory authority, it will submit its data processing facilities for an audit of the measures referred to in paragraph 1.

**Signatures:**

**On behalf of the data exporter: Biosight Limited**

*/s/ Ruth Ben Yakar*
Name (written out in full): Ruth Ben Yakar
Position: CEO
Address. 1 Hayarden St., Airport City, P.O.B 1083 Lod 7019802, Israel
Other Information necessary in order for the contract to be binding (If any):

Signature_____
**(stamp of organization)**

**On behalf of the data exporter: Importer: Pharm Research Associates (UK) Limited**

*/s/ Chris Gray - /s/ Uri-Ben-Or*
Name (written out in full): Chris Gray – Uri-Ben-Or
Position: VP, Operations Finance – Chief Financial Officer
Address: 500 South Oak Way, Green Park, Reading, Berkshire RO2 SAD
Other Information necessary in order for the contract to be binding (If any):

Signature_____
**(stamp of organization)**

**Part 2 - Appendix 1**

**This Appendix forms part of the Clauses and must be completed and signed by the parties.**

**Data exporter**

The data exporter is: Biosight Limited
(please specify briefly your activities relevant to the transfer):

The data exporter is a pharmaceutical company engaged in the discovery, development, manufacturing and sale of therapeutic products and clinical studies.

**Data importer**

The data importer is: Pharm Research Associates (UK) Limited
(please specify briefly activities relevant to the transfer):

The data importer is Contract Research Organization in the business of providing professional and state-of-the-art clinical and medical research services.

**Data subjects**

The personal data transferred concern the following categories of data subjects:

Study patient / subject

Investigator / investigator site staff

**Categories of data**

The personal data transferred concern the following categories of data:

- Health information
- Date of birth, where applicable
- Management of (Serious) Adverse Events in compliance with applicable data protection law
- CV - clinical experience and qualifications
- Financial disclosure/transparency requirements

**Special categories of data (if appropriate)**

The personal data transferred concern the following special categories of data:

Key-coded/pseudonymised health related data of patients.

**Processing operations**

The personal data transferred will be subject to the following basic processing activities (please specify):

Processing of personal data associated with the management of, and scientific analysis for clinical trials and samples.

**Signatures:**

**On behalf of the data exporter: Biosight Limited**

*/s/ Ruth Ben Yakar*
Name (written out in full): Ruth Ben Yakar
Position: CEO
Address. 1 Hayarden St., Airport City, P.O.B 1083 Lod 7019802, Israel
Other Information necessary in order for the contract to be binding (If any):

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*/s/ Chris Gray – /s/ Uri-Ben-Or*
Name (written out in full): Chris Gray – Uri-Ben-Or
Position: VP, Operations Finance – Chief Financial Officer
Address: 500 South Oak Way, Green Park, Reading, Berkshire RO2 SAD
Other Information necessary in order for the contract to be binding (If any):

Signature_____
**(stamp of organization)**

**Part 2 - Appendix 2**

This Appendix forms part of the Clauses and must be completed and signed by the parties.

Description of the technical and organizational security measures implemented by the data importer in accordance with Clauses 4(d) and 5(c).

**Access Control of Processing Areas**

Data importer implements suitable measures in order to prevent unauthorized persons from gaining access to the data processing equipment where the Personal Data is Processed. This is accomplished by:

- establishing security areas;
- securing the data processing equipment;
- establishing access authorizations for staff and third parties, including the respective documentation;
- access to data centres is logged and monitored; and
- data centres are protected by appropriate security measures.

**Access Control to Data Processing Systems**

Data importer implements suitable measures to prevent its data processing systems from being used by unauthorized persons. This is accomplished by:

- identification of the terminal and/or the terminal user to the data importer systems;
- automatic time-out of user terminal if left idle, identification and password required to reopen;
- automatic turn-off of the user ID when several erroneous passwords arc entered, log file of events (monitoring of break-in-attempts);
- issuing and safeguarding of access/identification codes;
- staff policies and training in respect of each staff access rights to Personal Data (if any), informing staff about their obligations; and
- utilisation of audit trail.

**Access Control to Use Specific Areas of Data Processing Systems**

Data importer commits that the persons entitled to use its data processing system are only able to access the data within the scope and to the extent covered by its access permission (authorization) and that Personal Data cannot be read, copied or modified or removed without authorization. This shall be accomplished by;

- staff policies and training in respect of each staff member’s access rights to the Personal Data;
- allocation of individual user accounts;
- utilisation of audit trail;
- release of data to only authorized persons; and
- control of files, controlled and documented destruction of data

**Availability Control**

Data importer implements suitable measures to ensure that Personal Data are protected from accidental destruction or loss. This is accomplished by:

- infrastructure redundancy; and
- data redundancy via data backup;

**Transmission Control**

Data importer implements suitable measures to prevent the Personal Data from being read, copied, altered or deleted by unauthorized parties during the transmission thereof or during the transport of the data media. This is accomplished by:

- use of appropriate firewall and encryption technologies; and
- as far as possible, all data transmissions arc logged and monitored

**Input Control**

Data importer implements suitable measures to ensure that it is possible to check and establish whether and by whom Personal Data have been input into data processing systems or removed. This is accomplished by:

- an authorization policy for the input of data, as well as for the reading, alteration and deletion of stored data (role based access management rules);
- authentication of the authorized personnel;
- utilization of user codes (passwords);
- all users who have access to Personal Data shall reset their passwords as specified in the relevant password policy; and
- areas housing the computer hardware and related equipment are capable of being locked.

**Data Importer System Administrators**

Data importer implements suitable measures to monitor its system administrators and to ensure that they act in accordance with instructions received. This is accomplished by:

- individual appointment of system administrators;
- adoption of suitable measures to register system administrators' access logs and keep them secure, accurate and unmodified for a reasonable period; and
- keeping an updated list with system administrators' identification details (e.g. name, surname, function or organizational area) and tasks assigned.

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Data importer implements suitable measures to ensure that data collected for different purposes and different clients can be Processed separately. This is accomplished by:

- access to data is separated through application security for the appropriate users; and
- modules within data importer's database separate which data is used for which purpose, i.e. by functionality and function;

**On behalf of the data exporter: Biosight Limited**

*/s/ Ruth Ben Yakar*
Name (written out in full): Ruth Ben Yakar
Position: CEO
Address. 1 Hayarden St., Airport City, P.O.B 1083 Lod 7019802, Israel
Other Information necessary in order for the contract to be binding (If any):

Signature_____
**(stamp of organization)**

**On behalf of the data exporter: Importer: Pharm Research Associates (UK) Limited**

*/s/ Chris Gray - /s/ Uri-Ben-Or*
Name (written out in full): Chris Gray – Uri-Ben-Or
Position: VP, Operations Finance – Chief Financial officer
Address: 500 South Oak Way, Green Park, Reading, Berkshire RO2 SAD
Other Information necessary in order for the contract to be binding (If any):

Signature_____
**(stamp of organization)**

**Exhibit 10.42**

**AMENDMENT #1**
**TO THE**
**MASTER AGREEMENT FOR CLINICAL TRIALS MANAGEMENT SERVICES**

This **Amendment #1** ("Amendment"), effective as of the 20th day of November, 2020, (the "Amendment Effective Date"), by and between **Pharmaceutical Research Associates, Inc**., together with its Affiliates, with offices at 4130 ParkLake Avenue, Suite 400, Raleigh, NC 27612, USA (hereinafter referred to as "PRA") and **Biosight Ltd.**, with offices at 1 Hayarden St., Airport City, P.O.B 1083 Lod 7019802, Israel (hereinafter referred to as "Sponsor"), both hereinafter referred as "Parties".

***W I T N E S S E T H:***

**WHEREAS,** under the terms of a certain Master Agreement for Clinical Trials Management Services, entered into on May 3, 2018 and effective as of November 20, 2017, (hereinafter the "Agreement") by and between the Parties, Sponsor agreed to retain PRA and PRA agreed to be retained by Sponsor, to perform the Services as more particularly described in the Agreement; and

**WHEREAS**, the Parties hereto have entered into certain additional agreements with respect to modification of the Agreement, and which they desire to memorialize in this Amendment.

**NOW THEREFORE**, in consideration of the premises and of the following mutual promises, covenants and conditions set forth herein, the Parties hereto agree as follows:

1. Section 4.1 of the Agreement is hereby amended to read in its entirety as follows:

"**4.1 Term**

Unless earlier terminated, this Agreement will commence on the Effective Date, and shall continue until November 20, 2021. In the event of an expiration or termination of this Agreement, any outstanding Task Order will continue until completion of the Services described in such Task Order or appropriate termination of the Task Order."

2. Miscellaneous

a. **Full Force and Effect.** Except as expressly amended by this Amendment, the Agreement shall continue in full force and effect as provided therein.

b. **Entire Agreement of the Parties.** This Amendment and the Agreement, constitutes the complete, final, and exclusive understanding and agreement of the Parties hereto, and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties respecting the subject matter hereof.

c. **Counterparts.** This Amendment may be executed in separate counterparts, each of which when so executed and delivered shall be a legally-binding original and all such counterparts shall together constitute one and the same instrument, binding on all Parties, notwithstanding that each of the Parties may have signed different counterparts. The Parties agree that delivery of an executed counterpart signature hereof by electronic mail in "portable document format" (".pdf") form, or by any other electronic means intended to preserve the original graphic and pictorial appearance of a document, will have the same effect as physical delivery of the paper document bearing the original signature.

IN WITNESS WHEREOF, the Parties have executed this Amendment by their authorized representatives as of the first date set forth above.

**ACCEPTED AND AGREED:**

| | |
|---|---|
| Biosight Ltd. | Pharmaceutical Research Associates, Inc. |
| By: */s/ Ruth Ben Yakar* | By: */s/ Wolfgang Michael* |
| Signature | Signature |
| Name: Ruth Ben Yakar | Name: Wolfgang Michael |
| Please Print Name | Please Print Name |
| Title: CEO | Title: VP Operations Finance |
| Date: July 22, 2021 | Date: July 22, 2021 |

# MASTER SERVICES AGREEMENT

This Master Services Agreement ("Agreement") is made and entered into as of June 16, 2017 (the "Effective Date"), by and between Albany Molecular Research, Inc., having its principal place of business at 26 Corporate Circle, Albany, New York 12203 (together with its Affiliates hereinafter collectively referred to as "AMRI") and BioSight Ltd., a company incorporated under the laws of Israel, having its principal place of business at 1 Hayarden St., Airport City, Lod 7019802, Israel (hereinafter "Customer") (AMRI and Customer hereinafter referred to as "the Parties").

WHEREAS, AMRI is engaged in the business of providing drug discovery, development and manufacturing services including synthetic and natural product chemical research and analysis, bio-assay development and screening, chemistry and bioscience consulting, medicinal chemical synthesis, computational chemistry services, parallel synthesis, manufacturing of specialty chemical products, process development, synthesis of compounds in accordance with current Good Manufacturing Practices ("cGMP"), analytical method development, validation, and release testing, stability studies, and related scientific services, (the "Services");

WHEREAS, Customer is engaged in the business of the discovery, development, manufacture and commercialization of pharmaceutical or other chemical products, and proposes to retain AMRI for the specific purpose of providing chemical research, compound synthesis and analysis, manufacturing of specialty chemical products and/or other related scientific Services which AMRI may offer.

NOW, THEREFORE, for the mutual promises set forth below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby further agree as follows:

1. AMRI Services.

A. AMRI agrees to provide Customer with Services of a nature as described generally above, and specifically in the proposals/Work Orders attached hereto. Such Work Orders will specify the scope of work to be undertaken, the conditions and timing under which work is to be completed, the amount of and payment terms for Services, and/or delivery terms. Each Work Order shall be dated, numbered, reference this Agreement, and shall be valid only upon signature of an authorized representative of each Party. Should any of the terms of any Work Order conflict with the general terms and conditions of this Agreement, the terms and conditions of this Agreement shall govern, unless otherwise explicitly stated in the Work Order. In the event any provision contained in this Agreement conflicts with any part of a purchase order provided by Customer for Services under this Agreement, the provision set forth in this Agreement shall take precedence and AMRI hereby specifically rejects any additional terms and/or conditions contained in any such purchase order.

B. AMRI shall, as applicable to and designated in, any given Work Order;

i. Provide technical consultation, technical assistance and product development assistance, as defined, for any Services entered into.

ii. Provide to Customer Certificates of Analysis to include, as appropriate, parameters such as elemental analysis, optical rotation, HPLC analysis, MS, TGA, moisture content by Karl Fischer titration, and NMR spectra on any compounds provided, and any additional parameters to support development, manufacturing and specifications set forth in an applicable Work Order.

iii. Comply with all applicable current governmental regulatory requirements, including but not limited to those contained in the U.S. Food, Drug and Cosmetic Act and the regulations promulgated pursuant thereto, all relevant U.S. environmental regulations, and perform experiments using standard and accepted cGMPs as specified in International Conference on Harmonization ("ICH") guide Q7 "ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients," as applied to the manufacture, testing, and quality control of Active Pharmaceutical Ingredients ("API"); and any regulatory requirements of the EU to the extent applicable.

iv. Provide written research reports to Customer describing full experimental procedures, analyses, data and results conducted and obtained in the performance of the Services ("Results"), in accordance with the procedures and timelines in the Work Order;

v. Retain experimental records, laboratory notebooks or laboratory notebook pages containing Results for not less than seven (7) years. After this time period, upon Customer's written request and at Customer's sole expense, AMRI shall provide to Customer: for non-cGMP projects, copies of applicable specific laboratory notebooks, laboratory notebook pages or other documentation, as mutually agreed upon in writing by the Parties, for retention in Customer's archives; and for cGMP projects, copies of executed batch records, deviation reports, investigation reports and analytical testing results of APIs or drug product or other documentation as mutually agreed upon in writing by the Parties. At AMRI, all such records will be maintained in accordance with AMRI's notebook policy, and in a secure area reasonably protected from fire, theft and destruction.

vi. Conform Deliverables (as defined in **Section 6(B)** of this Agreement) to the specifications of the Work Order and any material modifications to the Work Order as may be mutually agreed by the Parties.

C. AMRI will conform to its obligations identified herein and/or in the Work Order. Although no anticipated delays or limits in performing any Services are expected, if such delays or limits are encountered, AMRI shall promptly notify Customer. The Parties acknowledge that circumstances beyond the control of AMRI may affect the projected completion date. For the purpose of this Agreement, such circumstances include the suppliers' ability to meet AMRI's requirements in the event that such inability is not reasonably foreseeable at the time of execution of the Work Order. Customer agrees to use reasonable efforts to accommodate any reasonable change in timetables as a result of such delays. In the case of a Work Order for research chemistry Services, or registration or validation batches of compounds, or other Services involving experimental synthesis and/or scale-up of compounds (including all batches of product manufactured prior to the establishment of a validated manufacturing process), Customer acknowledges that specific results are unable to be guaranteed, and until the process is optimized and validated, there is no assurance that the results or the yield of the end product of a batch will be exactly as set forth in the batch record or Work Order, nor be exactly according to the product specifications, and may require re-work or reprocessing. With respect to such Services, Customer hereby acknowledges and agrees that so long as AMRI performs the Services in accordance with the procedures set forth in the master batch record and the applicable Work Order, Customer is obligated to pay for the Services performed.

D. Subject to **Section 1(C),** Customer may reject a batch of product solely if such batch materially fails to conform to the agreed specifications after the establishment of a validated manufacturing process. In such an event, Customer must notify AMRI in writing of its rejection within 30 days of delivery of the batch records or thirty days from the notification of availability of quality control samples for testing (if applicable), whichever is the later ("Notice Period"). The notice of rejection by Customer shall specify reasons for rejection and be accompanied by analyses or other documentation evidencing such reasons for rejection. Within thirty (30) days of receiving a notice of rejection, AMRI shall respond stating whether (i) it accepts the rejection, or (ii) it disputes the rejection, in which case the Parties shall elevate such dispute to senior executives for good faith negotiation as to whether the rejection is justified. If after good faith negotiation no mutual agreement is reached, the Parties shall refer such dispute to a mutually acceptable independent third party laboratory as an arbitrator with the appropriate expertise to assess the conformity or non-conformity of the rejected product to specifications at the time of Delivery. To supply data to such arbitrator, each Party will submit a sample of the product (in the case of AMRI a retained sample will be submitted), to a single independent qualified laboratory, mutually agreed upon by the Parties, for analysis and a determination whether, at the time of Delivery, the product complied with the specifications. Resulting data and analysis shall be provided to the arbitrator and to each Party. Both Parties shall be bound by the results of the independent arbitrator's review, the cost of which will be borne by the Party against whom the arbitrator rules. If such arbitrator determines that Customer's rejection of product was incorrect, Customer shall purchase and pay for both the initially rejected product and any replacement product produced at Customer's request. In the event that arbitrator rules that Customer rightfully rejected a batch of product, Customer shall have, in its sole discretion, the right to either replace as soon as possible the rejected portion of the batch, to re-work the product to specifications or to refund a pro rata portion of the amount paid by Customer with respect to such batch based on the percentage of such batch that is unusable. Notwithstanding any other provision of the Agreement, the remedy under the foregoing sentence shall be Customer's sole and exclusive remedy for failure of product to meet the requirements as set forth herein (provided however, that such limitation shall not derogate from Customer's right to seek any applicable remedy in the event of a third party claim against the Customer in connection with the foregoing).

2. Specific Obligations of Customer.

If applicable, Customer shall, as shall be explicitly stated in any given Work Order: (i) provide assistance to AMRI such as is deemed appropriate; (ii) provide Customer Materials (as defined herein) as necessary for AMRI to provide the Services; and (iii) comply with the payment terms of this Agreement and each Work Order.

3. Confidential Information.

A. With respect to any and all information disclosed by one Party (the "Disclosing Party") to the other Party (the "Receiving Party") and indicated as or marked as confidential at the time of disclosure, including oral information, which may include but not be limited to chemical synthesis or process data, proprietary chemicals, research reports, preclinical and clinical data and program results or any other information or data acquired or generated by the Disclosing Party as a result of this Agreement or from performance of the Services to be rendered hereunder (collectively "Confidential Information"), Receiving Party agrees that it will not, and will not permit any of its employees, consultants or representatives to: use said information other than for the purposes permitted under this Agreement; disclose any of said information to a third Party except as required for the purposes of this Agreement; or publish or submit for publication Confidential Information without Disclosing Party's prior written approval.

B. The Receiving Party's obligations with regard to Confidential Information shall continue for a period of ten (10) years from the termination of this Agreement.

C. The foregoing obligations shall not apply to the following:

i. information which is or lawfully becomes generally available to the public through no fault of Receiving Party. Provided that no combination or compilation of information will be deemed to be excluded form Confidential Information status, even if some or all of its component parts are generally available to the public, unless the combination or compilation itself is generally available to the public;

ii. information which is lawfully acquired by Receiving Party from third Parties who have a right to disclose the information;

iii. information which is developed by Receiving Party independently and without use of Disclosing Party's Confidential Information; and

iv. information that Receiving Party is legally required to disclose at the request of a legal or governmental agency or entity.

D. Confidential Information shall remain the property of Disclosing Party. Upon the written request of Disclosing Party, all tangible Confidential Information, including all copies thereof, shall be promptly destroyed or delivered to Disclosing Party, except that the Receiving Party may retain one (1) copy of the Confidential Information to ensure compliance hereunder.

E. Notwithstanding the provisions of Section 13 below, since a breach by Receiving Party of any of the confidentiality obligations set forth herein may result in irreparable and continuing damage to the Disclosing Party for which there may be no adequate remedy at law, Disclosing Party shall be entitled to seek injunctive relief and/or a decree for specific performance, and such other relief as may be proper in any competent court worldwide.

Terms of the Agreement. Neither Party shall disclose to any third party or to the public generally the terms or the existence of this Agreement without prior written consent of the other Party; provided that either Party may disclose such terms if required pursuant to applicable securities or other laws, rules and regulations and as part of a due diligence inquiry to an actual or potential investor provided that such recipient is subject to customary, written confidentiality obligations no less stringent than the confidentiality obligations imposed hereunder.

4. Term and Termination.

A. This Agreement shall terminate the later of: (i) three (3) years from the Effective Date ("Term"); or (ii) the date on which all Work Orders commenced prior to the third anniversary of the Effective Date are completed, unless earlier terminated by either Party in accordance with the provisions of this Section, or extended by mutual written agreement.

B. Sections 3B, 4, 5, 6, 8, 9, 10, 12, 13 and 15 hereof, shall survive the expiration or termination of this Agreement.

C. This Agreement may be terminated prior to the expiration of the Term only under the following conditions:

i. By Customer, if AMRI materially breaches any of the covenants and agreements under this Agreement, upon written notice to AMRI and if AMRI fails to cure such breach within thirty (30) days after written notice of such breach to AMRI.

ii. By AMRI, if Customer materially breaches any of the covenants and agreements under this Agreement, including but not limited to its payment obligations hereunder, upon written notice to Customer and if Customer fails to cure such breach within thirty (30) days after written notice of such breach to Customer.

iii. Either Party may immediately terminate this Agreement or any Work Order by a written notice in the event that the other Party: (a) becomes insolvent or shall make or seek to make an arrangement with, or an assignment for the benefit of, creditors; (b) proceedings in voluntary or involuntary bankruptcy shall be instituted by, on behalf of, or against the other Party; or (c) a receiver or trustee of the property of the other Party shall be appointed. In such instances, if AMRI is the terminating Party then AMRI shall not be obligated to complete any work in progress.

D. Effect of Termination: In the event of any termination or expiration of this Agreement, AMRI shall be entitled to payment for (a) Deliverables previously delivered to Customer, (b) completed or in process Services or Deliverables not yet delivered, and (c) any actual costs and non-cancellable costs incurred by AMRI and are previously set forth in the applicable Work Order.

5. Communications and Payments.

A. Communications: All notices, requests, demands, waivers and other communications required or
permitted to be given under this Agreement shall be in writing and may be given in the following methods:
personal delivery, registered or certified mail, postage prepaid, return receipt requested, or courier service with delivery confirmation. Notices shall be sent to the appropriate Party at its address given below (or at such other address for such Party as shall be specified by notice given hereunder):

| | |
|---|---|
| To AMRI: | Legal Department<br>Albany Molecular Research, Inc.<br>26 Corporate Circle |
| To Customer: | Albany, New York 12203<br>1 Hayarden St.,<br>Airport City, Lod 7019802, |
| With a copy to: | Israel.<br>Attn: Yuval Horn, Adv.<br>Amot Investments Tower<br>2 Weizmann St., 24th Floor<br>Tel-Aviv 6423902,<br>Israel. |

B. Payments: In consideration of the performance of Services by AMRI, Customer shall pay AMRI the fees for such Services as set forth in the corresponding Work Order. For all payments due in connection with this Agreement, Customer agrees to submit payment to AMRI no later than thirty (35) days after receipt of the invoice. Any and all taxes, duties or fees applicable to the sale, export or imports of materials or Deliverables or related to the performance of Services (other than taxes based upon AMRI's income) shall be borne solely by Customer.

C. Delivery: Any tangible Deliverable required to be delivered to Customer under a Work Order shall be shipped FCA AMRI Facilities (INCOTERMS 2010), unless agreed otherwise pursuant to any given Work Order. All shipping costs shall be the responsibility of Customer, Title to and risk of loss of any Deliverable shall transfer to Customer, at the earlier of: i) delivery of material; or ii) delivery of a Certificate of Analysis (or other tangible quality deliverable). If Customer does not take delivery of a Deliverable in accordance with the delivery timelines set forth in any given Work Order or purchase order, AMRI shall store the Deliverable at its facilities in accordance with industry standards and or an appropriate third-party storage location in accordance with industry standards at a monthly storage charge to Customer for the duration of storage, billed at AMRI's (or third-party's as applicable) then current standard storage monthly fees and minimums, pro-rated for any partial month. In such event, title and risk of loss to the Deliverable shall transfer to Customer upon the earlier of transfer to storage or delivery of the Certificate of Analysis or other applicable documentation.

6. Ownership of Intellectual Property.

Customer Materials. All materials, documents, information, programs, research reports, results, syntheses and suggestions of any kind and description supplied by or on behalf of Customer to AMRI in connection with the performance of Services ("Customer Materials") shall be the sole and exclusive property of Customer. Title to and risk of loss of Customer Materials shall remain with Customer at all times, and AMRI shall have no rights therein except as necessary to perform the Services; provided that AMRI will be liable to Customer for the cost of any lost or destroyed Customer Materials to the extent such loss or destruction results while under AMRI's control and/or from AMRI's negligence.

A. Deliverables. Any and all Results, compounds, materials, reports, data, Certificates of Analysis, or other deliverables generated by AMRI in the direct performance of the Services, including any ideas, inventions, discoveries, techniques, methods, processes, or know-how, whether patentable or not that are developed by AMRI directly from the Customer Materials or in connection therewith, shall be deemed "Deliverables" subject to the exceptions for Proprietary Technology (as defined herein). All such Deliverables shall be the sole and exclusive property of Customer, provided Customer fulfills its undisputed obligations under **Sections 2 and 5.** AMRI agrees to assign or cause to be assigned all rights in Deliverables to Customer. AMRI and its employees agree to cooperate with Customer in taking all reasonable steps which Customer believes necessary or desirable to secure its rights on this property, at the sole expense of Customer.

C. Proprietary Technology. Customer acknowledges that AMRI is in the business of providing services for a variety of organizations other than Customer. Accordingly nothing in this Agreement shall preclude or limit AMRI from providing similar services or developing materials for itself or other customers, or from utilizing the general knowledge gained during the course of its performance hereunder or using AMRI property to perform similar services for other parties, provided that such provision of services or development of materials does not constitute a breach of confidentiality under **Section 3** herein. All AMRI intellectual property, know-how, ideas, inventions, discoveries, concepts, scientific methods, computational and combinatorial techniques, biocatalysis technology, natural product libraries, and other AMRI technology and processes used or improved in the course of performing the Services which are general capabilities and do not specifically utilize the Deliverables, the Confidential Information of the Customer or Customer Materials(collectively, "Proprietary Technology") shall remain the exclusive property of AMRI, whether or not provided to Customer in the course of providing Deliverables. Notwithstanding anything express or implied to the contrary in this Agreement, the exclusive right and title to Proprietary Technology shall lie with AMRI. To the extent any Proprietary Technology is incorporated in the Deliverables AMRI hereby grants the Customer a worldwide, non-exclusive, perpetual, irrevocable, paid up, royalty-free, transferable, fully sub-licensable right and license to the Proprietary Technology solely to the extent necessary to use the Deliverable.

D. No Implied Rights. Except as otherwise expressly provided herein, neither Party shall have any right, title or interest to or in any patents, patent applications, trade secrets, know-how (whether patentable or unpatentable) or other intellectual property rights of the other Party.

7. Independent Contractors.

A. The Parties are and shall be independent contractors to one another, and nothing herein shall be deemed to cause this Agreement to create an agency, partnership or joint venture between the Parties. Further, nothing in this Agreement shall be interpreted or construed as creating or establishing the relationship of employer and employee between the Parties or between a Party and any employee or agent of the other Party. Neither Party shall at any time represent its relationship with the other Party as anything other than that of an independent contractor.

B. Neither Party, nor its employees, agents or subcontractors shall be (i) deemed employees of the other Party, nor (ii) entitled to participate in or receive any benefit or right as an employee of the other Party.

C. Each Party shall pay and report all federal and state income tax withholding, Social Security taxes and unemployment insurance applicable to such Party's employees.

8. Representations and Warranties; Limitations of Liability.

A. Representations and Warranties. Each Party represents and warrants to the other Party that: (i) such Party has full power and authority to execute and deliver this Agreement and to perform its obligations hereunder; (ii) this Agreement does not conflict with its duties and obligations under any other agreement to which it is a party; and (iii) this Agreement has been duly executed and delivered by such Party and constitutes a valid and legally binding obligation of such Party, enforceable in accordance with its terms.

B. AMRI warrants that any Proprietary Technology used in the performance of the Services will not infringe a third party's intellectual property rights or use third party's confidential information.

C. AMRI hereby warrants that it has the requisite expertise, skill, know-how, experience, personnel, facilities and equipment required in order to perform the Services (including handling with applicable hazardous materials), and shall do so in a professional, efficient and timely manner and in accordance with this Agreement and with the applicable cGMP.

D. In performing Services under this Agreement AMRI warrants that it will comply with all applicable laws, rules, regulations, and guidelines including cGMP. AMRI warrants that has all permits, licenses, authorizations, approvals, certificates and any similar authority necessary for the provision of the Services in accordance with the terms hereof (the "Permits"). All Permits are, and shall remain throughout the term of this Agreement, valid and in full force and effect.

E. AMRI hereby warrants that the Services and the Deliverables shall: (a) conform to the quality, quantity or requirements as set forth in the Agreement, the specifications provided by Customer to AMRI, the cGMP and the industry standards, and (b) be free from defects in material and workmanship in each case at the time of Delivery.

F. Disclaimer of Warranties. EXCEPT FOR THE WARRANTIES EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY WARRANTY, EXPRESS OR IMPLIED, REGARDING THE MATERIALS, SERVICES OR ANY DELIVERABLE, INCLUDING WITHOUT LIMITATION ANY WARRANTY REGARDING FITNESS FOR A PARTICULAR PURPOSE, QUALITY, MERCHANTABILITY OR NON-INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

G. Limitations on Liability.

a. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES FOR LOST PROFITS OR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE OR INDIRECT DAMAGES ARISING FROM OR RELATED TO THIS AGREEMENT, INCLUDING WITHOUT LIMITATION ANY BREACH OF A WARRANTY CONTAINED HEREIN OR OF ANY OBLIGATION TO PERFORM SERVICES OR TO PROVIDE ANY DELIVERABLE BY A SPECIFIED TIME. NOTHING HEREIN SHALL LIMIT EITHER PARTY'S INDEMNITY OBLIGATIONS UNDER THIS AGREEMENT.

b. AMRI'S AGGREGATE LIABILITY UNDER THIS AGREEMENT (WHETHER BASED ON BREACH OF CONTRACT, BREACH OF WARRANTY, NEGLIGENCE OR ANY OTHER LEGAL THEORY) SHALL NOT EXCEED THE AMOUNT EQUAL TO 2 TIMES THE TOTAL AMOUNT OF FEES PAID (OR DUE) BY CUSTOMER FOR THE SERVICES UNDER THE APPLICABLE WORK ORDER UNDER WHICH ANY SUCH CLAIM ARISES. THESE LIMITATIONS SHALL APPLY NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY. THE FOREGOING LIMITATION OF LIABILITY SET FORTH IN SUBSECTION "a" AND "b" SHALL NOT APPLY IN THE EVENT OF BREACH OF SECTION 3 ABOVE ("CONFIDENTIAL INFORMATION") BY EITHER PARTY, BREACH OF SECTION 6 BY EITHER PARTY, CLAIMS, DAMAGES, LIABILITIES, LOSSES, COSTS AND EXPENSES INCURRED AS A RESULT OF DEATH OR PERSONAL INJURY OR IN THE EVENT OF WILLFUL MISCONDUCT BY EITHER PARTY.

9. Indemnification.

A. Without derogating from and subject to the provisions of Section 8Ga above Customer shall indemnify and hold AMRI, its Affiliates and their directors, officers, employees and agents ("AMRI Indemnitee") harmless from and against any and all claims, damages, liabilities, losses, costs and expenses (including but not limited to reasonable attorneys' fees) directly resulting from a third party claim or action (collectively, "Claims") arising from or related to: (i) Customer's or a third party's use or sale of the Deliverables, or Customer's or a third party's manufacture, use or sale of any product or service incorporating the Deliverables, including without limitation any Claims attributable to any product incorporating Deliverables or other Customer product (whether based on strict liability, inherent design defect, negligence, failure to warn, breach of contracts or any other theory of liability); (ii) any Claims that any Deliverable or Customer Materials infringe a third Party's patent or other intellectual property rights; or (iii) any gross negligence or willful misconduct of Customer or any of its directors, officers, employees, or agents ("Customer Indemnitee"); except to the extent that such Claim is caused by the gross negligence, or willful misconduct of AMRI Indemnitees.

B. AMRI shall indemnify and hold Customer, its Affiliates and their directors, officers, employees and agents ("Customer Indemnitees") harmless from and against any and all Claims to the extent arising from (i) any gross negligence or willful misconduct of AMRI Indemnitees or (ii) AMRI's breach of its warranties under Section 8 of this Agreement; except to the extent that such a Claim is caused by the gross negligence or willful misconduct of Customer Indemnitees.

C. Indemnification Procedures. Any Party seeking indemnity hereunder shall: (i) give prompt written notice to the other Party (the "Indemnifying Party") of any Claim for which indemnification is sought; (ii) permit the Indemnifying Party to assume full responsibility to investigate, prepare for and defend against the Claim; (iii) reasonably assist the Indemnifying Party, at the Indemnifying Party's reasonable expense in the investigation of, preparation for and defense of such Claim; and (iv) not compromise or settle such Claim without the Indemnifying Party's prior written consent.

D. Responses to Subpoenas etc. In the event a subpoena or other court order requiring personal appearance or production of documents is received by AMRI in respect of litigation that Customer is involved in, Customer agrees that AMRI shall obtain its own counsel and Customer agrees to indemnify AMRI for all of AMRI's reasonable costs (including reasonable legal fees) reasonably relating to responding to such subpoena, any required internal investigations and all related legal proceedings.

10. Insurance.

Biosight shall maintain Clinical Trial insurance in accordance with the local terms and regulations where the Clinical trial going to be conduct. Biosight shall provide AMRI with Insurance certificate upon written request.

AMRI shall maintain appropriate product liability and commercial general liability insurance with respect to its obligations under this Agreement. The product liability insurance limits will be not less than $5,000,000 per claim and in the annual aggregate . AMRI shall provide Biosight with insurance certificates upon written request.

11. Force Majeure.

Neither Customer nor AMRI shall be liable for delays in performing or any failure to perform any obligations under this Agreement (other than Customer's payment obligations hereunder) if caused by the effects of fire, strike, war (declared or undeclared), insurrection, government restriction or prohibition, strike, force majeure or other causes reasonably beyond its control and without its fault, but the Party failing to perform shall use all reasonable efforts to resume performance of its obligations under this Agreement as soon as commercially practicable. Any episode of force majeure which continues for sixty (60) days from the date of notification of its existence shall give the non-affected Party the right to terminate this Agreement upon thirty (30) days additional notice. In the event the affected Party is Customer, any such termination by AMRI shall not relieve Customer of any of its payment obligations under this Agreement.

12. Assignment.

This Agreement shall be binding upon and inure to the benefit of the Parties and their successors and permitted assigns. Neither Party may transfer or assign, by operation of law or otherwise, its rights or obligations under this Agreement, in whole or in part, without the other Party's prior written consent, except that either Party may do so without prior consent to any Affiliate or to a successor of all or substantially all of the assets of the Party relating to the subject matter hereof, whether by purchase, acquisition or merger, but must give the other Party written notice of such assignment or transfer within thirty (30) days following the assignment or transfer. For the purposes of this Agreement the term "Affiliate" shall mean: any corporation, partnership, joint venture or other business arrangement which is controlled by, controlling or under common control with such Party and shall include without limitation any direct or indirect beneficial ownership of fifty percent (50%) or more of the voting stock or participating profit interest of such corporation or other business entity.

13. Dispute Resolution.

A. Choice of Law. The laws of England govern and control this Agreement and any disputes arising out of or relating to it, without regard to the principles of conflicts of laws. Any and all claims and disputes arising out of or related to this Agreement shall be submitted to arbitration in London, England under the rules then prevailing of the ICC and judgment may be entered on any award in a court of competent jurisdiction.

B. The Parties shall attempt in good faith to resolve promptly any dispute arising out of or relating to this Agreement by negotiation between executives who have authority to settle the dispute, prior to resorting to litigation.

14. Debarment.

The Parties each warrant that they have not knowingly, and shall not knowingly employ, contract with or retain any person directly or indirectly to perform services under this Agreement if such a person is debarred by the FDA under 21 U.S.C. 335(a) (Section 306, Federal Food, Drug and Cosmetic Act) or is under investigation by the FDA for debarment. In addition, the Parties represent that they have not engaged in any conduct or activity which could lead to debarment actions. In the event that either Party becomes aware of or receives notice that any person employed or retained by said Party involved in the Services, (i) comes under investigation by the FDA for a debarment action, (ii) is debarred, or (iii) engages in any conduct or activity that could lead to a debarment action, said Party shall promptly notify the other Party.

15. Miscellaneous.

A. AMRI will permit Customer to audit AMRI's relevant non-financial records during and for a period of twelve (12) months after the term of this Agreement with reasonable advance prior notice, during normal business hours, and not more than once per calendar year solely to permit Customer to confirm that the Services are or have been performed in compliance with applicable laws and regulations.

B. If any term or provision of this Agreement or the application thereof shall be invalid or unenforceable, the remainder of this Agreement shall be unaffected and each remaining term or provision of this Agreement shall be valid and be enforceable to the fullest extent permitted by law.

C. Waiver by either Party or the failure by either Party to claim a breach of any provision of this Agreement shall not be deemed to constitute a waiver or estoppel with respect to any subsequent breach of any provision hereof.

16. Entire Agreement.

A. This Agreement and any Work Orders attached hereto represent the entire agreement between the Parties with respect to the subject matter hereof and supersedes all prior understandings and agreements with respect thereto including without limitations the Terms & Conditions documents executed by the parties on March 2017.

B. No change or modification of the provisions of this Agreement shall be effective unless it is in writing and signed by a duly authorized officer of AMRI and Customer.

17. Counterpart.

This Agreement may be executed in two or more counterparts, by facsimile or Portable Document Format (PDF), each of which shall be deemed an original, but all of which, taken together, shall constitute one and the same legal instrument.

**IN WITNESS WHEREOF,** the Parties intending to be legally bound have caused this Agreement to be executed by their duly authorized representatives.

| ALBANY MOLECULAR RESEARCH, INC. | | Biosight Pharma | |
|---|---|---|---|
| By: | */s/ Lori Henderson* | By: | */s/ Dr. Ruth Ben-Yakar* |
| Name: | Lori Henderson | Name: | Dr. Ruth Ben-Yakar |
| Title: | SVP, General Counsel, Head of Business Development | Title: | CEO |
| Date: | June 16, 2017 | Date: | June 21, 2017 |

Annex: Work Order

**Exhibit 10.44**

INDEPENDENT RESEARCH FUNDING AGREEMENT

This Independent Research Funding Agreement (this "Agreement") is made this 15 day of July, 2020 (the "Effective Date") by and between: Biosight Ltd. (hereinafter referred to as "COMPANY"), address 3 Ha'yarden St., Airport City, Israel; and GFM (Groupe Francophone des MyélodysplasiES (hereinafter referred to as "INSTITUTION"), located at Service d'HématologieSéniors, Hôpital Saint Louis/ Université Paris 7, 1 avenue Claude Vellefaux/ 75010 Paris, France.

WHEREAS, COMPANY has agreed to provide funding and support to INSTITUTION and its employee **Prof Pierre FENAUX** ("Principal Investigator") to conduct an independent clinical trial according to a protocol and any related amendments (the "Protocol") entitled "**A Phase 2, Open-Label, Single Arm, Multi-Center Study to Assess the Efficacy and Safety of BST-236 as a Single Agent in Adults Unfit for Intensive Chemotherapy with Relapse or Refractory Acute Myelocytic Leukemia or Higher-Risk Myelodysplastic Syndrome**" (the "Study"), attached hereto as Exhibit A and incorporated herein by reference.

WHEREAS, INSTITUTION is equipped to undertake the Study under its own responsibility and under the direction of PRINCIPAL INVESTIGATOR and INSTITUTION and PRINCIPAL INVESTIGATOR have agreed to perform the Study as set forth in the Protocol and on the terms and conditions hereinafter set forth.

WHEREAS, COMPANY, INSTITUTION, and PRINCIPAL INVESTIGATOR are interested in the expansion and dissemination of scientific knowledge.

WHEREAS, COMPANY, as a condition for the funding and support of the Study, desires to bind, and INSTITUTION and PRINCIPAL INVESTIGATOR agree to be bound to the conditions of support identified herein.

NOW, THEREFORE, in consideration of the premises and the mutual promises and covenants expressed herein, the parties agree as follows:

1. **Performance of Study**

1.1 INSTITUTION and PRINCIPAL INVESTIGATOR agree to use their best efforts and professional expertise to perform the Study in accordance with the Protocol, all applicable legal and regulatory requirements, all written instructions and guidelines provided by the Company from time to time, including without limitation with respect to the storage, handling, use, administration and disposal of the Study Product, and in accordance with the terms and conditions of this Agreement. If INSTITUTION and/or PRINCIPAL INVESTIGATOR wish to modify the Protocol in any material respect, INSTITUTION and PRINCIPAL INVESTIGATOR shall notify COMPANY in advance of any such changes in writing. If these changes will affect the cost of the Study to be borne by COMPANY, INSTITUTION will submit to COMPANY a written estimate of such change in Study cost. COMPANY's prior review and, in its sole discretion, acceptance of any such changes shall be required prior to implementation, and the status quo shall persist with respect to such matter until COMPANY's consent is granted.

1.2 The INSTITUTION and PRINCIPAL INVESTIGATOR retain the sole and complete regulatory responsibility as the "sponsor" of the Study (in accordance with Art. 2 (e) of the 2001/20/EG guideline) and /or as defined at 21 CFR 312 and in guidance published by the Food and Drug Administration ("FDA") and foreign equivalents, including for all purposes of this Agreement, all cognizant national, state and provincial drug and health regulatory agencies). Neither INSTITUTION nor PRINCIPAL INVESTIGATOR shall represent to any third party, including participants enrolled in the Study ("Subjects"), that COMPANY is a Study sponsor. Except for the funding and the Study Product to be provided by COMPANY under this Agreement, the PRINCIPAL INVESTIGATOR and/or INSTITUTION are responsible for providing, at their own expense, all facilities, personnel, equipment, tools and other supplies necessary to perform the Study under this Agreement and in accordance with the Protocol. Any funding provided by COMPANY may not be used to compensate anyone, including physicians, for referring potential Subjects for enrollment in the Study.

1.3 INSTITUTION and PRINCIPAL INVESTIGATOR certify that they have secured or will secure, if required, a Clinical Trial Application (CTA) as well as any other required regulatory authorizations, prior to enrolling Subjects in the Study. If a CTA or equivalent is required, the PRINCIPAL INVESTIGATOR agrees to supply COMPANY with a copy of the respective Health Authority letter that assigns the PRINCIPAL INVESTIGATOR a study/application number. For studies conducted outside the United States, PRINCIPAL INVESTIGATOR agrees to supply COMPANY with a copy of the letter authorizing the clinical trial. The COMPANY shall submit the Investigational Medicinal Product Dossier in connection with the Study to the regulator.

1.4 In the event that the PRINCIPAL INVESTIGATOR ceases to be affiliated with INSTITUTION or becomes unwilling or unable to perform the duties required by this Agreement, INSTITUTION shall provide written notice to COMPANY within three (3) days of such change. In such event, INSTITUTION will designate a new PRINCIPAL INVESTIGATOR. COMPANY shall have the right to approve any new PRINCIPAL INVESTIGATOR designated by INSTITUTION. The new PRINCIPAL INVESTIGATOR shall be required to agree to the terms and conditions of this Agreement. In the event COMPANY does not approve such new PRINCIPAL INVESTIGATOR, COMPANY may terminate this Agreement in accordance with Section 14.2 below, without any cost to COMPANY, and INSTITUTION shall take all necessary steps to accommodate COMPANY's decision.

1.5 INSTITUTION and PRINCIPAL INVESTIGATOR represent and certify to COMPANY that each maintains, and shall maintain throughout the Term of this Agreement, all necessary authorization to enter into this Agreement, shall obtain all necessary institutional approvals prior to the start of the Study, and that the terms and conditions of this Agreement do not conflict with the institutional policies or any agreement to which INSTITUTION or PRINCIPAL INVESTIGATOR is a party.

1.6 PRINCIPAL INVESTIGATOR shall provide COMPANY with Study updates (e.g., enrollment, timelines) on no less than a quarterly basis in a form reasonably acceptable to, and containing such information reasonably requested by, COMPANY.

1.7 INSTITUTION agrees that each site involved in this Study shall, prior to beginning the Study, enter into an agreement with INSTITUTION regarding its participation in the Study. Each such agreement shall be directly entered into by the applicable site and INSTITUTION, shall be consistent with the terms of this Agreement, and shall include, without limitation and to the extent applicable, terms at least as protective of COMPANY's rights as those set forth in this Agreement. All Study sites shall be subject to COMPANY's approval in writing; provided that COMPANY shall have no obligation to inspect such sites prior to approval.

1.8 No party shall perform any actions that are prohibited by local and other anti-corruption laws, including but not limited to the U.S. Foreign Corrupt Practices Act and substantive provisions of applicable anti-bribery legislation (collectively, "Anti-Corruption Laws") that may be applicable. Without limiting the foregoing, no party shall make any payments, or offer or transfer anything of value, to any government official or government employee, to any political party official or candidate for political office or to any other third party related to the transaction in a manner that would violate Anti-Corruption Laws.

1.9 PRINCIPAL INVESTIGATOR shall conduct the Study in a manner conforming a reasonable and prudent clinical investigator or physician. The Study will be conducted in an efficient, diligent, professional and timely manner, and in accordance with all applicable standards, regulations and guidelines for good clinical practice ("**GCP**") and ethical conduct in connection with clinical studies and/or medical devices, including the World Medical Association Declaration of Helsinki entitled "Ethical Principles for Medical Research Involving Human Subjects", and the provisions of the current ICH Harmonized Tripartite Guideline for Good Clinical Practice (ICH-GCP) and ISO 14155.

2. **Ethics Committee ("EC") - Informed Consent - Authorizations**

2.1 In accordance with the laws and regulations applicable at the Study site(s), INSTITUTION and PRINCIPAL INVESTIGATOR shall be responsible for obtaining approval of the Protocol and its amendments (subject to Section 1.1 above), forms evidencing informed consent of all Subjects (or their legally authorized representatives) participating in the Study (each, an "Informed Consent Form"), Study recruitment procedures (e.g. advertisements, financial compensation) and any other relevant documents in connection with the Study, from the appropriate EC prior to commencement of the Study. For the sake of clarity, it is agreed and understood that the commencement of the Study is subject to the receipt of approval from the appropriate EC at each Study site. Each of the INSTITUTION and the PRINCIPAL INVESTIGATOR shall use its best efforts to obtain such approval as soon as possible. In the event the EC requires changes in, or the INSTITUTION and/or PRINCIPAL INVESTIGATOR intend to change, the Informed Consent Form, such changes shall be submitted to COMPANY prior to implementation. INSTITUTION and PRINCIPAL INVESTIGATOR shall be responsible for fulfilling all other authorization formalities related to the conduct of the Study (such as submitting a clinical trial application as described in Section 1 above) and if required, for obtaining the written authorization from any regulatory body with competent jurisdiction over the conduct of the Study (each, a "Health Authority" and collectively, the "Health Authorities") prior to commencement of the Study. INSTITUTION, on behalf of itself and the PRINCIPAL INVESTIGATOR, shall provide COMPANY with a copy of these authorizations. The PRINCIPAL INVESTIGATOR shall comply with all the requirements of the relevant EC and shall execute such assurances and other documents as such EC may request, a copy of which shall be provided to COMPANY. While COMPANY will make itself available to the extent necessary, and provide feedback to the extent requested, to facilitate any such filings with Health Authorities, all submission obligations shall remain on INSTITUTION and PRINCIPAL INVESTIGATOR, and INSTITUTION shall ensure notice of any such submissions is provided to COMPANY at least thirty (30) days prior to submission.

2.2 INSTITUTION and PRINCIPAL INVESTIGATOR shall be responsible for ensuring that the Informed Consent Form is signed by or legally on behalf of each Subject before participation in the Study. This informed consent document shall be the document approved by each of the Study sites' related ECs and the COMPANY, prior to the Subject's participation in the Study. INSTITUTION and PRINCIPAL INVESTIGATOR agree to include elements (i.e., risk language) in the Informed Consent Form that COMPANY considers materially relevant in light of its special knowledge of its Medical Affairs group with respect to the "Study Product". INSTITUTION and PRINCIPAL INVESTIGATOR further agree to maintain such approval until the completion of the Study, and re-obtain EC approval at any additional time intervals required by law or by INSTITUTION's or EC's policy. INSTITUTION and PRINCIPAL INVESTIGATOR will notify COMPANY promptly of any withdrawal or suspension of EC approval during the Term of this Agreement.

2.3 If requested by the COMPANY, INSTITUTION and PRINCIPAL INVESTIGATOR shall provide COMPANY with a copy of the letter of approval from each EC, the approved Informed Consent Form, any approved modified version thereof, and any relevant communications with each EC, which includes but is not limited to information which may affect the conduct of the Study.

3. **Adverse Event Reporting and Product Quality Complaints**

3.1 As the sponsor of the Study, the INSTITUTION and PRINCIPAL INVESTIGATOR shall be solely responsible for complying, within the required timelines, with any safety reporting obligation towards the competent Health Authorities, the ECs and the participating (co- or sub-) investigators, as defined in the applicable laws and regulations.

3.2 PRINCIPAL INVESTIGATOR and INSTITUTION will promptly (within one (1) business day) provide COMPANY or its designee with a copy of all serious adverse event reports, deaths and pregnancies related to the Study and/or the Study Product as more fully set forth in Exhibit B to this Agreement. In addition, PRINCIPAL INVESTIGATOR and INSTITUTION agree to follow up on safety information and promptly forward (within one (1) business day) to COMPANY any written, verbal, or electronic reports of suspected quality defect in the Study Product (or manufacture of the Study Product) or its COMPANY-provided packaging or labeling (including, but not limited to, actual or suspected product tampering, contamination, or mislabeling) ("Product Quality Complaints") within one (1) business day of PRINCIPAL INVESTIGATOR's or INSTITUTION's knowledge of the same. Product Quality Complaints shall be communicated to COMPANY at the following email address: liat@biosight-pharma.com

3.3 INSTITUTION and PRINCIPAL INVESTIGATOR agree to immediately update the Protocol and Informed Consent Form at the request of COMPANY for safety-related reasons. In the event of an adverse event or Product Quality Complaint, INSTITUTION and PRINCIPAL INVESTIGATOR shall provide COMPANY with all assistance and shall promptly take all measures as COMPANY may reasonably require.

4. **Monitoring - Audit/Inspection**

4.1 INSTITUTION and PRINCIPAL INVESTIGATOR agree that as sponsor of the Study they are solely responsible for the monitoring of the Study in compliance with good clinical practices ("GCP") and in accordance with the monitoring oversight plan attached hereto as Exhibit D.

4.2 During the Term of this Agreement, INSTITUTION and PRINCIPAL INVESTIGATOR agree to permit representatives of COMPANY (with at least five (5) days' notice), and/or any Health Authority, to examine at any reasonable time during normal business hours: (a) the facilities where the Study is being conducted; and (b) any relevant information, to the extent permitted by applicable laws and regulations, reasonably necessary to confirm that the Study Product is being used and administered consistent with the Protocol and in compliance with applicable laws and regulations and in conformance with the terms of this Agreement, to validate case reports against original data, and to make copies of such data, documents and records, and to monitor work performed, to ensure its compliance with the Study Protocol, applicable laws, regulations, guidelines and the terms of this Agreement. INSTITUTION and PRINCIPAL INVESTIGATOR shall immediately notify COMPANY if a competent Health Authority schedules or, without scheduling, begins an inspection of the site during the Term of this Agreement and for a period of five (5) years thereafter, and shall promptly provide COMPANY with a copy of correspondences, notices and any other documents and observations provided by or to such Health Authority relating to the Study and/or resulting from any such inspection.

4.3 INSTITUTION and PRINCIPAL INVESTIGATOR agree to take any reasonable actions requested by COMPANY to cure deficiencies noted during an audit or inspection performed by the COMPANY or a Health Authority.

5. **Study Product**

5.1 As part of the support provided by the COMPANY, COMPANY will provide to designated depos in Europe BST-236 (the "Study Product") in quantities to support the Protocol free of charge for eligible Subjects who are enrolled in the Study until such time as they complete the Study in accordance with the Protocol or the Study is otherwise terminated. This amount excludes any Study Product replaced due to either expiry dating, recall or damage, unless such expiration, recall or damage is attributable to any action or inaction taken by the INSTITUTION, PRINCIPAL INVESTIGATOR, or Study personnel. Not otherwise limiting the foregoing, INSTITUTION shall use reasonable efforts to provide COMPANY with a quarterly demand forecast for bulk planning purposes. INSTITUTION and PRINCIPAL INVESTIGATOR shall not order or collect from the designated depos in Europe quantity of the Study Product that exceeds the quantity actually required for the enrolled eligible Subjects under the Protocol.

5.2 COMPANY will also provide, to the extent applicable, reasonable support to INSTITUTION and PRINCIPAL INVESTIGATOR to enable them to comply with their sponsor's duties related to the manufacturing, supplying and quality of the Study Product (including those described in the International Conference on Harmonization Guidelines for Good Manufacturing Practices ("ICH GMPs")) and related information to be submitted to the competent Health Authorities. If COMPANY initiates a recall, INSTITUTION and PRINCIPAL INVESTIGATOR shall comply with this recall.

5.2.1. COMPANY and INSTITUTION shall promptly provide each other with any data or information in their possession (e.g., defective packaging material) that could result in a recall of the Study Product.

5.2.2. In the event of a potential or actual recall of Study Product already delivered to INSTITUTION or its designee, COMPANY and INSTITUTION shall consult and cooperate on any recall decision with the aim of reaching an agreement. COMPANY shall be responsible for the final recall decision for such Study Product and the INSTITUTION shall be responsible for any resulting communication with third parties.

5.3 COMPANY declares and warrants that the Study Product will be manufactured and controlled in compliance with the ICH GMPs. Notwithstanding anything herein to the contrary, COMPANY shall be entitled to subcontract the packaging, labeling, testing, release and delivery of Study Product, whether in whole or in part, to the third-party contractors which have been approved for use by the COMPANY. COMPANY will provide INSTITUTION and PRINCIPAL INVESTIGATOR written notification of required actions due to stability or other testing results for each lot provided. Upon Company's request, the parties shall enter into a separate Quality Agreement with respect to use of the Study Product by INSTITUTION and PRINCIPAL INVESTIGATOR in the Study.

5.4 All Study Product supplied to INSTITUTION will remain the exclusive property of COMPANY until administered to Subjects in accordance with Protocol requirements.

5.5 INSTITUTION and PRINCIPAL INVESTIGATOR shall be responsible for complete Study Product accountability and monitoring in accordance with good clinical practices, ICH GCPs (as applicable), the terms of this Agreement, the Protocol, and applicable law, and agree that Study Product provided by COMPANY under the terms of this Agreement shall be used only for this Study and enrolled Subjects. INSTITUTION shall ensure that Study Product is study-specific labeled and appropriately released prior to being given to any Subject. INSTITUTION shall ensure, and shall maintain appropriate records reflecting, that Study Product will be stored (in a secure and locked location to prevent theft or misuse), handled, accurately inventoried, administered to Subjects, distributed to participating sites, and destroyed or returned to depot in accordance with GCP, the terms of this Agreement, the Protocol, any instruction provided by COMPANY in writing, and all applicable law, administered only to Study Subjects, and that no expired Study Product will be given to any Subject in this Study. At the conclusion or termination of this Study, INSTITUTION shall ensure that all unused Study Product across all sites is promptly returned to COMPANY or its designee, or otherwise promptly disposed of, in accordance with COMPANY's instructions and following COMPANY's written approval. INSTITUTION will provide COMPANY with documentation of Study Product's destruction. After completion or termination of the Study, whichever is earlier, INSTITUTION shall account for all quantities used of the Study Product.

5.6 If any quantity of Study Product is, in the reasonable judgment of INSTITUTION, defective due to improper storage, shipping, or handling after being correctly dispatched or expires due to recruitment delays not otherwise contemplated by the recruitment schedule of the Protocol (collectively, "Defective Product"), INSTITUTION and PRINCIPAL INVESTIGATOR will not use the Defective Product in the Study, and will arrange at no additional cost to COMPANY, at Company's option, to either (i) return the Defective Product to Company, or (ii) for the prompt destruction of all Defective Product. INSTITUTION will provide COMPANY with documentation of such Defective Product's destruction.

5.7 If the INSTITUTION or PRINCIPAL INVESTIGATOR becomes aware during the conduct of the Study of any of the following information or circumstances relating to the Study Product, PRINCIPAL INVESTIGATOR will promptly notify COMPANY: (a) imposition by an applicable competent regulatory authority in any area of the world in which the Study Product is marketed of any prohibition or restriction of the Study Product's use; or (b) any new information that might influence the evaluation of the risks and benefits of the Study Product (e.g., either positive or negative results from clinical trials or other studies in relation to all indications and populations, whether or not use of the Study Product in that indication or population is approved under the relevant marketing authorization). PRINCIPAL INVESTIGATOR is to provide such notification to COMPANY promptly upon becoming aware of such information or circumstances, even if complete information is not yet available.

5.8 INSTITUTION and PRINCIPAL INVESTIGATOR will not submit bills to third party payment programs for the distribution or use of the free Study Product supplied by COMPANY in good faith solely for the use of Subjects enrolled in the Study, nor will INSTITUTION and/or PRINCIPAL INVESTIGATOR bill third party programs for the services rendered to administer Study Product to Study Subjects.

6. **Funding**

6.1 The total funding budget which COMPANY has agreed to provide to INSTITUTION and PRINCIPAL INVESTIGATOR to support the Study with the number of patients specified in the Protocol is as set forth in the Funding Budget attached hereto as **Exhibit C** and incorporated herein by reference. Parties acknowledges that the Company shall pay the fees specified in **Exhibit C** only in connection with Study Subjects who were actually enrolled to the Study and were treated with the Study Product at least one day in accordance with the provisions of the Protocol. Any and all sums due to other sites involved in the Study shall be paid by INSTITUTION from the total budget specified in **Exhibit C**, as may be amended in writing executed by both parties.

The payments will be transferred to the following account of the INSTITUTION:

Bank name: ***
Full address: ***
Number: ***
Beneficiary : ***
SWIFT /BIC code : ***
IBAN code : ***

6.2 The INSTITUTION and PRINCIPAL INVESTIGATOR assure and guarantee that the payments will be used only for the conduct of the Study in accordance with **Exhibit C**. The correct payment of taxes is to be ensured by the INSTITUTION and PRINCIPAL INVESTIGATOR. Payments are made as net payments. If any VAT is due on any Study Product, COMPANY will also pay VAT after receipt of a detailed invoice.

6.3 An invoice shall be provided to COMPANY for each installment due. Payments will be made within forty five (45) days as of the end of the calendar month in which a valid invoice was provided to the COMPANY by INSTITUTION. INSTITUTION shall provide COMPANY with a receipt for each installment**.**

6.4 If COMPANY is required by applicable law to make any tax deduction, tax withholding or similar payment from any amount paid or payable by COMPANY under this Agreement, then COMPANY shall deduct such amount from the payment due to INSTITUTION as prescribed by applicable law, unless INSTITUTION provides COMPANY with evidence of an exemption from the payment thereof**.**

6.5 The consideration set forth in **Exhibit C** hereto constitutes the sole and exclusive consideration payable by COMPANY for the conduct of the Study. The parties acknowledge and agree that the funding and support (including Study Product) provided by COMPANY to INSTITUTION and PRINCIPAL INVESTIGATOR pursuant to this Agreement represents a fair market value, has been negotiated in an arms-length transaction, and has not been determined in a manner that takes into account the volume or value of any referrals or other business otherwise generated between the parties and shall not obligate INSTITUTION and/or PRINCIPAL INVESTIGATOR to purchase, use, recommend or arrange for the use of any product of the COMPANY.

7. **Records; Reporting of Study Progress**

7.1 Each of INSTITUTION and PRINCIPAL INVESTIGATOR shall: (i) prepare and maintain complete and accurate written records, accounts, notes, reports and data of the Study and the use and handling of the Study Product, including source data and case report forms in accordance with the Study Protocol and applicable laws, regulations and guidelines; and (ii) retain all such records, reports and data after completion of the Study for such periods as determined by any applicable law or regulation, but no less than fifteen (15) years, at no additional cost to COMPANY.

7.2 During the term of this Agreement, PRINCIPAL INVESTIGATOR shall meet with the representatives of COMPANY, during customary working hours and to a reasonable extent, in order to report to COMPANY, on an ongoing and consecutive basis, and in order to update COMPANY in all matters related to the performance of the Study.

7.3 INSTITUTION and PRINCIPAL INVESTIGATOR shall report to COMPANY in writing the results and status of its research under this Agreement on a quarterly basis in a form and with such detail reasonably required by COMPANY, and shall issue a final Study report, in a form acceptable to COMPANY, which shall, at a minimum, include a full summary of safety and efficacy information from the Study, within ninety (90) days following: (a) completion of the Study; or (b) termination of this Agreement. Reports issued hereunder shall be sent to: liat@biosight-pharma.com

8. **Compliance with Applicable Laws**

8.1 INSTITUTION and PRINCIPAL INVESTIGATOR, being the sponsor, will conduct the Study and maintain records and data during and after the Term of this Agreement in compliance with all applicable legal and regulatory requirements,( including but not limited to the U.S. federal Food, Drug and Cosmetic Act, as amended by the U.S. Food and Drug Administration Amendments Act of 2007, 21 U.S.C. §301 et seq. and regulations thereunder, all applicable U.S. IND regulations, the U.S. Patient Protection and Affordable Care Act of 2010, the U.S. Controlled Substances Act, as amended, and the regulations promulgated thereunder), as well as generally accepted conventions such as the World Medical Association Declaration of Helsinki entitled "Ethical Principles for Medical Research Involving Human Subjects", and the standards for conduct of clinical research set forth in the International Conference on Harmonization Guidelines for Good Clinical Practices ("ICH GCPs") and ICH GMPs, to the extent applicable.

8.1.1. PRINCIPAL INVESTIGATOR may delegate duties and responsibilities to co- and sub-investigators or research staff only to the extent permitted by the regulations, and INSTITUTION shall ensure that all co- and sub-investigators to whom the PRINCIPAL INVESTIGATOR has the authority to delegate duties and responsibilities in relation to the Study and Study personnel comply will all applicable law and are bound to all applicable obligations on terms at least as restrictive as contained in this Agreement. INSTITUTION and PRINCIPAL INVESTIGATOR shall be responsible for ensuring that all co- and sub-investigators and Study personnel comply with the terms and conditions of this Agreement, and any failure by any co- or sub-investigator or Study personnel to so comply shall constitute a breach of this Agreement by INSTITUTION and PRINCIPAL INVESTIGATOR.

8.1.2. INSTITUTION and PRINCIPAL INVESTIGATOR shall maintain, and shall ensure that all Study personnel maintain, and carry out activities hereunder in compliance with, all applicable licenses, approvals, and certifications necessary for safely and properly conducting the Study under the Protocol throughout the Term of this Agreement.

8.2 Each party will comply with all applicable Data Protection Legislation in relation to the performance of its obligations under this Agreement and its conduct of the Study, including applicable laws and regulations governing the transfer of data outside of the national jurisdictions in which such Data Protection Legislation is enforced. Each party promptly will notify the other parties upon receiving knowledge of any violation of such Data Protection Legislation, including any breach of Personal Data.

The parties agree that each may be a data controller under the meaning of the EU General Data Protection Regulation (2016/679) (together with any relevant implementing legislation) ("GDPR"). INSTITUTION shall ensure that all Personal Data will be processed solely for the purpose of carrying out the Study, as well as to comply with any obligations of law or regulation, and/ or arising from the requirements of the competent Health Authority. INSTITUTION shall ensure that all Personal Data will be processed in such manner as to protect the integrity and confidentiality of the data and the rights of the interested parties, in compliance with adequate security and data protection measures. The parties agree to cooperate in good faith to ensure, and INSTITUTION and PRINCIPAL INVESTIGATOR will, and shall cause all sites and Study personnel to, ensure that Study Subjects may exercise their rights under applicable Data Protection Legislation, including, but not limited to, rights of access, rectification and/or deletion. INSTITUTION will make all Subject disclosures required by GDPR, and will ensure that all Study Subjects are informed that if they wish to exercise such rights, they must reach out directly to Study staff at the relevant site, given that INSTITUTION and COMPANY will receive coded information and generally will not have access to information that directly identifies Study Subjects. INSTITUTION also will ensure that Study Subjects are provided with contact information for Study staff and relevant data protection authorities.

8.2.1. For the purposes of this Agreement:

8.2.1.1. “Data Protection Legislation” means any applicable national, regional or international laws, regulations, directives or guidance documents pertaining to the data protection, privacy, confidentiality or security of Personal Data, including, without limitation, the EU Data Protection Directive (96/46/EC) (together with relevant national implementing legislation) and, beginning May 25, 2018, GDPR; and Deliberation no. 2016-262 of 21 July 2016.

8.2.1.2. “Personal Data” has the meaning given by applicable laws and regulations and includes, without limitation, any information (regardless of the medium and whether alone or in combination with other available information) that identifies or relates to an identified or identifiable natural person. Key-coded data is considered Personal Data even if the holder of that data does not have access to the key that links the data to the identity of an individual.

8.3 In the event that any part of this Agreement is determined to violate applicable laws and regulations the parties agree to negotiate in good faith revisions to the provision or provisions that are in violation. In the event the parties are unable to agree to new or modified terms as required to bring the entire Agreement into compliance, any party may terminate (and with respect to PRINCIPAL INVESTIGATOR, submit notice of ceasing participation in the Study such that a replacement may be found in accordance with Section 1) this Agreement on sixty (60) calendar days prior written notice to the other party.

9. **Ownership - Use of Data - Confidentiality - Registry - Publication**

All case report forms, results and other data (including without limitation, written, printed, graphic, video and audio material, and information contained in any computer database or computer readable form) created or developed during the course of the Study (the “Data”) shall be the property of INSTITUTION and PRINCIPAL INVESTIGATOR, which may utilize the Data for its own research and educational purposes, subject to and in accordance with applicable privacy laws and the terms of this Agreement, including without limitation the confidentiality provisions in this Section 9, and provided that INSTITUTION and PRINCIPAL INVESTIGATOR shall not use or permit any third party to use the Data for the commercial benefit of any third party. INSTITUTION and PRINCIPAL INVESTIGATOR hereby grant to COMPANY an unrestricted, perpetual, irrevocable, royalty-free, fully paid-up, worldwide license to the Data (including but not limited to an electronic copy of the Study database) to use it for any purpose it deems fit in compliance with applicable laws including without limitation, for the purpose of Additional Studies (including without limitation, publications and/or regulatory filings related to the Additional Studies). Provided however that Data that directly relates to, or is attributable to, required or useful for the development, production, commercialization or use of the Study Product or COMPANY Confidential Information shall be deemed “Company Proprietary Rights”. Company Proprietary Rights shall be the sole property of COMPANY, which may utilize the Company Proprietary Rights for any purpose it deems fit in compliance with applicable laws. Any and all Company Proprietary Rights shall be promptly disclosed to COMPANY but otherwise maintained in strict confidence. Each of INSTITUTION and PRINCIPAL INVESTIGATOR hereby assigns to COMPANY all Company Proprietary Rights and upon COMPANY’s request, INSTITUTION and PRINCIPAL INVESTIGATOR shall execute any document or instrument (including, deeds of assignment) and shall take all further acts reasonably required to transfer and/or assign all right, title and interest in and to the Company Proprietary Rights to COMPANY and/or to perfect COMPANY’s title therein, at COMPANY’s expense. COMPANY hereby grants to INSTITUTION a perpetual, irrevocable, royalty-free, fully paid-up, worldwide license to use the Data solely for its own noncommercial research and educational purposes, subject to and in accordance with applicable privacy laws and the terms of this Agreement, including without limitation the confidentiality provisions in this Section 9, and provided that INSTITUTION and PRINCIPAL INVESTIGATOR shall not use or permit any third party to use the Data for the commercial benefit of any third party.

9.1 All information concerning Study Product, or COMPANY's operations, such as COMPANY's patent applications, COMPANY Inventions, formulas, manufacturing processes, basic scientific data, prior clinical data and formulation information supplied by COMPANY to INSTITUTION or PRINCIPAL INVESTIGATOR or otherwise obtained or produced by INSTITUTION and/or its employees, service providers or assistants and/or the PRINCIPAL INVESTIGATOR, in connection with the Study and/or the Study Product and not previously published (the "COMPANY Confidential Information") are considered confidential and shall remain the sole property of COMPANY. Both during and after the Term of this Agreement, INSTITUTION and PRINCIPAL INVESTIGATOR shall maintain in confidence and use only in the conduct of the Study and evaluation of its results (i) information which is identified in the preceding sentence as confidential or which a reasonable person would conclude is the confidential and proprietary property of COMPANY and which is disclosed by or on behalf of COMPANY to INSTITUTION or PRINCIPAL INVESTIGATOR, and (ii) Data which is generated as a result of this Study. The preceding obligations shall not apply to Data or information (a) which has been published through no fault of INSTITUTION or PRINCIPAL INVESTIGATOR, (b) which COMPANY agrees in writing, may be used or disclosed, (c) which is published in accordance with Section 9.3, or (d) that is developed independently at INSTITUTION by persons who had no direct or indirect access to the COMPANY Confidential Information, as shown by contemporaneous written records. All COMPANY Confidential Information shall be returned to COMPANY at the earlier of the conclusion of this Study or termination of this Agreement or upon COMPANY request.

9.2 Prior to initiating enrollment, INSTITUTION and PRINCIPAL INVESTIGATOR, being the sponsor, shall, subject to the approval of the COMPANY in accordance with Section 9.2 below, register the Study in the public registry accessible for free (e.g., www.clinicaltrials.gov) in a manner that comports to prevailing editorial standards and statements (e.g., International Committee of Medical Journal Editors). Upon completion of the Study, INSTITUTION and PRINCIPAL INVESTIGATOR, being the sponsor, will seek to publish in the peer-reviewed literature the results of the Study and any background information provided by COMPANY that is necessary to include in any publication of Study results or necessary for other scholars to verify such research results, subject to the provisions of Section 9.3 below. Once published, INSTITUTION and PRINCIPAL INVESTIGATOR, being the sponsor, shall cite the publication on a clinical study results web site (e.g., www.clinicalstudyresults.org). If the results are not accepted for publication within 18 months of completion of all Study activities contemplated by the Protocol across all sites, INSTITUTION and PRINCIPAL INVESTIGATOR will post the results on a clinical study results web site (e.g., www.clinicalstudyresults.org) in the form of a clinical study report synopsis using the ICH E-3 format, subject to the provisions of Section 9.3 below. INSTITUTION and PRINCIPAL INVESTIGATOR shall provide proof of the registration and/or posting on a publicly available website. INSTITUTION and PRINCIPAL INVESTIGATOR acknowledge that COMPANY may be registered in public registries as the sponsor of Additional Studies and/or of the Study in other territories in which the COMPANY is the study sponsor.

9.3 Subject to the terms of this Section 9.3, INSTITUTION and PRINCIPAL INVESTIGATOR shall be free to publish or publicly present the results of the Study and any background information provided by COMPANY that is necessary to include in any publication of Study results or necessary for other scholars to verify such research results. The release or publication by INSTITUTION or PRINCIPAL INVESTIGATOR of any publication shall be subject to the prior written consent of COMPANY. Consent granted by COMPANY in respect of any particular publication shall not be deemed to be consent to any other publication. Each publication will adequately acknowledge and appropriately reflect the contribution of the investigators, researchers and/or employees of each of COMPANY and INSTITUTION or and the source of the information included therein, in accordance with customary scientific practice. Prior to submission for publication or presentation, INSTITUTION and PRINCIPAL INVESTIGATOR will provide COMPANY with at least sixty (60) days for review of a manuscript. PRINCIPAL INVESTIGATOR, and INSTITUTION will provide at least thirty (30) days for COMPANY to review abstracts, poster presentations or other materials. COMPANY shall have the right to: (i) make recommendations or comment on any proposed publication, which comments shall be discussed by INSTITUTION or PRINCIPAL INVESTIGATOR (as the case may be) and COMPANY, in good faith and in a timely manner, and incorporated into the said publication accordingly, and (ii) to object to the proposed publication because it contains Confidential Information or other information of COMPANY for which patent protection should be sought (prior to publication)or should be held confidential. Without derogating from the COMPANY's right to withhold its consent to a publication, upon the COMPANY's written request(i) INSTITUTION and PRINCIPAL INVESTIGATOR will withhold such publication for up to an additional sixty (60) days to allow for filing of a patent application and (ii) if COMPANY notifies INSTITUTION or PRINCIPAL INVESTIGATOR that the proposed publication contains any COMPANY Confidential Information or patentable information and so requests, INSTITUTION or INVESTIGATOR, as applicable, shall delete such information from the publication. INSTITUTION and PRINCIPAL INVESTIGATOR warrant the compliance of all Study investigators and other personnel involved with the Study with the provisions of this paragraph. If a particular Study is part of a multicenter study, INSTITUTION and PRINCIPAL INVESTIGATOR for such Study agree that the first publication of the results of such Study shall be made in conjunction with the presentation of a joint, multicenter publication of the Study results with the investigators and the institutions from all appropriate sites contributing data, analyses and comments. However, if such a multicenter publication is not submitted within twelve (12) months after conclusion, abandonment or termination of the Study at all sites, the INSTITUTION and/or such PRINCIPAL INVESTIGATOR or investigators may seek to publish the results from each site individually in accordance with this paragraph. INSTITUTION and PRINCIPAL INVESTIGATOR acknowledge that the COMPANY (alone or in collaboration with third parties) may conduct additional studies involving the Study Product under protocols similar to the Protocol within or outside the European Union (including without limitation, in the United States of America) ("**Additional Studies**"). Subject to the provisions of this Section 9, INSTITUTION and PRINCIPAL INVESTIGATOR shall share with the COMPANY the entire Study database to the extent required, at the discretion of the Company, for the conduct or registration of or publications related to, the Additional Studies.

10. **Materials; Inventions; Patents**

10.1 All tangible materials furnished by or on behalf of COMPANY or obtained during the conduct of the Study (collectively, together with all associated intellectual property rights, the "Materials") will remain the exclusive property of COMPANY. INSTITUTION and PRINCIPAL INVESTIGATOR may use Materials only as necessary to conduct the Study. INSTITUTION and PRINCIPAL INVESTIGATOR will not analyze or otherwise attempt to reverse engineer any Materials except as necessary to conduct the Study and will not transfer or make the Materials available to third parties, without the prior written consent of COMPANY.

10.2 "Invention" means all inventions, discoveries, know-how, and improvements, whether or not protectable under patent, copyright or other intellectual property law, resulting from the design or performance of the Study, or the use of the Study Product or the COMPANY Confidential Information. Inventions that directly relate to, or are attributable to, required or useful for the development, production, commercialization or use of the Study Product, or result from any research not authorized hereunder (a "COMPANY Invention") shall be the sole and exclusive property of COMPANY. INSTITUTION and/or PRINCIPAL INVESTIGATOR, as applicable, hereby assigns and agrees to assign all of its respective rights, title and interest in and to COMPANY Inventions to COMPANY, including all patents, copyrights and other intellectual property and proprietary rights therein.

10.3 All rights to any Invention other than a Company Invention that result of the work conducted under this Agreement in accordance with the Protocol shall be based on inventorship under European patent laws and shall be assigned to the owner of the resulting patent or patent application based on existing or executed employee or other agreements between the inventors and the INSTITUTION and/or the PRINCIPAL INVESTIGATOR. In consideration of COMPANY's support and funding for the Study, INSTITUTION and PRINCIPAL INVESTIGATOR will grant to COMPANY a non-exclusive, perpetual, worldwide, royalty-free license with the right to sublicense, to use each such Invention and intellectual property rights therein for any lawful purpose. INSTITUTION and PRINCIPAL INVESTIGATOR shall promptly disclose to COMPANY any such Invention or discovery arising under this Agreement.

11. **Debarment**

INSTITUTION and PRINCIPAL INVESTIGATOR shall not employ, contract with or retain any person directly or indirectly to perform services under this Agreement if such a person: (a) is or has ever been suspended, disqualified, excluded, or debarred by a competent Health Authority (including, if applicable, the U.S. FDA); (b) convicted of any felonies identified among the exclusion authorities listed on the U.S. Department of Health and Human Services, Office of Inspector General ("OIG") website, including 42 U.S.C. 1320a-7(a) http://oig.hhs.gov/fraud.asp; or (c) has been sentenced for malpractice related to the conduct of clinical trials. Upon written request from COMPANY, INSTITUTION and PRINCIPAL INVESTIGATOR shall, within ten (10) days, provide written confirmation that it has complied with the foregoing obligation. This shall be an ongoing representation and warranty during the Term of this Agreement and INSTITUTION and PRINCIPAL INVESTIGATOR shall immediately notify COMPANY of any change in the status of the representation and warranty set forth in this Section.

12. **Insurance**

INSTITUTION and PRINCIPAL INVESTIGATOR shall secure and maintain at their own expense in full force and effect through the performance of the Study (and following termination of the Study to cover any claims arising from the Study) general liability insurance, worker's compensation, employer liability insurance and professional liability insurance that contains no exclusion for products that do not have regulatory approval or clearance, no exclusion for clinical studies, and no exclusion for bodily injury caused by or relating to clinical studies in amounts appropriate to the conduct of the Study and in conformance with applicable legal and regulatory requirements as well as comprehensive and professional liability insurance of reasonable policy limits. For multi-country studies or studies with several participating sites, INSTITUTION and PRINCIPAL INVESTIGATOR shall ensure coverage for all these participating sites.

13. **Indemnification**

13.1 INSTITUTION and PRINCIPAL INVESTIGATOR, being the sponsor, agree that neither COMPANY, nor any of its affiliates or subsidiaries, their respective officers, directors, employees, contractors or agents will bear any responsibility or liability for claims, losses, injuries, or other damages, including any consequential, incidental, special, or indirect damages (including loss of profits or business opportunity), to the extent that any of the above arises from: (i) any breach of this Agreement by INSTITUTION or PRINCIPAL INVESTIGATOR or by any of the clinical staff involved in the Study, including any failure to comply with the terms of the Study Protocol or any deviation of the study protocol or the Company's written instructions with respect to the performance of the Study and/or use or administration of the Study Product; (ii) the failure by INSTITUTION, PRINCIPAL INVESTIGATOR and/or any of the clinical staff involved in the Study and/or any agents or contractors of Institution involved in the performance of the Study to comply with any applicable law, regulations, guidelines or other governmental requirements; (iii) the negligent, reckless or wrongful act, error or omission, willful misconduct or bad faith of INSTITUTION, PRINCIPAL INVESTIGATOR and/or any clinical staff and/or any agents or contractors of Institution involved in the performance of the Study; or (iv) any bodily injury to a third party (including a Study Subject) caused by act or omission of the INSTITUTION, PRINCIPAL INVESTIGATOR or the clinical stuff involved in the Study, and INSTITUTION and PRINCIPAL INVESTIGATOR will indemnify, defend, and hold COMPANY harmless and its respective subsidiaries and affiliates, and their respective officers, directors , employees, contractors and agents harmless from such liability. INSTITUTION and PRINCIPAL INVESTIGATOR shall not settle or compromise any claim for which COMPANY is indemnified without the prior written consent of COMPANY. COMPANY shall have no obligation of indemnification hereunder for any loss or damages arising out of the negligence or willful misconduct or failure to act of PRINCIPAL INVESTIGATOR, INSTITUTION, their officers, agents, and/or employees in connection with the conduct of the Study.

13.2 The parties agree that each party shall be liable for its own negligence, willful misconduct, acts, or omissions arising out of this Agreement; provided, however, that COMPANY will not be responsible for any treatment, adverse outcomes, or other costs associated with the Subjects whether related, directly or indirectly, to the Study Product or administration of the Study Product, and will not reimburse INSTITUTION, PRINCIPAL INVESTIGATOR, or any Subjects for any cost of medical care for injury or illness directly resulting from the administration of the Study. INSTITUTION and PRINCIPAL INVESTIGATOR will inform the Subjects of the foregoing limits of COMPANY'S responsibility.

13.3 INSTITUTION and PRINCIPAL INVESTIGATOR understand and agree that COMPANY makes no warranty, either express or implied, regarding the use of the Study Product in the Study. Without limiting the foregoing, COMPANY expressly disclaims any implied warranties of merchantability or fitness for a particular purpose.

14. **Term and Termination**

14.1 The term of this Agreement shall begin on the Effective Date stated above and end upon COMPANY's receipt of a final Study report and written notification that the Study Data have been accepted for publication in a peer-reviewed journal or until completion of all obligations herein, or until earlier termination as herein provided ("Term"). The INSTITUTION and the PRINCIPAL INVESTIGATOR will adhere to the following timelines:

(i) commencement of the Study/enrollment: 01/10/2020, but no later than six months after the Effective Date;

(ii) last Subject enrolled in the Study: 01/10/2022;

(iii) completion of final Study report for the treatment phase of the Study: no later than forty five (45) days after the last Subject completes his or her course of treatment;

(iv) completion of final Study report for the follow-up phase of the Study: 31/03/2024, but no later than six months after the last Subject's participation in the Study ends.

14.2 This Agreement may be terminated by COMPANY at any time in the exercise of its sole discretion upon fifteen (15) days prior written notice to INSTITUTION and PRINCIPAL INVESTIGATOR who immediately shall notify other Study sites of such termination. Reasons for termination of this Agreement may include but are not limited to:

(i) breach of contract, including failure to perform the Study in accordance with the terms of the Protocol, this Agreement, or applicable laws or regulations or if the PRINCIPAL INVESTIGATOR becomes debarred;

(ii) receipt of safety information that makes it prudent to do so; or

(iii) receipt of data suggesting lack of sufficient efficacy; or

(iv) noncompliance with applicable laws and regulations; or

(v) PRINCIPAL INVESTIGATOR becomes unaffiliated with INSTITUTION prior to the completion of the Study.

Notwithstanding the above, COMPANY may immediately terminate this Agreement and require that the Study be stopped if within its sole judgment, such immediate termination is necessary based upon considerations of Subject safety. This Agreement shall also automatically terminate if the authorization and approval to conduct the Study is rejected or withdrawn by the competent EC or regulatory authority. Upon receipt of notice of Study termination, INSTITUTION and PRINCIPAL INVESTIGATOR agree to promptly meet and confer to determine an appropriate phase-out for subjects participating in the Study, and INSTITUTION and PRINCIPAL INVESTIGATOR shall promptly terminate conduct of the Study to the extent medically permissible for any Subject. In the event of termination hereunder, other than as a result of a material breach by INSTITUTION or PRINCIPAL INVESTIGATOR, the total sums payable by COMPANY pursuant to this Agreement shall be equitably prorated for actual work advanced to the date of termination, with any unexpended funds previously paid by COMPANY to INSTITUTION or PRINCIPAL INVESTIGATOR being promptly refunded to COMPANY. Termination of this Agreement by COMPANY pursuant to this Section 14.2 shall be without penalty or liability therefor on the part of COMPANY or the payment of any compensation, except as explicitly aforesaid.

Termination of the Study and/or this Agreement for any reason shall not affect any of the rights and obligations of the Parties which shall have accrued prior to the effective date of the termination. Without derogating from the generality of the above, the provisions of Sections 7.1, 8.2, 9.1, 9.2, 10, 13, this 14.2, 17, 19 and 23 shall survive termination or expiration of this Agreement.

In case the Agreement or Study is terminated by the INSTITUTION or PRINCIPAL INVESTIGATOR, INSTITUTION or PRINCIPAL INVESTIGATOR agree to inform the COMPANY in writing, outlying the reasons for such earlier termination.

15. **Independent Parties**

INSTITUTION and PRINCIPAL INVESTIGATOR are acting in the capacity of independent parties hereunder and not as employees or agents of COMPANY.

16. **Conflict of Interest**

INSTITUTION and PRINCIPAL INVESTIGATOR confirm that there is no conflict of interest between the parties, or with any co- or sub-investigator, that would inhibit or affect their respective performance under this Agreement and confirm that such performance under this Agreement does not violate any other agreement with third parties. INSTITUTION and PRINCIPAL INVESTIGATOR will, and will cause all co- and sub-investigators to, promptly inform COMPANY if any conflict of interest arises during the performance of this Agreement. Not otherwise limiting the foregoing, as required by law, regulation, or COMPANY policy, PRINCIPAL INVESTIGATOR and each co- and sub-investigator shall provide financial disclosures of conflicts of interest to COMPANY as COMPANY may request, on forms approved by COMPANY. At the commencement of the Study and during the time the Study is being conducted and for one (1) year thereafter, the PRINCIPAL INVESTIGATOR and each co- and sub-investigator shall update such forms promptly and provide the same to COMPANY as may be requested or whenever any material change occurs in the information disclosed in the previous form.

If INSTITUTION, PRINCIPAL INVESTIGATOR, or any co- or sub-investigator is a member of a committee for any entity that sets formularies or develops clinical guidelines, then, during the term of the Study and for a period of two (2) years thereafter, INSTITUTION shall, and INSTITUTION shall require PRINCIPAL INVESTIGATOR and all co- and sub-investigators to: (a) disclose their involvement with the Study to such committee; and (b) comply with any procedures set forth by such committee with respect thereto.

17. **Publicity - Use of Name**

None of the parties shall use the name, trademark, service mark, or logo of any other party for any purposes, nor shall any party disclose the existence or substance of this Agreement except as required by law without prior written consent of the party whose name is proposed to be used. Notwithstanding the foregoing, COMPANY shall be entitled to disclose the existence and the substance of this Agreement as part of a due diligence inquiry or similar procedure or as part of representations under agreements to which the COMPANY is a party, subject to reasonable confidentiality undertakings.

18. **Exhibits**

In the event the standards, requirements, or obligations set forth on an Exhibit to this Agreement conflict with the Protocol and/or the terms herein, the terms of the Protocol, and then the terms of this Agreement, respectively, shall control.

19. **Notice**

Any notices given hereunder shall be sent by: (a) mail, return receipt requested; (b) overnight courier service; or (C) personally delivered as follows:

FROM INSTITUTION/PRINCIPAL INVESTIGATOR TO COMPANY:

To

Biosight Ltd.

3 Ha'yarden St.,

Airport City, Israel

FROM COMPANY TO INSTITUTION:
To
GFM
Pr. Pierre FENAUX
Service d'hématologie séniors
Hôpital St Louis / Université Paris 7
1 avenue Claude Vellefaux
75010 PARIS, France

20. **Assignment**

Neither INSTITUTION nor PRINCIPAL INVESTIGATOR shall assign their rights or duties under this Agreement to another without prior written consent of the other parties. COMPANY may assign and/or transfer this Agreement and any of its rights, privileges or obligations hereunder, at its discretion, to an affiliate and/or a successor in interest. Subject to the foregoing, this Agreement shall bind and inure to the benefit of the respective parties and their successors and assigns.

21. **Agreement Modifications**

This Agreement, including the Exhibits, may not be altered, amended or modified except by written document signed by all parties.

22. **Counterparts**

This Agreement may be executed in two or more counterparts, and signatures may be delivered by facsimile and via email in .PDF, each of which shall be deemed to be an original and all of which shall be deemed to constitute the same Agreement.

23. **Governing Law and Jurisdiction**

This Agreement shall be governed by and construed in accordance with the laws of England and Wales without regard to the application of principles of conflicts of law. Any dispute controversy or claim arising out of, or relating to this Agreement, its interpretation or performance hereunder shall be settled in the competent courts of London, England.

[*Remainder of Page Intentionally Blank*]

[*Signature Page Follows*]

**IN WITNESS WHEREOF,** the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the date first above written.

**Biosight Ltd.**

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| By: | */s/ Dr. Ruth Ben Yakar* |
| Name: | Dr. Ruth Ben Yakar |
| Title: | CEO |
| Date: | July 15, 2020 |

**INSTITUTION**

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| By: | *GFM* |
| Name: | Prof. Pierre FENAUX |
| Title: | President of GFM |
| Date: | July 17, 2020 |

**ACKNOWLEDGED AND AGREED TO:**

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| By: | */s/ Prof. Pierre FENAUX* |
| Name: | Prof. Pierre FENAUX |
| Title: | Principal Investigator |
| Date: | July 17, 2020 |

**Include Exhibits:**

**A. Protocol**
**B. Adverse Event Reporting**
**C. Budget**
**D. Investigator Monitoring Oversight Plan**

**Exhibit 10.45**

DATED August [_8_], 2021

STERLING WISCONSIN, LLC

and BIOSIGHT LTD.

MASTER AGREEMENT

THIS AGREEMENT dated is made BETWEEN:

(1) STERLING WISCONSIN, LLC a limited liability company organized under the laws of Wisconsin ("the Supplier"); and

(2) BIOSIGHT LTD., a limited liability company organized under the laws of Israel ("the Purchaser").

The Supplier and the Purchaser are collectively referred to as the "Parties" and each individually as a "Party".

BACKGROUND

(A) The Supplier is in the business of manufacturing and supplying active pharmaceutical ingredients, intermediates and other pharmaceutical ingredients.

(B) The Purchaser wishes to appoint the Supplier to Manufacture and supply the Products to the Purchaser under this MA.

(C) The Supplier shall Manufacture and supply the Products on the terms of this MA and on the terms set out in individual Product Orders to be executed by the Parties from time to time, the Price List and to the regulatory and compliance standards provided for within the Quality Agreement.

IT IS AGREED as follows:

## 1. DEFINITIONS AND INTERPRETATION

1.1 The definitions and rules of interpretation in this Section 1 apply:

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| "Affiliate" | means, in relation to either Party, any person, firm, trust, partnership, corporation, company or other entity or combination thereof that directly or indirectly Controls such Party, is Controlled by such Party or is under the common Control with such Party (and for the purpose of this expression "Control" shall mean in relation to any Party, the beneficial ownership of fifty percent (50%) or more (including ownership by trusts with substantially the same beneficial interests) of the issued share capital of, or the legal power to direct or cause the direction of the general management of the Party in question or its holding company or parent undertaking; |
| "Approvals" | means all registrations with and approvals from the relevant Regulatory Authority necessary to market and sell the relevant Product. |
| "Background" | means, with respect to either Party, all rights in Intellectual Property, and embodiments thereof that:<br>(a) come into the ownership or control of or are licensed to that Party on or after the Effective Date other than Foreground; or<br>(b) were owned by, controlled by or licensed to that Party prior to the Effective Date; |
| "Business Day" | means a day which is not Friday, Saturday or Sunday or a bank or national holiday in the United States of America or Israel; |

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| “Cancellation Fee” | has the meaning given in Clause 5.2; |
| “Change Order” | means a document detailing changes, agreed between the Parties, to a Product Order; |
| “Commercially Reasonable Efforts” | means, with respect to the efforts to be expended by either Party with respect to any objective, such reasonable and diligent efforts as such Party would normally use to accomplish a similar objective under similar circumstances as expeditiously as possible, which in no event shall be less than the standard of care generally adhered to in the industry of such Party for the providing of such efforts, but for the avoidance of doubt, it shall not involve incurring material expense which would not reasonably be expected by the Party concerned at the Effective Date and/or material risk which would not reasonably be expected by the Party concerned at the Effective Date; |
| “Confidential Information” | means in relation to each Party, all information of a confidential nature, including data, know-how and trade secrets relating to its business which come into the possession of the other Party pursuant to this MA, whether orally, or in documentary, electronic, or other form including the existence and terms of this MA; |
| “Contract Year” | means the period of twelve (12) months from and including the Effective Date and each consecutive period of twelve (12) months thereafter except that the last Contract Year of this MA shall be for such shorter period that commences on an anniversary of the Effective Date and expires on the expiration or termination of this MA; |
| “Delivery Date” | means the expected delivery date for each batch of Product as specified in the applicable Product Order; |
| “Effective Date” | means the date of this MA; |
| “End-Product” | means the formulated drug product manufactured by or for the Purchaser, of which the Product forms part; |
| “Force Majeure Event” | means any circumstances arising from or attributable to acts, events, omissions or accidents beyond the affected Party’s reasonable control, including but not limited to: acts of God including adverse weather conditions or , other natural disaster; epidemic, pandemic or disease that is required by law to be notified to a government or a public or regulatory authority, war, threat of or preparation for war, armed conflict, imposition of sanctions, embargo, import or export controls, breaking off of diplomatic relations or similar actions; terrorist attack, civil commotion or riots; nuclear, chemical or biological contamination; compliance with any law; any action taken by a government or by a public or regulatory authority; malicious or accidental damage; loss at sea; collapse of building structures, failure of plant machinery, machinery, computers or vehicles; any labour dispute, including but not limited to strikes, industrial action or lockouts; non-performance by suppliers or subcontractors; shortage of raw materials; and interruption or failure of utility service, including but not limited to electric power, gas, water, internet or data services. |

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| "Foreground" | means Purchaser's Foreground and Supplier Foreground; |
| "Good Manufacturing Practice" or "GMP" | means current practices with respect to the Manufacture of the Product being those practices from time to time required by:<br><br>(a) the International Conference on Harmonisation Guidelines, ICHQ7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients; and/or<br><br>(b) those practices from time to time required by provisions of 21 C.F.R., by the parts 210 and 211 and all applicable rules, regulations, orders and guidance published thereunder; and/or<br><br>subject to prior approval by the Supplier, those practices from time to time required by the regulations applicable to the supply of End-Product in such locality as the Purchaser may wish to supply the End-Product provided that such requirements shall in any event be no more onerous than the requirements set out in (a) and (b) above; |
| "Independent Laboratory" | means such laboratory as shall be mutually agreed between the Parties as shall be used for the purpose of Section 8; |
| "Insolvency Event" | means in relation to a Party, dissolution, liquidation, arrangement for the benefit of creditors, having a receiver appointed, bankruptcy or other insolvency or restructuring process (other than in relation to a solvent restructuring), or that Party suspends, or threatens to suspend, or ceases or threatens to cease to carry on all or a substantial part of its business; |
| "Intellectual Property" or "Intellectual Property Rights" | means all and any intellectual property of whatever nature in any part of the world including, without limitation, rights in designs, unregistered design right, registered designs, copyright, moral rights, rights in databases, patents, rights to inventions, trademarks, trade names and domain names, rights in get-up, rights to goodwill and to sue for passing off and unfair competition, know-how, trade secrets, logos, information, data, formulas, technology, techniques rights in confidential information, in each case whether registered or unregistered and including any and all applications (and rights to apply) for such rights, any renewals, extensions, divisions, continuations, continuations-in-part, additions, registrations, confirmations, re-examinations, supplementary protection certificates, or reissues; |
| "Losses" | means all liabilities, claims, demands, damages, losses, costs, expenses or money judgments (including attorney's fees and investigative and production costs) resulting from any actual or threatened third party claim, demand or action; |
| "Manufacture" or "Manufacturing" | means all steps involved in the production of Product, as set forth in the applicable Product Order, including processing, preparation, assembling, testing, labelling, packaging, and storage of Product at the Manufacturing Site; |
| "Manufacturing Licenses" | means all licenses and/or permits necessary for or required in connection with the Manufacture of the Product at the Manufacturing Site; |
| "Manufacturing Site" | means the manufacturing facility of the Supplier as specified in the Product Order; |

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| “Materials” | means the raw materials (including starting materials) and components used in the Manufacture of the Product; |
| “Minimum Lead Time” | means the period of time between the Product Order and the Delivery Date in relation to the relevant Product, as specified in the relevant Product Order; |
| “MA” | means this Master Agreement; |
| “Non-conforming Product” | as defined in Section 8.2; |
| “PPI Index” | means the Producer Price Index for Pharmaceutical Preparation Manufacturing as published by the U.S. Bureau of Labor Statistics or such other index as the Parties may agree in writing; |
| “Price” | means the price of the Product as set out in the applicable Product Order and calculated in accordance with the Price List; |
| “Price List” | means a price list that forms part of this MA and is attached hereto at Appendix 1. Subject to Section 10, the Price List will set out the prices for the Products and Supplier’s services at different development stages throughout the Term; |
| “Product” | means the product to be Manufactured and supplied as set out in the applicable Product Order; |
| “Product Order” | means an order that forms part of this MA for each Product order substantially in the form set out in Appendix 2 (Form of Product Order) and executed by authorized representatives of the Purchaser and the Supplier; |
| “Purchaser Foreground” | means any Intellectual Property first created, made, conceived, discovered or reduced to practice as a direct result of the performance by the Purchaser of its respective obligations under this MA; |
| “Purchaser’s Intellectual Property “ | Means: (a) Purchaser’s Foreground and (b) all data, information and Intellectual Property first created, made, conceived, discovered or reduced to practice as a direct result of the performance by the Supplier of its respective obligations under this MA or related to Purchaser’s Confidential Information, Purchaser’s Background, the Purchaser-Supplied Materials, the Product, or the End Product other than such data, information or Intellectual Property of a general nature related to Supplier’s business, manufacturing processes, quality control, testing and compliance procedures, Supplier’s Background or general microbial production; |
| “Purchaser Supplied Materials” | means all Materials to be supplied by, or on behalf of, the Purchaser for the performance of the processing activities (if any) as set forth in the applicable Product Order; |
| “Quality Agreement” | means an agreement that forms part of this MA for each Product and executed by authorized representatives of the Purchaser and Supplier, setting out the responsibilities of the Parties in relation to quality assurance and control obligations in connection with the production and shipment of the Product as required for compliance with GMP; |
| “Regulatory Authority” | means any national (e.g., the FDA), supra-national (e.g., the European Commission, the Council of the European Union, or the EMA), regional, state or local regulatory agency, department, bureau, commission, council or other governmental authority involved in the granting of regulatory or similar approvals for pharmaceutical products; |

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| “Reserved Time Slot” | means the applicable time slots for the Manufacturing as specified in each Product Order; |
| “Specification(s)” | means the specification(s) for the Product as set out in the applicable Product Order; |
| “Supplier Foreground” | means any Intellectual Property first created, made, conceived, discovered or reduced to practice as a direct result of the performance by the Supplier of its obligations under this MA, other than Purchaser Intellectual Property; |
| “Supplier Supplied Materials” | means any Materials that are necessary for the performance of manufacturing and supplying the Products which are not included within the definition of the “Purchaser Supplied Materials”; |
| “Term” | means the term of this MA specified under Section 26; and |
| “Wasted Conversion Costs” | any costs (both internal and external) outlined in the Product Order which are reasonably incurred by the Supplier in anticipation of Manufacturing Product which cannot be reutilized, cancelled or reallocated (including but not limited to Manufacturing costs, the cost of raw materials, packaging and waste costs and transportation and storage costs); |

1.2 For the purposes of this MA:

1.2.1 the headings and recitals are for convenience only and they shall not affect its construction or meaning;

1.2.2 references to Sections, Recitals, Appendices, Schedules and Paragraphs are to sections of, recitals, appendices and schedules to and paragraphs of this MA;

1.2.3 the Schedules and Appendices form part of this MA and the expression "this MA" includes the Schedules and Appendices;

1.2.4 unless otherwise expressly stated, references to any statute, statutory instrument, or regulation shall mean a reference to the current provision as amended from time to time, any successor legislation thereto and any regulations promulgated thereunder;

1.2.5 unless the context otherwise requires, words denoting the singular shall include the plural and vice versa and references to any gender shall include all other genders;

1.2.6 references to any person (which for the purposes of this MA shall include bodies corporate, unincorporated associations, partnerships, limited liability partnerships, limited liability companies, governments, governmental agencies and departments, statutory bodies or other entities, in each case whether or not having a separate legal personality) shall include the person's permitted successors and assigns; and

1.2.7 general words shall not be given a restrictive interpretation by reason of their being preceded or followed by words indicating a particular class of acts, matters or things and each reference throughout this MA to "includes" or "including" shall be construed without limitation.

## 2. FRAMEWORK AGREEMENT

2.1 This MA governs the overall relationship of the Parties and together with the Price List, any relevant Product Orders and Quality Agreement, sets out the terms and conditions which shall govern the Manufacture and supply by the Supplier of each of the Products and the performance of activities under this MA.

Product Orders

2.2 This MA is structured so that a separate Product Order shall be entered into for the development work, Manufacture and supply of different batches of the Product at different stages of development throughout the Term (it being understood that a particular Product Order may include an entire Product family and multiple Products as may be agreed to by the Parties and set forth in such Product Order).

2.3 Subject to the provisions of Section 5 below, each Product Order shall be agreed in the following manner:

2.3.1 the Purchaser may request that the Supplier develop, Manufacture and supply one or more Products and provide the Supplier with as much information as the Supplier may reasonably require in order to prepare a draft Product Order for the Products to be Manufactured and supplied;

2.3.2 following receipt of the information requested from the Purchaser, the Supplier shall, as soon as reasonably practicable, and no later than 10 days as of the receipt of information from the Purchaser, either:

(a) inform the Purchaser that it declines to provide the requested Products; or

(b) provide the Purchaser with a draft Product Order which will incorporate any proposal issued by the Supplier to the Purchaser.

2.3.3 if the Supplier provides the Purchaser with a draft Product Order pursuant to Section 2.3.2, the Supplier and the Purchaser shall discuss that draft Product Order; and

2.3.4 both Parties shall execute the draft Product Order if and when it is agreed upon.

2.4 A Product Order shall not enter into force, be legally binding or have any other effect unless:

2.4.1 the Product Order has been executed by authorized representatives of both the Purchaser and the Supplier; and

2.4.2 as of the date the Product Order is signed, this MA has not been terminated.

2.5 Each Product Order forms a separate contract incorporating the terms of this MA.

2.6 Once a Product Order has been agreed upon and executed in accordance with Section 2.3 and Section 5 below, no amendment shall be made to it except in accordance with Section 6 (Changes to Product Order), 10 (Prices) or Section 26.3 (Duration and Termination; Rescheduling and Reduction of Orders).

## 3. PURCHASE AND SUPPLY OF PRODUCT

3.1 The Supplier shall develop, Manufacture and supply the Product and the Purchaser shall purchase the Product in accordance with the terms of this MA, the terms of the applicable Product Order, and the terms of the relevant Quality Agreement.

3.2 The Supplier shall Manufacture the Product at the Manufacturing Site, in conformance with the Specification(s), current industry standards, required Approvals, applicable law, and applicable statutory and regulatory requirements, including but not limited to Good Manufacturing Practice.

## 4. THE PURCHASER'S OBLIGATIONS

4.1 The Purchaser shall:

4.1.1 reasonably cooperate with the Supplier in all matters relating to the Manufacture and supply of the Product;

4.1.2 provide to the Supplier in a timely manner all documents, information, items and materials in any form (whether owned by the Purchaser or a third party) required from the Purchaser under a Product Order or otherwise reasonably required by the Supplier in connection with the Manufacture and supply of the Product and ensure that to Purchaser's knowledge they are accurate and complete in all material respects;

4.1.3 if specified in any applicable Product Order, supply, or cause to be supplied to the Supplier at the Manufacturing Site, at no cost to the Supplier, the agreed upon quantity of the Purchaser Supplied Material, in accordance with the delivery schedule, Purchaser Material Specifications and any other relevant terms set out in the applicable Product Order; and

4.1.4 comply with any additional responsibilities of the Purchaser as set out in the applicable Product Order.

4.2 Without prejudice to the application of Section 19, and any other rights and remedies of the Parties under this MA (express or implied), to the extent and for so long as either Supplier's or Purchaser's, as applicable, performance of its obligations under this MA or a Product Order is prevented, hindered or delayed by any material act or omission of the other Party, its agents, subcontractors, consultants or employees, such Party, shall:

(a) not be in breach of this MA and shall be discharged from performing its obligations under the applicable Product Order;

(b) shall have no liability for any relevant liquidated damages; and

(c) the date for the performance of such Party's relevant obligations shall be extended, subject to such Party continuing to perform all other obligations not affected by such delay / failure of the other Party.

## 5. PRODUCT ORDERS

5.1 Having due regard to the Minimum Lead Time, the Purchaser shall provide the Supplier preliminary Product Order drafts that shall include, *inter alia*, the desired quantities and Specifications of the Products and the desired dates for development, Manufacturing and delivery of the Products by Supplier to the Purchaser. The Supplier will respond to each such preliminary draft Product Order received from the Purchaser with a proposed Product Order draft that includes all the details required for such Product Order as soon as reasonably practicable and no later than ten (10) Business Days following receipt. In the event that discussion is required regarding Prices, the timing of production and delivery, then the relevant planning personnel from both Parties will endeavor to agree upon and confirm any amendments to the proposed Product Order prior to it being accepted in writing by the Supplier. Following receipt of the proposed Product Order draft from the Supplier, the Parties shall use Commercially Reasonable Efforts to execute the Product Order soon as practicably possible. If the Parties are unable to agree upon and confirm any amendments to a proposed Product Order, either Party may require the matter to be resolved in accordance with the dispute resolution procedure in Section 37.

5.2 Other than in the event (i) of Supplier's breach of or non-conformance with the terms of this MA and/or the applicable Product Order, (ii) that Supplier is unable to meet Purchaser's demand as set forth in a Product Order; or (iii) that Supplier terminates this MA and/or the applicable Product Order other than due to Purchaser's material breach of the terms thereof, the Supplier will only accept Purchaser's cancellation or reduction of Product Orders and/or a negative adjustment (including any postponement) to the quantity of Products to be Manufactured under the applicable Product Order upon payment by the Purchaser for all related work in progress and compensation for any non-cancellable costs in accordance with this Clause 5.2. In respect of the services which are detailed in Table 1 of Appendix 1, to reflect the value of non-cancellable costs, the Purchaser will pay the Supplier (other than in the event of cancellation due to a reason specified in Subsections (i)-(iii) above of this Section 5.2) a cancellation fee equal to:

5.2.1 one hundred percent (100%) of the value of the applicable Wasted Conversion Costs as outlined in the Product Order (or the value of the relevant portion of the Wasted Conversion Costs outlined in the Product Order) if there is cancellation or reduction of Product Orders and/or a negative adjustment (including any postponement) to the quantity of Products to be Manufactured under the applicable Product Order less than forty five (45) calendar days prior to the Reserved Time Slot;

5.2.2 fifty percent (50%) of the value of the applicable Wasted Conversion Costs as outlined in the Product Order (or the value of the relevant portion of the Wasted Conversion Costs outlined in the Product Order) if there is cancellation or reduction of Product Orders and/or a negative adjustment (including any postponement) to the quantity of Products to be Manufactured under the applicable Product Order more than forty five (45) calendar days but less than ninety (90) calendar days prior to the Reserved Time Slot; and

(each a "**Cancellation Fee**"). No Cancellation Fee shall be payable if there is cancellation or reduction of Product Orders and/or a negative adjustment (including any postponement) to the quantity of Products to be Manufactured under the applicable Product Order of more than ninety (90) calendar days.

5.2.3 In respect of the services which are detailed in Table 2 of Appendix 1, to reflect the value of non-cancellable costs, the Purchaser will pay the Supplier (other than in the event of cancellation due to a reason specified in Subsections (i)-(iii) above of this Section 5.2) a cancellation fee detailed in each Product Order or, if no such detail is provided in the applicable Product Order, a cancellation fee equal to the Cancellation Fee identified in Section 5.2.1 and 5.2.2 above ("**PO Cancellation Fee**")

5.4 5.3 If a Product Order is cancelled or reduced in accordance with Clause 5.2 above and the Supplier is able to utilize the Manufacturing capacity reserved in anticipation of such cancelled or reduced Product Order for a third party, the Wasted Conversion Costs shall be reduced by a sum equal to the fee paid by such third party. All communication between the Parties pursuant to this Clause 5 shall be by email.

5.5 In all communications, the Supplier and the Purchaser may employ their standard forms, but nothing in those forms will be construed to modify or amend the terms of this MA, and, in the case of any conflict with the terms, the terms and conditions herein will control. Any terms and conditions set forth in a Order, confirmations or any other correspondence from the Purchaser that are in addition to, inconsistent with, or in conflict with the terms of this MA or the Product Order shall have no force or effect unless specifically agreed to in a writing signed by the Supplier which expressly references such terms.

## 6. CHANGES TO PRODUCT ORDERS

6.1 Either Party may propose changes to a Product Order. Proposed changes shall be discussed between the Parties in good faith, but no proposed changes shall come into effect until a relevant Change Order has been executed by both Parties.

6.2 If the Parties are unable to agree upon a Change Order to reflect the changes proposed by a Party to a Product Order, either Party may require the matter to be resolved in accordance with the dispute resolution procedure in Section 37.

## 7. DELIVERY

7.1 The Supplier shall make delivery of the Product Ex Works (Incoterms 2020) at the Manufacturing Site, unless otherwise agreed in the applicable Product Order, on the Delivery Date.

7.2 All Delivery Dates of the Products subject to development services are estimates only, except the Supplier shall use Commercially Reasonable Efforts to deliver the quantity of Product on the Delivery Date or as may otherwise be agreed in writing. The Supplier shall promptly notify Purchaser if the Supplier determines that it will not be able to deliver the Product by the Delivery Dates. In respect of Delivery Dates of the Products which are subject to a validated GMP process, a delay of no more fifteen (15) Business Days shall not be deemed a breach of this MA in the event that Supplier uses all Commercially Reasonable Efforts to deliver the quantity of Product on the Delivery Date and that the delay was communicated to the Purchaser in advance as soon as practicable.

7.3 If the Supplier delivers the Product on the Delivery Date or as may otherwise be agreed in writing in an applicable Product Order, and the Purchaser fails to take delivery or to give the Supplier adequate delivery instructions, the Supplier may charge for any reasonable additional expense incurred in storage and/or re-delivery.

7.4 Each delivery shall be accompanied by the documentation set forth in the applicable Product Order, and a copy of applicable shipping documentation shall be sent by email not later than the date of delivery.

## 8. REJECTION AND REPLACEMENT OF NON-CONFORMING PRODUCT

8.1 Upon receipt of each delivery from the Supplier or any third party on its behalf under this MA, the Purchaser or any third party on its behalf shall examine and test the Products for (a) defect and non-conformity with any applicable standards that the Products are required to meet under this MA and/or the applicable Product Order, including GMP if applicable; (b) in the case of Product manufactured to Specification, the failure of the Product to meet Specification, and (c) such testing as prescribed in the applicable Product Order; and shall report any adverse findings to the Supplier pursuant to Section 8.2.

8.2 The Purchaser may reject any Products delivered to it that do not comply with Section 23.1.1 (**Non-conforming Products**), provided that:

8.2.1 notice of rejection is given to the Supplier;

8.2.2 in the case of a defect that is apparent on normal visual inspection within the earlier of ten (10) Business Days of the Products' seal removal by the Purchaser or its designee or sixty (60) days of the date of actual delivery of the Product to Purchaser;

8.2.3 in the case of any defect in respect of Non-conforming Products which is not reasonably apparent on the date of actual delivery to Purchaser or upon the Product's seal removal, the Purchaser must provide written notice to the Supplier of the defect within fourteen (14) Business Days of the date on which the Purchaser became aware of, or ought reasonably to have become aware of the defect; and

8.2.4 none of the events listed in Section 8.4 apply.

8.3 If the Purchaser fails to give notice of rejection in accordance with Section 8.2 within twelve (12) months of the date of actual delivery to Purchaser of the Product, it shall be deemed to have accepted these Products and the Product shall be deemed to be in accordance with the Specification and except as set forth in Sections 8.6 and 8.7 all claims by the Purchaser concerning non-conformity of such product shall be deemed waived.

8.4 The Supplier shall not be liable for a Product's failure to comply with the warranty set out in Section 23.1.1 in any of the following events:

8.4.1 the Purchaser makes any further use of those Products after giving notice in accordance with Section 8.2;

8.4.2 the defect arises because the Purchaser failed to follow the Supplier's reasonable written instructions for the storage, commissioning, installation, use and maintenance of the Products or (if there are none) Good Manufacturing Practice;

8.4.3 the defect arises as a result of the Supplier duly following any drawing, design or Specification supplied by the Purchaser in writing;

8.4.4 the Purchaser alters or repairs those Products without the written consent of the Supplier, which alteration or repair caused the Product to become Non-confirming Product;

8.4.5 the defect arises as a result of wilful damage, gross negligence, or abnormal storage or working conditions on the part of the Purchaser; or

8.4.6 the Products differ from the Specification as a result of changes reasonably made to ensure they comply with applicable statutory or regulatory requirements, provided that such changes were approved in advance by the Purchaser in writing.

8.5 If the Purchaser rejects the Products in accordance with Section 8.2:

8.5.1 the Parties shall use Commercially Reasonable Efforts as soon as reasonably practicable to agree upon whether or not the delivery in question constitutes Non- conforming Product; and

8.5.2 the Purchaser shall store the Product at issue in a secure, clean and dry environment, and the Supplier shall be entitled at all reasonable times to inspect and/or analyze it.

8.6 The Parties shall use all Commercially Reasonable Efforts to resolve any dispute that may arise pursuant to this Section 8.6, but if the Parties fail to resolve such dispute within thirty (30) days of notification to the Supplier pursuant to Section 8.5, the issue of whether or not the delivery constitutes Non-conforming Product shall be determined by the Independent Laboratory or other independent consultant agreed by the Parties (the "**IC**") and the decision of the Independent Laboratory or the IC shall be final and binding on the Parties, unless there has been a manifest error, in which case, the matter shall be resolved in accordance with the dispute resolution procedure in Section 37. The decision of the Independent Laboratory or the IC must be in writing. The Independent Laboratory or the IC shall act as an expert and not as an arbitrator and (unless the Independent Laboratory or the IC otherwise determines) its fees shall be borne equally by the Parties, provided, however, that the Party against whom the IC or the Independent Laboratory's decision is given must reimburse the successful Party for its share of the costs.

8.7 If the Supplier agrees or the Independent Laboratory or the IC finds that any delivery of the Product is Non-conforming Product, the Supplier will, at the Purchaser's option:

8.7.1 refund the Price (or a proportionate part of the Price relating to the Non-conforming Product) to the extent the same has been paid; or

8.7.2 replace the Non-conforming Product with Product which complies with the requirements of this MA, or applicable Product Order such that the Supplier shall supply, at no extra cost, a replacement delivery to the Purchaser as soon as reasonably practicable. In the event Purchaser requires Supplier to replace such Product, Supplier shall use its Commercially Reasonable Efforts to deliver the quantity of Product that it had failed to deliver as soon as possible by means of expedited means of performance and delivery and shall be responsible for the additional cost thereof; and

8.7.3 collect at its own expense any rejected Product from wherever the Purchaser may reasonably direct or reimburse the Purchaser for any costs reasonably incurred in its disposal of the Non-conforming Product.

## 9. PASSING OF TITLE IN PRODUCT

9.1 Risk in and responsibility for the Product shall pass to the Purchaser in accordance with the applicable Incoterm as specified in Section 7.1 or in the applicable Product Order.

9.2 Title to the Product shall pass to the Purchaser upon delivery in accordance with the applicable Incoterm as specified in Section 7.1 or in the applicable Product Order.

## 10. PRICE OF PRODUCT

10.1 The Price payable by the Purchaser for the Product shall be set out in the applicable Product Order in accordance with the Price List.

10.2 Subject to Section 5.1 or any amendment agreed between the Parties pursuant to Section 28, Table 1 and Table 2 of the Price List at Appendix 1 shall bind the Parties throughout the Term. Notwithstanding the above, subject to Sections 10.4 and 10.5, once per Contract Year (including the first Contract Year), or at any time during a Contract Year if the costs of Materials vary by more than 5% (five per cent) since the Effective Date or since the date of the most recent price review pursuant to this Section 10.2, the Supplier may vary the Price for any future Product Order to reflect the increase or decrease, as the case may be, in the costs of Materials, including, but not limited to increases or decreases relating to currency fluctuations.

10.3 The Supplier shall act in good faith and endeavour to secure the best price reasonably obtainable in the circumstances.

10.4 Supplier shall maintain such records as may be reasonable in the circumstances to verify the calculation pursuant to Section 10.2. Supplier will, upon Purchaser's reasonable request and within one month of the variation pursuant to Section 10.2, provide such records (redacted as the Supplier may determine in its reasonable discretion) to the Purchaser for the strict purpose of allowing the Purchaser to verify the calculation. Purchaser shall agree to keep Supplier's business information confidential. If, following such verification, it is agreed between the Parties that an adjustment is required to any payments that have been made by the Purchaser, such adjustment shall be paid (in the case of an amount due to the Supplier) or credited (in the case of an amount due to the Purchaser) as an adjustment to the amount due on the monthly invoice prepared after the date of such agreement.

10.5 Once per Contract Year, commencing as of the third Contract Year, the Supplier may vary the Price in the Price List which will apply to any future Product Order to reflect the increase or decrease, as the case may be, in the Supplier's non-Materials costs since the Effective Date or since the date of the most recent price review pursuant to this Section 10.5, as the case may be. If the Purchaser does not consent to any change in the Price proposed by the Supplier pursuant to this Section 10.5, the Price shall increase by the lower of 3% (three per cent) or the percentage increase in the PPI Index since the beginning of the previous Contract Year.

10.6 The Price as adjusted in accordance with this Section 10 shall be effective for all future Product Orders placed by the Purchaser until the next scheduled price review, unless otherwise agreed in writing.

10.7 Unless otherwise agreed in an applicable Product Order, the Price and any other amounts payable pursuant to this MA or an applicable Product Order shall be exclusive of sales or other applicable taxes (other than taxes on Supplier's income). Purchaser may withhold any amounts as required by applicable law from any payments due in connection with this MA.

## 11. INVOICE AND PAYMENT

11.1 Subject to Section 11.2, the Supplier shall be entitled to invoice the Purchaser the Price upon the Supplier's delivery of the Product in accordance with the applicable Incoterm as specified in Section 7.1 or in the applicable Product Order, or pursuant to agreed upon payment milestones specified in the applicable Product Order or Price List.

11.2 Unless otherwise stated in the applicable Product Order, the Supplier shall be entitled to invoice the Purchaser:

11.2.1 for the Supplier Supplied Materials, to the extent that the Purchaser is expressly liable to pay for the same pursuant to the applicable Product Order upon the Supplier's delivery of the Product; and

11.2.2 for the Cancellation Fee (or PO Cancellation Fee), if applicable in accordance with Section 5.2, at any time after the date of cancellation or reduction of the relevant Product Order.

11.3 Each invoice issued by the Supplier hereunder shall specify:

11.3.1 the Price in respect of the Product in U.S. Dollars;

11.3.2 the quantity of Product delivered and the applicable Product Order;

11.3.3 the amount of sales or applicable taxes due (if any) in respect of the Product; and

11.3.4 any other amounts reimbursable or payable to the Supplier pursuant to this MA or the applicable Product Order.

11.4 Unless otherwise stated in the applicable Product Order, all amounts due to the Supplier hereunder shall be paid by the Purchaser in full and cleared funds in U.S. Dollars to the account designated by the Supplier in writing, within forty-five (45) calendar days from the end of the calendar month in which the Purchaser received the relevant invoice, without any set-off or counterclaim in respect of any liability of the Supplier. Notwithstanding the foregoing, in the event Purchaser reasonably disputes an invoice and provides Supplier with reasonable written detail of such dispute (on the grounds that the Product is Non- conforming Product or otherwise), Purchaser shall pay the undisputed portion of such invoice only. The failure to pay the reasonably disputed portion of any such invoice shall not be a breach under this MA.

11.5 Without prejudice to any other right or remedy that the Supplier may have, if the Purchaser fails to pay the Supplier any undisputed sum due under this MA on the due date, and such undisputed sum remains outstanding for a period of more than 30 days:

11.5.1 the Purchaser shall pay interest on the overdue undisputed sum from the due date until payment of the overdue sum. Interest under this Section 11.5.1 will accrue at the lower of: (a) two percent (2%) a year above the prime rate published in the *Wall Street Journal* on the date of payment, but at two percent (2%) a year for any period when that prime rate is below zero percent (0%), and (b) the maximum rate permitted by law, until payment is received; and

11.5.2 the Supplier may suspend performance of this MA (in whole or in part) or stop the transmission, of all or any of the Product and work in progress until all outstanding amounts, plus interest charged by the Supplier in addition thereto, is received in full by the Supplier, and the costs of the Supplier doing so are for the Purchaser's account.

11.6 Without prejudice to any other right or remedy that the Supplier may have, if the Purchaser fails to pay an undisputed invoice for ninety (90) days after the due date, then the Supplier will have the right, in its sole discretion, to terminate this MA and the applicable Product Order without penalty.

## 12. SUPPLY AND STORAGE OF MATERIALS AND PRODUCT

12.1 The Supplier shall be solely responsible for ordering the relevant quantities of the Supplier Supplied Materials for use in the Manufacture of the Product and shall ensure that they comply with the requirements of Good Manufacturing Practice and the provisions of this MA. Any such purchase from a supplier shall be on the Supplier's own behalf and not as an agent for the Purchaser.

12.2 If Purchaser requests, the Supplier shall store the Product at the Supplier's premises at Germantown for two (2) month free of charge following release by Purchaser, and thereafter at a daily rate (invoices will include any applicable taxes) as outlined in the applicable Product Order. The Product shall be deemed to have been delivered pursuant to Section 7.1 upon it being placed into storage by the Supplier other than in the event of gross negligence of Supplier in connection with the storage.

## 13. PRODUCT LICENSE

The Purchaser shall be responsible for the registration of the End-Products with all relevant authorities and the Supplier shall, at the Purchaser's expense to the extent that costs are reasonably and properly incurred, provide such assistance as the Purchaser may reasonably request in connection with such matters insofar as such assistance relates to the Manufacture of the Product and/or performance of this MA by the Supplier.

## 14. MANUFACTURING LICENSES

The Supplier shall obtain and maintain in full force and effect for the duration of this MA the Manufacturing License and all necessary permits, approvals and authorizations required under applicable laws in the country of Manufacture to enable the Supplier to Manufacture and supply the Product to the Purchaser.

## 15. QUALITY AGREEMENT

15.1 A separate Quality Agreement shall be entered into in relation to the quality assurance terms applicable to the Manufacture of the Product. Subject to Section 34, each Quality Agreement shall be governed by and incorporated into this MA.

15.2 The Quality Agreement sets out:

15.2.1 the mutually agreed quality standards applicable for the Manufacture of any Product in accordance with the Specification(s) and Good Manufacturing Practice; and

15.2.2 the roles and responsibilities of each party's personnel in relation to quality, regulatory and compliance matters.

## 16. PRODUCT RECALL

16.1 The Purchaser shall be solely responsible in accordance with applicable laws and regulations for the reporting to Regulatory Authorities of any complaints and product recalls relating to the End-Product which arise for any reason. The Supplier shall promptly advise the Purchaser of any occurrence or information which arises out of the Supplier's Manufacturing activities which have or could reasonably be expected to have adverse regulatory compliance and/or reporting consequences concerning the Product and/or the End-Product and promptly furnish copies of any related information or reports as requested by Purchaser or as further set forth and detailed in the Quality Agreement.

16.2 If the Purchaser or any Regulatory Authority deems that a recall of any lots of distributed End-Product is required, the recall process and strategy shall be as set forth in the Quality Agreement.

16.3 The costs of any action required by the Purchaser under this Section 16, shall be borne by the Supplier only in the event and to the extent that upon delivery of Product hereunder such Product did not conform to the Specification, GMP, or the terms of the Manufacturing Licenses; the need for the action is the result of a failure on the part of the Supplier to comply with its obligations under this MA or the Quality Agreement; or is the result of any negligence on the part of the Supplier; subject always to the Purchaser's duty to mitigate under Section 22.7.

## 17. INTELLECTUAL PROPERTY RIGHTS

17.1 This MA shall not affect the ownership of the respective Background of the Parties and nothing in this MA shall oblige either Party to maintain any rights that it has, or may have, in its Background for the benefit of the other Party or otherwise. Except as specifically provided herein, nothing in this MA shall be construed as granting any right in or license to either Party under any Background of the other Party.

17.2 Subject to the provisions of this Section 17, the Purchaser's Intellectual Property shall belong to and be the sole legal and beneficial property of the Purchaser. Supplier hereby assigns to Purchaser or its designee and shall continue to assign to Purchaser or its designee, all right, title and interest of Supplier in any Purchaser's Intellectual Property.

17.3 All Supplier Foreground shall belong to and be the sole legal and beneficial property of the Supplier. Purchaser hereby assigns to Supplier or its designee and shall continue to assign to Supplier or its designee, all right, title and interest of Purchaser in any Supplier Foreground.

17.4 To the extent that it has come to its notice, each Party shall promptly and fully notify the other Party of any actual, threatened or suspected:

17.4.1 infringement of any Intellectual Property of the other Party (to the extent it relates to this MA); and

17.4.2 claim by any third party that the activities of either Party pursuant to this MA (including the use, distribution or sale by the Purchaser of products or of any End Product or of any other product the manufacture of which uses or incorporates the Product), infringe any rights (including Intellectual Property rights) of any other person.

17.5 Each Party shall promptly at the request and cost of the other (whether during or after expiration or termination of this MA) sign and execute all such deeds and documents and do all such acts and things as the other Party may reasonably require to apply for, obtain and vest and maintain any Intellectual Property the other Party owns or to which the other Party should have title in accordance with Section 17.1, 17.2 or 17.3.

17.6 The Purchaser hereby grants to the Supplier a free, non-exclusive license to use any Background provided by the Purchaser together with any Purchaser's Intellectual Property solely for the purpose of fulfilling the Supplier's obligations under this MA. This license terminates automatically on the termination of this MA. Under no circumstances may Supplier transfer Purchaser Supplied Materials, Purchaser Background, Purchaser's Intellectual Property, or Product out of the relevant Manufacturing Site to any Affiliate, subcontractor and/or any other third party without Purchaser's prior written consent.

17.7 The Supplier hereby grants to the Purchaser a free, non-exclusive, perpetual, sublicensable, worldwide, license to use any Background provided by the Supplier together with any Supplier Foreground and Supplier Confidential Information to the extent required to make, have made, use, distribute, import, sell, or offer to sell End Products or the Products supplied by Supplier under this MA.

17.8 Except for the licenses expressly granted in this MA, no rights or licenses are granted by implication, estoppel or otherwise.

## 18. CONFIDENTIALITY

18.1 Each Party undertakes in relation to the Confidential Information of the other Party:

18.1.1 to keep all Confidential Information confidential and in a place and manner that ensures such confidentially (which in any event shall be not less than customary industry standards);

18.1.2 not to use Confidential Information except as strictly necessary for the purposes of performing its obligations under this MA (**Permitted Purpose**) (and in particular not to use Confidential Information to obtain a commercial, trading or any other advantage);

18.1.3 not, without the other Party's prior written consent, to disclose Confidential Information to any other person except those of its employees, officers, representatives, consultants and advisers who need to know the Confidential Information in connection with the Permitted Purpose; and

18.1.4 at the earlier of: (a) end of the Term, and (b) within seven (7) days following a written request by the disclosing Party at any time, to return all Confidential Information and all documents or media containing any such Confidential Information and any and all copies or extracts thereof or, where return is not possible or at the request of the disclosing Party, to delete, destroy or render inaccessible such Confidential Information, save for one confidential copy that may be retained in a Party's confidential files solely for purposes of monitoring compliance with the terms hereof and, where applicable, for the purposes of regulatory compliance. Any Confidential Information retained pursuant to the foregoing sentences shall remain subject to the confidentiality obligations under this MA until destroyed or no longer deemed Confidential Information based on Section 18.2 hereinafter.

18.2 Section 18.1 shall not apply to Confidential Information to the extent that it is or was:

18.2.1 already in the possession of the other free of any obligation of confidentiality on the date of its disclosure to such other Party;

18.2.2 received by the other independently from a third party free to lawfully disclose such information;

18.2.3 in the public domain other than as a result of a breach of this Section 18;

18.2.4 required to be disclosed:

(a) pursuant to applicable law, by any governmental or regulatory body or by a securities exchange of competent authority; or

(b) in connection with proceedings before a court of competent jurisdiction or under any court order or for the purpose of receiving legal advice, but only to the extent and for the purpose of that disclosure and provided that, to the extent it is legally permitted to do so, it gives the other Party as much notice of such disclosure as possible.

18.3 Without derogating from the foregoing, disclosure of the contents and the existence of this MA by a party in connection with a due diligence inquiry and subject to confidentiality undertakings at least as restrictive as those contained in this MA shall not be considered to be a breach of this MA.

18.4 Each Party acknowledges that Confidential Information is valuable and that damages might not be an adequate remedy for any breach of Section 18.1, and accordingly, a Party will be entitled, without proof of special damage, to an injunction and other equitable relief for any actual or threatened breach of this Section 18.

18.5 Except as provided in Section 17 hereof, no right or license, either express or implied, is granted under any Intellectual Property right by virtue of disclosure of Confidential Information under this MA or otherwise.

18.6 The confidentiality obligations under this Section 18 shall survive and remain in full force and effect after termination or expiration of this MA for any reason for a period of seven years or such longer period if trade secret protection shall apply.

## 19. FORCE MAJEURE

19.1 A Party shall not be in breach of this MA, nor liable for any failure or delay in performance of any obligations under this MA arising from or attributable to a Force Majeure Event.

19.2 Any Party that is subject to a Force Majeure Event shall not be in breach of this MA provided that it promptly notifies the other Parties in writing of the nature and extent of the Force Majeure Event causing its failure or delay in performance.

19.3 If the Force Majeure Event prevails for a continuous period of more than six (6) months, any Party may terminate this MA by giving fourteen (14) days' written notice to the other Party. Upon the expiration of this notice period, this MA will terminate.

## 20. RECORDS, INSPECTIONS & AUDITS

20.1 The Purchaser, its designee and representatives of applicable Regulatory Authorities, shall have the right from time to time during the Term of this MA at least once per Contract Year during the hours between 09:00 am to 5:00 pm on a Business Day, and (except in the case of Regulatory Authorities) upon not less than fifteen (15) Business Days prior written notice to enter and inspect the Manufacturing Site and any related utilities, any premise where Records (as defined below) are maintained and/or services used in the Manufacture of the Product, and Supplier's equipment, documents and records (including without limitation any Manufacturing Licenses and Records) for the purpose of determining compliance with the requirements of this MA or any Product Order and applicable laws or to the extent required to carry out GMP, quality, environmental and compliance audits of those parts of the Manufacturing Site involved in or which could have any impact on the Manufacture of the Product.

20.2 The Purchaser shall have the right to enter the Manufacturing Site at any time during normal business hours and upon not less than five (5) Business Days prior written notice to inspect any Product stored by the Supplier for the purpose of Section 8.1.

20.3 Where the Supplier is required to undertake an audit by a Regulatory Authority directly related to the Product, the Supplier shall at the expense of the Purchaser, undertake a pre–audit review to ensure compliance with the Regulatory Authority's requirements.

20.4 At its own expense, Supplier shall keep and maintain complete and accurate records of its performance of Manufacturing services pursuant to this MA ("**Records**"). The Records shall be prepared, maintained and retained consistent with generally accepted standards (a) in accordance with, and shall be subject to, the provisions of applicable laws and the procedures set forth in the Quality Agreement; (b) sufficient to demonstrate that any and all amounts invoiced to Purchaser under the Product Order are accurate and proper in both kind and amount; and (c) sufficient to demonstrate the accuracy of any representations or reports submitted to Purchaser under the MA. Records shall be maintained and stored in secure and readable formats agreed between the Parties. Purchaser will maintain all of the Records in accordance with its standard operating procedures. At no additional cost to Purchaser, Supplier will allow Purchaser to inspect Records upon reasonable notice, and shall deliver a copy to Purchaser upon its written request. Purchaser shall be further entitled to make use of such Records in connection with its regulatory activities.

## 21. SAFETY HAZARDS

21.1 The Parties will inform one another and keep one another informed of all safety hazards and changes in regulations and guidance (statutory or otherwise) which either Party knows or believes to impact the use, handling, storage, labelling, transport, treatment and disposal of the Product and each Party will ensure that the Product is handled by it in accordance with the special handling procedures required for the Product.

21.2 The Supplier will ensure that relevant consignments are safe, packaged, labelled so as to prevent any health risk to persons, property or the environment and properly marked with the appropriate internationally recognised danger symbols and that prominent hazard warnings appear in English on all packages and documents.

## 22. INDEMNITIES

22.1 Subject to Section 24, the Purchaser shall indemnify, defend and hold harmless the Supplier from and against any and all Losses to the extent arising out of or resulting from:

22.1.1 the material breach of this MA by the Purchaser;

22.1.2 Product recalls, End Product recalls, personal injury, product liability or property damage arising from or relating to the Purchaser's use, handling, design, labelling or sales of the Product or any End-Product or other product the manufacture of which uses or incorporates the Product except to the extent the Supplier is obligated to indemnify the Purchaser under Section 22.2;

22.1.3 any chemical process, procedure or materials provided by the Purchaser to the Supplier for use in performing its obligations under this MA except to the extent the Supplier is obligated to indemnify the Purchaser under Section 22.2; or

22.1.4 any claims alleging Supplier's proper use of the Purchaser Supplied Materials, infringes any rights (including, without limitation, any Intellectual Property rights) vested in any third party,

except to the extent the Supplier is obligated to indemnify the Purchaser under Section 22.2.

22.2 Subject to Section 24, the Supplier shall indemnify, defend and hold harmless the Purchaser from and against any and all Losses to the extent arising out of or resulting from:

22.2.1 the material breach of this MA or a Product Order by the Supplier;

22.2.2 the improper administration, use, handling, storage or other disposition of the Purchaser Supplied Materials in any form;

22.2.3 failure of Supplier to manufacture the Product according to GMP material non- conformance or material deviation of any of the required quality, quantity, storage, handling or packaging requirements as set forth in this MA, the Specifications, the applicable Product Order, the Quality Agreement, the Manufacturing Licenses or applicable laws;

22.2.4 any claims alleging that any of Supplier's acts hereunder (excluding Supplier's proper use of Customer Materials) infringes any rights (including without limitation any Intellectual Property rights) vested in any third party;

22.2.5 gross negligence, willful misconduct or illegality, on the part of Supplier or its Affiliates; or.

22.2.6 any Product recalls, End Product recalls, personal injury, product liability or property damage relating to or arising from any breach of the Supplier's warranties hereunder

except to the extent the Purchaser is obligated to indemnify the Supplier under Section 22.1.

22.3 The Party seeking indemnity hereunder shall notify the indemnifying Party in writing of any fact or circumstance which gives rise to liability for which the indemnified Party is indemnified hereunder with reasonable promptness after such fact or circumstance first comes to the attention of the indemnified Party, further provided, however, that the failure by the indemnified Party to give such notice shall not relieve the indemnifying Party of its indemnification obligations unless, and only to the extent that, the failure to give such notice actually prejudices the rights of the indemnifying Party.

22.4 If a demand, claim or action arising from any circumstance for which the indemnified Party is indemnified hereunder is brought by a third party, the indemnifying Party shall diligently defend such demand, claim or action at its expense with counsel of its choice and shall keep the indemnified Party informed with respect to such defence and shall take into consideration the reasonable requests of the indemnified Party with respect to the manner in which such defence is handled.

22.5 The indemnifying Party shall not have the right to compromise or settle such claim without written consent of the indemnified Party, which consent shall not be unreasonably refused or delayed.

22.6 The indemnified Party shall cooperate with the indemnifying Party in all reasonable ways in defense of any such demand, claim or action, at the indemnifying Party's expense.

22.7 Notwithstanding the indemnities granted under this MA, the Purchaser and the Supplier shall use Commercially Reasonable Efforts to mitigate any losses which they may respectively incur and in respect of which they may be entitled to be indemnified by the other Party pursuant to this Section 22.

22.8 The provisions of this Section 22 shall continue in force after termination or expiration of this MA.

## 23. WARRANTIES AND DISCLAIMERS

The Supplier Warranty

23.1 The Supplier warrants to the Purchaser that:

23.1.1 the Products shall meet the Specification when delivered and for the period of its shelf life as confirmed by the stability tests required under the Product Order and shall be Manufactured by the Supplier in compliance with GMP, the provisions of this MA and the Quality Agreement, all applicable law and with the appropriate level of skill and care by professional personnel, qualified to perform the Manufacturing procedures consistent with the technical requirements set forth in the Product Order;

23.1.2 it has the right to enter into this MA and Product Order and the execution, delivery and performance of this MA or a Product Order will not conflict with, violate or breach any agreement to which the Supplier is a party, nor does the execution, delivery and performance of this MA by Supplier violate any order, law or regulation of any court, governmental body or administrative or other agency having authority over it;

23.1.3 it has the appropriate facilities, skilled personnel, registrations, licenses permits and other governmental authorizations required to carry out its obligations under this MA;

23.1.4 it will perform its obligations under this MA in accordance with generally accepted standards of the industry and reasonable skill and care;

23.1.5 to its knowledge, it owns its Background and it has the unencumbered right to disclose its Background, the Supplier Foreground and the Supplier Confidential Information to the Purchaser and to authorise the Purchaser to use, and license to the Purchaser the use of, the Supplier's Background, Foreground and Confidential Information as permitted hereunder. During the Term, Supplier will not enter into any contract, arrangement or commitment which prohibits the grant of such license rights;

23.1.6 it will not knowingly infringe or misuse any rights (including without limitation any Intellectual Property rights) vested in any third party in its Manufacturing of the Products; and

23.1.7 all Product delivered hereunder will be transferred free and clear of any liens or encumbrances of any kind.

23.2 EXCEPT FOR THE FOREGOING, THE SUPPLIER MAKES NO WARRANTY OR REPRESENTATION OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF SATISFACTORY QUALITY, FITNESS FOR A PARTICULAR PURPOSE AND MERCHANTABILITY, AND ANY REPRESENTATION OR ANY WARRANTY THAT THE MANUFACTURE, USE OR SALE OF PRODUCT WILL NOT INFRINGE THE INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY.

23.3 IT IS ACKNOWLEDGED AND AGREED THAT THIS MA PROVIDES FOR THE CARRYING OUT OF EXPERIMENTAL RESEARCH AND THE USE OF EXPERIMENTAL MATERIALS WHOSE PROPERTIES AND SAFETY MAY NOT HAVE BEEN ESTABLISHED. ACCORDINGLY, SPECIFIC RESULTS CANNOT BE GUARANTEED AND ANY RESULTS, MATERIALS, INFORMATION OR INTELLECTUAL PROPERTY RIGHTS PROVIDED OR DELIVERED UNDER OR IN ACCORDANCE WITH THIS MA. WITHOUT LIMITING THE FOREGOING, THE SUPPLIER DOES NOT GIVE ANY WARRANTY THAT ANY PATENT APPLICATIONS MADE OR LICENSED PURSUANT TO THIS MA WILL RESULT IN VALID, GRANTED PATENTS, OR THAT THE PRODUCTS ULTIMATELY WILL ACHIEVE COMMERCIALLY VIABLE SALES.

The Purchaser Warranty

23.4 The Purchaser represents and warrants to the Supplier that:

23.4.1 it is entering into this MA solely to obtain Product relating to the manufacture by the Purchaser of drug products;

23.4.2 regulations relating to its activities under this MA, and its transportation, export, handling, storage, marketing, sale, distribution or other use by the Purchaser of any Product delivered hereunder or of any End-Product or other drug product into which any Product is incorporated by or on behalf of the Purchaser;

23.4.3 without limiting the foregoing, in no event will the Purchaser sell, market or distribute any Product or any End-Product or other drug products incorporating the Product to any third party for human or veterinary consumption prior to the completion of all necessary validation work required for compliance with Good Manufacturing Practices. For clarity, the validation of the Products shall be performed by the Supplier in accordance with Purchaser's written instructions as shall be set forth in the applicable Product Orders;

23.4.4 to its knowledge, the Purchaser owns its Background and it has the unencumbered right to disclose its Background and Confidential Information to the Supplier and to authorise the Supplier to use, and license to the Supplier the use of, the Purchaser's Background and Confidential Information for the purposes of performing the Supplier's obligations under this MA;

23.4.5 to its knowledge, proper use of any of the Purchaser's Background and Confidential Information by the Supplier as authorized under this MA, including without limitation, for the manufacturing of the Product by the Supplier and any required intermediate compounds, and the sale to the Purchaser of the Product by the Supplier contemplated hereunder, will not infringe the Intellectual Property Rights of any third party;

23.4.6 to its knowledge, the use, distribution or sale by the Purchaser of Products will not infringe the Intellectual Property Rights of any third party; and

23.4.7 it has the right to enter into this MA and Product Order and the execution, delivery and performance of them does not conflict with, violate or breach any other agreement to which the Purchaser is a party.

**24. LIMITATIONS OF LIABILITY**

24.1 Sections 24.4 and 24.6 set out the entire liability of the Supplier (including any liability for the acts or omissions of its officers, employees, agents or subcontractors) to the Purchaser in respect of:

24.1.1 any breach by the Supplier of this MA;

24.1.2 non or incomplete performance or contemplated performance by the Supplier of this MA;

24.1.3 negligence for which the Supplier is liable;

24.1.4 any other tortious act or omission or breach of statutory duty on the part of the Supplier or on the part of any of its employees, agents or subcontractors; and

24.1.5 any representation or statement arising under or in connection with this MA or by or on behalf of the Supplier.

24.2 The Supplier shall in all circumstances have no liability:

24.2.1 Resulting from or in connection with the Purchaser's breach of this MA or any Product Order;

24.2.2 by the Supplier following any instruction, process or specification provided in writing by the Purchaser; or

24.2.3 resulting from or in connection with any act, omission or delay by the Purchaser.

24.3 The Price of the Product is determined on the basis of the exclusions from and limitations of liability contained in this MA. Each Party expressly agrees that these exclusions and limitations are reasonable because of (amongst other matters) the likelihood that the amount of damages awardable to the other Party for breach of this MA may be disproportionately greater than the Price of the Product.

24.4 EXCEPT IN THE EVENT OF A BREACH OF ITS OBLIGATIONS OF CONFIDENTIALITY OR ITS INFRINGEMENT OR MISAPPROPRIATION OF THE OTHER PARTY'S INTELLECTUAL PROPERTY RIGHTS, IN NO EVENT SHALL ONE PARTY'S LIABILITY TO THE OTHER PARTY UNDER SECTION 22 OF THIS MA EXCEED THREE (3) TIMES THE PRICE PAID BY THE PURCHASER TO THE SUPPLIER DURING THE TWELVE MONTHS PRECEDING SUCH CLAIM.

24.5 EXCEPT IN THE EVENT OF A BREACH OF ITS OBLIGATIONS OF CONFIDENTIALITY OR ITS INFRINGEMENT OR MISAPPROPRIATION OF THE OTHER PARTY'S INTELLECTUAL PROPERTY RIGHTS AND SUBJECT TO SECTION 24.4, IN NO EVENT SHALL ONE PARTY'S LIABILITY TO THE OTHER PARTY UNDER THIS MA EXCEED TWO (2) TIMES THE PRICE PAID BY THE PURCHASER TO THE SUPPLIER DURING THE TWELVE MONTHS PRECEDING SUCH CLAIM

24.6 IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER FOR LOSS OF PROFIT, LOSS OF REPUTATION, LOSS OF BUSINESS, REVENUE OR GOODWILL, LOSS OF ANTICIPATED SAVINGS, LOSS OR DAMAGE TO DATA, OR CONSEQUENTIAL OR INDIRECT LOSS. FOR THE AVOIDANCE OF DOUBT, THIS LIMITATION SHALL NOT LIMIT THE PURCHASER'S OBLIGATIONS TO PAY FOR THE PRODUCTS PROPERLY RENDERED WHEN DUE.

24.7 Notwithstanding anything to the contrary herein, neither Party's liability to the other Party for:

24.7.1 death or personal injury resulting from the negligence of the Party concerned, its employees, agents or subcontractors; or

24.7.2 fraud (including fraudulent misrepresentation),

shall be excluded or limited, nor shall any other liability be excluded or limited to the extent such liability may not be excluded or limited as a matter of law.

## 25. INSURANCE

25.1 During the term of the MA, and for a period of five (5) years after its termination or expiration for any reason, each Party shall maintain, at its own cost, full and sufficient third party, public and product liability insurance, and such other types of insurance as are customary for persons and entities in this line of business, which may be by means of self-insurance, with sufficient coverage for its actual and potential liabilities hereunder and shall provide to the other party a certificate of such insurance (or equivalent) upon request. Without derogating from the above, during the term of the ma, supplier must maintain a comprehensive general liability insurance performing the services hereunder and an insurance covering any damage to the materials and the products, with insurance companies and in amounts as supplier customarily maintains for similar activities.

## 26. DURATION AND TERMINATION; RESCHEDULING AND REDUCTION OF ORDERS

26.1 This MA shall be effective as of the Effective Date and shall remain in full force and effect for a period of five (5) years after which period, subject to earlier termination in accordance with its terms, it will automatically terminate unless extended by agreement between the Parties in writing.

26.2 Either Party may terminate any Product Order by written notice at a date set in such notice in the event of a material breach of that Product Order, the Quality Agreement or the MA by the other Party, provided that, if the breach is curable, the breaching Party fails to cure such breach within twenty (20) calendar days from the date of such notice.

26.3 Purchaser may cancel any Product Order or reschedule for a later date than the applicable due Manufacturing/delivery date any Manufacturing/delivery of Products determined pursuant to any Product Order or reduce the quantity of Products ordered under any Product Order subject to payment of the Cancellation Fees (or PO Cancellation Fee) specified in Section 5.2 above.

26.4 If either Party experiences an Insolvency Event, it shall promptly notify the other Party in writing giving particulars of the circumstances whereupon such other Party may terminate this MA together with any Product Orders then in effect immediately by a written notice (for the avoidance of doubt, the MA together with any Product Orders in effect may be terminated upon the occurrence of an Insolvency Event notwithstanding that the notice may not have been given as required).

26.5 If, in the reasonable opinion of the Supplier or the Purchaser, the safety profile of the other Party deteriorates, or the other Party is associated with unethical behaviour and in the reasonable opinion of such Party, association with the other Party would bring the reputation of such Party into disrepute, such Party may terminate the MA and all Product Orders immediately by written notice.

26.6 Either the Supplier or the Purchaser may terminate the applicable Product Order if it reasonably determines that the manufacture of the Product is not feasible in accordance with the Specification or otherwise, for scientific or technical reasons despite Supplier applying Commercially Reasonable Efforts, or that a safety hazard of a type described in Section 21 exists that cannot be safely and appropriately managed by the Supplier. Such issue shall be discussed, and a sixty (60) day period shall be allowed for good faith discussions and attempts to resolve such problems (e.g., by modifications of the Product Order). If Supplier is and will remain unable to resolve the scientific or technical issues, then either Party may terminate the applicable Product Order by written notice.

26.7 Either Party may terminate this MA on thirty (30) days written notice to the other Party if there are no Product Orders then in effect.

## 27. CONSEQUENCES OF TERMINATION

27.1 Upon termination or expiration of this MA, each Party shall at the request of the other Party, within five (5) Business Days of such request and at the requesting Party's cost, return to Confidential Information of the requesting Party, together with all know-how and/or information of a technical nature relating to the relevant Product and its manufacture which it has in its possession and which were provided to it by the requesting Party, together with all copies thereof (except for one (1) copy, which may be retained for the purposes of complying with applicable regulatory obligations, or to perform and enforce its surviving obligations under this MA).

27.2 Upon termination or expiration of this MA, each Party shall at the request of the other Party, within thirty (30) Business Days of such request and at the requesting Party's cost, return to the requesting Party or otherwise destroy (at the requesting Party's election) all of the requesting Party's property, equipment, materials and inventory, except to the extent it is required to be retained by law or to comply with such Party's continuing obligations hereunder.

27.3 With effect from termination or expiration of the MA, neither Party shall make any use for any purpose whatsoever of any relevant Intellectual Property or Confidential Information which is the property of the other Party and shall ensure that copies thereof are dealt with in accordance with Section 18.

27.4 The Supplier agrees, at the Purchaser's expense, to provide the Purchaser with reasonable assistance with respect to any investigation or filing required by any Regulatory Authority with respect to Manufacture of the Product carried out prior to such termination or expiration even after the date of such termination or expiration.

27.5 Upon termination or expiration of this MA or a Product Order, the Supplier shall cease to produce the relevant Product for the Purchaser, and (except for in the event of termination of a Product Order pursuant to the provisions of Section 26.3 above) will issue the Purchaser with an invoice for all work in progress, unused Materials (to the extent Supplier is unable to use such materials for other products) and outstanding costs incurred by the Supplier in the Manufacture of the Product as detailed in the applicable Product Order (including without limitation, the Cancellation Fees (or PO Cancellation Fee) (if any)), unless terminated by the Purchaser for the Supplier's material breach under Section 26.2. Such invoice shall be paid in accordance with the provisions of Section 11.4.

27.6 Any termination or the expiration of this MA will not affect the coming into force or the continuance in force of any provision which is intended to come into or continue in force on or after such termination or expiration.

27.7 Termination of this MA shall not affect any rights, remedies, obligations or liabilities of the Parties that have accrued up to the date of termination, including the right to claim damages for any breach that existed on or before the date of termination.

## 28. AMENDMENT

No amendment to this MA shall be effective unless it is in writing and signed by the Parties.

## 29. WAIVER

29.1 A waiver of any right or remedy under this MA or by law is only effective if given in writing and shall not be deemed a waiver of any subsequent right or remedy.

29.2 A failure or delay by a Party to exercise any right or remedy provided under this MA or by law shall not constitute a waiver of that or any other right or remedy, nor shall it prevent or restrict any further exercise of that or any other right or remedy. No single or partial exercise of any right or remedy provided under this MA or by law shall prevent or restrict the further exercise of that or any other right or remedy.

## 30. NOTICES

30.1 Any notice to be given under this MA or any Product Order shall be:

30.1.1 in writing in the English language;

30.1.2 signed by or on behalf of the Party giving it; and

30.1.3 addressed to the other Party at its registered office or such other address as may have been notified for these purposes, marked for the attention of the CEO of the Purchaser, with a copy to General Counsel, Sterling Pharma Solutions Limited, Sterling Place, Dudley, Northumberland, NE23 7QG, United Kingdom**1** (in the case of the Supplier), and for the attention of Purchaser's counsel, Horn & Co. Law Offices, Amot Investments Tower, 2 Weizmann St. , 24th Floor, Tel-Aviv 6423902, Israel (in the case of the Purchaser).

30.2 A notice shall either be:

30.2.1 delivered by hand;

30.2.2 sent by registered or certified United States mail to an address in the United States with return receipt requested;

30.2.3 sent by reputable international overnight courier (if notice is to be served by post to an address outside the country from which it is sent); or

30.2.4 sent be electronic email or facsimile.

30.3 A notice shall be deemed to have been received:

30.3.1 if delivered by hand, upon signature of a delivery receipt;

30.3.2 if sent by registered or certified United States mail to an address in the United States, at 9.00am on the third (3rd) Business Day after posting;

30.3.3 if sent by reputable international overnight courier to an address outside the country from which it is sent, on signature of a delivery receipt;

30.3.4 if sent be email or facsimile, at 9.00am on the first (1st) Business Day after sending,

provided that a notice delivered or posted, as appropriate, after 5.00pm on any Business Day or on a non-Business Day shall be deemed delivered or posted, as appropriate, at 9.00am on the next Business Day.

## 31. RELATIONSHIP OF THE PARTIES

Nothing in this MA or any Product Order is intended to, or shall be deemed to, establish any partnership between any of the Parties, or constitute any Party to this MA the agent, fiduciary or employee of any other Party to this MA. No Party to this MA will have any authority to impose any obligation to a third party on any other Party to this MA.

## 32. ASSIGNMENT AND SUBCONTRACTING

32.1 Neither party will assign or transfer any rights or obligations under this MA without the other Party's prior written consent (not to be unreasonably withheld); except that either Party may assign or transfer any rights or obligations under this MA without such consent to an Affiliate or to its successor in interest by way of merger, acquisition or sale of all or substantially all of its assets to which this MA relates.

32.2 Subject to Purchaser's prior written consent, the Supplier's Affiliates may, from time to time, fulfil the Supplier's obligations under this MA.

## 33. ENTIRE AGREEMENT

33.1 This MA, the Product Orders, the Price List the Quality Agreements and any documents appended or expressly incorporated herein or therein constitutes the entire agreement between the Parties and supersedes and extinguishes all previous agreements, arrangements, promises, assurances, warranties, representations and understandings between them, whether written or oral, relating to its subject matter.

33.2 Each Party agrees that it does not rely on and will have no remedies in respect of any statement, representation, assurance or warranty (whether made innocently or negligently) that is not set out in this MA or the Product Order.

## 34. CONFLICT BETWEEN DOCUMENTS

34.1 If and to the extent there is a conflict, discrepancy or inconsistency between any of the provisions of:

34.1.1 the main body of this MA (including the Price List);

34.1.2 any Product Order;

34.1.3 any Quality Agreement; and

34.1.4 any other document or form used by the Parties,

the earlier listed document shall prevail over the later listed document, except:- i) to the extent that a document expressly and specifically states an intent to supersede any prevailing document MA on a specific matter; or ii) with respect to quality assurance and quality compliance matters in connection with the Products supplied by the Supplier, the terms of the Quality Agreement shall have priority over the terms of MA any document or form used by the Parties.

## 35. RIGHTS AND REMEDIES

Unless expressly stated in relation to any Section of this MA, the rights and remedies given to the Parties in this MA and any Product Orders are: i) in addition to; ii) without prejudice to; and

iii) not exclusive of; any and all other rights or remedies given to them whether by this MA, the Product Orders, by law or otherwise, and all such rights and remedies are cumulative.

## 36. SEVERABILITY

36.1 Each provision or sub-provision of this MA and each Product Order is severable and distinct from the others.

36.2 If any provision or sub-provision of this MA or any Product Order is or becomes to any extent invalid, illegal or unenforceable under any regulation or applicable law in any jurisdiction, but would be valid, legal and enforceable if the provision or sub-provision were modified, that provision or sub-provision will apply with whatever modification is necessary to make it valid, legal and enforceable. If such modification is not possible, it will be severed from the remainder of this MA or the applicable Product Order (as applicable), and in either case, neither the validity, legality or enforceability of the remaining provisions, nor the legality, validity or enforceability of such provision or sub-provision under the law of any other jurisdiction will be affected.

## 37. DISPUTE RESOLUTION

37.1 If any dispute arises in connection with this MA or any Product Order (**a Dispute**), either Party may by written notice (**a Referral Notice**) to the other Party refer the matter for resolution.

37.2 Once a Referral Notice has been served in relation to a Dispute, that Dispute shall be referred for resolution to the Representatives (who will be senior individuals in each Party as specified by the respective Parties to this MA at that time). Those Representatives shall meet at the earliest convenient time and in any event within ten (10) days of the date of service of the relevant Referral Notice and shall in good faith attempt to resolve the Dispute.

37.3 If a Dispute has not been resolved within twenty (20) days of such meeting of the Representatives, the Parties shall be free to seek for any lawful remedy or file any claim in the Competent Courts. The "**Competent Courts**" of London, England, shall have sole and exclusive jurisdiction to settle any disputes which may arise in connection with this MA or any other document executed by the Parties.

37.4 Nothing in this Section 37 will prevent or delay either Party from:

37.4.1 seeking orders for specific performance, interim or final injunctive relief in any competent court worldwide (and not necessarily in a Competent Court);

37.4.2 exercising any rights it has to terminate this MA, Quality Agreement or a Product Order; or

37.4.3 commencing any proceedings where this is necessary to avoid any loss of claim due to the rules on limitation of actions.

**38. THIRD PARTY RIGHTS**

Except as expressly stated in this MA or provided under Section 32, no third party, except any permitted successor or assign of any Party to this MA, has any rights to enforce any term of this MA.

**39. GOVERNING LAW**

This MA and any dispute or claim arising out of or in connection with its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the laws of England and Wales.

**40. COUNTERPARTS**

This MA and each Product Order may be executed in any number of counterparts by the Parties, each of which when executed and delivered shall constitute an original, but all of which together shall constitute one and the same agreement. Delivery of the executed Agreement by electronic means is equally as effective and binding as delivery of an originally-executed Agreement.

**41. ELECTRONIC SIGNATURE**

Each Party agrees to execute this MA by electronic signature (whatever form the electronic signature takes), and that this method of signature is conclusive of the Parties' intention to be bound by this MA.

IN WITNESS WHEREOF, the Parties have entered into this MA as of the Effective Date.

**SUPPLIER**

**Sterling Wisconsin, LLC**

By: */s/ Andrew Henderson*
Name: Andrew Henderson
Title: Chief Commercial Officer

**PURCHASER**

**BIOSIGHT LTD.**

By: */s/ Ruth Ben Yakar__& /s/ Roy Golan*
Name: Ruth Ben Yakar__& Roy Golan _____
Title: CEO_____EVP & CFO___

Appendix 1 – Price List

Appendix 2 – Sample Product Order

Appendix 3 – Template Change Order

**Exhibit 10.46**

**Separation Agreement (the "Agreement")**

By and between Biosight Ltd., with its registered office at 3 Hayarden St., Airport City, Lod, Israel (the "**Company**"), and RAM Technologies (RBY 2012) Ltd. (the "**CEO**") and Dr. Ruth Ben Yakar ("**Dr. Ben Yakar**"), dated this 7th day of October 2021.

**Whereas,** the, Company and the CEO are parties to a certain Consultancy Agreement, dated December 21, 2014 (as amended, the "**Consultancy Agreement**"); and

**Whereas,** Dr. Ben Yakar has been serving as a member of the Company's board of directors.

**Whereas**, on July 1, 2021, the Board of Directors of the Company (the "**Board**") approved a certain merger transaction between the Company, Advaxis Inc. and Advaxis Inc.'s subsidiary (the "**Merger**") pursuant to the terms and conditions set forth in the Agreement and Plan of Merger and Reorganization dated July 4, 2021 (as such agreement may be further amended by the parties thereto, the "**Merger Agreement**"); and

**Whereas**, the parties have reached certain agreements as further detailed herein, which shall enter into force and effect following and subject to the consummation of the Merger pursuant to the terms set forth below;

Therefore, it is hereby agreed by the parties as follows:

1. **Termination of Engagement**: Immediately following to and contingent upon the closing of the Merger (the "**Closing**") the CEO and Dr. Ben Yakar personally where applicable, shall: (i) resign from her Board position and cease to serve as an officer of the Company; and (ii) cease to act as the Company's CEO; (iii) support the Company in the handover of responsibilities and perform all tasks assigned to it/her by the Board for a proper transition of her position to the new Company's CEO (including without limitation, fully support the Merger) for a period of 12 months following the Closing (as such term is defined in the Merger Agreement) as a consultant of the Company (the "**Consultancy Period**"). The engagement of the parties shall automatically terminate upon the end of the Consultancy Period (subject to survival of provisions of the Consultancy Agreement which survive termination of the Consultancy Agreement, for the period and terms provided therein). In consideration for her services to the Company during the Consultancy Period, the CEO shall receive; (i) at the end of each month during the first three months of the Consultancy Period, an amount of NIS 92,400 + VAT; and (ii) at the end of each month during the remaining nine months of the Consultancy Period, an amount of NIS 5,000 + VAT. Continuing the provision of services under this section 1 by Dr. Ben Yakar (through the CEO) shall not be deemed as "Termination of Employment" for the purposes of Section 10.1 of Company's 2009 Israeli Share Option Plan.

2. **Compensation pursuant to the Consultancy Agreement and Board Resolutions**: Until the Closing, the Company shall continue to pay to the CEO the consideration to which the CEO is entitled pursuant to the Consultancy Agreement in accordance with the terms of the Consultancy Agreement and to any resolution of the Board, including without limitation, to the recommendations of the Board's Compensation Committee and the resolution of the Board with respect to Dr. Ben Yakar's annual bonus for 2021 dated March 22, 2021.

3. **Merger Bonus**: Following to and contingent upon the Closing, the CEO shall be entitled to a one-time bonus payment in the amount of NIS 550,000 + VAT (the "**Merger Bonus**"). The Merger Bonus will be paid within 14 days following the Closing.

4. **Options**: Immediately following and contingent upon the Closing the vesting of all the options that were granted to the Dr. Ben Yakar for her services as a member of the Company's Board pursuant to the terms of Company's 2009 Israeli Share Option Plan (the "**Plan**") which shall be non-vested on the date of the Closing shall accelerate, similar to the acceleration of all other Company's outstanding unvested options in the framework of the Merger Agreement, such that all such options shall be deemed fully vested as of the date of the Closing. Company undertakes that the shares purchased by Dr. Ben Yakar as a result of the exercise of her options under the Plan and assumption of such options by Advaxis Inc. shall not be subject to lock-up following the Merger, unless required by the lead banks and investors of the round of Private Investment in Public Equity contemplated by the Company. Notwithstanding the above, should such lead banks and investors require a lock up, the Company shall make its best efforts to avoid it with respect to Dr. Ben Yakar.

5. **Mutual non-disparagement**: The Company, including any of its officers and board members. will not disparage the CEO (nor Dr. Ben Yakar) or it/her performance or otherwise take any action or make any comment or statement, whether written or oral, that could reasonably be expected to adversely affect the CEO's personal or professional reputation. Similarly, the CEO and Dr. Ben Yakar will not disparage the Company or any of its directors, officers, or employees or otherwise take any action that could reasonably be expected to adversely affect the personal or professional reputation of the Company or any of its directors, officers, or employees. Nothing herein is to be construed as attempting to impede either party's obligation, as applicable, to respond to inquiries required by law.

6. **Continued Obligations**: Nothing herein is intended to derogate from the Company, the CEO's or Dr. Ben Yakar's obligations under the Consultancy Agreement or any applicable law, including with respect to non-competition and/or confidentiality, for the specific periods stated therein, as set forth in the Consultancy Agreement.

7. **D&O Insurance and D&O Indemnification:** Dr. Ben Yakar's D&O insurance and indemnification agreement dated April 13, 2016 (and entered into effectiveness on May 1, 2016) shall continue to be in full force and effect following the termination date of the CEO's and Company's engagement, according to the terms provided thereof, but in any case, it shall remain in full force, at least, until such time as it remains in effect for all former directors and officers of the Company.

8. **Mutual Waiver**: Other than with respect to the transactions contemplated herein, this Agreement constitutes a waiver of any claim(s) that either party might have, as of the date hereof, against the other party.

9. **Taxes**: The CEO and Dr. Ben Yakar shall be solely responsible for income tax and other taxes and related payments required by law and applied on it/her in connection with the compensation paid to the CEO and Dr. Ben Yakar under this Agreement (including the options granted to Dr. ben Yakar under the Plan in accordance with the terms of the option agreements provided to Dr. Ben Yakar for her services as a member of the Board of Directors, which are subject to the conditions of Section 102(b)(2) (Capital Gain route) of the Israeli Tax Ordinance) and the Consultancy Agreement (), provided, however, that the Company may withhold any amounts as required by applicable law for tax purposes from any payments or other forms of compensation hereunder or in connection with this Agreement and/or the Consultancy Agreement.

10. **Further Waiver and Indemnification by the CEO and Dr. Ben Yakar**: Subject to the Company's fulfillment of its undertakings and declarations under this agreement, each of the CEO and Dr. Ben Yakar agrees and undertakes that (i) the above payments constitute the full, appropriate, and sole consideration for any claims or demands it/she might have against the Company with respect to it/her engagement period with the Company; (ii) apart from the aforesaid, it/she will not be entitled to any additional consideration or compensation in connection with the period of it/her engagement with the Company, and - (iii) it/she waives all claims, demands or rights against the Company. Each of the CEO and Dr. Ben Yakar will hold the Company and any of its directors, officers, employees, and service providers harmless of any damage or liability, relating to any payment or compensation component that a competent court of law may determine in the future CEO was entitled to under the Consultancy Agreement and/or during its engagement period with the Company. Nothing in this section or the preceding section is intended to derogate from Dr. Ben Yakar's rights as an option holder or, as applicable, as a shareholder of the Company.

11. **Termination Date for This Agreement:** In the event that the Closing shall not take place until the End Date (as such term was defined in the Merger Agreement), subject to extensions of the End Date pursuant to the terms of the Merger Agreement, this Agreement shall automatically be terminated and have no force and effect.

12. **Governing Law and Jurisdiction:** This Agreement shall be exclusively governed by and construed in accordance with the laws of the State of Israel. Any dispute in connection with this Agreement or any of the transactions contemplated hereby shall be resolved exclusively in the competent court in Tel Aviv-Jaffa, Israel.

13. **Entire Agreement**: This Agreement constitutes the entire understanding of the parties hereto and as such supersedes any oral or written agreement previously executed by the CEO and the Company.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above-mentioned.

*/S/ DR. PINI ORBACH*

**BIOSIGHT LTD.**

BY: DR. PINI ORBACH
TITLE: DIRECTOR

*/S/ DR. RUTH BEN YAKAR*

**DR. RUTH BEN YAKAR**

*/S/ DR. RUTH BEN YAKAR*

**RAM TECHNOLOGIES (RBY 2012) LTD.**

BY: D R. RUTH BEN YAKAR
TITLE:

**Exhibit 21.1**

Subsidiaries of Advaxis, Inc.

Advaxis Ltd.

**Exhibit 23.1**

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the inclusion in this Registration Statement of Advaxis, Inc. on Amendment No. 1 to Form S-4 (File No. 333-259065) of our report dated January 22, 2021, with respect to our audits of the financial statements of Advaxis, Inc. as of October 31, 2020 and 2019 and for each of the two years in the period ended October 31, 2020, which report appears in the Prospectus, which is part of this Registration Statement. We also consent to the reference to our Firm under the heading "Experts" in such Prospectus.

Our report on the financial statements refers to a change in the method of accounting for leases in 2020 due to the adoption of ASU No. 2016-02, Leases (Topic 842), as amended, effective November 1, 2019 using the modified retrospective transition approach.

*/s/ Marcum LLP*

Marcum LLP
New York, NY
October 11, 2021

**Exhibit 23.2**

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We hereby consent to the use in this Registration Statement on Form S-4 of Advaxis, Inc. of our report dated August 25, 2021 relating to the financial statements of Biosight Ltd., which appears in this Registration Statement. We also consent to the reference to us under the heading "Experts" in such Registration Statement.

Tel-Aviv, Israel
October 13, 2021

*/s/ Kesselman & Kesselman*
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited

Kesselman & Kesselman, *146 Derech Menachem Begin, Tel-Aviv 6492103, Israel,*
*P.O Box 7187 Tel-Aviv 6107120, Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, www.pwc.com/il*

**EXHIBIT 23.4**

**CONSENT OF CELLO HEALTH BIOCONSULTING**

We hereby consent to the references to Cello Health BioConsulting and to our Opportunity Assessment for BST-236, dated September 23, 2021 (the "Report") prepared on behalf of Biosight Ltd., including the use of information contained within the Report in this Registration Statement on Form S-4 of Advaxis, Inc. (Registration No. 333-259065) to be filed with the U.S. Securities and Exchange Commission (the "Registration Statement"). We also hereby consent to the filing of this letter as an exhibit to the Registration Statement. In giving such consent, we do not hereby admit that we are within the category of persons whose consent is required under Section 7 of the Securities Act of 1933, as amended (the "Securities Act"), or the rules and regulations of the Securities and Exchange Commission (the "Commission") thereunder, nor do we hereby admit that we are experts with respect to any part of the Registration Statement within the meaning of the term "experts" as used in the Securities Act or the rules and regulations of the Commission thereunder.

CELLO HEALTH BIOCONSULTING

By: */s/ Virginia Johnson*
Name: Virginia Johnson
Title: CEO
October 13, 2021

**Exhibit 99.1**

CELLO HEALTH BioConsulting

Previously Defined Health

# OPPORTUNITY ASSESSMENT FOR BST-236

## Final Draft Deliverable

September 2021
Prepared for BioSight

BIOSIGHT

## Table of Contents

## Executive Summary (1/11):
## High Unmet Need in R/R MDS and AML Patients with Limited Options Available; KOLs Intrigued by Bringing Intensive Chemotherapy to Unfit Patients

- The unmet need is high in MDS and AML for effective and tolerable therapies to improve mortality, AML transformation rates (in MDS), and quality of life.
  - Although unmet need exists throughout the spectrum of AML & MDS, the **greatest need is among the R/R high-risk MDS and unfit AML** patients without targeted mutations as they currently have no therapeutic recourse. Historically, these patients have been a **challenging population for clinical development** as they tend to be frail, highly refractory, and at imminent risk of mortality or AML progression (in MDS).
- A number of competitive clinical programs are in development in high-risk MDS and R/R AML that may impact the future treatment algorithm and raise clinical benchmarks in each respective setting. Despite several recent drug approvals in AML, **patient outcomes are not yet being broadly impacted and the majority of patients eventually relapse.**
- Overall, **BST-236's design as a novel prodrug cytarabine was regarded as promising**, especially since cytarabine is one of the most active anti-leukemic drugs deployed. *"I'm intrigued by the tolerability and toxicity data."*
  - The **MRD-negativity data reported at ASCO2021 alludes to a "profoundly" responsive treatment**, and the **tolerability profile may allow the use of aspacytarabine in patients who otherwise are unfit to receive traditional intensive cytarabine**.
    - *"This is very interesting because that means that there is a very profound response to Product X…, especially for patients aged 75 or older that there [have] so good MRD results…"*
- Although BST-236 monotherapy data is promising, KOLs are more interested in seeing BST-236 in combination with Venetoclax, since this is in the direction the field is heading. AML treaters have increasingly become more comfortable with managing the toxicities associated with Ven+Aza, driving response rates to 50-65%.
  - However, there is clear opportunity for combination: *"…there's clearly a synergy with venetoclax in cytotoxic chemo".*
- While BST-236 offers a more tolerable profile to free cytarabine, it is **not recommended to be developed as an "improved cytarabine" story**, as there may be downstream obstacles with payers who will use **generic cytarabine as the pricing benchmark with a premium, rather than a novel drug entity**.
  - Payers believe **BST-236 can be sold at a similar price or premium to Venetoclax at nearly $20K/cycle** (Venetoclax @ $13K/cycle). **Annual pricing of up to $150,000/Year** was deemed feasible by payers and can generate substantial revenue across both AML and MDS. *"…will not have concerns for BST-236 as a combination if priced similarly to Venetoclax."*

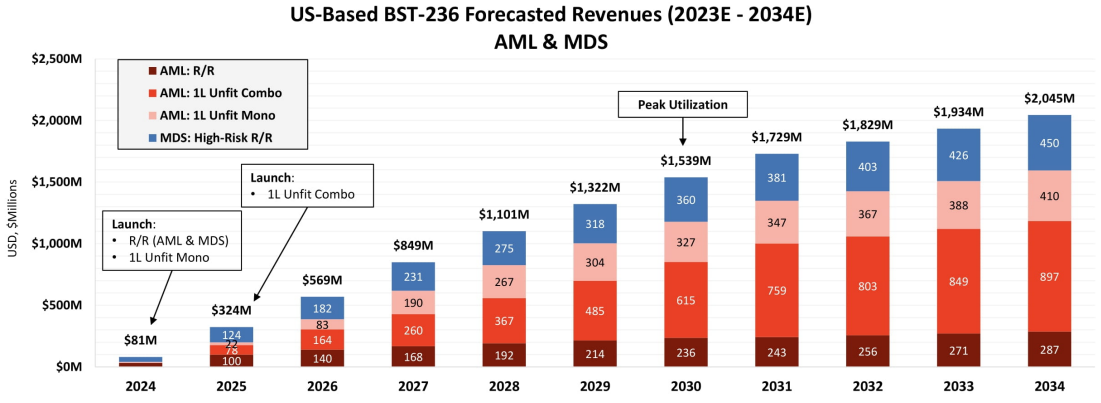
*CHBC incorporated both payer and KOL feedback to inform a revenue forecast for and net-present valuation for BST-236.*

## Executive Summary (2/11):

**BST-236 has the Potential to Offer Unfit AML Patients High Therapeutic Value in Front-line as Monotherapy and in Combo with SoC; Furthermore, Mono use in AML and MDS R/R Settings Generate Sizable Revenues – Approval in any of these Settings Yield Positive rNPV**

- Based on current unmet needs, optimal positioning is recommended in the following settings (3 in AML, 1 in MDS):
  - **(1) R/R Unfit AML (monotherapy):** currently no approved therapies exist and a fast-to-market strategy (single-arm P2 based approval is feasible)
    - *CHBC Forecasts **$236M** in US sales by peak utilization (2030) in this setting.*
  - **(2) 1L, Unfit AML (combo):** KOLs were more enthusiastic of combining BST-236 with Ven/Aza than monotherapy, since the current standard of care is Ven + Aza in frontline unfit
    - *CHBC forecasts **$759M** in US sales by peak utilization (2031) in this setting.*
  - **(3) 1L, Unfit AML & Secondary AML (monotherapy):** the furthest developed setting will have the quickest launch with accelerated approval in 2024, but may be used in secondary AML only after the BST + Ven/Aza combo (TPP #2) gets approved the next year
    - *CHBC forecasts **$327M** in US sales by peak utilization (2030) in this setting.*
  - **(4) R/R High-Risk MDS (BST-236 monotherapy):** similar to TPP #1 where there are no options post-HMA in high-risk MDS
    - *CHBC Forecast **$360M** in US sales by peak utilization (2030) in this setting.*
- Although the frontline unfit combination setting has the highest revenues projected and largest market share if approved, obtaining an approval in any of the above four (4) settings will yield a positive risk-adjusted NPV.

## Executive Summary (3/11):
## BST-236 Revenue Forecast Model Output
**Total Revenues Projected to Peak at ~$2.3B ($1.78B AML, $504M MDS) in the US by 2036**



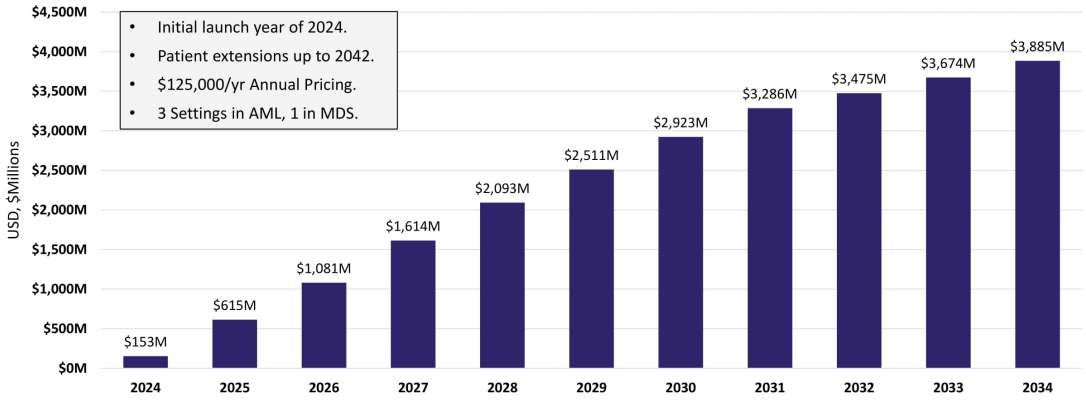

| *USD $Millions* | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2030 | 2031 | 2032 | 2033 | 2034 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| US Revenue | $81M | $324M | $569M | $849M | $1,101M | $1,322M | $1,539M | $1,729M | $1,829M | $1,934M | $2,045M |
| WW Revenue | $153M | $615M | $1,081M | $1,614M | $2,093M | $2,511M | $2,923M | $3,286M | $3,475M | $3,674M | $3,885M |

CHBC Primary & Secondary Research

## Executive Summary (4/11):
## Worldwide Revenues for BST-236 May Reach Up to $3.9B in Global Sales in AML & MDS

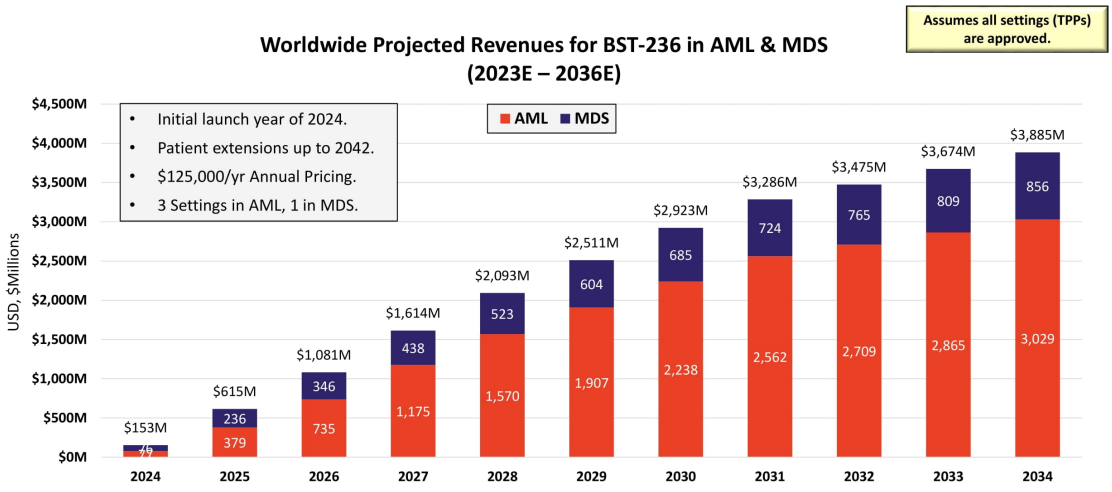
**Worldwide Projected Revenues for BST-236 in AML & MDS (2023E – 2036E)**

Assumes all settings (TPPs) are approved.

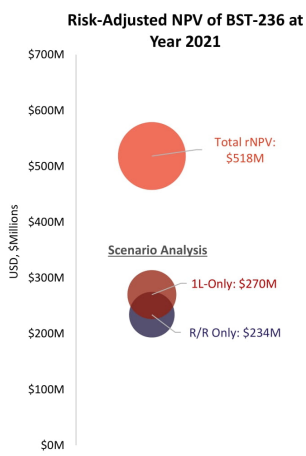


**Executive Summary (5/11):**

**Worldwide Revenues for BST-236 May Reach Up to $3.9B in Global Sales (2034); AML Constituting Majority of Revenues (~$3.0B) and MDS Nearly $900M (2034)**



## Executive Summary (6/11):
## Each of the TPPs Yield a Positive rNPV at Current Year 2021, Indicating Strong Value Even in Downside Cases of Only One Approval




| Setting | rNPV-2021 | Comments |
|---|---|---|
| **AML TPP#1:** R/R | ***$71M*** | Approval in 2024 based off Ph2 data in a very high unmet need market. Trial is including both AML & MDS patients in the R/R setting. |
| **AML TPP#2:** 1L Unfit Combo | ***$233M*** | Highest revenue potential using BST +/- Ven/Aza, launching in 2025 after initial monotherapy approval. |
| **AML TPP#3:** 1L Unfit Mono / Secondary AML | ***$41M*** | Priority setting with accelerated approval in 2023 and pending Phase 3 for full approval completing in by the end of 2026. |
| **MDS TPP#4:** High-Risk R/R | ***$174M*** | Opportunity for substantial revenue stream in MDS with approval from the same TPP #1 trial, launching in 2024. |
| **Total NPV** | ***$518M*** | |

| Scenario Analysis | | |
|---|---|---|
| **Setting** | **rNPV-2021** | **Comments** |
| **Frontline-Only Approval**<br>*- AML TPP#2: 1L Unfit Combo*<br>*- MDS TPP#3: 1L Unfit Mono & Sec. AML* | ***$270M*** | Frontline is the more valuable positioning, but comes with larger expenses, especially considering the nearly $80M Phase 3 that will be required after accelerated approval. |
| **R/R-Only Approval**<br>*- AML TPP#1: R/R*<br>*- MDS TPP#4: R/R H/R* | ***$234M*** | R/R setting still provides a strong valuation due to the large revenue stream in MDS, which peaks at around $500M by 2036. Trial costs are fairly low in this setting since they are typically shorter and may benefit from a Phase 2 approval. |

## Executive Summary (7/11):

## BST-236 is Projected to be a Profitable Investment Across Multiple Settings and Generates Profit Beginning 2025, One Year After Initial Approvals in AML & MDS

| Operating Profits | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2030 | 2031 | 2032 | 2033 | 2034 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **BST-236 Revenues** | | | | **$81M** | **$324M** | **$569M** | **$849M** | **$1,101M** | **$1,322M** | **$1,539M** | **$1,729M** | **$1,829M** | **$1,934M** | **$2,045M** |
| *AML Revenues* | | | | *$41M* | *$199M* | *$387M* | *$618M* | *$826M* | *$1,004M* | *$1,178M* | *$1,348M* | *$1,426M* | *$1,508M* | *$1,594M* |
| *MDS Revenues* | | | | *$40M* | *$124M* | *$182M* | *$231M* | *$275M* | *$318M* | *$360M* | *$381M* | *$403M* | *$426M* | *$450M* |
| Cost of Goods Sold | | | | $5M | $21M | $36M | $54M | $70M | $85M | $98M | $111M | $117M | $124M | $131M |
| ***Operating Profit*** | ***$0M*** | ***$0M*** | ***$0M*** | ***$76M*** | ***$303M*** | ***$533M*** | ***$795M*** | ***$1,031M*** | ***$1,237M*** | ***$1,440M*** | ***$1,619M*** | ***$1,712M*** | ***$1,810M*** | ***$1,914M*** |
| **Operating Expenses** | | | | | | | | | | | | | | |
| *Total Operational Expenses (R&D, Commercialization, G&A, etc).* | *$36M* | *$48M* | *$56M* | *$81M* | *$106M* | *$111M* | *$118M* | *$120M* | *$138M* | *$156M* | *$171M* | *$180M* | *$188M* | *$197M* |
| ***Net Income** (after tax)* | ***$36M*** | ***$48M*** | ***$56M*** | ***$5M*** | ***$142M*** | ***$304M*** | ***$487M*** | ***$656M*** | ***$791M*** | ***$925M*** | ***$1,042M*** | ***$1,103M*** | ***$1,168M*** | ***$1,236M*** |

***Financial Summary***

| Launch Year | Breakeven Point | Revenue at Peak Utilization |
|---|---|---|
| **2024*** | **2024** | **$925M (by 2030)** |

***BST-236 Valuation Summary***

| Setting | | rNPV | Commentary |
|---|---|---|---|
| AML | Unfit R/R | *$71M* | 2024 approval from Ph2 data in a very high unmet need market. Trial includes both AML & MDS patients in the R/R setting. Reduced patient numbers after frontline approval to avoid re-treatment. |
| | 1L Unfit Combo | *$233M* | Highest revenue potential using BST +/- Ven/Aza, launching in 2025 after initial monotherapy approval. |
| | 1L Unfit Mono | *$41M* | Priority setting with accelerated approval in 2023 and Ph3 for full approval completing in by the end of 2027. After BST+VenAza is approved, monotherapy revenue is reduced and may be relegated to 2° AML. |
| MDS | High-Risk R/R | *$174M* | Opportunity for substantial revenue stream in MDS with approval from the same TPP #1 trial, launching in 2024. |
| **Total NPV** | | **$518M** | |

## Executive Summary (8/11) – AML:
## Surge of Approvals, Most Addressing Biomarker-Driven Strategies, While More Recently *Venetoclax/HMA* Approval is Transforming Care for Frontline Unfit/Elderly Patients

- Historically, **AML has been a static field** since the introduction of 7+3 cytarabine and anthracycline-based regimens from the 1970s which has set a gold standard for younger, **fit patients eligible for intent-to-cure** induction and consolidation regimens.
- However, in the past 3-4 years, there has been an **influx of approvals (~10): Both targeted agents for molecularly defined patient segments, and broader acting reformulations and novel agents** which offers patients more tolerable and effective options.
- Since being granted accelerated approval in 2018 and full approval in 2020, ***Venetoclax* in combination with azacitabine offers more unfit/older patients new hope to achieve remission**.
  - In addition, the combination can serve as an option for fit/young patients who were **previously non-optimal candidates for 7+3** intensive chemo. However, considerations **for *Venetoclax's* toxicity (e.g., prolonged cytopenia) may limit its uses** in maintenance settings or with other combinations.
- **Most current late-stage assets and recent approvals are biomarker driven** (e.g., FLT3, IDH1/2) for subpopulation stratification, opposed to broader patient populations.
  - Additionally, based on regulatory changes, targeted therapies are **getting approvals now through response rate endpoints (CR/CRh)**, instead of OS (e.g., Xospata's ADMIRAL trial).
  - Similarly, **MRD-negativity** is also being considered as a surrogate endpoint in specific biomarker defined patient segments and treatment settings (e.g., Kronos Bio NPM1-mutated AML). BioSight may look to leverage this as BST-236 treatment resulted in 73% MRD negativity (8/11 MRD-evaluable patients).
    - *"It's really a biological achievement that has a clinical relevance."*
- However, clinical practice has demonstrated that the field is only **beginning to understand how to maximize the benefit of targeted therapeutics** for AML since so far, they have only demonstrated **intermittent or short-duration clinical benefit** such that patients will still need broad-acting treatments.
- KOLs believe if tolerable drugs, potentially like BST-236, can be used to **give high-intensity therapy to elderly patient with co-morbidities safely**, this can be *"transformative."*

## Executive Summary (9/11) – AML cont.:
## Incremental Advancement of Cytotoxic and Epigenetic Reformulations – Innovation of Novel Immunomodulators, Targeted Agents and Combinations Thereof

- Most of the active frontline trials are being evaluated as **combinations of novel agents with current SoC** (e.g., HMAs, Venetoclax) or historically approved agents (e.g., other chemos). There is **strong development across each setting**, with an abundance of trials (>130) in the R/R setting alone, due to its high unmet need, lack of SoC, and opportunity for accelerated approval.
- Aside from novel therapeutics, there has been new **approvals of reformulation,** such as ***Vyxeos*** (liposomal daunorubicin-cytarabine) and ***Onureg*** (oral azacitadine) which can improve therapeutic index and address ease of administration and QoL.
  - Analyst are projecting $250-300M revenues for *Vyxeos* and $800M-1B for *Onureg*, which support the sizable available market for novel reformulations.
  - In fact, there are clear markets for **specific settings and patient populations** within the treatment paradigm.
    - *Vyxeos* is approved for secondary- and therapy-related-AML;
    - *Onureg* approved for maintenance post first-CR for patients unfit for intensive therapy.
  - KOLs addressed the potential in **specific markets for BST-236 as consolidation** post-induction (replacing HiDAC), slightly **"fitter"** patients who may still be **eligible for transplant**, or even patients **unfit for adequate Venetoclax regimens**.

## Executive Summary (10/11) – MDS:
## High Risk MDS Trial Intensity is Greatest in 1L, While High Risk R/R has Significant Development Opportunities with No SoC

- MDS has more modest clinical development activity:
  - Most targeting the 1L higher-risk MDS patient populations in combination with azacitidine.
    - However, *"There's such low rates of CR with azacitidine that it is really a bit unsatisfactory. That's, I think, where the big unmet need in MDS sits."*
  - In the **R/R setting**, there is **no SoC approved** for patients so clinical trials use best supportive care or physicians' choice as **seemingly low clinical benchmarks, yet no agent has been yet to be successful in this setting**.
    - *"…this is a very, very unmet need patient population, no question about it."*
- **Higher-risk MDS is becoming increasingly competitive** not only from an unmet need perspective, but also from big pharma-owned agents in advanced development (e.g., Gilead's ***magrolimab***, Takeda's ***pevonedistat***).
  - KOLs believe these can provide new therapeutic options for patients, as roughly **70% are expected to relapse after 1L** treatment with HMA. Particularly, KOLs indicated their enthusiasm for drugs like pevonedistat that can be added to other therapies without contributing to more toxicities.
  - However, pevonedistat's recent Phase 3 failure leaves an opportunity for accelerated approval in frontline high-risk.
  - Although not approved, KOLs indicated off-label usage of *Ven+Aza* in some high-risk R/R patients due to the lack of SoC. Additionally, the combination was granted **breakthrough designation in July 2021 for frontline high-risk**.
  - Nearly all active clinical trials in H/R MDS are combination strategies – **most in combination with HMA**.

## Executive Summary (11/11) – MDS cont.:
## Due to Poor Responses in Frontline and no SoC in R/R, There is Enthusiasm of BST-236 With Low Clinical Benchmarks to Meet

- Multiple KOLs commented that **BST-236 can be used in more than half of high-risk patients in the post-HMA setting**, which can be a sizable market share. *"If there is a new drug with an acceptable safety profile in this setting, it would be very interesting because all patients would receive this drug, anyway."*
  - Additionally, KOLs mentioned that frontline usage of BST-236 monotherapy is also a possibility considering the poor benchmarks set by azacitabine. Combinations, however, might be a concern due to potential myelosuppression.
    - Secondary positions mentioned by KOLs are niches in AML-like MDS patients or elderly patients who fail HMA, but are seemingly fit for transplants.

- On the lower-risk MDS patients, **treatment endpoints are different than H/R**. Overall, the objectives of **L/R treatment are to reduce the number of transfusions required** – and transfusion independence – along with delaying disease progression and potentially curing the patient.
  - For instance, **Luspatercept** received approval in 2020 by improving the number of RBC-transfusion independent patients and is projected to be a **blockbuster with sales forecasted to reach $1.4B by 2026 globally**. Thus, there is **large market potential for effective treatments in L/R MDS**.
    - KOLs, however, did not recommend low-risk as an opportunity for BST-236 as there is much greater unmet need in the higher-risk group.

# Disease Overview

# AML

# AML is the Most Common Acute Leukemia in Adults, With An Incidence of Nearly 20,000 New Cases Per Year in the US Alone

AML

| Overview | |
|---|---|
| **Disease Description** | • AML is a malignant disorder characterized by abnormal growth and differentiation of hematopoietic stem cells (HSCs), in which immature myeloid precursors (myeloblasts) accumulate in the bone marrow and peripheral blood. This expansion of immature myeloid cells occurs at the expense of the normal production of their terminally differentiated counterparts, such as red blood cells, platelets, and white blood cells (WBCs).<br>• The clinical presentation of AML at diagnosis varies from an incidental finding on a routine blood test through to a life-threatening illness that requires immediate intervention. |
| **Patient Demographics & Segmentation** | • AML is a disease of the elderly with a median age at diagnosis of 68 years. No predisposing risk factor can be identified in most individuals diagnosed with AML. The risk of developing AML or MDS is moderately increased by exposure to DNA-damaging agents, such as benzene, cigarette smoke, ionizing radiation (usually due to therapeutic radiotherapy) and cytotoxic chemotherapy. AML secondary to ionizing radiation and/or cytotoxic chemotherapy is referred to as therapy-related AML.<br>• AML patients are typically segmented based on whether they are fit to receive intensive induction therapy (unfit patients 35-50%, fit patients 65-50%; however, percentages may vary between academic and community hospitals).<br>• Common biomarkers include FLT3 mutations (30% of all AML patients [FLT3-ITD, 25%; FLT3-TKD, 7-10%]), IDH1/2 mutations (20% of AML patients collectively), and CD33 (80-90% of AML patients). |
| **Epidemiology** | • AML is the most common acute leukemia in adults, with an estimated 20,240 new cases and over 11,000 deaths in the US annually. In 2016, there were an estimated 61,048 people living with AML in the US. The age-standardized incidence rate of AML among individuals >18 years of age ranges from 30 to 40 per million. The male to female ratio normally ranges from 1.1 to 1.3, rising to around 1.8 at 80–84 years of age. The 5-year survival rate among AML patients is only 29.5% [SEER]. Generally, the incidence and prevalence of AML are rising as the population ages and more patients develop secondary AML from prior cancer treatment. |
| **Prognosis & Unmet Needs** | • Unmet need spans almost all patient segments, as the primary opportunity for curative therapy is induction chemo (7+3) and allogeneic transplant, which is limited to fit patients, typically <60 years old. Even in these patients, relapse is very frequent and fatal, ranging from 35-80% depending on risk.<br>• For the majority of patients who are >60 and are unfit for intensive chemotherapy, the prognosis has recently improved drastically due to approval of venetoclax in combination with azacitidine, which has improved response rates to ~65% and may allow for allogeneic transplant in select cases. Better prognostic markers based on sequencing, minimal residual disease (MRD) analysis, and new targeted therapies hold promise for improving AML treatment outcomes further. |
| **Existing Barriers & White Space Opportunities** | • All selected settings in AML are viewed as potentially viable for development due to high unmet need across each patient population. Significant competition exists in all settings that have a defined regulatory path and larger patient segments have increasingly high benchmarks, regardless of the approach. |

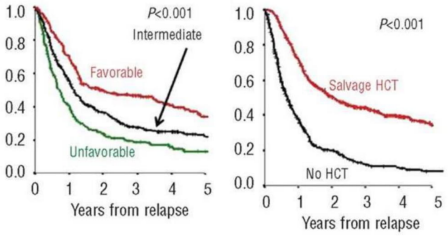
UpToDate, SEER, Nature Reviews AML, Leukemia. 2019 Feb;33(2):299-312. Am J Clin Pathol. 2011 Jan; 135(1): 35–45., Haematologica. 2019 Feb; 104(2): 305–311., Blood Cancer J. 2014 Jun; 4(6): e218., Leuk Lymphoma. 2016 Aug; 57(8): 1965–1968., CHBC Primary Research

## Unmet Need Spans All Patient Segments in AML as the Majority Eventually Relapse

AML

- The incidence and prevalence of AML are rising as the population ages and more patients develop secondary AML from prior cancer treatment.
  - AML has a median age of 68 often with comorbidities and intrinsic resistance mechanisms.
- The only opportunity for curative therapy is an option only for fit patients, induction chemo '7+3' and HSCT consolidation or salvage chemotherapy.
- Majority of AML patients are elderly with poor prognosis that are unfit to receive curative therapy.
  - Efficacy benchmarks in newly diagnosed unfit patients include ORR of 66% and median OS of 14.7 months for venetoclax (Venclexta) + azacitidine.
  - Efficacy benchmarks in R/R fit patients include 8.4 months mOS and 17% ORR in patients treated with azacitidine and 26% CR and 11.6 months mRFS in CD33+ patients treated with gemtuzumab ozogamicin (Mylotarg).
  - Directed therapies are effective only for patients with specific mutations, ~50% of AML patients.
- High relapse rates across all patient cohorts contribute to poor outcomes in AML patients, highlighting unmet need in all examined settings.

**Overall Survival Rates After First Relapse by Cytogenetic Risk Category and Salvage HCT**




Survival Post-induction

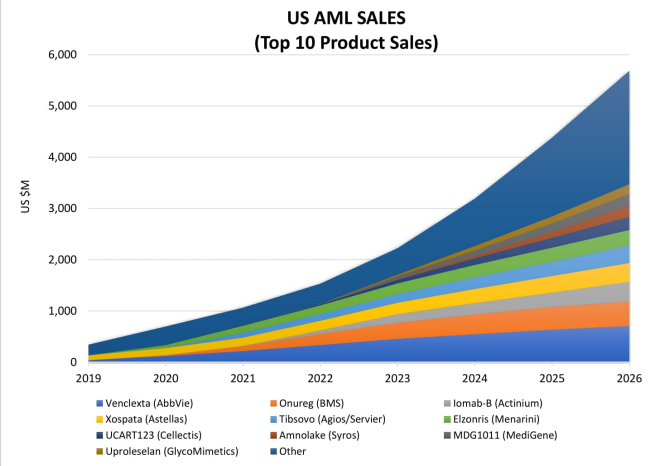
| | Risk | HiDAC | Allo SCT |
|---|---|---|---|
| 4yr OS | Good | 52% | ~50% |
| | Int. | 30% | 48% |
| | Poor | 15% | 40% |
| TRM | | 5% | 20% |

[1] CHBC Primary Research and Insights [2] VIALE-A venetoclax+Aza results[3] Mylotarg PI [4] Leuk Res. 2015 Feb;39(2):124-30 [5] Best Pract Res Clin Haematol. 2018 Dec;31(4):384-386

## The US AML Market is Projected to Rise Rapidly to ~$6B Annually by 2026

AML

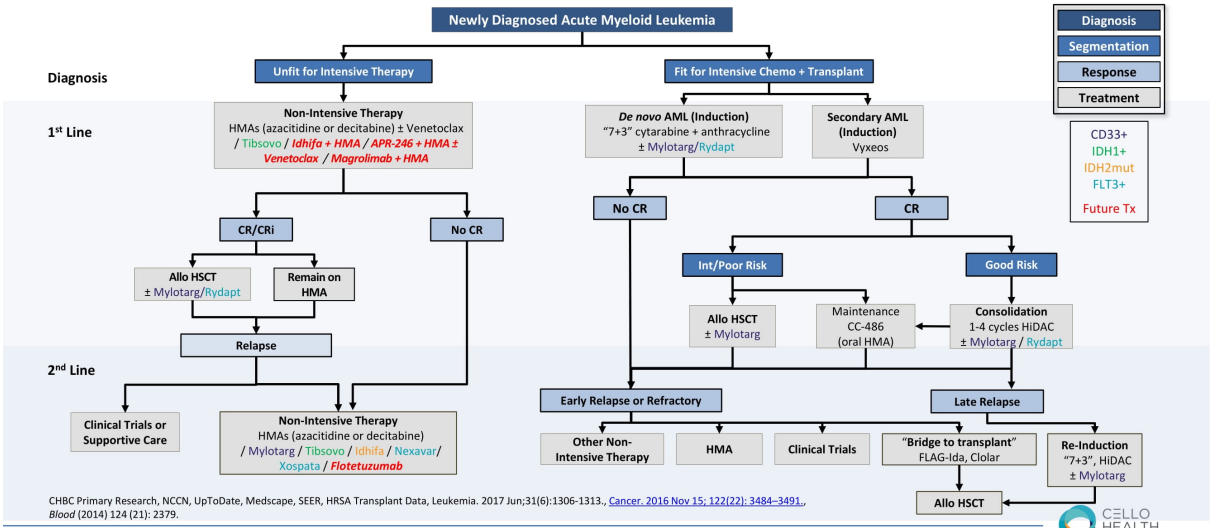
- The WW AML market is currently ~$1B annually and is projected to rise significantly over the next several years due to sales of multiple new targeted agents.
- Currently there are >10 branded therapies approved for treatment of AML; many are targeted therapies approved for patients with a specific molecular profile (i.e. FLT3-ITD or TKD mutant, CD33+, etc.).
- AbbVie's Venclexta (venetoclax) oral BCL2 inhibitor recently approved for combination with HMA for unfit AML patients is expected to grow significantly to a market leading $706M in annual US sales by 2026.
- Cell therapies are expected to play a role in AML in the near future, although the extent may be limited by the lack of AML specific antigens.




[1] Evaluate Pharma

## Targeted Agents Have Recently Been Approved for Patients Carrying Specific Mutations but Intensive Chemotherapy ± Transplant Remains the Only Potentially Curative Therapy

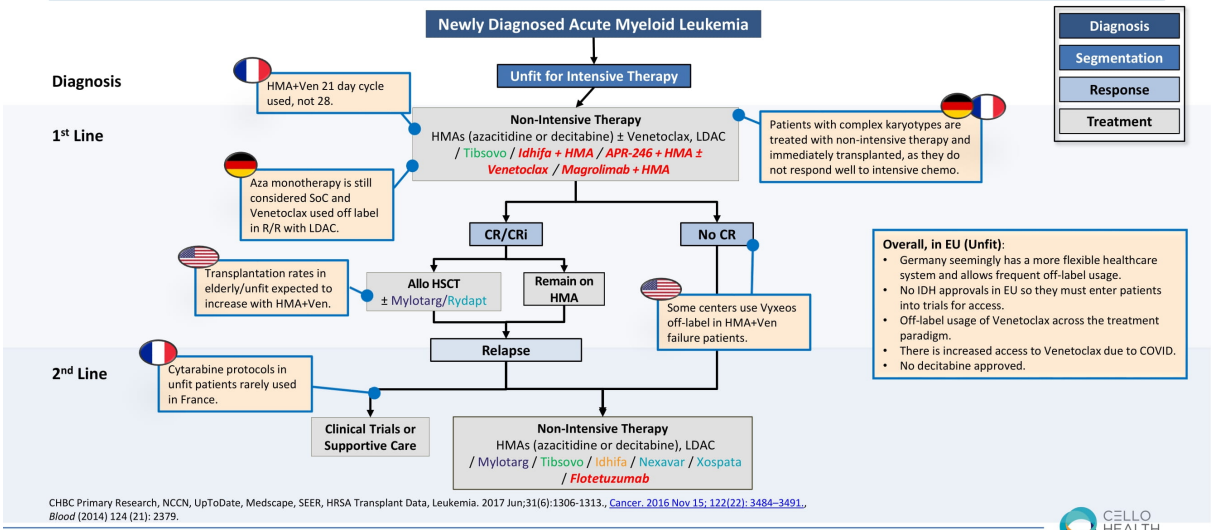
AML




CHBC Primary Research, NCCN, UpToDate, Medscape, SEER, HRSA Transplant Data, Leukemia. 2017 Jun;31(6):1306-1313., Cancer. 2016 Nov 15; 122(22): 3484–3491., *Blood* (2014) 124 (21): 2379.

# Differences in Treatment From US & EU: Unfit

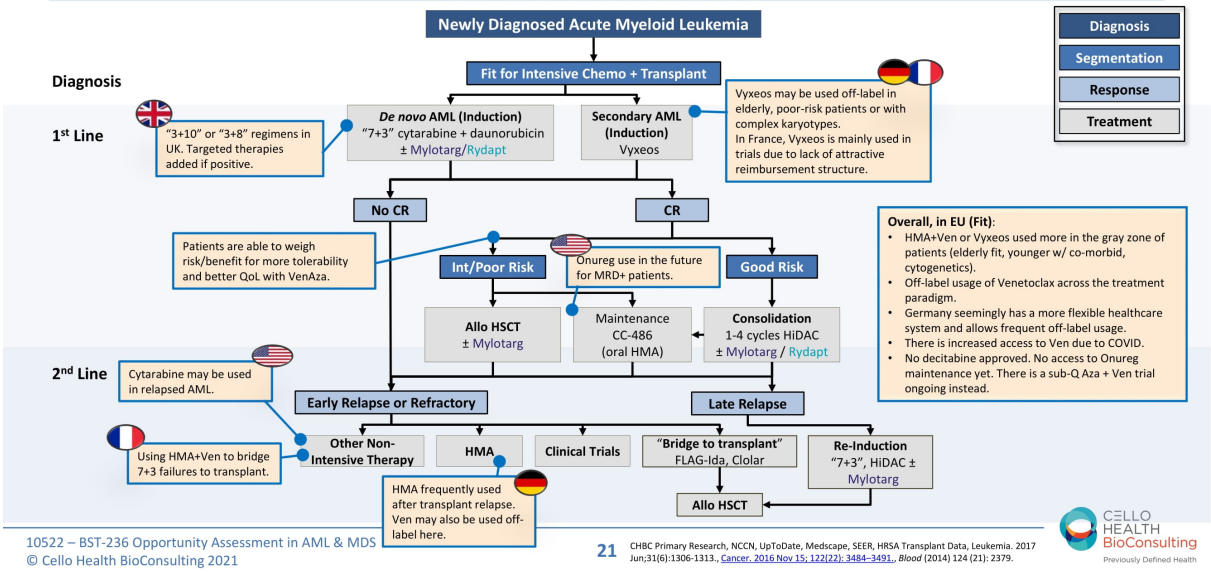
AML




CHBC Primary Research, NCCN, UpToDate, Medscape, SEER, HRSA Transplant Data, Leukemia. 2017 Jun;31(6):1306-1313., Cancer. 2016 Nov 15; 122(22): 3484–3491., *Blood* (2014) 124 (21): 2379.

# Differences in Treatment From US & EU: Fit

AML








CHBC Primary Research, NCCN, UpToDate, Medscape, SEER, HRSA Transplant Data, Leukemia. 2017 Jun;31(6):1306-1313., Cancer. 2016 Nov 15; 122(22): 3484–3491., *Blood* (2014) 124 (21): 2379.

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# AML – Market Benchmarks

## Newly Approved Therapies in AML Cost $50,000 - $200,000 Per Course

AML

| Generic Name (Brand, Company) | MoA | WAC Pkg Price | Dosing (from PI) | Duration/Cycles | Total Price |
|---|---|---|---|---|---|
| Gilteritinib (Xospata, Astellas) | FLT3 inhibitor | $24,333 (40 mg/90 ea.) | 120 mg QD | Until disease progression or toxicity (median 108 days) | $97,332 |
| Midostaurin (Rydapt, Novartis) | FLT3 inhibitor | $9,461 (25 mg/56 ea.) | 50 mg BD on Days 8 to 21 of each induction or consolidation cycle | Days 8-21 of each induction/consolidation cycle | $18,922 (price for 1st induction only) |
| Ivosidenib (Tibsovo, Agios) | IDH1 inhibitor | $28,380 (250 mg/60 ea.) | 500 mg QD | Until disease progression or toxicity (median 129 days) | $141,900 |
| Venetoclax (Venclexta, Abbvie/ Genentech) | BCL2 inhibitor | $12,908 (100 mg/120 ea.) | 400 QD after 3 day ramp-up | Until disease progression or toxicity (median 7 cycles) | $90,356 |
| Enasidenib (Idhifa, BMY/Agios) | IDH2 inhibitor | $28,246 (100 mg/30 ea.) | 100 mg QD | Until disease progression or toxicity (median 192 days) | $197,722 |
| Gemtuzumab ozogamicin (Mylotarg, Pfizer) | CD33-directed ADC | $8,830 (ea.) | 3 mg/m$^2$ (R/R) | Single course on cycle days 1, 4, and 7, followed by consolidation therapy (R/R) | $26,490 |
| Azacitidine (Vidaza, BMS) | HMA | $585 (100 mg, ea) | 75 mg/m2 QD for 7 days | Until disease progression or toxicity (median 3 cycles in R/R, 7 in 1L) | $24,570 R/R $57,330 1L |

Redbook, Venclexta PI, Rydapt PI, Mylotarg PI, Idhifa PI, Tibsovo PI, Xospata PI. Blood. 2019 Jan 3;133(1):7-17. Blood. 2017 Aug 10;130(6):722-731, EHA25 Presentation .

# Current and Future Benchmarks in AML: Unfit 1L

AML

| Drug (Brand, Company) | Approval Year | Setting | mOS | mEFS | ORR | Safety (>5% of population) | Regimen |
|---|---|---|---|---|---|---|---|
| Azacitidine | 2004 | 1L unfit AML | 10.4 months[3] (N=241) | 6.7 months[3] (N=241) | 27.8%[3] (N=241) | Grade ≥3 AEs: 28% febrile neutropenia, 26.3% neutropenia, 23.7% thrombocytopenia, 19.1% pneumonia, 15,7% anemia, 6.8% leukopenia, 5.1% hypokalemia. | Azacitidine 75 mg/m$^2$ per day administered subcutaneously for 7 consecutive days per 28-day treatment cycle |
| Venetoclax (Venclexta, Abbvie/ Genentech) + HMA | 2018 | 1L AML (unfit pts.) | 14.7 Months[1] (N=286) | N/A | 66.4% CR+CRi[1] (N=286) | Grade ≥3 AEs: febrile neutropenia (43%), decreased WBC count (31%), anemia (25%), thrombocytopenia (24%), neutropenia (17%), and pneumonia (13%). | 400 or 600 mg PO QD after 3 day ramp-up (+ azacitidine/decitabine or cytarabine, respectively) |
| Pevonedistat (Takeda) + Aza | Failed Phase 3 (Sep 2021) | 1L low blast AML | 23.6 months[5,6] (N=36) | N/A | N/A | Grade ≥3 AEs: neutropenia (33%), febrile neutropenia (26%), decreased neutrophils (21%), anemia (19%), thrombocytopenia (19%), and pneumonia (12%). | 75 mg/m$^2$ IV or subcutaneous aza on Days 1-5,8,9; pevonedistat 20 mg/m2 via 60-min. (±10) IV infusion on Days 1, 3, and 5 in 28-day cycles. |

[1] EHA25 Presentation [2] Venclexta PI. [3] Blood. 2015 Jul 16; 126(3): 291–299 [4] Leuk Res. 2015 Feb;39(2):124-30 [5] Takeda Press Release – Data, [6] Pev Failure Press Release

# Current and Future Benchmarks in AML: Unfit 1L Primary Refractory

AML

| Drug (Brand, Company) | Approval Year | Setting | mOS | mEFS | ORR | Safety (>5% of population) | Regimen |
|---|---|---|---|---|---|---|---|
| Azacitidine | 2004 | R/R AML | 8.4 months[2] (N=130) | N/A | 17%[2] (N=130) | Grade ≥3 AEs: 28% febrile neutropenia, 26.3% neutropenia, 23.7% thrombocytopenia, 19.1% pneumonia, 15,7% anemia, 6.8% leukopenia, 5.1% hypokalemia. | Azacitidine 75 mg/m$^2$ per day administered subcutaneously for 7 consecutive days per 28-day treatment cycle |
| Gemtuzumab ozogamicin (Mylotarg, Pfizer) | 2017 | CD33+ R/R AML | N/A | 11.6 months RFS[3] (N=57) | 26% CR[4] (N=57) | Grade ≥3 AEs: sepsis (32%), fever (16%), rash (11%), pneumonia (7%), bleeding (7%). No Grade 4 toxicity was observed. | R/R AML (single-agent): 3 mg/m2 (up to one 4.5 mg vial) on Days 1, 4, and 7 |
| Flotetuzumab (MacroGenics) | Unknown | Refractory AML | N/A | N/A | 32.1% CR+CRh+CRi [5] (N=28) | Grade ≥3 AEs: lymphocytopenia (19.4%), anemia (19.4%), thrombocytopenia (16.1%), leukopenia (16.1%), neutropenia (12.9%), Infusion related reaction/Cytokine Release Syndrome (12.9%) [6] | 500 ng/kg/day administered as a 7 -day/week continuous infusion. |

[1] Blood. 2015 Jul 16; 126(3): 291–299 [2] Leuk Res. 2015 Feb;39(2):124-30 [3] Mylotarg PI [4] Oncologist. 2018 Sep;23(9):1103-1108 [5] Flotetuzumab [6]Flotetuzumab phase 1

# Current and Future Benchmarks in AML: R/R

AML

| Drug (Brand, Company) | Approval Year | Setting | mOS | mEFS | ORR | Safety (>5% of population) | Regimen |
|---|---|---|---|---|---|---|---|
| Azacitidine | 2004 | R/R AML | 8.4 months[2] (N=130) | N/A | 17%[2] (N=130) | Grade ≥3 AEs: 28% febrile neutropenia, 26.3% neutropenia, 23.7% thrombocytopenia, 19.1% pneumonia, 15,7% anemia, 6.8% leukopenia, 5.1% hypokalemia. | Azacitidine 75 mg/m$^2$ per day administered subcutaneously for 7 consecutive days per 28-day treatment cycle |
| Gemtuzumab ozogamicin (Mylotarg, Pfizer) | 2017 | CD33+ R/R AML | N/A | 11.6 months RFS[3] (N=57) | 26% CR[4] (N=57) | Grade ≥3 AEs: sepsis (32%), fever (16%), rash (11%), pneumonia (7%), bleeding (7%). No Grade 4 toxicity was observed. | R/R AML (single-agent): 3 mg/m2 (up to one 4.5 mg vial) on Days 1, 4, and 7 |
| DFP 10917 (Delta-Fly Pharma) | Unknown (December 2022, Ph3 estimated primary completion) | R/R AML | 6.9 months[7] (N=29) | N/A | 48.3%[7] 20.7% CR[7] (N=29) | Grade ≥3 AEs: leukopenia (53.3%), thrombocytopenia (46.7%), anemia (36.7%), neutropenia (16.7%), and fatigue (3.3%). | 6 mg/m$^2$ /day, 14-day continuous intravenous infusion |

[1] Blood. 2015 Jul 16; 126(3): 291–299 [2] Leuk Res. 2015 Feb;39(2):124-30 [3] Mylotarg PI [4] Oncologist. 2018 Sep;23(9):1103-1108 [5] hASH-2017-Abstract [6] phase-iii-trial-evaluating-uproleselan [7] Cancer. 2019 May 15;125(10):1665-1673

# Current Benchmarks in AML TP53

AML

| Drug (Brand, Company) | Approval Year | Setting | mOS | mEFS | ORR | Safety (>5% of population) | Regimen |
|---|---|---|---|---|---|---|---|
| Azacitidine | 2004 | 1L TP53 unfit pts. (Based on Aza + placebo arm in VIALE-A) | N/A | N/A | 0% CR+CRi*[5] (N=145) | Grade ≥3 AEs: 28% febrile neutropenia, 26.3% neutropenia, 23.7% thrombocytopenia, 19.1% pneumonia, 15,7% anemia, 6.8% leukopenia, 5.1% hypokalemia. | Azacitidine 75 mg/m$^2$ per day administered subcutaneously for 7 consecutive days per 28-day treatment cycle |
| Venetoclax (Venclexta, Abbvie/ Genentech) + Aza | 2018 | 1L TP53 AML (unfit pts.) | N/A | N/A | 55.3% CR+CRi*[5,6] (N=53) | Grade ≥3 AEs: febrile neutropenia (43%), decreased WBC count (31%), anemia (25%), thrombocytopenia (24%), neutropenia (17%), and pneumonia (13%). | 400 or 600 mg PO QD after 3 day ramp-up (+ azacitidine/decitabine or cytarabine, respectively) |
| Magrolimab (Forty Seven/Gilead) + Aza | Unknown (September 2020, Ph1b estimated primary completion) | 1L TP53 AML (unfit pts.) | N/A | N/A | 75% CR+CRi*[3] (N=9) | Common AEs: anemia (38%), fatigue (21%), neutropenia (19%), thrombocytopenia (18%) and infusion reaction (16%). | Magrolimab dose escalation regimen (1-30 mg/kg QW, Q2W Cycle 3+), Aza was dosed 75mg/m$^2$ days 1-7 |
| APR-246 (Aprea) + Aza | Unknown (June 2020, Ph1/2 estimated primary completion) | TP53 AML | N/A | N/A | 50% CR*[2] (N=8) | Febrile neutropenia in 36%, neurological AEs in 40% (6% Gr3): (ataxia (25%) associated with cognitive impairment (8%), acute confusion (8%), isolated dizziness (6%) and facial paresthesia (2%)). | APR-246 4500 mg IV/d (6-hour infusions, days 1-4) followed by AZA 75 mg/m$^2$/d (days 4-10) in 28 day cycles |

Regarding **Ven + Aza,** a breakdown of CR vs. CRi results was not available. It is also worth noting that the CR + CRi for this combo was >70% for AML patients w/ IDH1/2 or FLT3 mutations (from the Ph3 VIALE-A trial)

**in 1L unfit AML pts. ** in R/R AML pts.*

[1] EHA25 APR-246 [2] Aprea press release [3] J Clin Oncol 38: 2020 (suppl; abstr 7507) [4] Oncologist. 2018 Sep;23(9):1103-1108 [5] EHA25 Presentation [6] https://aml-hub.com/medical-information/viale-a-trial-update-or-venetoclax-and-azacitidine-combination-for-the-treatment-of-older-patients-with-newly-diagnosed-aml.

# MDS

## MDS Encompasses a Continuous Disease Spectrum Consisting of a Diverse Group of Clonal Hematopoietic Stem Cell Disorders Characterized by Impaired Blood Cell Production & Cytopenias

MDS

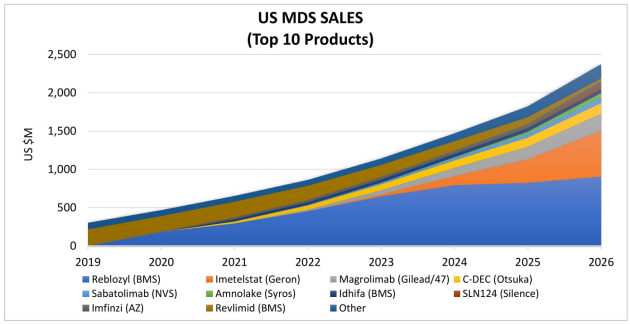
| Overview | |
|---|---|
| **Disease Description** | • The myelodysplastic syndromes (MDS) comprise a heterogeneous group of malignant hematopoietic stem cell disorders characterized by dysplastic and ineffective blood cell production and risk of transformation to AML.<br>• Patients with MDS have a variable reduction in the production of normal red blood cells, platelets, and mature granulocytes. As a result, patients with MDS are at risk for symptomatic anemia, infection, and bleeding, as well as progression to acute myeloid leukemia (AML), which is often refractory to treatment. |
| **Patient Demographics & Segmentation** | • MDS occurs most commonly in older adults and may occur *de novo* or arise years after exposure to potentially mutagenic therapy (e.g. radiation exposure, chemotherapy).<br>• MDS patients are typically segmented based on the Revised International Prognostic Scoring System (IPSS-R) which takes into account bone marrow blast percentage, cytogenetics, and cytopenias to categorize patients into 5 risk groups (very low to very high risk) based on risk of mortality and transformation to AML. |
| **Epidemiology** | • The annual MDS age-adjusted incidence in the US is ~4.0/100K persons (~13K), and the incidence substantially rises with age. In the US it is believed to afflict 40-60K people. MDS occurs most commonly in older adults, with a median age at diagnosis in most series of ≥65 years and a male predominance. |
| **Prognosis & Unmet Needs** | • Approximately 2/3$^{rd}$ of MDS patients are considered low risk while 1/3$^{rd}$ are high risk. The goal of treatment in low-risk patients is improving quality of life while the goal of treatment in high-risk MDS is improving survival outcomes.<br>• Many MDS patients, particularly low-risk patients, die due to bone marrow failure (vs. AML progression).<br>• Prognosis typically depends on patients' IPSS-R categorization. Median survival in each prognostic risk category is as follows: Very low risk, ~9.9 years; Low risk, 5.3 years; Intermediate risk, 3.0 years; High risk, 1.6; Very high risk: 0.8 years.<br>• Median time to 25% AML evolution in each prognostic risk category is as follows: Very low risk, not reached >10 years ; Low risk, 10.8 years; Intermediate risk, 3.2 years; High risk, 1.4; Very high risk: 0.73 years. |
| **Existing Barriers & White Space Opportunities** | • Currently available treatment options are largely ineffective in most MDS patients; however, the high-risk MDS (HR MDS) pipeline is becoming increasingly competitive.<br>• Transplant remains the only curative treatment option yet only 5-10% of all high risk MDS patients ultimately receive a transplant. |

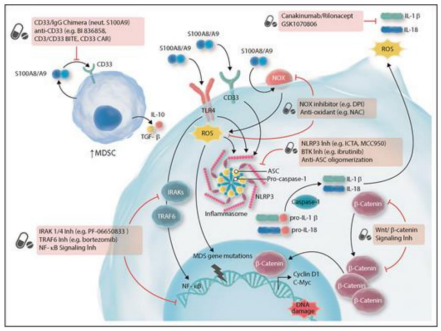
[1] SEER Cancer Statistics [2] SEER Explorer [3] UptoDate [4] CHBC Primary Research [5] Blood. 2012 Sep 20;120(12):2454-65. [6] SEER Cancer Explorer [7] Blood Rev. 2019 Mar;34:1-15 [8] Cowen, Feb 2021

## A Growing Number of Developers Have Recognized the High Unmet Need and Opportunity in MDS; Accordingly, the MDS Market Is Anticipated To Increase From <$500M to $2.4BN Sales in the US By 2026

MDS

- Myelodysplastic syndromes (MDS) are a heterogenous collection of myeloid neoplasms characterized by ineffective hematopoiesis and cytopenias as well as a risk of clonal evolution and progression to acute myeloid leukemia (AML).
- Unmet need is high in MDS, as allogeneic hematopoietic stem cell transplants (allo-HSCT) remains the only treatment option with curative potential yet <10% of patients are transplant-eligible.
  - HMAs are the only treatment option for transplant-ineligible high-risk patients; however, therapeutic options are anticipated to increase rapidly over the upcoming years as clinical programs progress in both low- and high-risk MDS.




[1] Evaluate Pharma [2] Up to Date [3] Blood. 2019 Mar 7;133(10):1039-1048.

## Unmet Need Is High in MDS For Effective, Tolerable Therapies To Improve Both Clinical Outcomes and Quality of Life, Particularly in High-Risk and TP53-Mutant Patients

MDS

- MDS patients overall are at risk of mortality due to disease-related complications (bone marrow failure, infection, hemorrhage) or AML transformation.
  - Even low-risk patients often die of MDS-related causes.
  - There remains considerable unmet need for effective therapies in high-risk MDS (HR MDS) as transplant remains the only treatment option with curative potential, yet <10% of patients are eligible for transplant.
    - The therapy-related mortality rate among transplanted patients is 15-30%. Of the remaining patients, approximately one-third relapse and one-third are cured.
- Quality of life is also impacted as many MDS patients require ongoing supportive care (i.e. frequent blood transfusions and growth factors).

**MDS Clinical Outcomes by IPSS-R* Risk Group**

| IPSS-R Risk Group | mOS (yrs) | Time to 25% AML evolution (yrs) |
|---|---|---|
| Very Low | 8.8 | NR |
| Low | 5.3 | 10.8 |
| Intermediate | 3.0 | 3.2 |
| High | 1.6 | 1.4 |
| Very High | 0.8 | 0.73 |

**TP53-Mutant MDS**

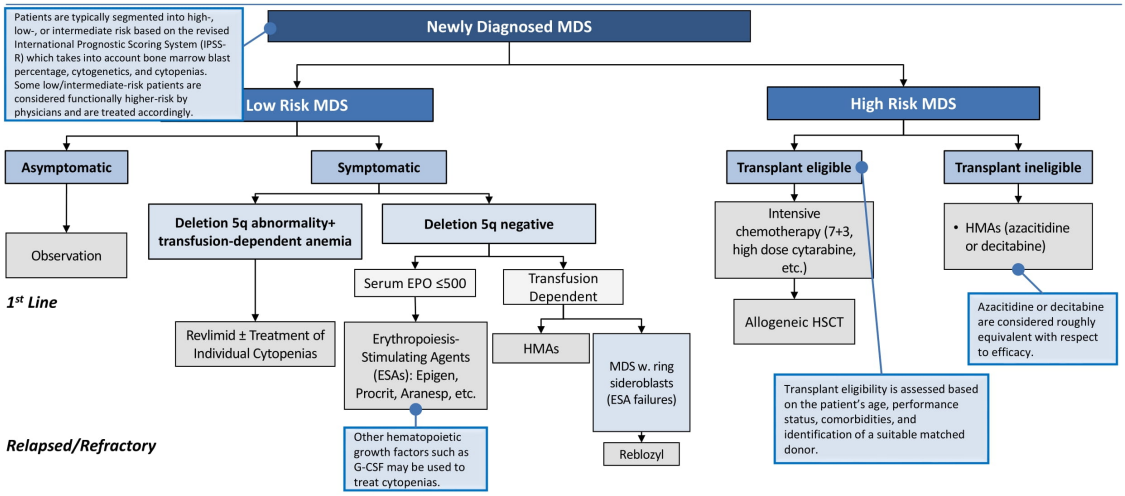
- Unmet need is particularly acute in TP53-mutant MDS due to poorer prognosis in this patient segment.
- Patients with TP53 mutations who receive HMAs often respond favorably to treatment, but response duration is shorter and overall survival tends to be lower (6 mo. mOS vs. 18 mo. mOS).
- Among patients who undergo allo-HSCT, TP53 mutation is associated with shorter survival and a shorter time to relapse vs. patients without a TP53 mutation.

* IPSS-R: Revised International Prognostic Scoring System

[1] CHBC Primary Research and Insights [2] Cancer. 2010 May 1; 116(9): 2174–2179. [3] Dtsch Arztebl Int. 2013 Nov; 110(46): 783–790. [4] Blood Cancer J. 2018 May 24;8(5):47. [5] Br J Haematol. 2013 Mar;160(5):660-72. [6] Leukemia volume 33, pages 1747–1758 (2019) [7] DFCI Case Study [8] N Engl J Med 2017; 376:536-547

# The Treatment Algorithm For MDS Is Limited As There Are Few Approved Agents for MDS and Transplant Remains the Only Curative Treatment Option

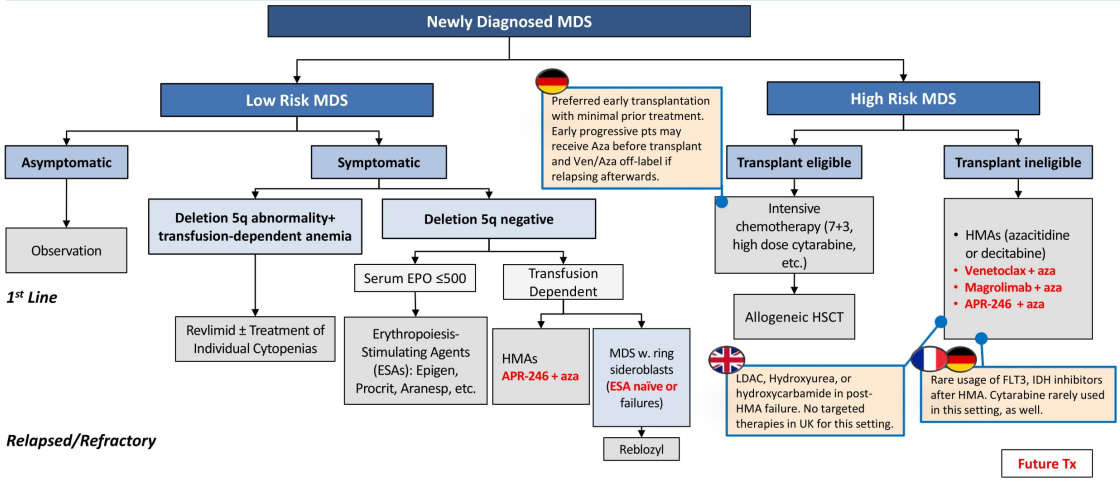
MDS




[1] CHBC Primary Research [2] Blood. 2012 Sep 20;120(12):2454-65. [3] NCCN Guidelines [4] Revlimid PI [5] ASH 2014 Poster [6] SEER Hematopoietic Project [7] UptoDate

# The Future MDS Treatment Algorithm is Anticipated to Change Significantly Pending Approval of Promising Pipeline Therapies

MDS




[1] CHBC Primary Research [2] Blood. 2012 Sep 20;120(12):2454-65. [3] NCCN Guidelines [4] Revlimid PI [5] BMS Press Release [6] *Blood* (2019) 134 (Supplement_1): 5410. [6] Leukemia. 2019 Jul;33(7):1747-1758. [7] Clinicaltrials.gov [8] Adis [9] Blood Adv 2020 Feb 11;4(3):482-495.

# MDS – Market Benchmarks

## Pricing Analogs (HMAs) Trend Low in High-Risk MDS As Most Approved Products Are Off-Patent or Approaching Patent Expiration

MDS

| Generic Name (Brand, Company) | MoA | WAC Pkg Price | Dosing (from PI) | Duration/ Cycles | Price per Cycle/Month | Total Annual Treatment Price |
|---|---|---|---|---|---|---|
| Azacitidine (Vidaza, BMS) | HMA | $585 (100 mg, ea) | 75 mg/m2 QD for 7 days via IV or SC injection q4w for a minimum of 4 to 6 cycles until disease progression or toxicity | Median of 9 cycles[1] | $8,193 per cycle | $73,740 |
| Decitabine (Dacogen, Otsuka America Pharmaceutical, Inc.) | HMA | $1,796 (50 mg, ea) | 15 mg/m2 administered by IV over 3 hours repeated every 8 hours for 3 days q6w | Median DoR 288 days[4] | $16,168 per cycle | $97,013 |
| Luspatercept (Reblozyl, BMS) | TGF-β modulator | $3,441 (25 mg, ea) | 1 mg/kg luspatercept q3w until disease progression or toxicity | Median duration of transfusion independence 30.6 months | $13,764 per cycle | $137,647** |
| Lenalidomide (Revlimid, BMS) | IMiD | $16,023 (25 mg, 21 ea) | 10 mg QD PO on Days 1-21 of repeated 28-day cycles. | Median duration of exposure 32 weeks[3] | N/A | $228,902* |

**The actual treatment cost is likely lower since nearly half of patients require dose interruptions or reductions to recover from cytopenias*

***The actual treatment cost may be higher since physicians have the option to increase the dose if patients fail to respond*

[1] Lancet Oncol. 2009 Mar; 10(3): 223–232 [2] Redbook [3] Blood (2011) 118 (14): 3765–3776. [4] Dacogen PI [5] N Engl J Med. 2020. PMID: 31914241 Clinical Trial. [6] Reblozyl PI

## Pricing Analogues (HMA) in the HMA-Failure Setting Fall Within The $8-9K Range Per Cycle

MDS

| Setting | Generic Name (Brand, Company) | MoA | WAC Pkg Price | Dosing (from PI) | Duration/Cycles | Price per Cycle/Month | Total Annual Treatment Price |
|---|---|---|---|---|---|---|---|
| MDS: HMA-failure | Azacitidine (Vidaza, BMS) | HMA | $585 (100 mg, ea) | 75 mg/m2 QD for 7 days via IV or SC injection q4w for a minimum of 4 to 6 cycles until disease progression or toxicity | Median of 6 cycles[1] | $8,190 per cycle | $24,570 |
| MDS: HMA-failure | Decitabine (Dacogen, Otsuka America Pharmaceutical, Inc.) | HMA | $1,796 (50 mg, ea) | 20 mg/m2 QD for 5 days | Median of 3 cycles[2] | $8,980 per cycle | $26,940 |

FDA Labels; [1] Curr Opin Hematol. 2014 Mar; 21(2): 123–130. [2] Leuk Lymphoma. 2008 Apr;49(4):690-5.

## Clinical Benchmarks in 1L Higher-Risk MDS Are Low, Underscoring An Unmet Need For Effective Therapies; However, Benchmarks are Likely to Increase Considerably in Near Future

MDS

| Drug (Trade Name, Company, MoA) | Approval Year | Setting | mOS | mPFS | ORR (CR) | Safety (occurring in >5% of pts.) | Regimen |
|---|---|---|---|---|---|---|---|
| Azacitidine (Vidaza, BMS) | 2004 | 1L HR MDS | 24.5 months[1,2] | 14.1 months** [1,2] | 29% (17% CR)[1,2] | Grade ≥3 AEs: neutropenia (91%) thrombocytopenia (85%), anemia (68%). | 75 mg/m2 SC azacitidine QD for 7 days q4w (delayed as needed until blood-count recovery) for at least six cycles |
| Decitabine (Dacogen, Otsuka America Pharmaceutical, Inc.) | 2006 | MDS (all subtypes) | N/A | 288 days[4] (median response duration) | 17% (9% CR)[4] | Grade ≥3 AEs: neutropenia (87%), thrombocytopenia (85%), febrile neutropenia (23%) | 3 day regimen: 15 mg/m2 decitabine administered by IV over 3 hours repeated every 8 hours for 3 days, repeat q6w |
| Venetoclax + azacitidine | Anticipated 2024[6] | 1L HR MDS | 74% 18 mo. OS | N/A | 31% CR[11] (n=57) | Grade ≥3 AEs: neutropenia (61%), thrombocytopenia (39%), leukopenia (31%), and anemia (20%), febrile neutropenia (31%) | 75 mg/m2 azac QD for days 1-7 of each 28 day cycle+ escalating doses of ven (100, 200 and 400 mg) daily for 14 of 28-day cycles. |
| Pevonidestat + azacitidine | N/A | 1L HR MDS | 23.9 months[5] | 20.2 months (EFS) [5] | 79% (52% CR)[5] (n=67) | Grade ≥3 AEs[5]: neutropenia (33%), febrile neutropenia (26%), decreased neutrophil count (21%), anemia (19%), thrombocytopenia (19%), and pneumonia (12%) | 75 mg/m2 IV or subcutaneous aza on Days 1-5,8,9; pevonedistat 20 mg/m2 via 60-min. (±10) IV infusion on Days 1, 3, and 5 in 28-day cycles. |
| Magrolimab + azacitidine | Anticipated 2022[6] | 1L HR MDS | N/A | mDOR NR at 6.4 months[8] | 91% (42%)[8] (n=33) | Grade ≥3 AEs[7]: anemia (~40%), neutropenia (~10%), thrombocytopenia (~10%), fatigue (~5%), febrile neutropenia (25%), hypotension (~10%), WBC decreased (~5%), infections (~15%) | 75 mg/m2 aza QD for 7 days + 1mg/kg priming dose of magro followed by a maintenance dose of 30mg/kg qw or q2w |

*** Time to disease progression, relapse after CR or PR, or death*

[1] Lancet Oncol. 2009 Mar; 10(3): 223–232. [2] J Clin Oncol. 2006 Aug 20;24(24):3895-903. [3] Vidaza PI [4] Dacogen PI [5] Takeda Press Release [6] Evaluate Pharma [7] ASH 2019 Presentation [8] Gilead Press Release [9] MedCityNews [10] GlobeNewsWire [11] ASH 2019 Abstract [12] Onconova Corporate Presentation June 2020 [13] ASH 2019 Abstract

## Eprenetapopt is Likely to Set the Benchmark in TP53 Mutant MDS, Which Is Characterized by Poor Prognosis and Survival Despite Initial Responses to HMA Treatment

MDS

| Drug (Trade Name, Company, MoA) | Approval Year | Setting | mOS | mPFS | ORR | Safety (occurring in >5% of pts.) | Regimen |
|---|---|---|---|---|---|---|---|
| Azacitidine (Vidaza, BMS, HMA) | 2004 | MDS | 212-246 days[3,4] | N/A | 46%[3] | Grade ≥3 AEs[5]: neutropenia (91%) thrombocytopenia (85%), anemia (68%) | 75 mg/m2 SC azacitidine QD for 7 days q4w (delayed as needed until blood-count recovery) for at least six cycles |
| Eprenetapopt/APR-246 + azacitidine (Aprea Therapeutics, TP53 Activator) | Anticipated 2022 | TP53 Mutant MDS | N/A | N/A | 88% (61% CR)[2] (n=34) | Grade ≥3 AEs: febrile neutropenia (33%), WBC decreased (29%), lung infection (25%), neutrophil count decreased (29%), platelets decreased (25%) | 4,500 mg fixed dose APR-246 via IV daily (days 1-4) and AZA daily for 7 days (days 4-10 or 4-5 and 8-12) in 28-day cycles |

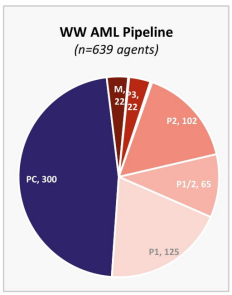
[1] Evaluate Pharma [2] Aprea ASH Recap Presentation [3] Haematologica. 2014 Oct; 99(10): e179–e181. [4] Blood (2013) 122 (21): 2797. [5] Vidaza PI

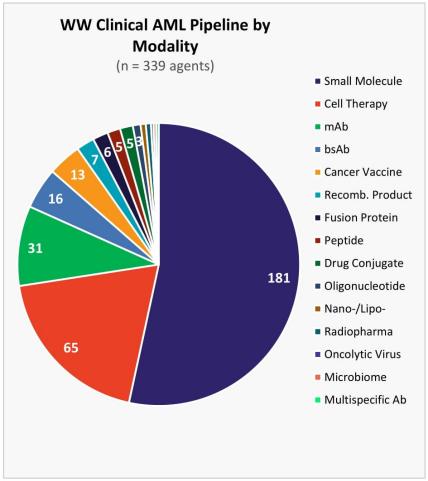
# Competitive Landscape

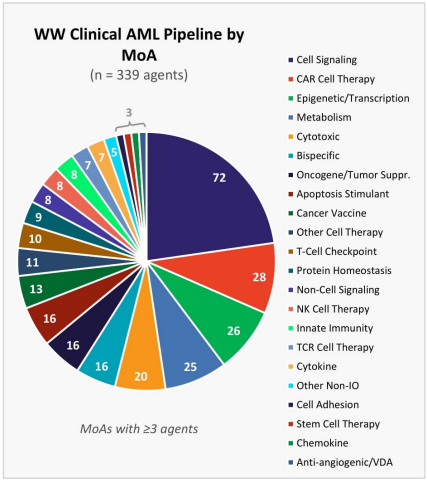
# AML – Pipeline Analysis

# Worldwide AML Pipeline Analysis

AML



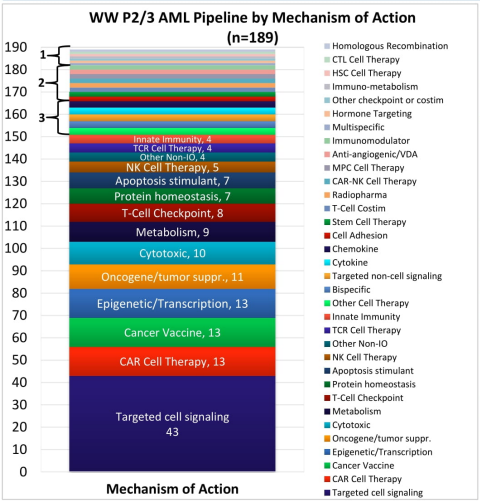




Sources: Adis R&D Insight, Clarivate Analytics Cortellis, CHBC Insight

# Clinical AML Pipeline Led by Targeted Therapies, Followed by IO-Based Modalities

AML




**Oncogene/Tumor Suppressor:** p53-mediated tumor cell apoptosis may be induced by drugs, such as a second-generation MDM2 inhibitor.

- **Idasanutlin ± Cytarabine (Roche, Phase 3)**
  - Idasanutlin has been evaluated in R/R AML pts as a monotherapy and in combination with cytarabine in a Phase Ib dose escalation study, with 1 CR and 1 PR (n=9) observed in the monotherapy arm; a CR rate of 25% (n=19) was observed in the combination arm with a median PFS of 10.5 months in pts with cCR. The Phase 3 trial evaluating idasanutlin in combination with cytarabine versus cytarabine alone in R/R AML pts has since been terminated for poor efficacy.

**T-Cell Checkpoint:** T cell checkpoint inhibitors.

- **Pembrolizumab + Azacitidine (Investigator Initiated, Phase 2)**
  - The safety and efficacy of pembro + aza is being evaluated in an ongoing study in R/R and newly diagnosed unfit AML pts. 4/29 evaluable R/R AML pts had CR or CRi (2 and 2, respectively); 8/17 evaluable newly diagnosed unfit patients had CR or CRi (6 and 2, respectively).
  - A Phase 2 in 1L H/R MDS also read out in ASH2020 with an ORR of 80% (in 17 pts), 3 pts with CR.

**Cytokine:** Bispecific molecules redirect T lymphocytes to kill CD123-expressing malignant cells.

- **Flotetuzumab (MacroGenics, Phase 1/2)**
  - A P1/2 study of flotetuzumab in R/R AML pts is underway with segmentation for primary induction failure and early relapsed. 14 out of 44 pts (14%) had CR/CRh/CRi, with 8 patients proceeding to HSCT (57%).

**Cell Adhesion:** E-selectin antagonists disrupt cell survival activation pathways and enhance chemotherapy response by disrupting the chemo-protected bone marrow microenvironment.

- **Uproleselan (GlycoMimetics, Phase 3)**
  - A P1/2 study of uproleselan added to MEC chemotherapy in R/R AML showed a CR rate of 41% and a median OS of 8.8 m (n=16) at RP2D; OS was reported to be 12.7 months in a group of high-risk pts, as stated in a 2019 ASH press release. A double-blind, placebo-controlled P3 trial will evaluate the efficacy of uproleselan with standard salvage chemotherapy in R/R AMP pts and is expected to enroll 380 pts.

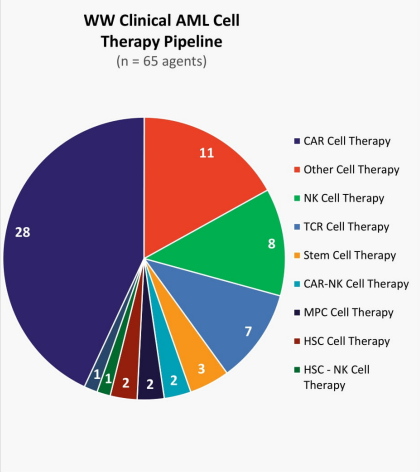
**Innate Immunity Antagonist:** Monoclonal antibodies may target factors such as CD47, activating cell types that mediate innate immunity.

- **Magrolimab + Azacitidine (Forty Seven, Phase 1b)**
  - An open-label P1b/2 trial evaluating Hu5F9-G4 (magrolimab) + azacitidine. A Phase 1b trial of magrolimab+AZA was initiated in MDS/AML patients with results demonstrating high response rates. In the AML cohort, 52 pts were treated, and 34 pts were evaluable. ORR 65% (22/34), 44% CR (15/34), 12% CRi (4/34).

Idasanutlin ± Cytarabine, Flotetuzumab, Uproleselan (P1/2), Uproleselan (P1/2); Uproleselan (P3), Magrolimab + Aza, Pembro + Aza in AML, Pembro + Aza in MDS

# Worldwide AML Cell Therapy Analysis by Cell Types and Targets

AML




| Cell Types | Non-Targets | CD123 | CD19 | CD33 | 3+ Targets | NKG2D | HA-1 | WT1 | CD7 | CD38 | CLL1 / CD33 | PRAME | CD33 / CLL1 | CCL1 | CD44 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| CAR Cell Tx | P1 | P2 | P3 | P2 | P2 | P1 | | | P2 | P1 | P1 | | P1 | P1 | P2 |
| Other Cell Tx | P2/3 | | | | P1 | | P1 | | | | | | | | |
| NK Cell Tx | P2 | | | | | P1 | | | | P1 | | | | | |
| TCR Cell Tx | P1/2 | | | | | | P1 | P2 | | | | P1/2 | | | |
| Stem Cell Tx | P3 | | | | | | | | | | | | | | |
| CAR-NK Cell Tx | | | | P2 | | | | | | | | | | | |
| MPC Cell Tx | P3 | | | | | | | | | | | | | | |
| HSC Cell Tx | P2 | | | | | | | | | | | | | | |
| HSC - NK Cell Tx | P1 | | | | | | | | | | | | | | |
| CTL Cell Tx | | | | | P2 | | | | | | | | | | |

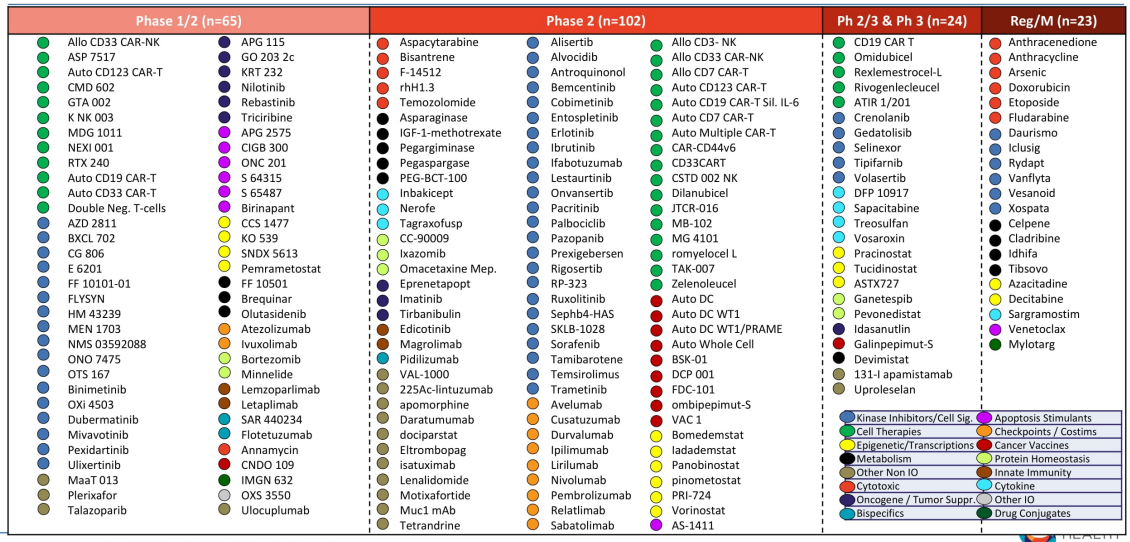
*Phase represents highest phase program within each cell.*

Legend: Number of Trials
1 — 11

Sources: Adis R&D Insight, Clarivate Analytics Cortellis, CHBC Insight

AML

# WW Clinical Stage AML Pipeline (Phase 1/2 to Marketed)








Sources: Adis R&D Insight, Clarivate Analytics Cortellis, CHBC Insight

# WW Clinical Stage AML Pipeline (Phase 1)

AML

| | |
|---|---|
| Kinase Inhibitors/Cell Sig. | Apoptosis Stimulants |
| Cell Therapies | Checkpoints / Costims |
| Epigenetic/Transcriptions | Cancer Vaccines |
| Metabolism | Protein Homeostasis |
| Other Non IO | Innate Immunity |
| Cytotoxic | Cytokine |
| Oncogene / Tumor Suppr. | Other IO |
| Bispecifics | Drug Conjugates |

**Phase 1 (n=125)**

- BG T19
- BG-NE1
- CD123CAR-41BB-CD3zeta-EGFRt
- CYAD-02
- CYNK-001
- E-CEL UVEC
- FT 516
- FT 538
- HSC-100
- IM-23
- INB-100
- JEZ-567
- LB-1910
- MANA 312
- MDG-1021
- NKX-101
- PRGN-3006
- RC-1012
- RNA CART123
- TCB-002
- TEG 001
- TRGFT-201
- UCART-123
- UniCAR02 T CD123
- Double negative T-cells
- CD123 CAR-T
- CD38 CAR-T
- Allo HA-1 TCR-T
- CLL1-CD33 cCART
- Multi-Targeted CTLs
- ICT-01
- APTO-253
- AZD-4573
- BTX-A51
- CA 4948
- CWP-291
- FN-1501
- HAO-472
- HMPL 523
- LY 3214996
- MAX-40279
- MEN 1112
- nintedanib
- NMI 900
- pemigatinib
- QHRD-107
- SEL-120
- SKI-G-801
- Batiraxcept
- CYC-140
- Dinaciclib
- Donafenib Tosylate
- fadraciclib
- Voruciclib
- ALRN-6924
- JSP-191
- PIM 447
- RG 7775
- Milademetan
- CB 5339
- LAM-003
- VSV-hIFNbeta-NIS
- ABBV-184
- AMG 427
- AMG-330
- AMG-673
- AMV-564
- APVO-436
- GEM-333
- JNJ-63709178
- JNJ-67571244
- MCLA-117
- RG 6007
- Vibecotamab
- BAY 1436032
- BAY-2402234
- Elesclomol sodium
- Enfludenib
- HMPL-306
- JNJ 74856665
- LY-3410738
- pegzilarginase
- PTC-299
- RP 7214
- TQB 3455
- OXPHOS inhibitor
- Hu-8F4
- Nedisertib
- SEA-CD70
- Fosmanogepix
- Retifanlimab
- Spartalizumab
- F-16-IL-2 fusion
- ABBV-744
- BPI-23314
- CC-95775
- H3B-8800
- mivebresib
- NTX-301
- OPB 111077
- PLX 2853
- PLX 51107
- TAS-1440
- valemetostat
- BCL-201
- CFI 400945
- LP-108
- PRT-1419
- tolinapant
- ZN-d5
- Murizatoclax
- Tapotoclax
- CC 90002
- IO 202
- Poly ICLC - Oncovir
- TTI-621
- Bermekimab
- KHK 2823
- Teleukin
- Camidanlumab tesirine
- CLT 030
- TAS 1553
- TH-1579

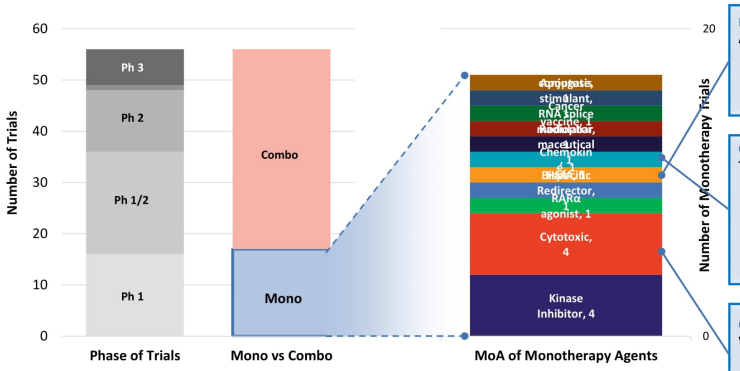
Sources: Adis R&D Insight, Clarivate Analytics Cortellis, CHBC Insight

# AML – Clinical Trial Landscape

# Monotherapy Treatment-Naïve Unfit AML Trials Led by Novel Cytotoxic or Kinase Inhibitors Like PIM, MEK, and TrkA

1L Unfit Mono

## Phase & MoA of Assets in 1L Unfit AML Trials (n=56 trials)*




**HMA:**

**ASTX727 (Astex, Phase 3)**

- In February 2018, Astex initated a Phase III trial in patients unfit for standard induction therapy to compare ASTX727 to IV decitabine. Results reported in the MDS and CMML cohorts, not AML.

**Chemokine:**

**Tipifarnib (Kura Oncology, Phase 2)**

- In October 2016, Kura initiated a Phase II study in unfit 1L AML, along with cohorts in CMML and MDS/MPN to determine the effect of the CXCL12-targeted inhibitor. Data has been reported for the CMML and MDS/MPN cohorts.
- Tipfarnib was originally rejected by the FDA for unfit AML in 2005 when J&J was developing the program.

**Cytotoxic:**

**Vyxeos (Jazz/Fred Hutch, Phase 2)**

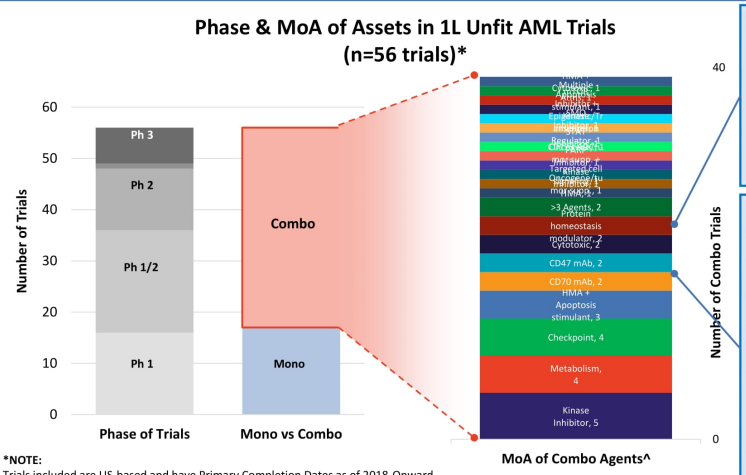
- In March 2020, Jazz initiated a Phase II study to determine the 3-yr OS of patients who are unfit for standard first line treatment.

***NOTE:**
Trials included are US-based and have Primary Completion Dates as of 2018-Onward.
Trials with both mono & combo arms were captured as combo.

[1] Adis Insight [2] Clarivate Analytics Cortellis [3] ClinicalTrials.gov [4] CHBC Analysis

# Broad Diversity of Combinations in Frontline Unfit AML; Led by Targeted Therapies in Combo with SoC (Aza, Ven, Chemos)

1L Unfit Combo




***NOTE:**
Trials included are US-based and have Primary Completion Dates as of 2018-Onward.
^Trials with both mono & combo arms were captured as combo. Agents added to SoC (chemos, HMAs, Ven) were not denoted.

[1] Adis Insight [2] Clarivate Analytics Cortellis [3] ClinicalTrials.gov [4] CHBC Analysis

**Protein homeostasis:**

**Pevonedistat + Azacitidine (Takeda, Phase 3)**

- In November 2017, Takeda initiated the phase III PANTHER trial in patients with higher-risk MDS, CML or low-blast AML. In August 2019, phase III PEVOLAM was initiated for newly diagnosed unfit patients.
- Primary Results from the Phase 2 Pevonedistat-2001 Trial of Pevonedistat + Azacitidine showed in LB-AML mOS of 23.6 months in the pevonedistat combination arm vs. 16 months with azacitidine alone.
- In Sep 2021, Takeda released a statement saying pev did not meet its primary endpoint of EFS.

**CD47-Targeting Agent**

**Magrolimab + Azacitidine (Forty Seven, Phase 1b)**

- A Phase 1b trial of magrolimab + AZA was initiated in MDS/AML patients with preliminary results demonstrating high response rates.
- Forty-Seven/Gilead and Genentech initiated a Phase I/2 study to evaluate magrolimab + Aza + venetoclax, on July 2020.

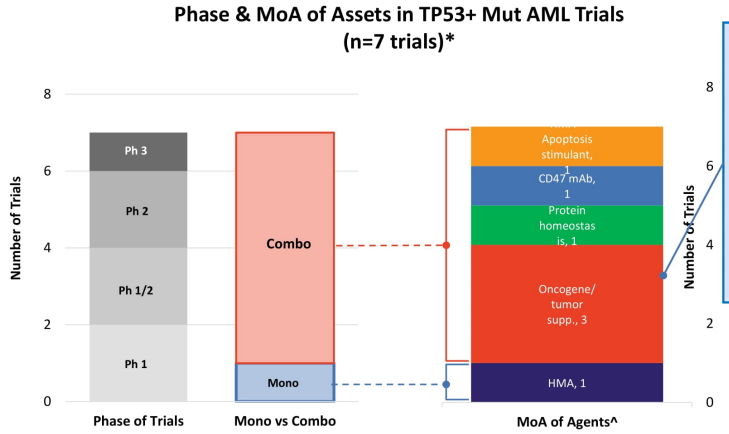
**CD70-Targeating Agent**

**Cusatuzumab + Azacitidine (Argenyx/JNJ, Phase 2, CULMINATE)**

- An open-label P2 trial evaluating cusatuzumab + azacytidine in newly diagnosed AML who are not candidates for intensive chemotherapy was initiated in July 2019. Results demonstrated 27% (n=14/52) patients experienced a CR, cCR of 40% (n=21/52), and 30-day mortality of ITT population was 9.6% (5/52).
- In December 2019, J&J/Argenyx initiated a Phase Ib study to evaluate cusatuzumab ± azacitidine ± venetoclax (ELEVATE).

# Small Clinical Universe in TP53 Mutant AML; Aprea Reporting Data in Combination with Aza and Announces Several Additional Trials

TP53 Mut.




**Oncogene/Tumor Suppressor (p53):**

**APR-246 (Aprea Therapeutics, Phase 2)**

- A Phase II study of APR-246 in combination with Aza in TP53-mutated patients reported an ORR of 33% (out of 18 pts), with 17% CR (27% and 0% CR in AML with less than and more than 30% marrow blasts, respectively). With a median follow-up of 9.7months, median OS was 13.9mon in AML and 3.0mon in AML with more than 30% marrow blasts.
- Another Phase II study to determine the effects of APR-246 in combination with Aza in TP53-mutated AML following allogenic stem cell transplant was initiated in Sep 2019. Trial results have not been reported.
- A third Phase I trial has been initiated in Dec 2019 with APR-246 in combination with Aza and Venetoclax. No trial results posted yet but an interim report claimed no DLTs so far.

***NOTE:**

Trials included are US-based and have Primary Completion Dates as of 2018-Onward.

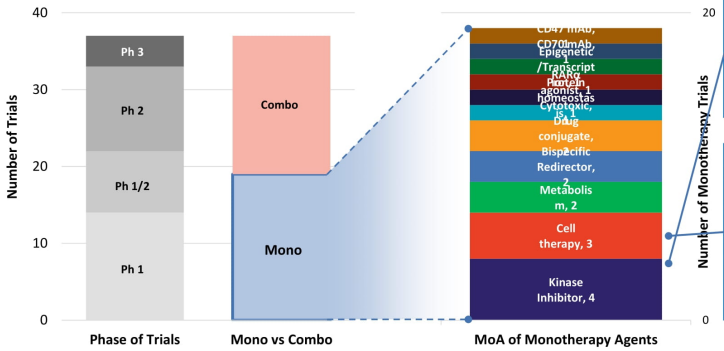
^Trials with both mono & combo arms were captured as combo. Agents added to SoC (chemos, HMAs, Ven) were not denoted.

[1] Adis Insight [2] Clarivate Analytics Cortellis [3] ClinicalTrials.gov [4] CHBC Analysis

# Targeted Therapies and Even Complex Modalities like Cell Therapies are Being Explored as Monotherapies in Primary Refractory Groups

Unfit Prim. Ref. Mono

## Phase & MoA of Assets in Unfit Primary Refractory AML Trials (n=37 trials)*




**Kinase Inhibitor :**

**Xospata (Astellas, Phase 3)**

- Already approved in R/R AML, Astellas reported in March 2021 results of their COMMODORE Trial which specifically includes primary refractory AML. Astellas is planning to submit this trial data to the NMPA for full approval in China.

**Cell Therapy:**

**FT538 (Fate Therapeutics, Phase 1)**

- Fate has initiated a Phase 1 trial in advanced malignancies including MM and AML patients who are primary refractory or relapsed after one or more re-induction attempts.
- FT538 is an iPSC-derived NK cell therapy engineered to express a high-affinity non-cleavable CD16 receptor, an IL-15 receptor-fusion protein on the membrane, and a CD38 knock-out.

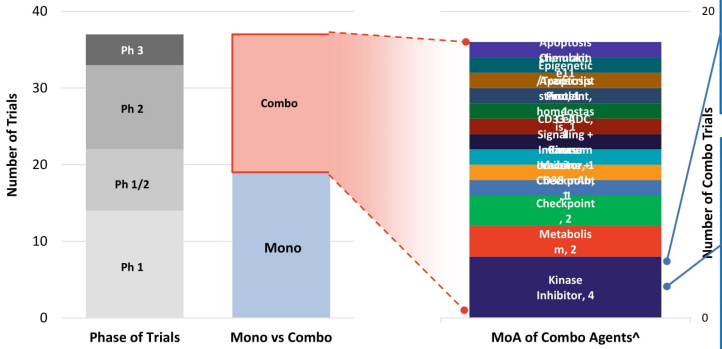
***NOTE:**
Trials included are US-based and have Primary Completion Dates as of 2018-Onward.
Trials with both mono & combo arms were captured as combo.

[1] Adis Insight [2] Clarivate Analytics Cortellis [3] ClinicalTrials.gov [4] CHBC Analysis

# Similarly, Kinase Inhibitors Are Being Used in Combination with Aza for Primary Refractory Unfit Patients

Unfit Prim. Ref. Combo

## Phase & MoA of Assets in Unfit Primary Refractory AML Trials (n=37 trials)*




**Kinase Inhibitor:**

**Alvocidib (Sumitomo Dainippon, Phase 2)**

- Alvocidib is a small molecule cyclin-dependent kinase 9 (CDK9) inhibitor.
- In January 2020, Sumitomo Dainippon initiated the phase 2 trial to evaluate the safety and efficacy of alvocidib in patients with AML who have either relapsed from or refractory to venetoclax in combination with azacitidine or decitabine.

**Kinase Inhibitor:**

**CX-01 (Cantex Pharmaceuticals, Phase 1)**

- CX-01 (Dociparstat sodium) is a glycosaminoglycan compound derived from porcine heparin that retains the anti-inflammatory activity of heparin.
- Patients with HMA-refractory (received 4 or more cycles of HMA without response or disease progression on HMA therapy) AML or MDS (INT-1 or greater) were treated with CX-01 + Azacitidine.
- Results of the study were presented in ASH 2019, ORR was 27%, mOS was 221 days (95% CI 179 days-not reached). [ASH2019]

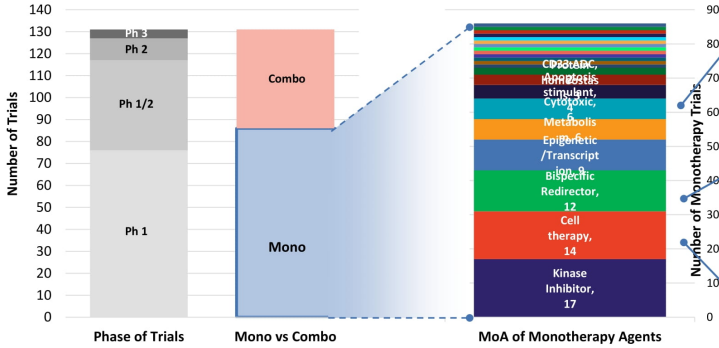
***NOTE:**
Trials included are US-based and have Primary Completion Dates as of 2018-Onward.
^Trials with both mono & combo arms were captured as combo. Agents added to SoC (chemos, HMAs, Ven) were not denoted.

[1] Adis Insight [2] Clarivate Analytics Cortellis [3] ClinicalTrials.gov [4] CHBC Analysis

# Due to the Overwhelming Unmet Need, There is Plenty of Clinical Activity in R/R AML, Both in the Form of Small Molecules and Novel Biologics

R/R Mono

## Phase & MoA of Assets in R/R AML Trials (n=131 trials)*




**Cytotoxic:**

**DFP-10917 (Delta-Fly, Phase 3)**

- DFP-10917 (radgocitabine) inhibits DNA polymerase and results in S-phase arrest, while prolonged exposure induces DNA fragmentation, G2/M arrest, and apoptosis.
- A Phase 3 study in heavily pre-treated AML is ongoing. A prior Phase 1/2 was presented during ASH 2016 (#616), which achieved a 48% ORR (6 CRs, including 2 who transitioned to HSCT, 7 CRi with 3 transitioning to HSCT, and 1 CRp).

**Bispecific Redirector:**

**AMG-330 (Amgen, Phase 1)**

- AMG-330 (eluvixtamab) is a anti-CD33xCD3 bispecific by Amgen. Data presented during EHA2020 (#EP582) reported that 8 out of 60 pts responded (3 CR, 4 CRi, and 1 is morphologic leukemic-free). Gr≥3 CRS in 9 pts (15%).

**Cell Therapy:**

**FT516 (Fate, Phase 1)**

- Data was reported via press release on May 2021 for the use of iPSC-Derived NK Cells in R/R AML. 6/9 pts treated showed anti-leukemic activity and 4 patients achieved an objective response with complete clearance of leukemic blasts in marrow. 3 out of the 4 responders achieved CRi. No DLTs, CRS, neurotox, GvHD.

**FT538 (Fate, Phase 1)**

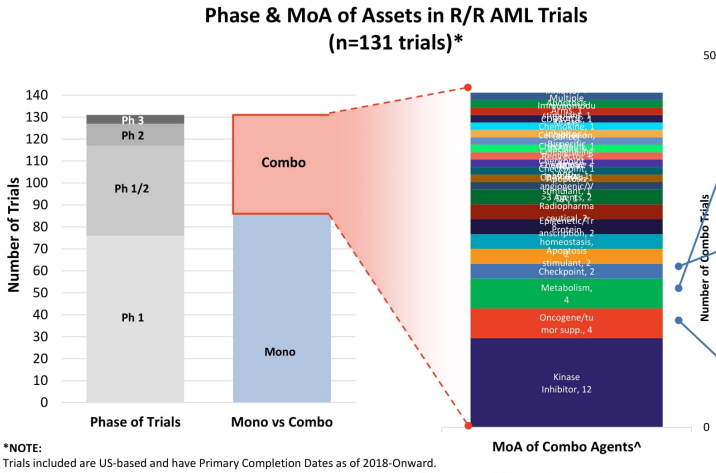
- FT538 is an iPSC-Derived NK cell with CD38 KO. 3 pts were treated and of the 2 evaluable pts, both showed anti-leukemic activity, and one achieved CRi.

***NOTE:**
Trials included are US-based and have Primary Completion Dates as of 2018-Onward.
Trials with both mono & combo arms were captured as combo.

[1] Adis Insight [2] Clarivate Analytics Cortellis [3] ClinicalTrials.gov [4] CHBC Analysis

# Numerous Agents are Being Combined Largely with Current SoC Agents Like HMAs, Chemos, and Venetoclax

R/R Combo




**Metabolism Combination:**

**Devimistat + HDAC + Mitoxantrone (Rafael, Phase 3)**

- Devimistat is currently in a Phase 3 trial in elderly R/R AML patients. Prior results from the same combination demonstrated a 52% composite CR (CR+CRi) and 12.4 mon OS.
- Other data from Devimistat have been demonstrated in pancreatic and t-cell lymphomas.

**Checkpoint Combination:**

**Pembrolizumab + HDAC (Merck, Phase 2)**

- Final results of Phase 2 combination study were reported during ASH2019. Out of 37 pts treated, 16 had refractory disease and 16 had relapsed AML with CD1 duration <1yr. ORR was 46% with composite CR of 38%. 9 pts received allo HSCT. Median OS 8.9 mon, EFS, 6.9 mon, and DFS 5.7 mon. No instances of Gr>3 GvHD.

**Oncogene/Tumor Suppressor Combination:**

**ALRN-6924 + Cytarabine (Merck, Phase 2)**

- Interim results from the combination of cytarabine with the MDMX/MDM2-p53 inhibitor ALFN-6924 was presented early 2018. At release, 33 AML/MDS patients have been recruited across two dosing regimens. So far, there has been two marrow complete responses.

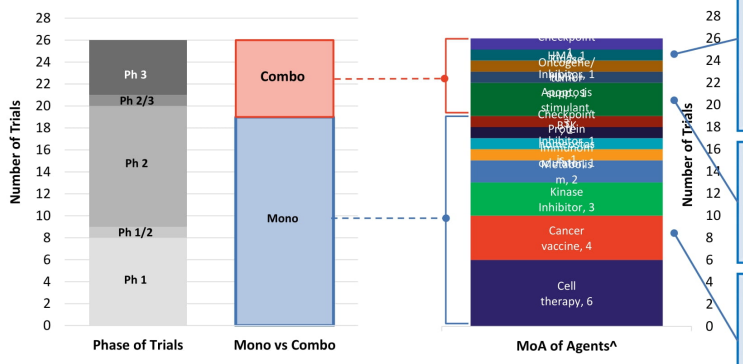
***NOTE:**
Trials included are US-based and have Primary Completion Dates as of 2018-Onward.
^Trials with both mono & combo arms were captured as combo. Agents added to SoC (chemos, HMAs, Ven) were not denoted.

[1] Adis Insight [2] Clarivate Analytics Cortellis [3] ClinicalTrials.gov [4] CHBC Analysis

# Some Complex Modalities like Peptide Vaccines and Cell Therapies are Being Evaluated in Maintenance; Current Available Data is in HMAs

Maintenance

## Phase & MoA of Assets in Maintenance Trials (n=26 trials)*




**HMA:**
**CC-486 + BSC (BMS/Celgene, Phase 3)**

- In the Phase 3 QUAZAR AML-001 trial, oral Aza plus BSC was administered as a maintenance therapy for patients in CR. Data presented during ASH2020 (#1036) reported improved OS and RFS compared to placebo, regardless of prior consolidation cycles (n=472).
- Additionally, comparing MRD+ and MRD- patients, oral Aza resulted in improved OS in MRD+ pts median 14.6 vs 10.4mon and MRD- pts median 30.1 vs 24.3mon (ASH2020 #692).

**HMA + Apoptosis Stimulant:**
**Aza + Venetoclax (AbbVie, Phase 3)**

- A Phase 3 trial (VIALE-M) of Aza + Ven is ongoing in patients in first remission after chemo to evaluate improvement in RFS. The trial initiated in March 2020 and is enrolling 360 pts.

**Kinase Inhibitor:**
**Crenolanib (Arog, Phase 2)**

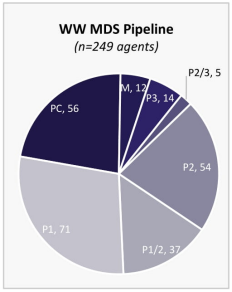
- Data presented during ASH2020 (#1980) was in 20 FLT3+ pts who received allo HSCT. 85% of patients remain alive and in remission. 3 pts with MRD are all alive and in remission. 2 pts relapsed and a third relapsed after stopping treatment due to prolonged drug hold for liver GvHD.

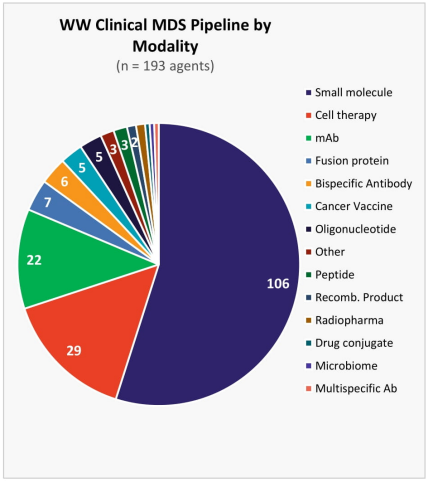
***NOTE:**
Trials included are US-based and have Primary Completion Dates as of 2018-Onward.
^Trials with both mono & combo arms were captured as combo. Agents added to SoC (chemos, HMAs, Ven) were not denoted.

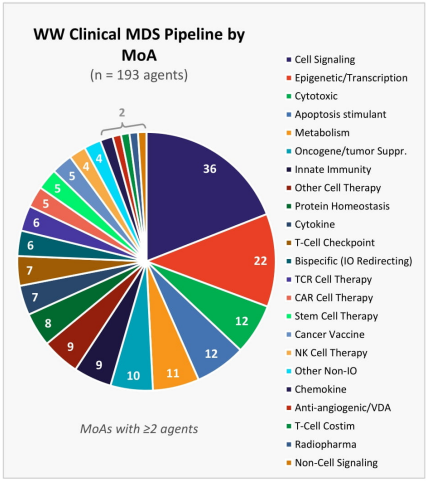
[1] Adis Insight [2] Clarivate Analytics Cortellis [3] ClinicalTrials.gov [4] CHBC Analysis

# MDS – Pipeline Analysis

# Worldwide MDS Pipeline Analysis



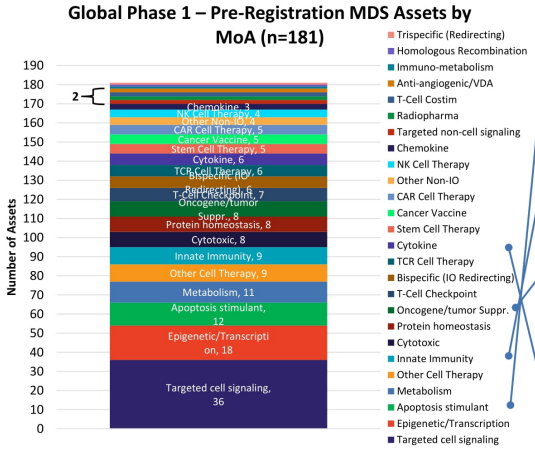




Sources: Adis R&D Insight, Clarivate Analytics Cortellis, CHBC Insight

# Clinical-Stage MDS Pipeline Dominated by Pathway Inhibitors and Transcriptional Regulators

MDS




**Apoptosis Stimulant**

- **Venetoclax in MDS (AbbVie/Genentech, Phase 2, BCL-2 inhibitor)**
  - In 2017, AbbVie and Genentech initiated a P1b study (NCT02966782) evaluating the safety and efficacy of venetoclax monotherapy and venetoclax+azacitidine (aza) in relapsed/refractory MDS pts. In the combo group, 37 pts were evaluable. CR + marrow CR (mCR) was 40%, observed in 15 pts (CR 3, mCR12). Heme improvement achieved by 25% (9/36) and mCR+HI was achieved by 42% (5/12). mPFS was 9.1mon and 12mon OS estimate was 65%.
  - In 2017 a Ph 1b dose-finding study (NCT02942290) of venetoclax + aza in treatment-naïve MDS pts was initiated. ORR was 77%, including CR and mCR achieved by 42% and 35%.

**Innate Immunity**

- **Magrolimab in MDS (Forty Seven, Phase 1, Anti-CD47 antibody)**
  - A P1b trial evaluating magrolimab + aza in 1L intermediate to high-risk MDS and AML pts is ongoing. Results presented at ASCO2020 showed a 91% (30/33) ORR and 42% CR, 24% mCR). Responses deepened with 56% CR in pts with >6 mon follow-up. Median DoR and median OS not reached.

**Oncogene/Tumor Suppressor Gene**

- **APR-246 (Aprea Therapeutics, Phase 3, Mutant p53 activator)**
  - In two P1b/II trials (n1=33 and n2=24) evaluating APR-246 in combination with azacitidine (AZA) in patients with TP53 mutant MDS and AML, ORRs of 88% and 71% were observed with 61% and 54% CRs, respectively. The mOS for all enrolled patients in the first trial was 10.8 months while the mOS in the second trial had not been reached at a median follow-up of 6.4 months. In Jan 2020, the combination was granted breakthrough status.

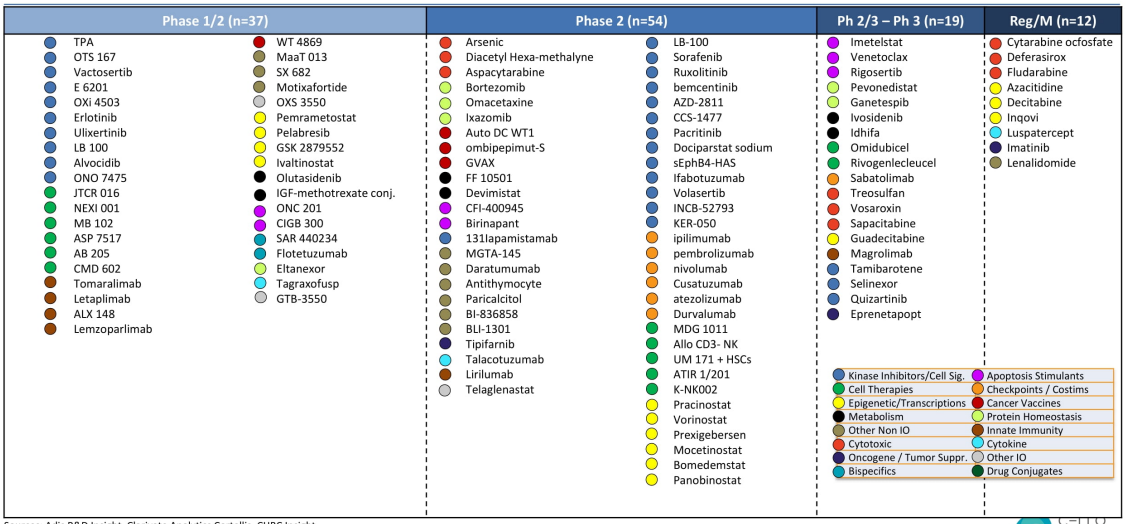
**Cytokine Targeting**

- **Luspatercept (Acceleron Pharma/Celgene, Marketed-Phase 3 Expansion, TGF-β inhibitor)**
  - Aside from being approved in post-ESA for low-risk MDS,, Luspatercept is also being evaluated vs erythropoietin-stimulating agents as 1L treatment for pts with lower-risk MDS In the Ph 3 COMMANDS trial (NCT03682536).
  - In the Ph 3 MEDALIST trial (NCT02631070) in transfusion-dependent pts with very low to intermediate-risk MDS with RS (n=153) , 37.9% (58/153) of pts treated with luspatercept demonstrated RBC transfusion independence ≥ 8 weeks compared with 13.2% (1/76) for placebo.

Adis Insight, Clarivate Analytics Cortellis, ClinicalTrials.gov, CHBC Analysis, Luspatercept P3 MEDALIST, Magrolimab P1b (ASCO2020), Venetoclax P1b R/R Combo (ASH 2020), Venetoclax P1b Combo (ASH 2020), Aprea Press Release

# WW Clinical Stage MDS Pipeline (Phase 1/2 to Marketed)

MDS




Sources: Adis R&D Insight, Clarivate Analytics Cortellis, CHBC Insight

# WW Clinical Stage MDS Pipeline (Phase 1)

| | |
|---|---|
| Kinase Inhibitors/Cell Sig. | Apoptosis Stimulants |
| Cell Therapies | Checkpoints / Costims |
| Epigenetic/Transcriptions | Cancer Vaccines |
| Metabolism | Protein Homeostasis |
| Other Non IO | Innate Immunity |
| Cytotoxic | Cytokine |
| Oncogene / Tumor Suppr. | Other IO |
| Bispecifics | Drug Conjugates |

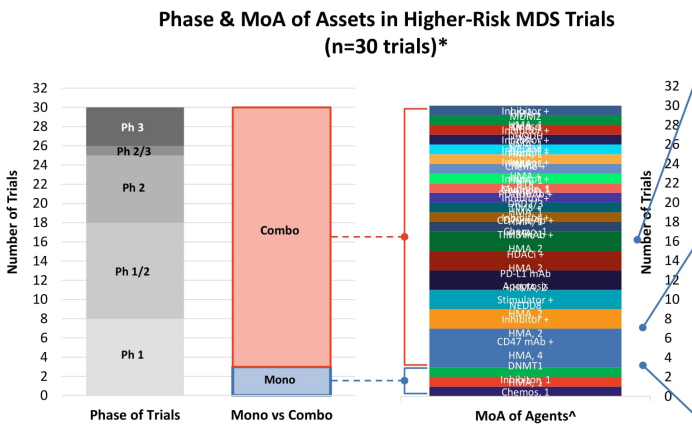
| Phase 1 (n=71) | | |
|---|---|---|
| TRGFT-201 | CC-95775 | JNJ-67571244 |
| NKX-101 | PLX-2853 | APVO 436 |
| MDG-1021 | PLX 51107 | AMG-330 |
| CLL1-CD33 cCART | H3B-8800 | AMV 564 |
| PRGN-3006 | PRT-543 | CC 90002 |
| CYAD-01 | NTX-301 | TTI-621 |
| MANA 312 | Onametostat | Poly ICLC |
| CYAD-02 | JSP-191 | CC 90009 |
| MT- 401 | PIM 447 | CB 5339 |
| E-CEL UVEC | Milademetan | Spartalizumab |
| PACTN | APG 115 | SEA-CD70 |
| HSC-100 | ALRN-6924 | TH-1579 |
| TEG-001 | Cenersen | TAS 1553 |
| INB-100 | Pegzilarginase | CD40L GVAX |
| BPX-701 | HMPL-306 | Talazoparib |
| K NK 003 | SLN-124 | 225Ac-lintuzumab |
| Fadraciclib | JNJ 74856665 | |
| Selumetinib | LY-3410738 | |
| PRI-724 | S 055746 | |
| AZD-4573 | Asunercept | |
| CYC-140 | S 64315 | |
| BTX-A51 | LP-108 | |
| Ibrutinib | PRT-1419 | |
| CA 4948 | YL 13027 | |
| SEL-120 | Nerofe | |
| CWP-291 | Bermekimab | |
| APTO-253 | KHK 2823 | |
| CYC 140 | | |

Sources: Adis R&D Insight, Clarivate Analytics Cortellis, CHBC Insight

# MDS – Clinical Trial Landscape

# HMA Combinations with Small Molecules and Even Biologics Constitute the Majority of H/R MDS Trials

Higher Risk




***NOTE:**
Trials included are US-based and have Primary Completion Dates as of 2018-Onward.
^Trials with both mono & combo arms were captured as combo.

[1] Adis Insight [2] Clarivate Analytics Cortellis [3] ClinicalTrials.gov [4] CHBC Analysis

**TIM3 Inhibitor:**

**MBG453 + HMA (Novartis, Phase 3)**

- Novartis has initiated several Phase 3 studies evaluating the combination of MGB453 (sabatolimab: TIM3 mAb) and HMA in H/R MDS.
- Earlier studies presented during ASH2020 (#657) reported 61% ORR (33.3% CR) in H/R MDS patients when combined with Decitabine, and 64.7% ORR (11.8% CR) with Aza.

**NEDD8 Inhibitor:**

**Pevonedistat + HMA (Takeda, Phase 3)**

- Takeda/Millenium initiated a Phase 3 trial to determine whether pevonedistat combined with Aza can improve EFS when compared to Aza monotherapy. Trial initated in 2017 with no data available yet.
- Prior, an abstract was presented at ASH2020 (#653) for the same combination as a Phase 2 study (NCT02610777) in H/R MDS. Out of n = 67 pts, EFS was longer with P+A vs A (median 20.2 vs 14.8 mos) and median OS was 23.9 vs 19.1 mos.
- In Sep 2021, Takeda released a statement saying pev did not meet its primary endpoint of EFS.

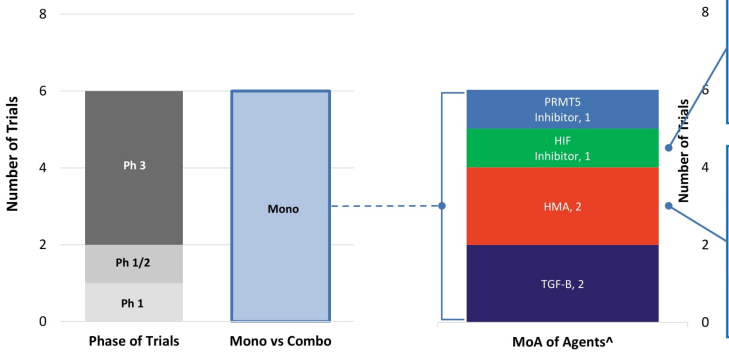
**CD47 Inhibitor:**

**Magrolimab + HMA (Gilead, Phase 3)**

- Gilead initiated a Phase 3 trial to determine whether magrolimab (CD47 mAb) + Aza can increase CR rates and prolong OS compared to a placebo combination with Aza in untreated high-risk MDS patients.
- Previously, their Phase 1b/2 study testing the same combination reported an ORR of 92% and 50% CR, while 33% achieved a marrow CR, and 8% achieved hematologic improvement (n = 24 pts).

# There is Limited Clinical Development in L/R MDS

## Phase & MoA of Assets in Lower-Risk MDS Trials (n=6 trials)*




**HIF Inhibitor:**

**FG-4592 (Roxadustat) (FibroGen, Phase 3)**

- Interim results from a Phase 3 trial in L/R MDS was reported during ASH2020 (#1277). N = 24 transfusion-dependent L/R MDS patients were enrolled. Four patients (16.7%) remained TI for > 20 weeks (1 at 1.5 mg/kg dose level and 3 at 2.5 mg/kg dose-level) at 52 weeks. In patients with TI duration ≥ 140 days (n = 4), the mean (SD) TI duration was 324.5 (121.22) days.

**HMA:**

**CC-486 (BMS, Phase 3)**

- Interim results from a Phase 3 trial in L/R MDS was reported during EHA2020 (#S180). As of data cutoff of n=107 pts treated with the oral HMA, significantly more patients treated achieved TI for ≥56 days (31% vs. 11% placebo). Median TI durations where 11.1 mon vs 5.0 mon. Primary endpoints have been met so far.
- However, Gr3-4 AEs occurred in 90% of pts treated, with most common being neutropenia (47%), thrombocytopenia (29%), and febrile neutropenia (29%).

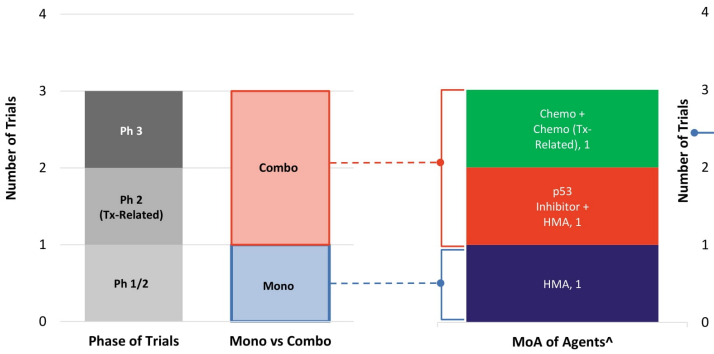
***NOTE:**
Trials included are US-based and have Primary Completion Dates as of 2018-Onward.
^Trials with both mono & combo arms were captured as combo.

[1] Adis Insight [2] Clarivate Analytics Cortellis [3] ClinicalTrials.gov [4] CHBC Analysis

## Similarly, There is Limited Activity in the Tx-Related Setting, Along with All-Comers

Tx-Related; All-risk

### Phase & MoA of Assets in Treatment-Related (1 trial)* & All-Risk (2 trials*) MDS




**Chemo Combination:**

**Vosaroxin + Cytarabine (Vanderbilt-Ingram, Phase 2)**

- Final results from the VITAL Phase 2 trial, which included therapy-related MDS patients, were reported during ASH2019 (#616). Results were not reported for the tx-related MDS patients; all data was for AML. To summarize, CR was achieved in 48% of patients. Gr 4 thrombocytopenia in 76%, Gr 5 infection and colitis in 5% and 2%, respectively.

***NOTE:**
Trials included are US-based and have Primary Completion Dates as of 2018-Onward.
^Trials with both mono & combo arms were captured as combo.

[1] Adis Insight [2] Clarivate Analytics Cortellis [3] ClinicalTrials.gov [4] CHBC Analysis

# Primary Research

# AML – TPPs

## Provisional/Draft TPP (1):
## R/R AML as Monotherapy Post-HMA Regimen

AML

| Target Patient Population | R/R, Unfit AML patients, failing an HMA regimen | | | |
|---|---|---|---|---|
| | Experimental Arm | | Benchmark | Benchmark |
| **Treatment Regimen** | BST-236 | | Gemtuzumab ozogamicin (Mylotarg for CD33+ AML patients)[1] | Decitabine* (R/R AML patients)[2] |
| **Efficacy** | **Base:**<br>CR: 35%<br>ORR: 40%<br>mOS: 12 mos. | **Optimal:**<br>CR: 45%<br>ORR: 55%<br>mOS: 15 mos. | CR: 26%<br>ORR: 33.3%<br>mOS: 8.4 mos. | CR: 21%<br>ORR: 30%<br>mOS: 8.5 mos. |
| **Safety** | Safer, no black box warning | | Grade ≥3 AEs: sepsis (32%), fever (16%), rash (11%), pneumonia (7%), bleeding (7%) | Grade 3-4 nonhematologic toxicity (27%) |
| **Dosing** | IV (final dosing TBD – ongoing) | | IV | IV, 20 mg/m$^2$ daily, given in 5 or 10-day cycles |

CHBC Primary Research [1] Mylotarg PI, J Adv Pract Oncol. 2019 Jan-Feb; 10(1): 68–82 [2] Leuk Lymphoma. 2017 Sep;58(9):1-7. [3] Leuk Res. 2015 Feb;39(2):124-30; *Note: retrospective study

## Provisional/Draft TPP (2): Front-line Therapy in Unfit AML (Combination)

AML

| **Target Patient Population** | Newly diagnosed AML patients unfit for intensive induction chemotherapy (e.g., adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy) | | |
|---|---|---|---|
| | Experimental Arm | | Comparator Arm |
| **Treatment Regimen** | BST-236 ± HMA *or* Venetoclax | | Venetoclax + HMA[1] |
| **Efficacy** | **Base:**<br>CR: 45%<br>mOS: 18 months | **Optimal:**<br>CR: 65%<br>mOS: 20 months | CR: 37%<br>mOS: 14.7 months |
| **Safety** | Comparable TRAE rates | | Grade ≥3 AEs: febrile neutropenia (43%), decreased WBC count (31%), anemia (25%), thrombocytopenia (24%), neutropenia (17%), and pneumonia (13%). |
| **Dosing** | IV (final dosing TBD – ongoing) | | Oral |

*Note: real-world use of Ven/Aza occurring in broader (e.g., fitter) cohort than registration trial. Some clinicians report 60-70% CR with DoR ≤2.5 years*

CHBC Primary Research, [1] Venclexta (venetoclax) prescribing information https://www.rxabbvie.com/pdf/venclexta.pdf

## Provisional/Draft TPP (3):
## Front-line Therapy in Unfit AML (Monotherapy)

AML

| Target Patient Population | Newly diagnosed AML patients unfit for intensive induction chemotherapy (e.g., adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy) OR with secondary AML patients who have had prior exposure to HMA | | |
|---|---|---|---|
| | Experimental Arm | Comparator Arm | Benchmark |
| **Treatment Regimen** | BST-236 | Venetoclax + HMA[1] | Vyxeos[2] |
| **Efficacy** | **Base:**<br>CR: ≥60%<br>mOS: ≥17.0 months | CR: 37%<br>mOS: 14.7 months | CR: 38%<br>mOS: 9.6 months |
| **Safety** | Comparable TRAE rates | Grade ≥3 AEs: febrile neutropenia (43%), decreased WBC count (31%), anemia (25%), thrombocytopenia (24%), neutropenia (17%), and pneumonia (13%). | Prolonged thrombocytopenia (28%) and neutropenia (17%) during Induction 1.<br>Grade ≥3 AEs: febrile neutropenia (66%), bacteremia (23%), pneumonia (20%), hypoxia (12%). |
| **Dosing** | IV (final dosing TBD – ongoing) | Oral | IV, daunorubicin 44 mg/m2<br>and cytarabine 100 mg/m2 varying on first and second induction, and consolidation |

CHBC Primary Research, [1] Venclexta (venetoclax) prescribing information https://www.rxabbvie.com/pdf/venclexta.pdf, [2] Vyxeos prescribing information https://pp.jazzpharma.com/pi/vyxeos.en.USPI.pdf

# BST-236 for Treatment of AML

## Physician Interview Summary

AML

Overview & Current Treatment | Unmet Needs & Future Landscape | Reaction to BST-236 Overview | BST-236 Positioning & Future Use

### Overview & Current Treatment

- AML is highly heterogeneous, primarily considered a disease of older individuals, and is associated with a grim prognosis, particularly for the frail who are intolerant to 1L intensive chemotherapy.
- Nearly all patients have a bone marrow exam to evaluate morphology, cytogenetics and for genetic analysis encompassing all the clinically-relevant mutations identified in AML to date.
  - Blood counts/chemistry, a metabolic panel and patient "*fitness*" are also routine components of the diagnostic evaluation.
  - "Fit" vs. "Unfit" patients segmented on age (typically ±75 yrs) and performance/functional status.
- Newly diagnosed patients who can get treated in academic centers of excellence are typically young/fit and eligible for remission induction therapy, whereas smaller regional centers tend to have AML populations more skewed towards the unfit/elderly segment as they're not well enough to travel.
- 7+3 is the preferred induction regiment for fit AML patients, as there is curative potential with ~70% of patients achieving a CR. However, patients with certain genetic alterations (e.g., complex karyotypes, p53 mut) do not respond well to intensive chemo and may be offered Vyxeos off-label or non-intensive regimens, and potentially transplanted. (FR/GR).
- Generally, EU KOLs are comfortable using Vyxeos in elderly patients & Venetoclax in R/R or bridge-to-transplant regimens off-label or through trial enrollment. Similarly, patients with IDH mutations are recommended to enroll in trials since IDH inhibitors (e.g., ivosedinib, enasidenib) are not approved in EU.
- There is an increasing number of unfit AML, or even some fit, patients being treated with the HMA+Venetoclax combination, driving an estimated >60% CR rate in the US.
  - Although, Ven/HMA is not approved in EU, there is off-label usage in 1L unfit and sometimes later-line settings. Patients identified as poor-risk are recommended to be treated with the combination as well.

### Unmet Needs & Future Landscape

- In aggregate, 75% of all AML patients will relapse, with a five-year survival remaining <30%.
- Resistance to therapy and acquired resistance to targeted agents remains a major hurdle in AML, and prolonged cytopenia, neutropenia & anemia are significant concerns of treatment with existing cytarabine-based regimens, specifically.
- Unmet needs exist across all settings since still the overwhelming minority of patients are cured, regardless of the improved CR rates from modern therapies.

### Reaction to BST-236

- The concept of repurposing and redesigning a conventional cytotoxic was regarded as promising, especially cytarabine which is considered to be one of the most active anti-leukemia drugs for AML: *"You get patients into CR with high-dose cytarabine on its own pretty reliably."*
- Based on some of the clinical data presented, KOLs were initially intrigued by the response rates: *"I think the response rates are not too bad in the elderly population",*
- However, experts commented on the need for an improved cytarabine where higher CR rates are demonstrated with a reduced toxicity profile.
- One KOL remarked on the lack of QoL data in AML and it would be meaningful to understand how long myelosuppression lasts in patients (i.e. median duration of platelet toxicity, neutropenia, days of antibiotics etc.). *"I'm intrigued by the tolerability and toxicity data, I just think, at the minute, it's a bit one dimensional. I would like a better understanding of that." "…changing the pharmacology of an established, older treatment could make sense that it might be more beneficial than the standard."*
  - However, others noted the good safety profile: *"I think from a tolerability perspective it does look overall good"*
- KOLs involved in BST-236 trials have commented on the clear benefits of high-intensity chemotherapy administered in a more tolerable manner, even as a monotherapy. There is cautious enthusiasm since the data is still early. *"…the more I recognize that there are patients who I think are very appropriate to [treat with BST-236]. There are patients that I would treat with this."*
  - One commented on the initial conception of BST-236 and described the product as potentially *"transformative"* and *"phenomenal"* if it can be used to give high-intensity therapy to elderly patients safely with comorbidities.
- In regard to the MRD results presented, multiple KOLs viewed that as an interesting finding: *"This is very interesting because that means that there is a very profound response to Product X…, especially for patients aged 75 or older that there are so good MRD results, so I think this is very interesting and especially that there was 100% complete hematological recovery in responders, so this is really good results for the drug."*
  - *"It's really a biological achievement that has a clinical relevance"*
- KOLs are more intrigued to see BST-236 combined with Venetoclax and others due to its safety profile, since the monotherapy data, albeit promising, is not enough compared to the potential of CR rates from combo regimens.

## BST-236 Positioning & Future Use

- Preliminary positioning for BST-236 would be post-Ven/HMA in unfit patients as monotherapy, or in unfit patients not eligible for Ven/HMA.
  - Consider longer-term studies which allow BST-236 to be positioned in combination with Aza ± Venetoclax in earlier line of treatment.
  - May be intriguing to use as consolidation therapy post-CR in fit patients and replace HiDAC.
  - Potential niche in frontline monotherapy treatment for unfit patients who are still candidates for transplant or even unfit for Venetoclax.
  - Since there is no prolong neutropenia, BST-236 can potential be combined with neutropenia-providing drugs like anthracyclines, gemtuzumab, targeted therapies.
- Potential upside of replacing generic cytarabine may require several head-to-head trials to demonstrate similar or improved efficacy with a more tolerable profile across the settings in which cytarabine is used.

## MDS – TPPs

## Provisional TPP:
## 2L R/R, HMA-Failure Setting for MDS Patients | Single-Arm P2 Based Approval

MDS

| **Target Patient Population** | Intermediate/high risk MDS patients who have progressed on frontline HMA therapy [2L] | | | |
|---|---|---|---|---|
| | Experimental Arm | | Benchmarks | Benchmarks |
| **Treatment Regimen** | BST-236 | | Decitabine (2L) | Physician's choice[2] |
| **Efficacy** | **Base:**<br>CR: 20-25%<br>mOS: 9 mos. | **Optimal:**<br>CR: 25-30%<br>mOS: 12 mos. | CR: 21%[1]<br>ORR: 28%<br>mOS: 6 mos. | • **BSC** (ORR: N/A; mOS: 4.1 mos.)<br>• **Low-dose chemo** (ORR: 0%, mOS 7.3 mos.)<br>• **Intensive chemo** (ORR: 14%, mOS: 8.9 mos.)<br>• **Investigational tx** (ORR: 11%, mOS: 13.2 mos.)<br>• **Allo HSCT** (ORR: 68%, mOS: 19.5 mos.) |
| **Safety** | **Grade ≥3 AEs:**<br>**Base:** Lower toxicity vs. current benchmarks<br>**Optimal:** Significantly lower toxicity vs. current benchmarks | | **Grade ≥3 AEs:**<br>• febrile neutopenias (33%) | Physician's choice |
| **Dosing** | IV (final dosing TBD – ongoing)<br>**Base**: 5 cycles | **Optimal**: 8 cycles | 20 mg/m$^2$ IV over one hour daily times five days | Physician's choice |

CHBC Insight; BSC: Best Supportive Care; [1] Leuk Lymphoma. 2008 April ; 49(4): 690–695. [2] J Clin Oncol. 2011 Aug 20;29(24):3322-7.

# BST-236 for Treatment of MDS

## Physician Interview Summary

MDS

Overview & Current Treatment | Unmet Needs & Future Landscape | Reaction to BST-236 Overview | BST-236 Positioning & Future Use

### Overview & Current Treatment

- Patients with MDS have a variable reduction in the production of normal red blood cells, platelets, and mature granulocytes. As a result, patients with MDS are at risk for symptomatic anemia, infection, and bleeding, as well as progression to AML, which is often refractory to treatment.
- MDS patients are typically segmented based on the Revised International Prognostic Scoring System (IPSS-R) which accounts for bone marrow blast percentage, cytogenetics, and cytopenia to categorize patients into 5 risk groups (very low to very high risk) based on risk of mortality and transformation to AML. Approximately 50% of MDS patients are considered low risk while 50% are high risk.
- Patients can be classified as '**intermediate**' risk at diagnosis (~20%) and treated similar to low/high risk patients depending on molecular or clinical factors. Almost half of intermediate patients typically progress to high risk MDS or AML.
- **High risk:** The majority of patients are treated with azacitidine (AZA) frontline (90%) of which ~**25%** achieve a CR and have a hematological improvement rate of 50-60%. Patients who progress on an HMA are predominantly considered for BSC or clinical trials in the R/R setting.
- For patients who have failed AZA, approximately half progress to AML in ~3 months.
- Low-dose cytarabine is almost never used by itself for treatment of high risk MDS.

### Unmet Needs & Future Landscape

- There remains a high unmet need for effective treatments targeting high risk, transplant ineligible patients:

  *"There's such low rates of CR with azacitidine that it is really a bit unsatisfactory. That's, I think, where the big unmet need in MDS sits."*

- The pipeline for this risk group is becoming increasingly competitive and is anticipated to change significantly pending approval of promising agents (e.g. magrolimab, APR-246, MGB-453, pevonidestat in 1L with HMA) targeting various pathways. With some current off-label usage of Ven/Aza in MDS, KOLs are interested in drugs like pevonidestat that can be added on without contributing more to toxicity.
  - *Interviews were prior to pevonedistat press release failing endpoint of EFS.*

## Reaction to BST-236

- In the context of MDS, cytopenia is the main issue associated with cytarabine, which subsequently exacerbates the risk of neutropenic sepsis as a result.
- Multiple KOLs commented particularly that around half of patients within the post-HMA setting, if not more, would be available for a treatment like BST-236.
  - *"I think the reason, patients are desperate. Who wouldn't be, to try something else? …if the treatment is well-tolerated you would certainly give this a go."*
  - *"If there is a new drug with an acceptable safety profile in this setting, it would be very interesting because all patients would receive this drug, anyway."*
- KOLs spoke on the clear benefit of having a more tolerable chemotherapy:
  - *"If I tell my patient tomorrow that this is a standard chemo and this is a drug that is the pro drug of a standard chemo but we think it's a lot better tolerated, you think it would be a challenge to put people on that kind of protocol? I would want to go on that."*
- One KOL specifically mentioned the use of a cytarabine-analog in MDS may result in responses that correlate more with overall survival than with azacitadine.

## BST-236 Positioning & Future Use

- Experts recommended optimal positioning in the HMA-failure setting where currently no approved therapies exist. BST-236's product profile would need to demonstrate improvement in mOS, CR (~25%) and blood counts to be compelling.
  - Potential for a niche opportunity in MDS patients who are presenting more AML-like progression who would be treated similarly to AML.
  - Another niche for patients in the "gray zone" up to 70 years old that fail HMA, but may be reconsidered for transplants.
- KOLs also commented on the possibility of evaluating BST-236 as a single-agent in the frontline considering AZA represents poor SoC. A combination strategy with an HMA is feasible, however myelosuppression would be a concern.

# Payer Summaries

| Country | Organization | Role | Sample |
|---|---|---|---|
| US | National managed care organization | Pharmacy Director | 1 |
| US | National managed care organization | Chief Medical Director | 1 |
| US | Pharmacy Benefits Management Services | Executive Vice President | 1 |
| France | Le Comité économique des produits de santé (CEPS) | Former member | 1 |
| Germany | Health insurance fund | Head of Medicines | 1 |
| UK | NHS Payer advisory board, Professor | Advisor to NICE, NHS Drugs & Therapeutics Committee Appraisals | 1 |

# BST-236 for Treatment of AML & MDS

## Payer Research Summary

### US: FDA Approval Will Enable Reimbursement in Oncology

- Price is expected to be $10-20K per cycle in the US, benchmarking branded therapies such as Venetoclax, Mylotarg.
- As oncology is protected class, once approved by FDA, the product will be reimbursed, with a prior authorization by label.
- Off-label use can also be reimbursed if it is included in NCCN and/or ASCO guidelines.
- As new therapies emerge, at product launch, contracting/discount would likely be the driver for "preferred" product status on the formulary.

No or low barrier for price and reimbursement in the US

### EU3: Clinical / HTA Assessment is Key For Price & Reimbursement

- Assessment on clinical benefits/HTA will determine price and reimbursement.
  - Price is mostly negotiated between payers and pharma companies.
  - List price is transparent, but contracting is expected with confidential discount.
  - Venetoclax + HMA was just approved, currently under review for ASMR rating, G-BA and NICE HTA assessment. If positive, could be a favourable price benchmark.
- If BST-236 is viewed as a cytarabine analogue, the reference price is very low (benchmark is cytarabine). However, it is not 100% clear whether the product will be assessed as a new drug.
- Off-label use must be requested and approved.

EU market is much more challenging with rigorous clinical/HTA assessment and lower price levels compared to the US

### Positive Product Perception With Overall Survival (OS) Data & Better Tolerability

- Payers acknowledge high unmet needs in the described TPPs.
- Overall survival (OS) needs to show at least 3 months improvement.
- Safety and tolerability is less relevant for price and reimbursement consideration but could help patient compliance and increase access.
- It is not recommended to be positioned to replace cytarabine.

Start with the patient segments to demonstrate the highest value

- **Differentiate from cytarabine** so BST-236 can be perceived and assessed as a **new novel drug**.
  - Highlight it is a conjugate of cytarabine and asparagine.
  - Avoid the "cytarabine analogue" story, otherwise, cytarabine will be used as price benchmark.
    - This is more critical in Europe:
      - If **asparagine is also active with cytotoxic activity, the drug will be viewed as a novel combination therapy**. If cytarabine is the **only active agent**, then it will be a cytarabine analogue, **price benchmark is cytarabine (UK).**
      - It is likely to be assessed as a new drug via AMNOG (DE).

- Clinical Development:
  - Start with patient segments that demonstrate the highest value: **less treatment options**, **better price comparator**, **earlier in the treatment pathway**… (e.g., TPP 2).
  - Consult payers earlier when possible (e.g., DE: G-BA) to get advice on clinical trial design and comparator.
  - Accelerate the clinical programs and launch timeline as much as possible, as cell therapies are expected to be a paradigm shift within 5 years.

- Collect data on patient population, treatments with comparators, including treatment duration and cost, etc. to prepare for price negotiation.

- Engage KOLs for endorsement, RWE and publications, advocate product inclusion in the treatment guidelines.

# Product X for Treatment of AML/MDS

## Payer Interview Summary

**Payers 1-3**

**Treatment Landscape & Unmet Needs** | **Perception of Product X TPP** | Access, Pricing, & Reimbursement | Data Requirements on Access

### Treatment Landscape & Unmet Needs

- Oncology management is not complex, treatments are normally reimbursed **per label** and with **prior-authorization on specialty tier.** Off-label use will be **reimbursed if regimen is included in NCCN/ASCO guidelines**, even if not approved by FDA.
  - Preference of drug and costs are not a burdening obstacle as there are generally a lack of alternative treatment options.
  - Off-label use is managed by physicians submitting request to be approved by a committee of pharmacists and physicians.
- Safety and tolerability have some influence in AML/MDS treatment, however, **OS is the main driver**. Payers would like to see new treatment options with **both extended meaningful survival and good quality of life.**
- Payers expect **more targeted and combination regimens to emerge**, with even cell & gene therapies potentially playing a bigger role in the space in the next 4-5 years.
- Unmet need is considered high across all AML/MDS settings. The **highest unmet need being in elderly, high-risk patients with comorbidities and R/R patients** (in AML and MDS). Additionally, there is unmet need for **fit patients who relapse, are suboptimal candidates for intensive therapy, or have complications** due to AEs.

### Perception of Product X TPPs

- Payers advise **BST-236 should NOT be positioned as replacement of cytarabine**, considering the difficulty to demonstrate survival benefit compared to cytarabine. Particularly, BST-236 is advised to be used in patients **unfit for intensive chemotherapy**. As for **MDS, a new therapy with OS improvement for high-risk patients** is certainly a "*paradigm changer*".
- Better tolerability is a minor benefit for payers. **Efficacy is more impactful**; with a **minimum of 3-month improvement in OS** (optimal 6 months). PFS and ORR are next in the order of importance to demonstrate. However, *"over the last few years, most of the drugs that are approved don`t even have OS data. Some of them just have ORR."* ***"It is good that you are showing incremental survival advantage as well as better toxicity"***
- Need to see more data on AEs, like GI, bleeding, and neutropenia, **but it seems to be a "*clean drug*". *"As AEs are manageable and with OS improvement, the product can be quickly adopted by KOLs and become standard of care"*.**
- Payers appreciate the IV administration as the usage can be confirmed and billed. **Frequency of IV will be necessary to determine** as every 10 days is acceptable, any more frequent may pose obstacles.

# Product X for Treatment of AML/MDS

## Payer Interview Summary

**Payers 1-3**

Treatment Landscape & Unmet Needs | Perception of Product X TPP | **Access, Pricing, & Reimbursement** | **Data Requirements on Access**

### Access, Pricing & Reimbursement Potential

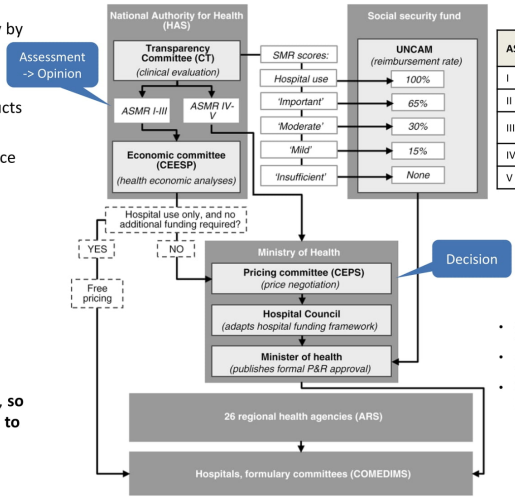
- Price is not a main issue in oncology since it is a *"protected class"*; products are usually reimbursed (*"payers are not comfortable not covering due to price."*). AML/MDS are not considered big spending items due to comparatively low incidence as well as limited treatment options. Payer formulary management is likely limited.
- Payers consider a price around **$10-20K/cycle** (compared to **Venetoclax at 13k per cycle**) is acceptable and straightforward to be reimbursed per label. But if price is over $20K/cycle, it could present some challenges, unless rebate is offered. **An annual price of $150-200K may be considered**, however, those are ceiling values, and the price may have to be lower. When new similar products become available, price can be an important driver for the selection of preferred product.
  - In general, a more specific label, ideally with biomarker stratification, will be preferred by payers for price and reimbursement.
- Despite that combination therapy is expensive, **payers will not have concerns for BST-236 as a combination if priced similarly to Venetoclax**.
- No indication-based pricing, only one price to be determined by comparators per TPPs. Prior authorization will be per indication per label.
- *"The value is in patients that have been very resistant and difficult to treat without any other FDA approved choices have demonstrated anywhere from 3 to 6 months OS improvement with improved safety profile"*

### Data Requirements & Impact on Access

- Anticipating the evolving standard of care/comparator, it is important to see "***how product holds up against standard of care*** *that is evolving with new products".*
- Translate better toxicity data to demonstrate **lower total cost of care**, e.g., **reduced hospitalization**, **overall patient treatment cost**, etc. Additionally, collecting patient-reported outcomes may support the story. These aspects may not influence the reimbursement decision, but pharma companies use these factors to charge higher prices.
  - More detailed AE data may be required. In particular, GI AEs as patients will discontinue treatment if they have grade 3 or 4 diarrhea.
- Payers' perception changed completely if the product were to replace cytarabine, as it is only a reformulated drug at higher price but *"without meaningful clinical benefit"*. Payers recommend the value proposition to highlight the product as a new treatment option for unfit patients where cytarabine cannot be used.

# France: Pricing and Reimbursement Overview

- Reimbursement and price are determined separately by **HAS** and **CEPS**.
- All drugs have to be assessed by HAS:
  - For inclusion in a positive list of reimbursed products (hospital and retail lists)
  - Assessment is by CT and based on medical evidence
    - Efficacy, tolerability, comparator, target population, treatment pathway, interest of public health
  - Recommendation of SMR and ASMR ratings that determine the level of reimbursement and price respectively
  - CEESP: conduct HTA for ASMR I-III or high budget impact
- **CEPS negotiates price-volume agreements**.
- Majority of the approved medicines in the past few years received SMR "important" and ASMR V ratings, **so price has to be lower than comparator**. **This has led to delayed launch and reimbursement in France.**




| ASMR | Clinical added value | Price vs. comparator |
|---|---|---|
| I | Major | Possible price premium, and faster access |
| II | Significant | |
| III | Moderate | |
| IV | Minor | Comparable |
| V | No | Lower |

- **SMR**: actual benefit, determines reimbursement rate
- **ASMR**: improvement in actual benefit, determines price
- **UNCAM**: National Union of Health Insurers

https://www.researchgate.net/figure/Market-access-process-for-drugs-in-France-ARS-Regional-Health-Agencies-COMEDIMS_fig1_284176539

## French Payer Insights

### Price is negotiated based on ASMR rating and comparator.

- ASMR III is only possible with OS improvement in oncology. Also possible if comparator has ASMR III
  - Although historically, ASMR III has been hard to obtain
- **Comparative treatment cost is the reference price.**
  - **If no comparator, the prior line of therapy will be used.**
  - **If no clinical comparator, then an economic comparator can be used as proxy.**
- As IV for in-patient setting, product should aim to be placed on ***liste-en-sus ("extra list")***, which receives funding from health insurance in addition to the "standard" DRG.
  - To be on liste-en-sus, ASMR needs to be I-III.
  - ASMR IV or V can be on liste-en-sus if comparator is already on liste-en-sus .
  - If not on liste-en-sus, but in DRG, it is not good.
- Price (net) is typically agreed with confidential rebates or discount and a cap to control the usage. Then a list price is derived. No confidential agreements for generics.
- Pricing committee could add follow-up contract that Product X price will decrease if comparator price decreases.

### Start with smaller patient population.

- Payer advised to start with smaller patient population that demonstrates the highest value with no or limited alternative (TPP1) ***"building with blocks"***
- For future indication expansion, list price remains, likely with higher discount and bigger cap, or a price-volume agreement with tiered discount %
- However, indication extension could trigger reassessment of ASMR
- **If starting with 3 indications together, comparator price, patient population and market share will be weighted and compounded to set one price.** However, this is very complex, negotiation process could be lengthy.
- Most likely, **Product X will receive ASMR IV, critical to choose the right comparator** and the **associated favourable reference price**.
- **Higher price is only possible with demonstrated differentiation** to the comparator.

## French Payer Insights – Recommendations

**Keep it simple and focused for an easier price negotiation.**

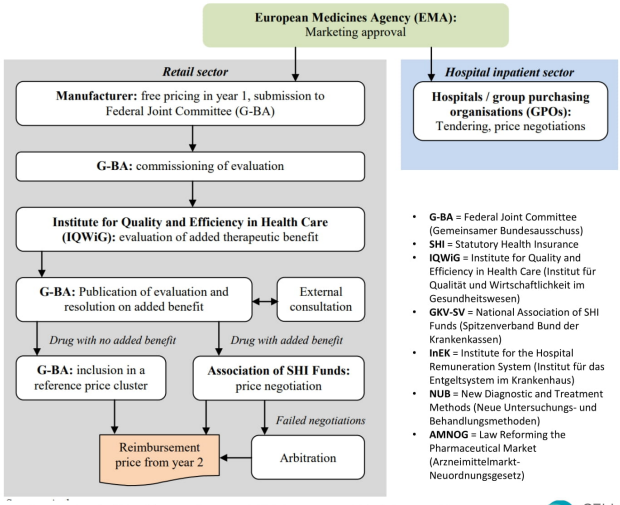
- Keep it **simple**:
  - After SMR and ASMR are recommended, CEPS negotiates price. They are not clinicians; focus is on economics.
  - **To bring 3 indications together could be too complex.**
- Look for indicators:
  - The time-to-reach price agreement could be an indicator how value is perceived (if it is long, value is not high)
  - Sometimes payers might not be happy about the rating on the comparator, which could present a challenge.
- Once ASMR is assigned, the pharma company has 2 weeks to accept or appeal. It is advised to engage the pricing committee at this point to get guidance on what argument to make. It should focus on the main argument: easier to use, instead of a long exhaustive list.

**Relevant ASMR rating and pricing information on comparators:**

- **Venetoclax** (Venclyxto®) + rituximab: ASMR IV (2019 for CLL)
- **Venetoclax + HMA** was just approved for unfit AML in EU, ASMR unknown now
- **Dacogen®** was removed from reimbursement in 2018 due to SMR reassessed to "insufficient". Comparator arm for TPP1 and TPP3 should take this into consideration
- **Vidaza®** was assigned ASMR II in 2009, reassessed to SMR "insufficient" for unfit AML (no reimbursement)
- **Vidaza®** and 1 generic are on liste-en-sus, reference price is low
- **Rydapt®**: ASMR IV (2018), reassessed to ASMR V in 2021
- **Xospata®** (gilteritinib) – ASMR IV (2020)

# Germany: Pricing and Reimbursement Overview

- Year 1 post marketing authorization:
  - Prescription drugs are reimbursed upon marketing authorization by health insurance unless included in G-BA negative list.
  - **Pharma companies are free to set price**.
- Added therapeutic value will be assessed by IQWiG
- After year 1:
  - Based on the **added therapeutic value**, **a price will be negotiated with GKV-SV** (association of insurance funds) to be effective
  - Prices of innovative drugs are mainly negotiated.
- When considered **therapeutically equivalent, drugs can be clustered in groups and subject to maximum reimbursement amounts** (reference group).




- **G-BA** = Federal Joint Committee (Gemeinsamer Bundesausschuss)
- **SHI** = Statutory Health Insurance
- **IQWiG** = Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen)
- **GKV-SV** = National Association of SHI Funds (Spitzenverband Bund der Krankenkassen)
- **InEK** = Institute for the Hospital Remuneration System (Institut für das Entgeltsystem im Krankenhaus)
- **NUB** = New Diagnostic and Treatment Methods (Neue Untersuchungs- und Behandlungsmethoden)
- **AMNOG** = Law Reforming the Pharmaceutical Market (Arzneimittelmarkt-Neuordnungsgesetz)

https://www.oecd.org/health/health-systems/Pharmaceutical-Reimbursement-and-Pricing-in-Germany.pdf

## German Payer Insights

### Payer influence on oncology treatment is limited

- Onkopedia guidelines are followed:
  - A guideline portal for practising doctors
  - For diagnosis and treatment of hematological and oncological diseases
  - Jointly developed and used in DE, AU, CH
    - Germany: DGHO (Deutsche Gesellschaft für Hämatologie und Medizinische Onkologie e.V.)
    - Austria: OeGHO (Österreichische Gesellschaft für Hämatologie & Medizinische Onkologie)
    - Switzerland: SSH/SGH (Schweizerische Gesellschaft Für Hämatologie); SSMO/SSOM/SGMO (Schweizerische Gesellschaft für Medizinische Onkologie)
- Difficult for payers to impose restrictions on oncologists who only value clinical data and ***"see AMNOG as an artificial process for price"***
- **Payers send letters to doctors to guide the use of treatment** (e.g., to inform that a particular medicine has a contract with rebate and therefore it is preferred)
- However, **payers have no visibility to patient condition and treatment.**

### Price is negotiated based on added therapeutic benefits assessed by G-BA/IQWIG

- New drugs (with new API) will undergo AMNOG process with 2 steps:
  1) HTA assessment by G-BA/IQWIG to determine added therapeutic benefits
  2) Price negotiations between GKV-SV and pharma company
- If NO added benefits, product will be placed in existing reference group, typically with low price level.
- Unmet needs do not play a role in HTA assessment
- For HTA: OS, morbidity and safety advantages (e.g., less blood transfusions), QoL (via standard questionnaire, EORTC QLQ-C30 for oncology) are all relevant.
  - **PFS is considered not relevant for patients, so not an endpoint**
- When comparator is not clear or lack of alternatives, **best supportive care will be used for comparison.**
- **Price negotiation is based on annual treatment cost** and list price
  - Premium list price is possible, but with confidential rebates and capping

## German Payer Insights – Recommendations

### Earlier line treatment is recommended to have a higher impact in the treatment paradigm

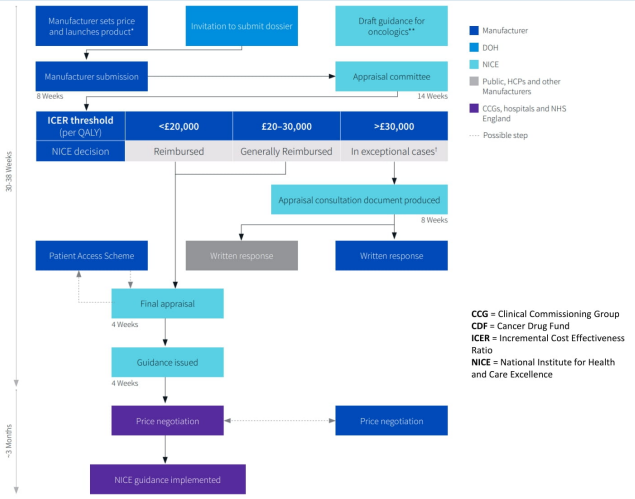
- All 3 TPPs are perceived with good data and added value, but the highest impact is in earlier treatment (frontline unfit AML).
- Must clearly demonstrate target patient sub-groups.
- Be aware of treatment alternatives and cost (how often and how long they are used).
- Pharma companies should provide own data on patient population for each indication and RWE, if available.
  - G-BA does not have access to data from sick funds
- **One price for multiple indications.**
  - Price for each indication is calculated based on the corresponding comparator
  - Patient population in each indication will be weighted to set the price
  - Pharma company can shift patient population to higher priced indication to get a more favourable price
- **Orphan designation automatically gets added value.**

### Get consultation with G-BA for advice and differentiate from Cytarabine to be assessed as a new drug

- Request **consultation with G-BA** for early advice on study design and comparators (takes 5-6 months to get appointment)
  - Questions must be structured and specific, it is not open discussion
- Venetoclax is currently going through HTA assessment
- **Product is likely to be assessed as a new drug** with AMNOG
  - **If the product is considered as an analogue to Cytarabine, there will be no AMNOG assessment, price of Cytarabine will be applied**. Broader access (like Cytarabine) could be possible.
  - As a new drug assessed via AMNOG, price will depend on added benefits over comparators (not set by Cytarabine price)
- Off-label use must be requested and approved. Physicians will get fines with unauthorized off-label use.
- Pharma companies have withdrawn products from Germany due to commercial reasons, but it is relatively limited, only about 5 drugs per year.

# UK: Pricing and Reimbursement Overview

- Free pricing, however, **products that are not cost effective will not be reimbursed**.
- Reimbursement decision-making is highly centralized, conducted by NICE according to defied CE thresholds.
  - **NICE assessments are rigorous and lengthy, requiring a substantial body of evidence.**
  - NICE recommendations are highly influential and referenced by many countries globally.
- Regions and hospitals must manage their own budgets and are also key stakeholders in the reimbursement process.
- An appraisal consultation document is produced if the committee does not recommend the product or suggest restriction to reimbursement (e.g. for sub-population only).
- Manufacturers may use Patient Access Scheme or risk-sharing to improve CE for NICE to recommend reimbursement
- The CDF provides interim funding. It is typically used when there is uncertainty to be addressed through further data collection in the NHS or clinical studies




**CCG** = Clinical Commissioning Group
**CDF** = Cancer Drug Fund
**ICER** = Incremental Cost Effectiveness Ratio
**NICE** = National Institute for Health and Care Excellence

https://drugdevelopment.labcorp.com/content/dam/covance/assetLibrary/salessheets/Pricing-Reimbursement-England-SSCMA052.pdf

## NICE holds a strict standard and procedure for appraisal and reimbursement recommendations

- Number of AML patients have increased 7-10% over the last 10 years as population grow older, about 4000 new cases per year.
- AML/MDS treatment follows NICE guidelines based on ESMO.
- For unfit patients, 2-3 comparators typically used: low dose cytarabine, Azacitidine, best supportive care. **NICE decides on the comparators for assessment.**
- **NICE's cost per QALY standard threshold = £20,000 to £30,000**
- Premium pricing is driven by efficacy.
  - OS is the most relevant efficacy measure
  - **At least 3 months OS improvement is needed**
- **Safety might improve access but has no impact on price.**
- Different contracting schemes are used to address different issues:
  - If it is cost effectiveness: pay for performance
  - If it is budget impact: financial agreement, e.g., cap
  - If it is uncertainty of clinical outcomes: outcome-based agreement, risk-sharing

## Cytarabine analogue vs. new novel drug

- **Unmet need is considered highest for unfit R/R AML**
- **Viewed as a "safer Cytarabine" if cytarabine is the only active agent**
  - **Cytarabine will be price benchmark, up to 20% price premium with mOS > 3 months.**
  - However, physicians likely to adopt Product X, "squeeze out standard Cytarabine", leading to broad access. Case study to investigate further: pegylated liposomal doxorubicin hydrochloride (PLDH)
  - Product X shall replace low-dose Cytarabine in combination with Vidaza in all AML and MDS indications, and to be included in the guidelines.
- **If asparagine is also active with cytotoxic activity, the drug will be viewed as a novel combination therapy.**
- NICE recommendation vs. CDF (Cancer Drug Fund)
  - CDF is interim funding for new cancer drugs, giving patients access to these treatments
  - When NICE does not want to grant routine reimbursement and reluctant to reject completely, conditional reimbursement is given with real-world evidence (RWE) collection requirement, typically for 3-5 years
  - If pharma company agrees, product then enters CDF, but not paid at full price
  - Once pharma company collects RWE, NICE re-assess

## UK Payer Insights – Recommendations

### Factors to consider for NICE

- Cost per QALYs threshold is higher for life-extending treatment at the end of life
  - If life expectancy < 2 years, cost per QALY will double with a mOS improvement of 3 months.
- If direct comparison of efficacy is not possible, indirect comparison could be looked at.
- Due to Covid pandemic, oral treatments are preferred to IV.
  - This preference is expected to continue
  - Even physician visits will be done virtual first (e.g., on Zoom)
- NICE expects CAR T therapy to come soon.

***"NICE might lose interest in biologic cancer treatments, only a short time window for Product X to get reimbursement"***

### Relevant pricing and reimbursement information on comparators

- **Currently several AML treatment under NICE review, due to low price comparators, some products have withdrawn, including**:
  - **Daurismo** (Glasdegib) from Pfizer: in combination with low dose Cytarabine for unfit AML
  - **Cantuzumab** (ARGX-110) from Janssen.
- Azacitidine is not recommended for treating AML with over 30% bone marrow blasts in people >=65 years who are not eligible for HSCT .
- List price of liposomal cytarabine–daunorubicin is £4,581 per 50-ml vial, with a confidential discount.
  - Incremental cost-effectiveness ratio (ICER) < £50,000 per QALY gained
- Venetoclax + HMA is under NICE review, outcome expected end of 2021
  - **If positive, could be a good price comparator assuming Product X is not assessed as Cytarabine analogue.**

# BST-236 Forecast

## Executive Summary:
## Forecast Methodology and Caveats (AML and MDS)

### Methodology

- This project includes a **US 10-year patient-based forecast** that leverages the primary and secondary research to model and support the potential value for BST-236 in both AML and MDS.
- Key inputs include disease incidence, patient segmentation (e.g. low vs high risk MDS, fit vs unfit AML), peak shares across scenarios (base vs. upside), adherence rate, price per therapy cycle and price growth. Both AML and MDS patient-based flows can be found in the following slides.
- Patient build, product positioning and utilization were based on secondary sources along with primary research (**n=14** phone interviews with **US & EU-based** experts (US: 6 KOLs, EU: 8 KOLs)
- The pricing assumption was pressure-tested from payer research interviews and benchmarked against the price of therapies used across both the AML and MDS selected settings.

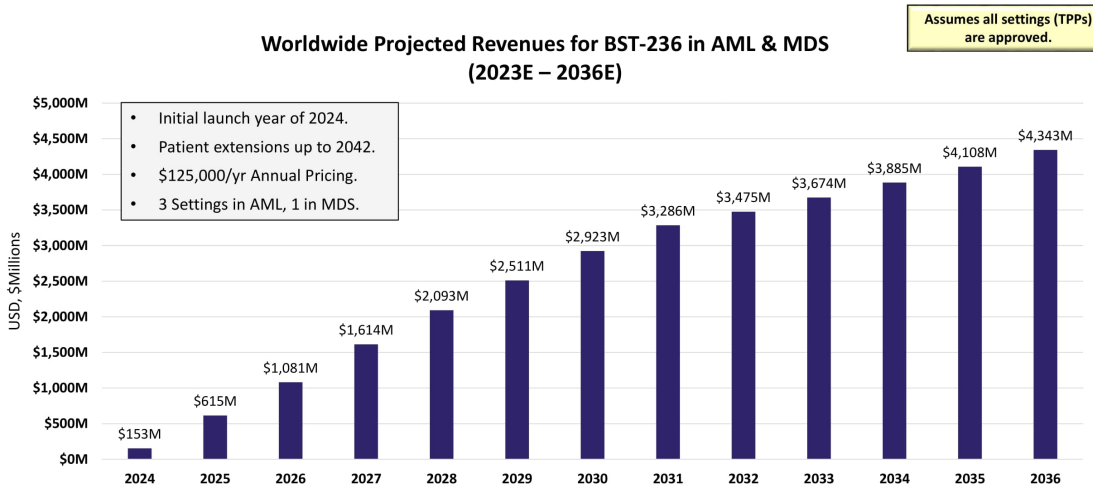
### Model Caveats

1) Our model does not account for the impact from potential competitor approvals and the clinical probability of success for BST-236 throughout the regulatory process. (The rNPV will account for clinical risk.)
2) Sales are US-focused. An Ex-US conversion factor was implemented using historical & well-documented sales from Rituxan globally. Similar conversions for European and UK markets were incorporated.
3) **Launch years for each of the settings are accelerated**, as approval in frontline settings will most likely require Phase 3 trials. A subsequent model including a Phase 3 trial will be considered and move the launch year further.
4) **Pricing will be heavily reliant on the initial approval setting.**

CHBC Primary Research

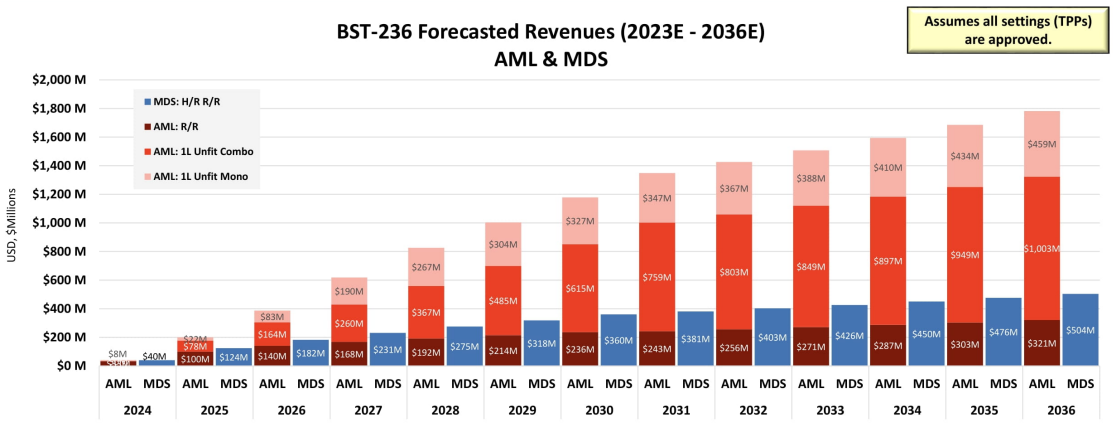
## Worldwide Revenues for BST-236 May Reach Up to $4.4B in Global Sales in AML & MDS

**Assumes all settings (TPPs) are approved.**



# BST-236 Revenue Forecast Model Output

## Total Revenues Projected to Peak at ~$2.3B in the US by 2036; WW Peak Sales May Reach $4.4B by 2036




| *USD $Millions* | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2030 | 2031 | 2032 | 2033 | 2034 | 2035 | 2036 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| US Revenue | $81M | $324M | $569M | $849M | $1,101M | $1,322M | $1,539M | $1,729M | $1,829M | $1,934M | $2,045M | $2,162M | $2,286M |
| WW Revenue | $153M | $615M | $1,081M | $1,614M | $2,093M | $2,511M | $2,923M | $3,286M | $3,475M | $3,674M | $3,885M | $4,108M | $4,343M |

# AML

## Provisional/Draft TPP (1):
## R/R AML as Monotherapy Post-HMA Regimen

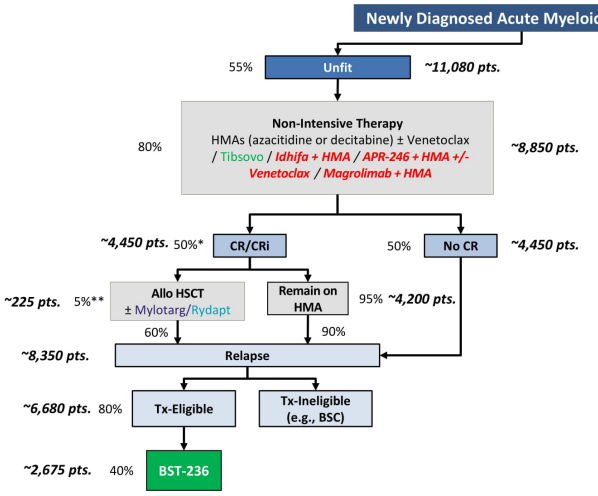
AML

| Target Patient Population | R/R, Unfit AML patients, failing an HMA regimen | | | |
|---|---|---|---|---|
| | Experimental Arm | | Benchmark | Benchmark |
| **Treatment Regimen** | BST-236 | | Gemtuzumab ozogamicin (Mylotarg for CD33+ AML patients)[1] | Decitabine* (R/R AML patients)[2] |
| **Efficacy** | **Base:**<br>CR: 35%<br>ORR: 40%<br>mOS: 12 mos. | **Optimal:**<br>CR: 45%<br>ORR: 55%<br>mOS: 15 mos. | CR: 26%<br>ORR: 33.3%<br>mOS: 8.4 mos. | CR: 21%<br>ORR: 30%<br>mOS: 8.5 mos. |
| **Safety** | Safer, no black box warning | | Grade ≥3 AEs: sepsis (32%), fever (16%), rash (11%), pneumonia (7%), bleeding (7%) | Grade 3-4 nonhematologic toxicity (27%) |
| **Dosing** | IV (final dosing TBD – ongoing) | | IV | IV, 20 mg/m$^2$ daily, given in 5 or 10-day cycles |

CHBC Primary Research [1] Mylotarg PI, J Adv Pract Oncol. 2019 Jan-Feb; 10(1): 68–82 [2] Leuk Lymphoma. 2017 Sep;58(9):1-7. [3] Leuk Res. 2015 Feb;39(2):124-30; *Note: retrospective study

# Patient Flow for BST-236 in AML (TPP 1): R/R Unfit, Monotherapy

AML




CD33+ only
IDH1+ only
IDH2mut only
FLT3+ only
Future Therapy

**Rationale**:

- As unfit patients progress through frontline treatment, options are limited. Patients are typically in rough shape and either fall out of the treatment paradigm (e.g., to BSC) or enroll in clinical trials. There are a multitude of R/R clinical trials ongoing at any given time.
- With BST's approval in R/R, the peak utilization of the drug will be around 40%, with a sensitivity applied +/- 10% due to the reasons stated above.

***Note**: Sensitivities will be applied for:*
** Sens. 37-70%*
*** Sens. 5-15%*

## Provisional/Draft TPP (2): Front-line Therapy in Unfit AML (Combination)

AML

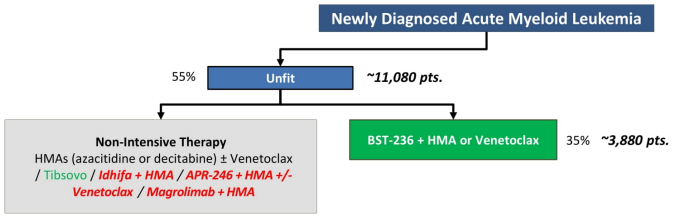
| Target Patient Population | Newly diagnosed AML patients unfit for intensive induction chemotherapy (e.g., adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy) | | |
|---|---|---|---|
| | Experimental Arm | | Comparator Arm |
| **Treatment Regimen** | BST-236 ± HMA *or* Venetoclax | | Venetoclax + HMA[1] |
| **Efficacy** | **Base:**<br>CR: 45%<br>mOS: 18 months | **Optimal:**<br>CR: 65%<br>mOS: 20 months | CR: 37%<br>mOS: 14.7 months |
| **Safety** | Comparable TRAE rates | | Grade ≥3 AEs: febrile neutropenia (43%), decreased WBC count (31%), anemia (25%), thrombocytopenia (24%), neutropenia (17%), and pneumonia (13%). |
| **Dosing** | IV (final dosing TBD – ongoing) | | Oral |

*Note: real-world use of Ven/Aza occurring in broader (e.g., fitter) cohort than registration trial. Some clinicians report 60-70% CR with DoR ≤2.5 years*

CHBC Primary Research, [1] Venclexta (venetoclax) prescribing information https://www.rxabbvie.com/pdf/venclexta.pdf

# Patient Flow for BST-236 in AML (TPP 2): 1L Unfit Combination with HMA/Ven

AML




CD33+ only
IDH1+ only
IDH2mut only
FLT3+ only
Future Therapy

**Rationale**:

- KOLs have reported their growing enthusiasm with the Ven+Aza combination, especially as they become more comfortable with managing the associated toxicities. Patients are being treated longer now on the combination than the median cycles reported in the label (7 cycles for label, with 10+ cycles reported by KOLs).
- As such, BST's utilization in this space will be dictated by the comparative data from BST + Ven/Aza against Ven+Aza. Sensitivity for the utilization of 35% will be applied in the forecast of +/- 10%.

## Provisional/Draft TPP (3):
## Front-line Therapy in Unfit AML (Monotherapy)

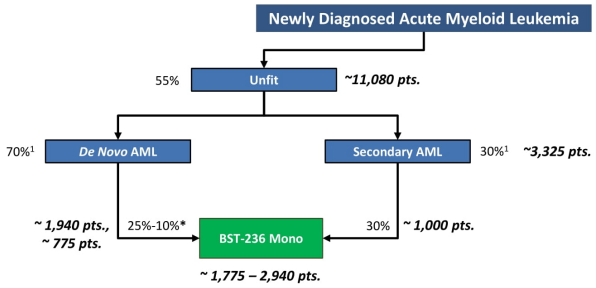
AML

| Target Patient Population | Newly diagnosed AML patients unfit for intensive induction chemotherapy (e.g., adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy) OR with secondary AML patients who have had prior exposure to HMA | | |
|---|---|---|---|
| | Experimental Arm | Comparator Arm | Benchmark |
| **Treatment Regimen** | BST-236 | Venetoclax + HMA[1] | Vyxeos[2] |
| **Efficacy** | **Base:**<br>CR: ≥60%<br>mOS: ≥17.0 months | CR: 37%<br>mOS: 14.7 months | CR: 38%<br>mOS: 9.6 months |
| **Safety** | Comparable TRAE rates | Grade ≥3 AEs: febrile neutropenia (43%), decreased WBC count (31%), anemia (25%), thrombocytopenia (24%), neutropenia (17%), and pneumonia (13%). | Prolonged thrombocytopenia (28%) and neutropenia (17%) during Induction 1.<br>Grade ≥3 AEs: febrile neutropenia (66%), bacteremia (23%), pneumonia (20%), hypoxia (12%). |
| **Dosing** | IV (final dosing TBD – ongoing) | Oral | IV, daunorubicin 44 mg/m2<br>and cytarabine 100 mg/m2 varying on first and second induction, and consolidation |

CHBC Primary Research, [1] Venclexta (venetoclax) prescribing information https://www.rxabbvie.com/pdf/venclexta.pdf, [2] Vyxeos prescribing information https://pp.jazzpharma.com/pi/vyxeos.en.USPI.pdf

# Patient Flow for BST-236 in AML (TPP 3): 1L Unfit Monotherapy & Secondary AML

AML




CD33+ only
IDH1+ only
IDH2mut only
FLT3+ only
Future Therapy

**Rationale**:

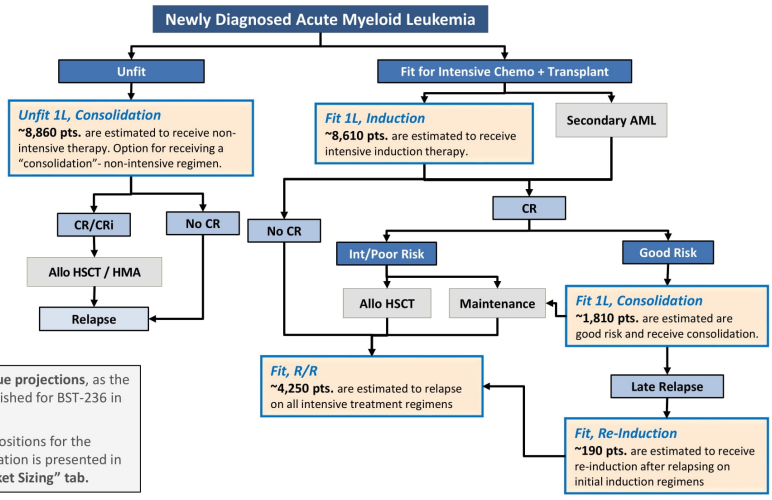
- As referenced in TPP2, KOLs are growing increasingly comfortable with using Ven+Aza combination in patients. Thus, the utilization of BST-236 as a monotherapy frontline will most likely be limited (25%), then be further reduced pending the approval of TPP2 (BST + Ven/Aza), as the theory will be for increased efficacy. However, a portion of patients may still be treated with BST monotherapy in the future if they are deemed unfit for Venetoclax.
- Additionally, with the data released in ASCO2021, a niche population may still remain for unfit secondary AML patients, regardless of future approvals as a combination.

[1] *ASCO Educational Book* 38 (May 23, 2018) 555-573.

# Market Sizing of Additional Potential Upside Positions for BST-236

AML

| Upside Positions | # of Pts. (2021) |
|---|---|
| Unfit 1L, Consolidation | ~8,860 pts. |
| Fit 1L, Induction | ~8,610 pts. |
| Fit, R/R | ~4,250 pts. |
| Fit 1L, Consolidation | ~190 pts. |
| Fit, Re-Induction | ~1,810 pts. |

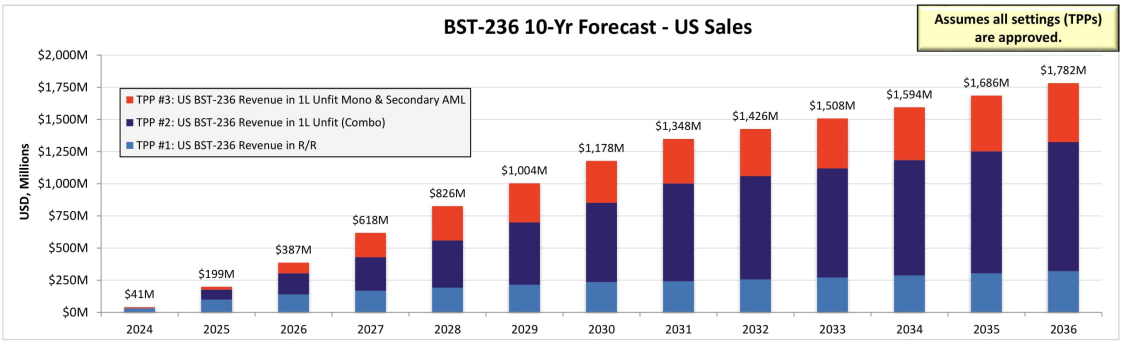



- **The above positions were not studied for revenue projections**, as the forecast was built around the specific TPPs established for BST-236 in AML and evaluated with KOL feedback.
- However, general market sizing of these upside positions for the future were calculated and more detailed information is presented in the **Excel forecast model under the "AML – Market Sizing" tab.**

# BST-236 Revenue Forecast Model Output – Setting Comparison

## Combination Treatment in Newly Diagnosed Unfit AML Serves as the Largest Contributor to Revenue

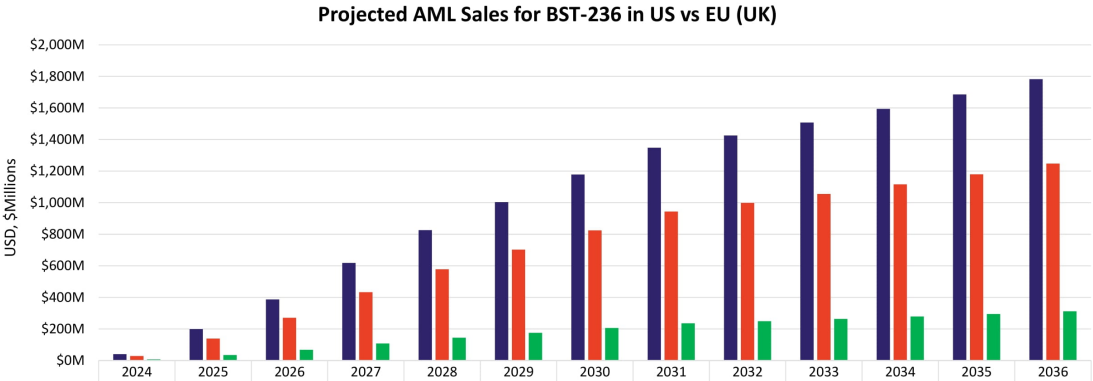
AML




| Forecasted Revenues for BST-236 | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Year | | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2030 | 2031 | 2032 | 2033 | 2034 | 2035 | 2036 |
| TPP #1 | US BST-236 Revenue in R/R | $33M | $100M | $140M | $168M | $192M | $214M | $236M | $243M | $256M | $271M | $287M | $303M | $321M |
| | *# of Pts Treated.* | *401* | *1,157* | *1,551* | *1,773* | *1,926* | *2,051* | *2,150* | *2,104* | *2,119* | *2,133* | *2,148* | *2,163* | *2,179* |
| TPP #2 | US BST-236 Revenue in 1L Unfit (Combo) | $0M | $78M | $164M | $260M | $367M | $485M | $615M | $759M | $803M | $849M | $897M | $949M | $1,003M |
| | *# of Pts Treated.* | *0* | *541* | *1,090* | *1,646* | *2,211* | *2,783* | *3,363* | *3,950* | *3,978* | *4,006* | *4,034* | *4,062* | *4,091* |
| TPP #3 | US BST-236 Revenue in 1L Unfit (Mono & 2nd AML) | $8M | $22M | $83M | $190M | $267M | $304M | $327M | $347M | $367M | $388M | $410M | $434M | $459M |
| | *# of Pts Treated.* | *58* | *154* | *550* | *1,202* | *1,611* | *1,745* | *1,785* | *1,804* | *1,818* | *1,831* | *1,844* | *1,857* | *1,870* |

## Global Projections Still May Exceed $1.2B in EU4 and $300M in UK Alone

AML




| | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2030 | 2031 | 2032 | 2033 | 2034 | 2035 | 2036 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| US | $41M | $199M | $387M | $618M | $826M | $1,004M | $1,178M | $1,348M | $1,426M | $1,508M | $1,594M | $1,686M | $1,782M |
| EU4 | $29M | $139M | $271M | $433M | $578M | $702M | $825M | $944M | $998M | $1,055M | $1,116M | $1,180M | $1,248M |
| UK | $7M | $35M | $68M | $108M | $145M | $176M | $206M | $236M | $250M | $264M | $279M | $295M | $312M |

# Forecast Inputs for AML (1/4)

**Forecast Inputs**

| Variables | Inputs | Sources/Rationale |
|---|---|---|
| **Patient Demographics** | | |
| US Population | 330,266,809 | CHBC Secondary (United States Census Bureau 2021) |
| Annual Growth Rate | 0.7% | US Census Bureau |
| AML Incidence Rate | 0.006% | SEER AML Incidence |
| **Patient Segmentation** | | |
| UNFIT | | |
| **% Patients who are Unfit/Elderly** | 55% | CHBC Primary, Appl Health Econ Health Policy. 2013 Jun;11(3):275-86., Hematology Am Soc Hematol Educ Program. 2016 Dec 2; 2016(1): 339–347. |
| % of Patients Treated first-line | 95% | CHBC Assumption |
| **% Patients who are Secondary AML (Unfit)** | 30% | ASCO Educational Book 38 (May 23, 2018) 555-573 |
| % of Patients who received Non-Intensive Therapy | 80% | CHBC Primary; Patients using BST-236 in first-line will be discounted when estimating the number of R/R patients to prevent capturing patients who have already experienced BST-236. |
| % of Patients who achieve CR/CRi on Non-Intensive Therapy | 50% | CHBC Primary; CHBC Insight |
| % of Patients who are fit enough to receive Allo HSCT | 5% | CHBC Primary; CHBC Insight |
| % of Patients who relapse after transplant | 60% | CHBC Primary; https://news.cancerconnect.com/leukemia/allogenic-stem-cell-transplant-for-acute-myeloid-leukemia |
| % of Patients who remain on Non-Intensive Therapy | 95% | CHBC Primary |
| % of Patients who relapse after Non-Intensive Therapy | 90% | CHBC Primary |
| % of Patients who do not achieve CR on Non-Intensive Therapy | 50% | CHBC Primary |
| % of Patients who are still eligible for treatment | 80% | CHBC Primary |

# Forecast Inputs for AML (2/4)

**Forecast Inputs**

| Variables | Inputs | Sources/Rationale |
|---|---|---|
| **Patient Segmentation** | | |
| FIT | | |
| **% Patients who are Fit for Intensive Chemo + Transplant** | 45% | CHBC Primary, Appl Health Econ Health Policy. 2013 Jun;11(3):275-86., Hematology Am Soc Hematol Educ Program. 2016 Dec 2; 2016(1): 339–347. |
| % of Patients Treated with Induction (7+3 or Vyxeos for Secondary AML) | 95% | CHBC Assumption |
| % of Patients who fail to achieve CR on 7+3 or Vyxeos (Secondary AML) | 30% | CHBC Primary; N Engl J Med. 2009 Sep 24. 361(13): 1249-59; Blood (2016) 128 (22): 2792. |
| % of Patients who achieve CR on 7+3 or Vyxeos (Secondary AML) | 70% | CHBC Primary; N Engl J Med. 2009 Sep 24. 361(13): 1249-59; Blood (2016) 128 (22): 2792. |
| % of Patients who receive consolidation after CR from Induction | 30% | J Lab Physicians. 2019 Apr-Jun; 11(2): 133–137. |
| % of Patients who relapse after consolidation | 35% | UpToDate "Post-remission therapy for acute myeloid leukemia in younger adults" |
| % of Patients who receive re-induction therapy with intensive chemo | 30% | CHBC Assumption; Various intensive chemo regimens have been experimented - no clear standard yet. |
| % of Patients who receive Allo HSCT | 70% | J Lab Physicians. 2019 Apr-Jun; 11(2): 133–137. |
| % of Patients who relapse after Allo HSCT | 60% | CHBC Primary; https://news.cancerconnect.com/leukemia/allogenic-stem-cell-transplant-for-acute-myeloid-leukemia |
| % of Patients who are still eligible for R/R treatment | 80% | CHBC Primary |

## Forecast Inputs for AML (3/4)

| Variables | Inputs | Sources/Rationale |
|---|---|---|
| **BST-236 Peak Use Share** | | |
| Peak Use TPP#1 (R/R, Unfit, Monotherapy) | 40% | CHBC Primary; CHBC Assumption |
| R/R Re-treatment of 1L Unfit failure patients | 20% | CHBC Assumption |
| Peak Use TPP#2 (1L, Unfit, Combo) | 35% | CHBC Primary; CHBC Assumption |
| Peak Use TPP#3 (1L, Unfit, Mono) - Start Rate | 25% | CHBC Assumption |
| Peak Use TPP#3 (1L, Unfit, Mono) - End Rate | 10% | CHBC Assumption |
| Peak Use TPP#3b (1L, Secondary AML, Mono) | 30% | CHBC Assumption |
| Adherence Rate | 95% | CHBC Assumption |
| **Market Dynamics** | | |
| Uptake Scenario - R/R | Logarithmic | CHBC Assumption; Usage in R/R AML will be high due to lack of SoC |
| Uptake Scenario - 1L Unfit Combo | Linear | CHBC Assumption; Usage in 1L Unfit AML combo will have steady uptake as clinicians become more comfortable switching from HMA+Ven to BST-236 + HMA/Ven combination |
| Uptake Scenario - 1L Unfit AML, Secondary AML Mono | Logistic | CHBC Assumption; Usage in 1L unfit AML monotherapy will be most likely slower due to HMA+Ven SoC |
| TPP#1 - Launch Year - R/R | Q1 – 2024 | Client Input. |
| TPP#2 - Launch Year - 1L Unfit Combo | Q1 – 2025 | Client Input |
| TPP#3 - Launch Year - 1L Unfit Mono & Secondary AML | Q1 – 2024 | Client Input. Approval from interim Ph3 data with product launching 2H 2023. |
| Patent Expiry Date | 2042 | Client provided patent expiry year |
| Patent Cliff Scenario | Exp. Decay | Decay due to modality |
| Conversion Factor for Ex-US Sales | 0.9 | EvaluatePharma; Historical analog of Rituxan NHL sales for US:Ex-US sales (2012-2017) |
| Conversion Factor for EU Sales (EU4) | 0.7 | GlobalData; Historical analog of Pembrolizumab NSCLC sales for US:EU sales (2019-2023) |
| Conversion Factor for UK Sales | 0.25 | GlobalData; Historical analog of Pembrolizumab NSCLC sales for UK:EU sales (2019-2023) |

# Forecast Inputs for AML (4/4)

AML

**Forecast Inputs**

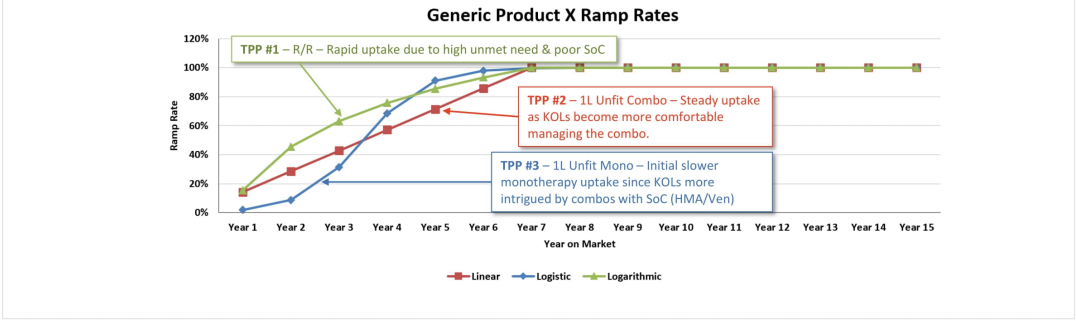
| Variables | Inputs | Sources/Rationale |
|---|---|---|
| **Pricing** | | |
| | | |
| **BST-236** | | |
| **Annual Pricing Model:** | | |
| Price Per Year - 1L | $125,000 | CHBC Payer Research (See Pricing Analog Tab & Payer Research Summaries in Powerpoint) |
| Price Per Year - R/R | 60% of 1L Annual Price | 60% of 1L annual price since R/R patients are generally not treated very long in this setting. |
| | | |
| **Downside Pricing Model:** | | |
| Price per Cycle | $15,000 | CHBC Payer Research (See Pricing Analog Tab & Payer Research Summaries in Powerpoint) |
| No. of Cycles - R/R | 3 | CHBC Assumption (Assuming same median cycles as Aza in R/R patients) |
| No. of Cycles - 1L Unfit, Combo | 3 | Client input |
| No. of Cycles - 1L Unfit, Mono & Secondary AML | 3 | Client input |
| | | |
| Price Growth (Pre-Launch) | 2.0% | Industry Standard (Inflation) |
| Price Growth (Post-Launch) | 5.0% | CHBC Assumption (Venetoclax price growth by 5% each year) |

*The Annual Pricing Model was selected for the projections.*

# BST-236 Ramp to Peak was Modeled on Various Statistical Curves Based on the Level of Unmet Need & Presence of an Established SoC

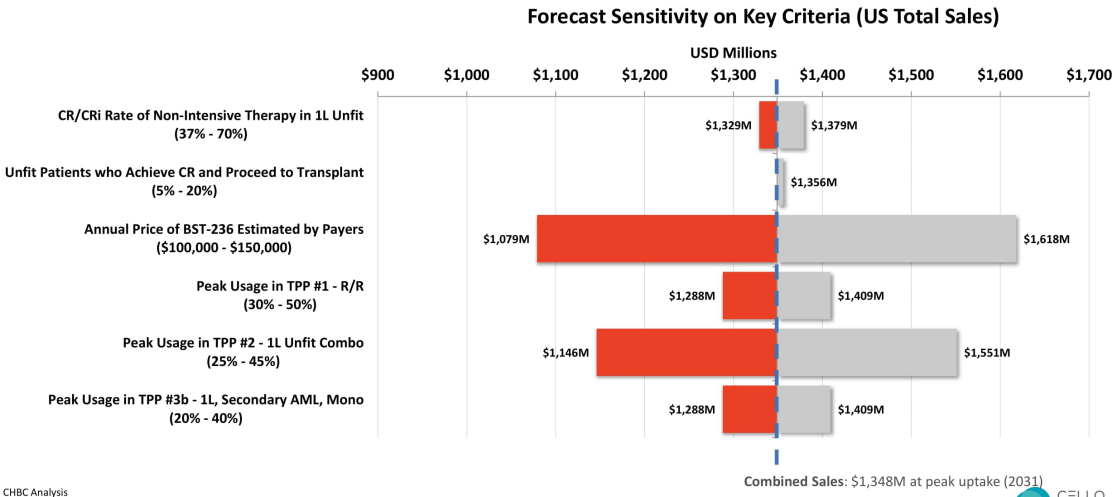
AML

| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Curve Shapes** | **Year 0** | **Year 1** | **Year 2** | **Year 3** | **Year 4** | **Year 5** | **Year 6** | **Year 7** | **Year 8** | **Year 9** | **Year 10** | **Year 11** | **Year 12** | **Year 13** | **Year 14** | **Year 15** |
| **Linear** | 0% | 14% | 29% | 43% | 57% | 71% | 86% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| **Logistic** | 0% | 2% | 9% | 32% | 68% | 91% | 98% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| **Logarithmic** | 0% | 15% | 46% | 63% | 76% | 85% | 93% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% |



## Upside Pricing to $150K/Yr May Increase Revenues by $250M; Revenues Sensitive to Usage in Frontline Unfit in Combo with Ven/Aza

AML




**Combined Sales**: $1,348M at peak uptake (2031)

CHBC Analysis

## Comparison with BioSight's Model:

### CHBC Forecasted Sales in Frontline & R/R Unfit AML Settings, Accounting for Patient Cannibalization, Risk Stratification, and Patient's Falling Out of Treatment Paradigm

CHBC incorporates a similar cut of 55% for unfit patients in AML.

| Biosight - BST236 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **$ million** | **2020E** | **2021E** | **2022E** | **2023E** | **2024E** | **2025E** | **2026E** | **2027E** |
| **BST - 236** | | | | | | | | |
| **Revenue** | | | | | | | | |
| **United States** | | | | | | | | |
| AML Diagnosed Patients ('000s) | 21.5 | 21.9 | 22.3 | 22.8 | 23.2 | 23.6 | 24.1 | 24.5 |
| *Market Growth Rate* | *1.90%* | *1.90%* | *1.90%* | *1.90%* | *1.90%* | *1.90%* | *1.90%* | *1.90%* |
| Target Patient Population in US ('000s) | 11 | 11 | 12 | 12 | 13 | 13 | 14 | 15 |
| *% of total AML patients - Candidates for BST236 (Unfit patients 2022-2* | *50.0%* | *51.0%* | *52.0%* | *53.0%* | *54.0%* | *57.0%* | *60.0%* | *63.0%* |
| BST236 Penetration ('000s) | - | - | - | 0.24 | 1.25 | 2.42 | 3.76 | 5.26 |
| *% of total AML unfit/fit patients (Biosight's penetration)* | *0.0%* | *0.0%* | *0.00%* | *2.00%* | *10.00%* | *18.00%* | *26.00%* | *34.00%* |
| Pricing ('000s/yr) | 105.37 | 105.37 | 105.37 | 105.37 | 105.37 | 105.37 | 105.37 | 105.37 |
| *US inflation rate* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* |
| **BST236 US Revenues ($ millions)** | **0.0** | **0.0** | **0.0** | **25.4** | **131.9** | **255.4** | **395.8** | **553.8** |
| **Probability Adjusted BST236 US Revenues ($ millions)** | **$0.0** | **$0.0** | **$0.0** | **$25.4** | **$131.9** | **$255.4** | **$395.8** | **$553.8** |
| *% growth* | | | | | | *93.6%* | *54.9%* | *39.9%* |

A price of $125,000/yr was set for BST-236, as determined through payer research. A scenario of pricing per cycle ($15k/cycle) is also recorded in the forecast model separately as a downside.

Additional cuts throughout the patient journey are implemented, as patients fall out of the treatment paradigm. Small group proceeds to transplant and may be cured.

CHBC used variable penetration rates (10-40%) depending on the settings BST-236 may be approved for. Additionally, patients receiving BST in frontline will be removed from the available patient population for R/R.

Client-Provided Model

# MDS

# Patient Flow for BST-236 in MDS

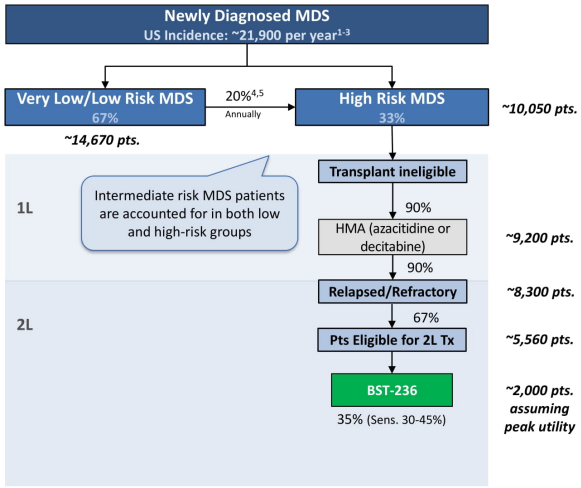
## Base Scenario

- Assumes BST-236 will meet the minimal target product profile and garner a market share of 35%

## Upside Scenario

- Assumes BST-236 will meet the optimal target product profile and garner a market share of 45%

- Utilization rates for BST-236 were set to 35-45% for conservative measures. MDS is a moving target with patients requiring treatment at precise moments before transitioning to AML. Additionally, a large portion of patients enter into trials.




[1] LLS Fact Sheet, [2] Blood (2011) 117 (26): 7121–7125, [3] Curr Hematol Malig Rep. 2015; 10(3): 272–281, [4] SEER. [5] CHBC Primary Research

## Provisional TPP:
## 2L R/R, HMA-Failure Setting for MDS Patients | Single-Arm P2 Based Approval

MDS

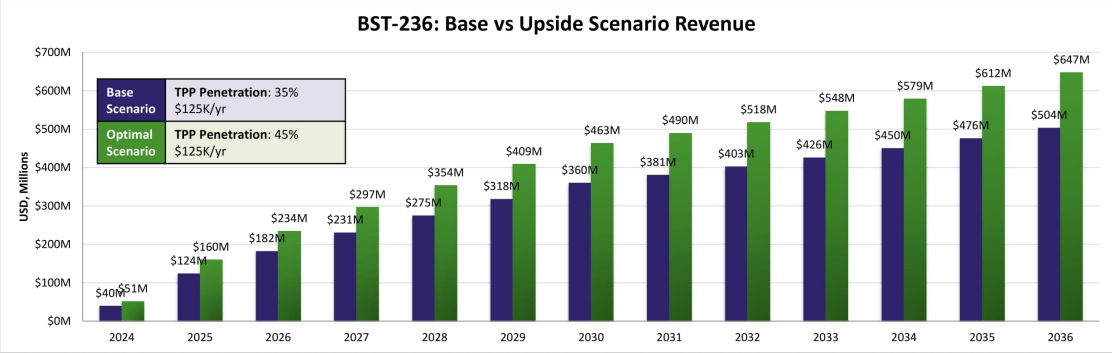
| **Target Patient Population** | Intermediate/high risk MDS patients who have progressed on frontline HMA therapy [2L] | | | |
|---|---|---|---|---|
| | Experimental Arm | | Benchmarks | Benchmarks |
| **Treatment Regimen** | BST-236 | | Decitabine (2L) | Physician's choice[2] |
| **Efficacy** | **Base:**<br>CR: 20-25%<br>mOS: 9 mos. | **Optimal:**<br>CR: 25-30%<br>mOS: 12 mos. | CR: 21%[1]<br>ORR: 28%<br>mOS: 6 mos. | • **BSC** (ORR: N/A; mOS: 4.1 mos.)<br>• **Low-dose chemo** (ORR: 0%, mOS 7.3 mos.)<br>• **Intensive chemo** (ORR: 14%, mOS: 8.9 mos.)<br>• **Investigational tx** (ORR: 11%, mOS: 13.2 mos.)<br>• **Allo HSCT** (ORR: 68%, mOS: 19.5 mos.) |
| **Safety** | **Grade ≥3 AEs:**<br>**Base:** Lower toxicity vs. current benchmarks<br>**Optimal:** Significantly lower toxicity vs. current benchmarks | | **Grade ≥3 AEs:**<br>• febrile neutopenias (33%) | Physician's choice |
| **Dosing** | IV (final dosing TBD – ongoing)<br>**Base**: 5 cycles | **Optimal**: 8 cycles | 20 mg/m$^2$ IV over one hour daily times five days | Physician's choice |

CHBC Insight; BSC: Best Supportive Care; [1] Leuk Lymphoma. 2008 April ; 49(4): 690–695. [2] J Clin Oncol. 2011 Aug 20;29(24):3322-7.

# BST-236 Revenue Forecast Model Output – Scenario Comparison

## Revenue Dependent on Peak Utilization Based on Increased CR and OS Endpoints

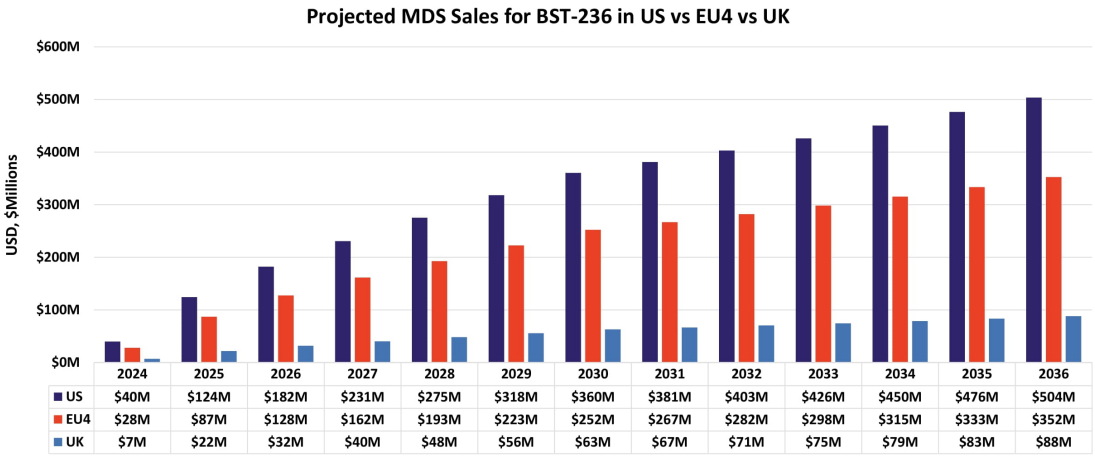
MDS




| Forecasted Revenues for BST-236 | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Year | | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2030 | 2031 | 2032 | 2033 | 2034 | 2035 | 2036 |
| Base | US Total BST-236 Revenue | $40M | $124M | $182M | $231M | $275M | $318M | $360M | $381M | $403M | $426M | $450M | $476M | $504M |
| | US Total Number of Patients Treated | *293* | *867* | *1210* | *1460* | *1658* | *1825* | *1969* | *1983* | *1997* | *2011* | *2025* | *2039* | *2053* |
| Optimal | US Total BST-236 Revenue | $51M | $160M | $234M | $297M | $354M | $409M | $463M | $490M | $518M | $548M | $579M | $612M | $647M |
| | US Total Number of Patients Treated | *376* | *1115* | *1556* | *1877* | *2132* | *2346* | *2532* | *2550* | *2568* | *2585* | *2604* | *2622* | *2640* |

## Projections of BST-236 in EU4 May Reach $350M and Around ~$90M in UK Alone

MDS

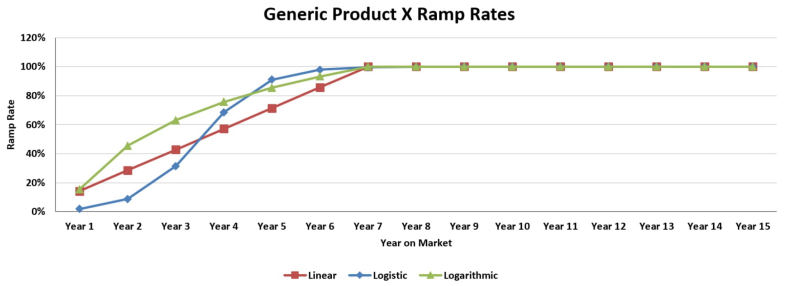



| | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2030 | 2031 | 2032 | 2033 | 2034 | 2035 | 2036 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| US | $40M | $124M | $182M | $231M | $275M | $318M | $360M | $381M | $403M | $426M | $450M | $476M | $504M |
| EU4 | $28M | $87M | $128M | $162M | $193M | $223M | $252M | $267M | $282M | $298M | $315M | $333M | $352M |
| UK | $7M | $22M | $32M | $40M | $48M | $56M | $63M | $67M | $71M | $75M | $79M | $83M | $88M |

## BST-236 Ramp to Peak was Modeled on a Logarithmic Curve Considering a Steeper Uptake is Likely to Occur Given No FDA Approved Therapies Exist in the HMA-Failure Setting

MDS

| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Curve Shapes** | **Year 0** | **Year 1** | **Year 2** | **Year 3** | **Year 4** | **Year 5** | **Year 6** | **Year 7** | **Year 8** | **Year 9** | **Year 10** | **Year 11** | **Year 12** | **Year 13** | **Year 14** | **Year 15** |
| **Linear** | 0% | 14% | 29% | 43% | 57% | 71% | 86% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| **Logistic** | 0% | 2% | 9% | 32% | 68% | 91% | 98% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| **Logarithmic** | 0% | 15% | 46% | 63% | 76% | 85% | 93% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% |



# Forecast Inputs for MDS (1/2)

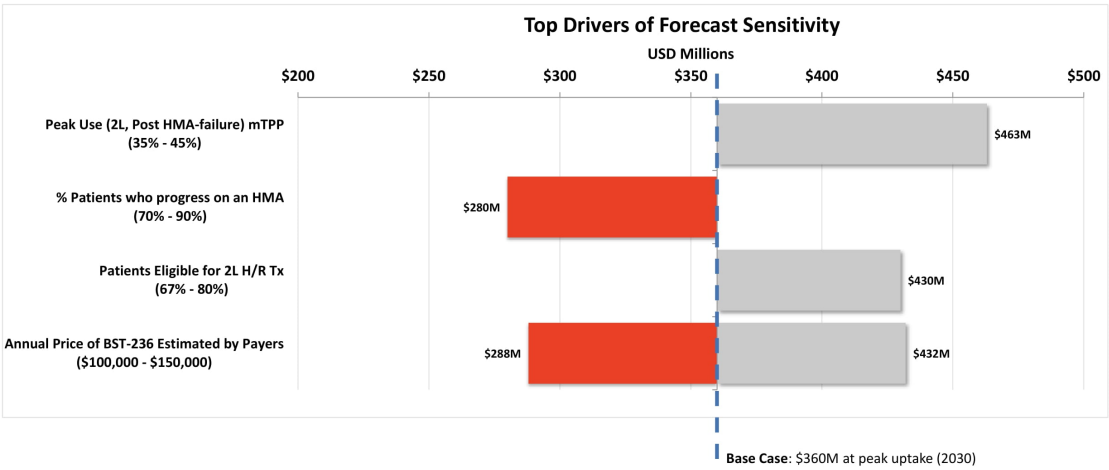
**Forecast Inputs**

| Variables | Inputs | Sources |
|---|---|---|
| | | |
| US Population | 330,266,809 | CHBC Secondary (United States Census Bureau 2021) |
| Annual Growth Rate | 0.7% | US Census Bureau |
| MDS Incidence Rate | 0.007% | LLS Fact Sheet: 4.5/100k, Blood (2011) 117 (26): 7121–7125: 3.3/100k<br>Curr Hematol Malig Rep. 2015; 10(3): 272–281: 5.3-13.1/100k |
| % of MDS Patients Diagnosed/Treated | 95% | CHBC Insight |
| | | |
| **Patient Segmentation** | | |
| | | |
| **% Patients with Very Low/Low Risk MDS** | 67% | CHBC Primary (Accounts for portion of Int Risk MDS patients who are treated as Low Risk) |
| % Patients who transform from Very Low/Low to High Risk MDS (annually) | 20% | CHBC Primary |
| **% Patients with High/Very High Risk MDS** | 33% | CHBC Primary (Accounts for portion of Int Risk MDS patients who are treated as High Risk) |
| % Patients treated with an HMA | 90% | CHBC Primary |
| % Patients who progress on an HMA | 90% | CHBC Primary |
| % Patients eligible for 2L treatment (non-transformed) | 67% | CHBC Primary; Journal of Hematopathology volume 4, pages69–79(2011) |
| | | |
| **BST-236 Peak Use Share** | | |
| | | |
| Peak Use (2L, Post HMA-failure) mTPP | 35% | CHBC Primary (mTPP vs oTPP); Based on KOL provided range between 30%-45% |
| Peak Use (2L, Post HMA-failure) oTPP | 45% | CHBC Primary (mTPP vs oTPP); Based on KOL provided range between 30%-45% |
| | | |
| Adherence Rate | 95% | CHBC Insight |

## Forecast Inputs for MDS (2/2)

| Variables | Inputs | Sources |
|---|---|---|
| **Market Dynamics** | | |
| Uptake Scenario | Logarithmic | Logarithmic uptake scenario used (steep uptake given no FDA approved therapies exist) |
| Launch Year | 2024 | Client provided 2024 Launch |
| Patent Expiry Date | 2033 | Client provided patent expiry year |
| Patent Cliff Scenario | Logistic | Steep decay due to modality |
| **Pricing** | | |
| **BST-236** | | |
| Price Per Year | $125,000 | CHBC Payer Research (See Pricing Analog Tab & Payer Research Summaries in Powerpoint) |
| Price Per Cycle (Downside Scenario) | $15,000 | CHBC Payer Research (See Pricing Analog Tab & Payer Research Summaries in Powerpoint); Reducing price per cycle to accommodate for increased number of cycles. |
| No. of Cycles Per Year – Base | 5 | CHBC Assumption (More cycles than Decitabine but less than Aza considering Decitabine is the more commonly used agent in 2L) |
| No. of Cycles Per Year - Optimal | 8 | CHBC Assumption; Based on optimal TPP |
| Price Growth (Pre-Launch) | 2.0% | Industry Standard (Inflation) |
| Price Growth (Post-Launch) | 5.0% | CHBC Insight (Venetoclax price growth by 5% each year) |
| Conversion Factor for Ex-US Sales | 0.9 | EvaluatePharma; Historical analog of Rituxan NHL sales for US:Ex-US sales (2012-2017) |
| Conversion Factor for EU Sales (EU4) | 0.7 | GlobalData; Historical analog of Pembrolizumab NSCLC sales for US:EU sales (2019-2023) |
| Conversion Factor for UK Sales | 0.25 | GlobalData; Historical analog of Pembrolizumab NSCLC sales for UK:EU sales (2019-2023) |

## Annual Pricing and Peak Utilization are the Main Drivers of Forecast Sensitivity




CHBC Analysis

## Comparison with BioSight's Model:

### CHBC Forecasted Sales in 2L H/R MDS, Accounting for Risk Stratification and Patient's Falling Out of Treatment Paradigm

CHBC incorporated a 33% cut to select for H/R MDS patients from the diagnosed patient pool.

| $ million | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E | 2026E | 2027E | 2028E | 2029E | 2030E |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **BST - 236** | | | | | | | | | | | |
| **Revenue** | | | | | | | | | | | |
| **United States** | | | | | | | | | | | |
| MDS Diagnosed Patients ('000s) | 15.0 | 15.4 | 15.8 | 16.2 | 16.6 | 17.0 | 17.4 | 17.8 | 18.3 | 18.7 | 19.2 |
| *Market Growth Rate* | *2.50%* | *2.50%* | *2.50%* | *2.50%* | *2.50%* | *2.50%* | *2.50%* | *2.50%* | *2.50%* | *2.50%* | *2.50%* |
| Target Patient Population in US ('000s) | 14 | 14 | 14 | 15 | 15 | 15 | 16 | 16 | 16 | 17 | 17 |
| *% of total MDS patients - Candidates for BST236 (Unfit patients 2022-2027; 2027 and above all patients)* | *90.0%* | *90.0%* | *90.0%* | *90.0%* | *90.0%* | *90.0%* | *90.0%* | *90.0%* | *90.0%* | *90.0%* | *90.0%* |
| BST236 Penetration ('000s) | - | - | - | - | 0.30 | 1.07 | 1.88 | 2.73 | 3.62 | 4.55 | 5.53 |
| *% of total MDS unfit/fit patients (Biosight's penetration)* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *2.00%* | *7.00%* | *12.00%* | *17.00%* | *22.00%* | *27.00%* | *32.00%* |
| Pricing ('000s/yr) | 105.37 | 105.37 | 105.37 | 105.37 | 105.37 | 105.37 | 105.37 | 105.37 | 105.37 | 105.37 | 105.37 |
| *US inflation rate* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* |
| **BST236 US Revenues ($ millions)** | **0.0** | **0.0** | **0.0** | **0.0** | **31.4** | **112.7** | **198.0** | **287.5** | **381.3** | **479.7** | **582.7** |
| **Probability Adjusted BST236 US Revenues ($ millions)** | **$0.0** | **$0.0** | **$0.0** | **$0.0** | **$31.4** | **$112.7** | **$198.0** | **$287.5** | **$381.3** | **$479.7** | **$582.7** |
| *% growth* | | | | | | *258.8%* | *75.7%* | *45.2%* | *32.6%* | *25.8%* | *21.5%* |

A price of $125K/year was set based on both analogous products and payer research. A downside case of $15K/cycle was explored, and the subsequent revenue projections are in the MDS forecast model.

Cuts for patients failing 1L HMA (90%) and still being eligible for 2L MDS treatment (67%) were applied.

CHBC used 35-45% penetration rates (base & upside scenarios) with a quick ramp time due to the high unmet need in this 2L setting.

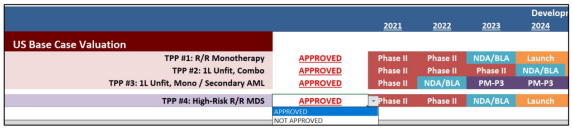
Client-Provided Model

# NPV of BST-236

# Executive Summary:
# Risk-Adjusted NPV Methodology (AML and MDS)

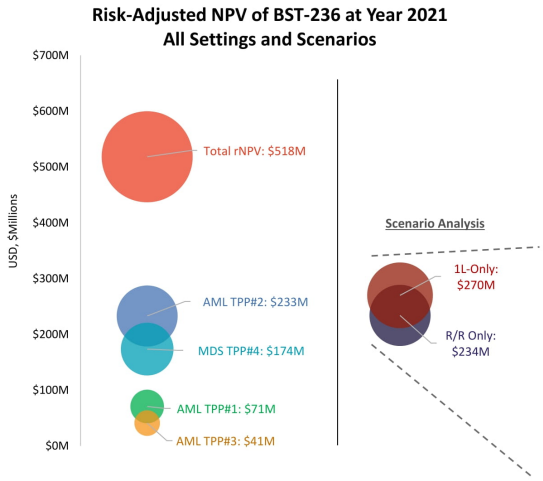
## Methodology

- The risk-adjusted NPV (rNPV) incorporates the BST-236 forecast developed for BioSight. Specifically, the **US-Only sales** were integrated.
- Key inputs include the development pathway for the specific settings (3 TPPs for AML, 1 for MDS), cost assumptions for the trials, cost of goods sold, G&A costs, S&M costs, organizational costs, and more. The **main cost assumptions were leveraged directly from the client-provided forecast version R.09.**
- Each setting has its own valuation section, costs, probabilities of success, and so on. For completeness, the sum based on AML and MDS indications, along with the total sum for the product are indicated in all sections of the NPV.
  - i.e. Total AML COGS is the sum of the COGS of each of the 3 TPPs for the indication.
- The default layout of the rNPV is such that every setting (all 4 TPPs) is approved. There is a built-in scenario analysis (i.e. drop-down menus on rows 13-17) in which the user can select for approvals and failures in particular settings, to understand the valuation of BST-236 based on upside and downside cases. Adjusting the selection will automatically update the valuations. See below:




- The general flow of the rNPV is as follows: i) import revenue for specific setting, ii) calculating COGS as a % of revenue, iii) calculating operational expenses (OpEx) that includes commercialization costs, trial development, and more, iv) discounted cash flow (DCF) for future revenues, v) baseline NPV, vi) risk-adjusting the NPV using probabilities of success per phase for each setting.

# Each of the TPPs Yield a Positive rNPV at Current Year 2021, Indicating Strong Value Even in Downside Cases of Only One Approval




| Setting | rNPV-2021 | Comments |
|---|---|---|
| **AML TPP#1:** R/R | ***$71M*** | Approval in 2024 based off Ph2 data in a very high unmet need market. Trial is including both AML & MDS patients in the R/R setting. |
| **AML TPP#2:** 1L Unfit Combo | ***$233M*** | Highest revenue potential using BST +/- Ven/Aza, launching in 2025 after initial monotherapy approval. |
| **AML TPP#3:** 1L Unfit Mono / Secondary AML | ***$41M*** | Priority setting with accelerated approval in 2023 and pending Phase 3 for full approval completing in by the end of 2026. |
| **MDS TPP#4:** High-Risk R/R | ***$174M*** | Opportunity for substantial revenue stream in MDS with approval from the same TPP #1 trial, launching in 2024. |

| Scenario Analysis | | |
|---|---|---|
| **Setting** | **rNPV-2021** | **Comments** |
| **Frontline-Only Approval**<br>*- AML TPP#2: 1L Unfit Combo*<br>*- MDS TPP#3: 1L Unfit Mono & Sec. AML* | ***$270M*** | Frontline is the more valuable positioning, but comes with larger expenses, especially considering the nearly $80M Phase 3 that will be required after accelerated approval. |
| **R/R-Only Approval**<br>*- AML TPP#1: R/R*<br>*- MDS TPP#4: R/R H/R* | ***$234M*** | R/R setting still provides a strong valuation due to the large revenue stream in MDS, which peaks at around $500M by 2036. Trial costs are fairly low in this setting since they are typically shorter and may benefit from a Phase 2 approval. |