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

**FORM 8-K/A**  
(Amendment No. 1)

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): January 19, 2023

**AYALA PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)	001-36138 (Commission File Number)	02-0563870 (IRS Employer Identification No.)
9 Deer Park Drive, Suite K-1 Monmouth Junction, NJ (Address of principal executive offices)		08852 (Zip Code)

Registrant's telephone number, including area code: (609) 452-9813

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act: None

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 13(a) of the Exchange Act.

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## EXPLANATORY NOTE

On October 18, 2022, Ayala Pharmaceuticals, Inc. (f/k/a Advaxis, Inc.) (the “Registrant”) entered into an Agreement and Plan of Merger (the “Merger Agreement”), by and among the Registrant, Old Ayala, Inc. (f/k/a Ayala Pharmaceuticals, Inc.), a Delaware corporation (“Old Ayala”), and Doe Merger Sub, Inc. (“Merger Sub”), a Delaware corporation and a wholly-owned subsidiary of the Registrant. On January 19, 2023, pursuant to the Merger Agreement, Merger Sub merged with and into Old Ayala, with Old Ayala continuing as the surviving company and a wholly-owned subsidiary of the Registrant (the “Merger”).

On January 25, 2023, the Registrant filed with the Securities and Exchange Commission (the “SEC”) a Current Report on Form 8-K (the “Original Form 8-K”) to report the consummation of the Merger. The Merger Agreement and additional information on the details of the Merger may be found therein. Among other things, this Amendment No. 1 to the Original Form 8-K amends and supplements Item 9.01 of the Original Form 8-K to provide the financial statements and pro forma financial information required under Items 9.01(a) and (b) of Form 8-K, which were excluded from the Original Form 8-K in reliance on the instructions to such items.

Although Old Ayala is now a direct subsidiary of the Registrant, for accounting purposes the Merger is treated as a “reverse acquisition” and Old Ayala is considered the accounting acquirer. Accordingly, as of the closing of the Merger, Old Ayala’s historical financial condition and results of operations replace the Registrant’s historical financial condition and results of operations for all periods prior to the Merger and, for all periods ending after the Merger, the financial condition and results of operations of both companies will be included in the Registrant’s financial statements. However, the audited consolidated financial statements of Old Ayala as of December 31, 2022 and 2021 filed with this Amendment No. 1 relate to a period closing prior to the Merger, and therefore all information presented relates to Old Ayala on a standalone basis.

We sometimes refer herein to the Registrant, on a standalone basis prior to the consummation of the Merger, as “Pre-Merger Advaxis.”

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## Item 9.01. Financial Statements and Exhibits.

### (a) Audited Financial Statements

The audited consolidated financial statements of Old Ayala (the accounting acquiror in the Merger) for the years ended December 31, 2022 and 2021 are attached as Exhibit 99.1 hereto. We have attached the consent of KFGK, Old Ayala's independent auditors, as Exhibit 23.1 to this Form 8-K/A.

The audited consolidated financial statements of Old Ayala filed with this Amendment relate to a pre-Merger closing period, and therefore all information presented relates to Old Ayala on a standalone basis.

### (b) Unaudited Pro Forma Financial Information.

The unaudited pro forma condensed combined financial information of Old Ayala (the accounting acquiror in the Merger) for the fifty-two weeks ended December 31, 2022 and of Pre-Merger Advaxis (the accounting acquiree in the Merger) for the fifty-two weeks ended October 31, 2022 are attached as Exhibit 99.2 hereto.

In preparing the unaudited pro forma condensed combined financial information that was included in the proxy statement/prospectus dated December 12, 2022 that was included in Amendment No. 1 to the Registration Statement on Form S-4 (File No. 333-268586), which related to the offering of securities of Pre-Merger Advaxis issued in the Merger, Pre-Merger Advaxis determined that the appropriate presentation in such pro forma financial information would be to account for the Merger solely as a business combination. Following the Merger and prior to the date hereof, the Registrant has determined that the Merger should be accounted for partially as a business combination and partially as a recapitalization, and the pro forma financial information contained in this Amendment No. 1 reflects such treatment.

### (d) Exhibits.

Exhibit No.	Description
23.1	<a href="#">Consent of Independent Registered Public Accounting Firm</a>
99.1	<a href="#">Audited consolidated financial statements of Old Ayala for the years ended December 31, 2022 and 2021</a>
99.2	<a href="#">Unaudited pro forma condensed combined financial information of Old Ayala for the fifty-two weeks ended December 31, 2022 and of Pre-Merger Advaxis for the fifty-two weeks ended October 31, 2022</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

April 6, 2023

**AYALA PHARMACEUTICALS, INC.**

By: /s/ Kenneth A. Berlin

Name: Kenneth A. Berlin

Title: President and Chief Executive Officer

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We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-8 No. 333-130080) pertaining to the 2004 Stock Option Plan of Ayala Pharmaceuticals, Inc. (f/k/a Advaxis, Inc.);
- (2) Registration Statement (Form S-8 No. 333-193007) pertaining to the 2005 Stock Option Plan, the Amended and Restated 2009 Stock Option Plan, the 2011 Omnibus Incentive Plan and the 2011 Employee Stock Purchase Plan of Ayala Pharmaceuticals, Inc. (f/k/a Advaxis, Inc.);
- (3) Registration Statement Form S-8 No. 333-197465) pertaining to the 2011 Omnibus Incentive Plan, as amended of Ayala Pharmaceuticals, Inc. (f/k/a Advaxis, Inc.);
- (4) Registration Statement (Form S-8 No. 333-204939) pertaining to the 2015 Incentive Plan of Ayala Pharmaceuticals, Inc. (f/k/a Advaxis, Inc.);
- (5) Registration Statement (Form S-8 No. 333-210285) pertaining to the 2015 Incentive Plan of Ayala Pharmaceuticals, Inc. (f/k/a Advaxis, Inc.);
- (6) Registration Statement (Form S-8 No. 333-217218) pertaining to the 2015 Incentive Plan and the 2011 Employee Stock Purchase Plan of Ayala Pharmaceuticals, Inc. (f/k/a Advaxis, Inc.);
- (7) Registration Statement (Form S-8 No. 333-222483) pertaining to the 2015 Incentive Plan and the 2011 Employee Stock Purchase Plan of Ayala Pharmaceuticals, Inc. (f/k/a Advaxis, Inc.);
- (8) Registration Statement (Form S-8 No. 333-223851) pertaining to the 2018 Employee Stock Purchase Plan of Ayala Pharmaceuticals, Inc. (f/k/a Advaxis, Inc.); and
- (9) Registration Statement (Form S-8 No. 333-239469) pertaining to the 2015 Incentive Plan of Ayala Pharmaceuticals, Inc. (f/k/a Advaxis, Inc.)

and to the inclusion of our report dated March 31, 2023 (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 1 to the consolidated financial statements), with respect to the consolidated financial statements of Old Ayala, Inc. for the years ended December 31, 2022, included in this Amendment No. 1 to Current Report on Form 8-K.

KOST FORER GABBAY AND KASIERER  
A member firm of Ernst & Young Global

Tel Aviv, Israel  
April 6, 2023

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## AYALA PHARMACEUTICALS, INC.

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**Report of Independent Registered Public Accounting Firm  
To the Shareholders and the Board of Directors of**

**AYALA PHARMACEUTICALS, INC.**

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Ayala Pharmaceuticals, Inc. (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2022, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

**The Company's Ability to Continue as a Going Concern**

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations, has a negative cash flows from operating activities, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated 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 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 misstatements, 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/ KOST FORER GABBAY & KASIERER  
KOST FORER GABBAY & KASIERER

A Member of Ernst & Young Global

We have served as the Company's auditor since 2017.

Tel-Aviv, Israel

March 31, 2023

**AYALA PHARMACEUTICALS, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
U.S. dollars in thousands (except share and per share data)

	<u>December 31,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
<b>Assets</b>		
Current Assets:		
Cash and Cash Equivalents	\$ 2,408	\$ 36,982
Short-Term Restricted Bank Deposits	110	122
Trade Receivables	234	-
Prepaid Expenses and Other Current Assets	436	2,636
<b>Total Current Assets</b>	<b><u>3,188</u></b>	<b><u>39,740</u></b>
Long-Term Assets:		
Deferred issuance costs	1,953	-
Other Assets	206	267
Operating lease right of use asset	1,462	-
Property and Equipment, Net	960	1,120
<b>Total Long-Term Assets</b>	<b><u>4,581</u></b>	<b><u>1,387</u></b>
<b>Total Assets</b>	<b><u>\$ 7,769</u></b>	<b><u>\$ 41,127</u></b>
<b>Liabilities and Stockholders' Equity:</b>		
Current Liabilities:		
Trade Payables	\$ 4,080	\$ 3,214
Operating lease liabilities	419	-
Other Accounts Payables	3,037	3,258
<b>Total Current Liabilities</b>	<b><u>7,536</u></b>	<b><u>6,472</u></b>
Long-Term Liabilities:		
Long-term operating lease liabilities	1,332	-
Long-Term Rent Liability		497
<b>Total Long-Term Liabilities</b>	<b><u>\$ 1,332</u></b>	<b><u>\$ 497</u></b>
Stockholders' Equity:		
Common Stock of \$0.01 par value per share; 200,000,000 shares authorized at December 31, 2022 and 2021; 14,381,361 and 14,812,737 shares issued at December 31, 2022 and 2021, respectively; 14,080,383 and 13,956,035 shares outstanding at December 31, 2022 and 2021, Respectively.	\$ 139	\$ 139
Additional Paid-in Capital	147,916	145,160
Accumulated Deficit	(149,154)	(111,141)
<b>Total Stockholders' Equity</b>	<b><u>(1,099)</u></b>	<b><u>34,158</u></b>
<b>Total Liabilities and Stockholders' Equity</b>	<b><u>\$ 7,769</u></b>	<b><u>\$ 41,127</u></b>

The accompanying notes are an integral part of the consolidated financial statements.



**AYALA PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**U.S. dollars in thousands (except shares and per shares data)**

	Year ended December 31, 2022	Year ended December 31, 2021
Revenue from License Agreement	\$ 692	\$ 3,506
Cost of Revenue	(602)	(3,506)
Gross Profit	90	—
Research and Development	\$ 27,851	\$ 29,941
General and Administrative	9,742	9,277
Operating Loss	(37,503)	(39,218)
Financial income (expenses), net	74	(260)
Loss before taxes on income	(37,429)	(39,478)
Taxes on Income	(584)	(776)
Net Loss	\$ (38,013)	\$ (40,254)
Net Loss per Share attributable to Common Stockholders, Basic and Diluted	\$ (2.46)	\$ (2.80)
Weighted Average Shares Used to Compute Net Loss per Share, Basic and Diluted	15,448,931	14,398,905

The accompanying notes are an integral part of the consolidated financial statements.

**AYALA PHARMACEUTICALS, INC.**  
**STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY**  
**U.S. dollars in thousands (except share amounts)**

	<u>Common Stock</u>		<u>Additional paid-in capital</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' (Deficit) Equity</u>
	<u>Number</u>	<u>Amount</u>			
Balance as of December 31, 2020	12,728,446	\$ 128	\$ 109,157	\$ (70,887)	\$ 38,398
Proceeds from Issuance of common stock and warrants, net of issuance cost of \$1,724	333,333	3	23,259	—	23,262
Proceeds from Issuance of common stock, net of issuance cost of \$438	827,094	8	9,959	—	9,967
Exercise of Stock Option	18,328	*	101	—	101
Stock Based Compensation	48,834	*	2,684	—	2,684
Net Loss	—	—	—	(40,254)	(40,254)
Balance as of December 31, 2021	<u>13,956,035</u>	<u>\$ 139</u>	<u>\$ 145,160</u>	<u>\$ (111,141)</u>	<u>\$ 34,158</u>
Share based compensation	114,909	*	2,244	—	2,244
Proceeds from issuance of common stock, net of issuance costs of \$14	310,417	*	512	—	512
Net Loss	—	—	—	(38,013)	(38,013)
Balance as of December 31, 2022	<u>14,381,361</u>	<u>\$ 139</u>	<u>\$ 147,916</u>	<u>\$ (149,154)</u>	<u>\$ (1,099)</u>

\* Represents an amount lower than \$1.

The accompanying notes are an integral part of the consolidated financial statements.

**AYALA PHARMACEUTICALS, INC.**  
**STATEMENTS OF CONSOLIDATED CASH FLOWS**  
U.S. dollars in thousands

	<b>Year Ended December 31, 2022</b>	<b>Year Ended December 31, 2021</b>
<b>Cash Flows from Operating Activities:</b>		
Net Loss	\$ (38,013)	\$ (40,254)
Adjustments to reconcile Net Loss to Net Cash used in Operating Activities:		
Shared Based Compensation	2,244	2,684
Depreciation	162	168
(Increase) Decrease in Prepaid Expenses and other Assets	2,232	(1,174)
Decrease (Increase) in trade receivables	(234)	681
Increase (Decrease) in Trade Payables	(472)	(512)
Decrease in operating lease right-of-use assets	288	-
Decrease in operating lease liabilities	(536)	-
Increase (Decrease) in other Accounts Payable	(181)	51
Net Cash used in Operating Activities	<u>(34,510)</u>	<u>(38,356)</u>
<b>Cash Flows from Investing Activities:</b>		
Purchase of Property and Equipment	(2)	(5)
Net Cash used in Investing Activities	<u>(2)</u>	<u>(5)</u>
<b>Cash Flows from Financing Activities:</b>		
Exercise of Stock Options	-	101
Issuance of common stock and warrants, net	-	23,262
Proceeds from issuance of common stock, net	512	9,967
Prepaid Transaction expenses	(615)	-
Net Cash used in Financing Activities	<u>(103)</u>	<u>33,330</u>
Decrease in Cash and Cash Equivalents and Restricted Cash	(34,615)	(5,031)
Cash and Cash Equivalents and Restricted Cash at Beginning of the Year	37,339	42,370
Cash and Cash Equivalents and Restricted Cash at End of the Year	<u>\$ 2,724</u>	<u>\$ 37,339</u>
<b>Supplemental Disclosure of Non-Cash Activities</b>		
Lease liabilities arising from new right-of-use assets	\$ 537	\$ -
Non-cash deferred issuance costs	\$ 1,338	\$ -
Supplemental Disclosures of Cash Flow Information:		
Cash Paid for Income Taxes	\$ 244	\$ 209
	<b>Year Ended December 31, 2022</b>	<b>Year Ended December 31, 2021</b>
Cash and Cash Equivalents	\$ 2,408	\$ 36,982
Restricted Cash	110	122
Restricted Cash in Other Assets	206	235
Cash and Cash Equivalents and Restricted Cash at End of the Year	<u>\$ 2,724</u>	<u>\$ 37,339</u>

The accompanying notes are an integral part of the consolidated financial statements.

**AYALA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. General**

- a) Ayala Pharmaceuticals, Inc. (the “Company”) was incorporated in November 2017. The Company is a clinical stage oncology company dedicated to developing and commercializing small molecule therapeutics for patients suffering from rare and aggressive cancers, primarily in genetically defined patient populations. The Company’s current portfolio of product candidates, AL101 and AL102, target the aberrant activation of the Notch pathway with gamma secretase inhibitors.
- b) In 2017, the Company entered into an exclusive worldwide license agreement with respect to AL101 and AL102. See note 6.
- c) The Company’s lead product candidates, AL101 and AL102, have completed preclinical and Phase 1 studies. AL102 is currently being evaluated in a pivotal Phase 2/3 trial (RINGSIDE) in patients with Desmoids tumors and is being evaluated in a Phase 1 clinical trial in combination with Novartis’ BMCA targeting agent, WVT078, in Patients with relapsed/refractory Multiple Myeloma. AL101 is currently being evaluated in a Phase 2 trial (ACCURACY) in patients with recurrent/metastatic adenoid cystic carcinoma (“R/M ACC”) bearing Notch-activating mutations is ongoing.
- d) The Company has a wholly-owned Israeli subsidiary, Ayala-Oncology Israel Ltd. (the “Subsidiary”), which was incorporated in November 2017.

### *Going Concern*

The Company has incurred recurring losses since inception as a research and development organization and has an accumulated deficit of \$149.2 million as of December 31, 2022. For the year ended December 31, 2022, the Company used \$34.5 million of cash in operations. The Company has relied on its ability to fund its operations through public and private equity financings. The Company expects operating losses and negative cash flows to continue at significant levels in the future as it continues its clinical trials. As of December 31, 2022, the Company had approximately \$2.4 million in cash and cash equivalents, which, without additional funding, the Company believes will not be sufficient to meet its obligations within the next twelve months from the date of issuance of these consolidated financial statements. The Company plans to continue to fund its operations through public or private debt and equity financings, but there can be no assurances that such financing will continue to be available to the Company on satisfactory terms, or at all. If the Company is unable to obtain funding, the Company would be forced to delay, reduce or eliminate its research and development programs, which could adversely affect its business prospects, or the Company may be unable to continue operations. As such, those factors raise substantial doubt about the Company's ability to continue as a going concern.

The consolidated financial statements have been prepared assuming that the Company will continue as a going concern. Therefore, the consolidated financial statements for the year ended December 31, 2022 do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern.

## 2. Significant Accounting Policies

### Basis of Presentation

The consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”). The significant accounting policies followed in the preparation of the consolidated financial statements, are as follows:

#### *Use of Estimates:*

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company’s management believes that the estimates, judgment and assumptions used are reasonable based upon information available at the time they are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the consolidated financial statements. Actual results could differ from those estimates.

#### *Consolidated Financial Statements in U.S. Dollars*

A substantial portion of the Company’s financing activities, including equity transactions and cash investments, are incurred in U.S. dollars. The Company’s management believes that the U.S. dollar is the currency of the primary economic environment in which the Company operates. Thus, the functional and reporting currency of the Company is the U.S. dollar.

A subsidiary’s functional currency is the currency of the primary economic environment in which the subsidiary operates; normally, that is the currency of the environment in which a subsidiary primarily generates and expends cash. In making the determination of the appropriate functional currency for a subsidiary, the Company considers cash flow indicators, local market indicators, financing indicators and the subsidiary’s relationship with both the parent company and other subsidiaries. For subsidiaries that are primarily a direct and integral component or extension of the parent entity’s operations, the U.S. dollar is the functional currency.

The Company has determined the functional currency of its foreign subsidiary is the U.S. Dollar. The foreign operation is considered a direct and integral part or extension of the Company’s operations. The day-to-day operations of the foreign subsidiary are dependent on the economic environment of the U.S. Dollar.

Accordingly, monetary accounts maintained in currencies other than the U.S. dollar are remeasured into U.S. dollars in accordance with Statement of the Accounting Standard Codification (“ASC”) No. 830 “Foreign Currency Matters” (“ASC No. 830”). All transaction gains and losses of the remeasured monetary balance sheet items are reflected in the statements of operations as financial income or expenses as appropriate.

#### *Principles of Consolidation*

The consolidated financial statements include the accounts of the Company and the Subsidiary. Intercompany balances and transactions have been eliminated upon consolidation.

#### *Cash and Cash Equivalents and Short-term restricted bank deposits*

The Company considers all highly liquid certificates of deposits with original maturities of three months or less from the purchase date to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market accounts in the United States and are stated at carrying value which approximate their fair values. Short-term restricted bank deposits consist of a bank deposit accounts that serves as collateral for a credit card agreement and lease agreements at one of the Company’s financial institutions.

### *Property and Equipment, Net*

Property and equipment are stated at cost, minus accumulated depreciation. Depreciation is calculated on a straight-line basis over the estimated useful lives of the related assets, at the following annual rates:

Computers and Software	33%
Lab Equipment	15%
Office Furniture and Equipment	7-9%

Leasehold improvements are amortized on a straight-line basis over the shorter of the assets' estimated useful life or the remaining term of the lease.

Maintenance and repair costs are expensed as incurred.

### *Impairment of Long-Lived Assets*

The Company's long-lived assets are reviewed for impairment in accordance with ASC No. 360, "Property, Plant and Equipment," whenever events or changes in circumstances indicate that the carrying amount of an asset (assets group) may not be recoverable. If indicators of impairment exist and the undiscounted future cash flows that the assets (assets group) are expected to generate are less than the carrying value of the assets (assets group), the Company reduces the carrying amount of the assets through an impairment charge, to their estimated fair values. During the years ended December 31, 2022, and 2021, no impairment indicators have been identified.

### *Accrued Post-Employment Benefit*

Under Israeli employment laws, employees of the Company are included under Section 14 of the Severance Compensation Act, 1963 ("Section 14") for a portion of their salaries. According to Section 14, these employees are entitled to monthly payments made by the Company on their behalf with insurance companies.

Payments in accordance with Section 14 release the Company from any future severance payments with respect to those employees. The obligation to make the monthly deposits is expensed as incurred. In addition, the aforementioned deposits are not recorded as an asset in the consolidated balance sheet, and there is no liability recorded as the Company does not have a future obligation to make any additional payments. Severance costs amounted to approximately \$0.3 million and \$0.3 million for the year ended December 31, 2022 and 2021, respectively.

The Company maintains a 401(k) retirement savings plan for its U.S. employees. Each eligible employee may elect to contribute a portion of the employee's compensation to the plan. As of December 31, 2022, and 2021, the Company has matched 100% of all employee contributions, up to 6% of the employee's base salary.

### *Leases*

The Company's leases include offices for its facilities, as well as car leases, which are all classified as operating leases. Short-term leases with a term of 12 months or less are not recorded on the balance sheet. The Company does not separate lease components from non-lease components.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease. Operating lease liabilities and their corresponding right-of-use assets are recorded at commencement date. The Company records lease liabilities based on the present value of lease payments over the lease term. The ROU asset also includes any lease payments made and excludes lease incentives. The Company generally uses an incremental borrowing rate to discount its lease liabilities, as the rate implicit in the lease is typically not readily determinable. Certain lease agreements include renewal options that are under the Company's control. The Company includes optional renewal periods in the lease term only when it is reasonably certain that The Company will exercise its option.

Certain lease agreements contain variable payments, which are expensed as incurred and not included in the operating lease right-of-use ("ROU") assets and liabilities.

### *Fair Value of Financial Instruments:*

The Company measures and discloses the fair value of financial assets and liabilities in accordance with ASC Topic 820, "Fair Value Measurement." Fair value is based on 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.

Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The accounting standard establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

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 inputs that are based on inputs not quoted on active markets but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data are available.

Restricted bank deposits, trade receivables, trade payables are stated at their carrying value, which approximates fair value due to the short time to the expected receipt or payment date.

#### *Research and Development*

Research and development costs are expensed as incurred. Research and development costs include payroll and personnel expenses, consulting costs, external contract research and development expenses, raw materials, drug product manufacturing costs, and allocated overhead including depreciation, rent, and utilities. Research and development costs that are paid in advance of performance are classified as a prepaid expense and amortized over the service period as the services are provided.

#### *Acquired In-Process Research and Development*

In an asset acquisition, the initial costs of rights to in-process research and development projects acquired are expensed as R&D in the consolidated statements of operations unless the in-process research and development has an alternative future use.

#### *Clinical Trial Costs*

Clinical trial costs are a component of research and development expenses. The Company bases its expenses related to Clinical Research Organization (“CRO”) on the services received, and efforts expended pursuant to agreements with them. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. In instances where payments made to CROs exceed the level of services provided and result in a prepayment of the research and development expenses. For reoccurring services fees, the Company calculates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services varies from the calculation, the Company adjusts the accrual or amount of prepaid expenses accordingly. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

#### *Patent Costs*

Legal and related patent costs are expensed as incurred as their realization is uncertain. Costs related to patent registration are classified as general and administrative expenses, and costs related to acquired patents are classified as research and development expenses in the accompanying consolidated statements of operations.

#### *Contingent Liabilities*

The Company accounts for its contingent liabilities in accordance with ASC No. 450, “Contingencies”. A provision is recorded when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. With respect to legal matters, provisions are reviewed and adjusted to reflect the impact of negotiations, estimated settlements, legal rulings, advice of legal counsel and other information and events pertaining to a particular matter. As of December 31, 2022, and 2021, the Company is not a party to any litigation that could have a material adverse effect on the Company’s business, financial position, results of operations or cash flows.

#### *Income Taxes*

The Company accounts for income taxes in accordance with ASC 740, “Income Taxes”. This standard prescribes the use of the liability method whereby deferred tax asset and liability account balances are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company provides a valuation allowance, if necessary, to reduce deferred tax assets to their estimated realizable value, if it is more likely than not that some portion of the entire deferred tax asset will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740-10, “Income Taxes”. Accounting guidance addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the consolidated financial statements, under which a Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position.

The tax benefits recognized in the consolidated financial statements from such a position should be measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate settlement.



### *Concentrations of Credit Risk*

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash and cash equivalents. Bank deposits are held by accredited financial institutions and these deposits may at times be in excess of insured limits. Money Market funds are of Prime A and only invested in government issued securities. The Company limits its credit risk associated with cash and cash equivalents by placing them with financial institutions that it believes are of high-quality credit rating. The Company has not experienced any losses on its deposits of cash or cash equivalents.

Company's trade receivables are from one customer as of December 31, 2022, and December 31, 2021. In addition, the potential risk of loss with any one counterparty resulting from this type of credit risk is monitored on an ongoing basis. The Company grants credit of 45 days to this one customer.

### *Stock-Based Compensation*

The Company measures its stock-based payment awards made to employees, directors, and non-employee service providers based on estimated fair values. The fair value of each option award is estimated on the grant date using the Black-Scholes option pricing model. The Company recognizes compensation expenses based on the accelerated method over the requisite service period. The Company recognizes forfeitures of awards as they occur.

The Black-Scholes option pricing model requires a number of assumptions, of which the most significant are share price, expected volatility, expected option term (the time from the grant date until the options are exercised or expire), risk-free rate, and expected dividend rate. After the IPO, the fair value of each ordinary share was based on the closing price of the Company's publicly traded ordinary shares as reported on the date of the grant.

### *Expected volatility*

As the Company has a short trading history for its ordinary shares, the expected volatility is derived from the average historical share volatilities of several unrelated public companies within the Company's industry that the Company considers to be comparable to its own business over a period equivalent to the option's expected term.

### *Expected Dividend Yield*

The Company has historically not paid dividends and has no foreseeable plans to pay dividends, therefore the Company uses an expected dividend yield of 0%.

### *Risk-Free Interest Rate*

The risk-free interest rate is based on the yield from U.S. Treasury zero-coupon bonds with an equivalent expected term.

*Expected Term* The expected option term is calculated for options granted to employees and directors using the "simplified" method. Under this approach, the expected term is presumed to be the midpoint between the weighted average vesting term and the contractual term of the option. The simplified method makes the assumption that the employee will exercise share options evenly over the period when the share options are vested and ending on the date when the share options expire. The expected option term for options granted to non-employees is based on the contractual term. Changes in the determination of each of the inputs can affect the fair value of the share options granted and the results of operations of the Company.

Restricted shares are value as fair value of shares on date of grant.

### *Basic and Diluted Net Loss per Share*

Basic loss per share is computed by dividing the net loss by the weighted average number of shares of Common Stock outstanding during the period. Diluted loss per share is computed by dividing the net loss by the weighted average number of shares of Common Stock outstanding together with the number of additional shares of Common Stock that would have been outstanding if all potentially dilutive shares of Common Stock had been issued. Diluted net loss per share is the same as basic net loss per share in periods when the effects of potentially dilutive shares of Common Stock are anti-dilutive.

### *Segment Information*

Financial information is available for evaluation by the chief operating decision maker, the Company's Chief Executive Officer, in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment. Operating segments are defined as components of an enterprise in which separate financial information is evaluated regularly by the chief operating decision maker in deciding how to allocate resources and assessing performance.

### *Revenue Recognition*

The Company recognizes revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers, which applies to all contracts with customers. Under Topic 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 Topic 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.

At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within the contract and determines those that are performance obligations and assesses whether each promised good or service is distinct.

Customer option to acquire additional goods or services gives rise to a performance obligation in the contract only if the option provides a material right to the customer that it would not receive without entering into that contract.

In a contract with multiple performance obligations, the Company develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation, which determines how the transaction price is allocated among the performance obligations.

The Company evaluates each performance obligation to determine if it can be satisfied at a point in time or over time.

Revenue is recognized when control of the promised goods or services is transferred to the customers, in an amount that reflects the consideration the Company expect to be entitled to receive in exchange for those goods or services.

In December 2018, the Company entered into an Evaluation Option to acquire License Agreement (the "Novartis Agreement") with Novartis International Pharmaceutical Limited ("Novartis") for which the company is paid for its research and development costs. For additional details regarding the Novartis Agreement, refer to Note 6.

The Company concluded that there is one distinct performance obligation under the Novartis Agreement: Research and development services, obligation which is satisfied over time.

Revenue associated with the research and development services in the amount of \$0.6 million and \$3.5 million was recognized in 2022 and 2021 respectively.

The Company concluded that progress towards completion of the research and development performance obligation related to the Novartis Agreement is best measured in an amount proportional to the expenses incurred from the total estimated expenses. The Company periodically reviews and updates its estimates, when appropriate, which may adjust revenue recognized for the period. The transaction price to be recognized as revenue under the Novartis Agreement consists of the reimbursable research and development costs.

### Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued the ASU No. 2016-02, *Leases (Topic 842)*. The standard outlines a comprehensive lease accounting model that supersedes the previous lease guidance and requires lessees to recognize lease liabilities and corresponding right-of-use (“ROU”) assets for all leases with lease terms greater than 12 months. The guidance also changes the definition of a lease and expands the disclosure requirements of lease arrangements. The Company adopted the standard in the first quarter of 2022 using the modified retrospective method. Results for reporting periods beginning after December 31, 2021, have been presented in accordance with the standard, while results for prior periods have not been adjusted and continue to be reported in accordance with the Company’s historical accounting. The cumulative effect of initially applying the new leases standard was recognized as an adjustment to the opening consolidated balance sheet as of January 1, 2022.

The Company elected a package of practical expedients for leases that commenced prior to January 1, 2022, and did not reassess historical conclusions on: (i) whether any expired or existing contracts are or contain leases; (ii) lease classification for any expired or existing leases; and (iii) initial direct costs capitalization for any existing leases.

This standard has a significant impact on the Company’s consolidated balance sheet but did not have a significant impact on the Company’s consolidated statements of operations. The most significant effects relate to the recognition ROU assets and lease liabilities on consolidated balance sheet for offices for its and car operating leases.

Upon adoption, the Company recognized lease liabilities and corresponding ROU assets, adjusted for the accrued rent and remaining lease incentives received on the adoption date, as follows:

	<b>January 1, 2022</b>	
	<b>ROU assets</b>	<b>Lease liabilities</b>
Offices	\$ 1,448	\$ 2,020
Cars	302	267
<b>Total operating leases</b>	<b>\$ 1,750</b>	<b>\$ 2,287</b>

See Note 4, *Leases* for further details.

In August 2020, the FASB issued ASU 2020-06, *Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity (“ASU 2020-06”)*. The final guidance issued by the FASB for convertible instruments eliminates two of the three models in ASC 470-20 that require separate accounting for embedded conversion features. Separate accounting is still required in certain cases. Additionally, among other changes, the guidance eliminates some of the conditions for equity classification in ASC 815-40-25 for contracts in an entity’s own equity. The guidance also requires entities to use the if-converted method for all convertible instruments in the diluted earnings per share calculation and include the effect of share settlement for instruments that may be settled in cash or shares, except for certain liability-classified share-based payment awards. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. Adoption of the standard did not have a material impact on the financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which simplifies the accounting for income taxes by removing a variety of exceptions within the framework of ASC 740. These exceptions include the exception to the incremental approach for intra-period tax allocation in the event of a loss from continuing operations and income or a gain from other items (such as other comprehensive income), and the exception to using general methodology for the interim period tax accounting for year-to-date losses that exceed anticipated losses. The guidance will be effective for the Company beginning January 1, 2022, and interim periods in fiscal years beginning January 1, 2023. Early adoption is permitted. The Company Adoption of the standard did not have a material impact on the financial statements.

### Recently Issued Accounting Pronouncements Not Yet Adopted

As an “emerging growth company,” the Jumpstart Our Business Startups Act (“JOBS Act”) allows the Company to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. The Company has elected to use this extended transition period under the JOBS Act. The adoption dates discussed below reflects this election.

In June 2016, the FASB issued ASU No. 2016-13 (Topic 326), *Financial Instruments—Credit Losses: Measurement of Credit Losses on Financial Instruments*, which replaces the existing incurred loss impairment model with an expected credit loss model and requires a financial asset measured at amortized cost to be presented at the net amount expected to be collected. The guidance will be effective for the Company for fiscal years beginning after December 15, 2022. The Company believes adoption of the standard will not have a material impact on the financial statements.

### 3. Property and Equipment, net

Property and Equipment, net consists of the following:

	December 31, 2022	December 31, 2021
	(in thousands)	
Cost:		
Computers and Software	\$ 73	\$ 73
Lab Equipment	296	294
Office Furniture and Equipment	146	146
Leasehold Improvements	1,105	1,105
	<u>1,620</u>	<u>1,618</u>
Less: Accumulated Depreciation	660	498
Property and Equipment, Net	<u>\$ 960</u>	<u>\$ 1,120</u>

Depreciation expenses for the years ended December 31, 2022, and 2021 was approximately \$162 thousands and \$168 thousands, respectively.

### 4. Leases

In January 2019, the Company signed a new lease agreement. The term of the lease is for 63 months and includes an option to extend the lease for an additional 60 months. As part of the agreement, the lessor also provided the Company an amount of approximately \$0.5 million paid in arrears for of leasehold improvements. The amount was recorded as an incentive and is taken into account when computing the ROU asset.

The Subsidiary obtained a bank guarantee in the amount of approximately \$0.2 million for its new office lease agreement.

**The Company has the following operating ROU assets and lease liabilities:**

	December 31, 2022	
	ROU assets	Lease liabilities
Offices	\$ 1,273	\$ 1,612
Cars	189	139
<b>Total operating leases</b>	<u>\$ 1,462</u>	<u>\$ 1,751</u>

  

	December 31, 2022
	Lease liabilities
Current lease liabilities	\$ 419
Non-current lease liabilities	1,332
<b>Total lease liabilities</b>	<u>\$ 1,751</u>

The following table summarizes the lease costs recognized in the consolidated statement of operations:

	<b>December 31, 2022</b>
Operating lease cost	\$ 442
Variable lease cost	10
<b>Total lease cost</b>	<b>\$ 452</b>

As of December 31, 2022, the weighted-average remaining lease term and weighted-average discount rate for operating leases are 3.25 years and 7.7%, respectively. The following table presents supplementary cash flow information regarding the company's operating leases:

	<b>December 31, 2022</b>
Cash paid for amounts included in the measurement of lease liabilities	\$ 444
Right of use assets obtained in exchange for operating lease liabilities	\$ 1,751

The following table summarizes the future payments of the Company for its operating lease liabilities:

	<b>December 31, 2022</b>
2023	\$ 445
2024	345
2025	309
2026	308
2027	308
After 2027	411
<b>Total undiscounted lease payments</b>	<b>\$ 2,126</b>
Less: Interest	375
<b>Total lease liabilities - operating</b>	<b>\$ 1,751</b>

**Lease Disclosures Related to Periods Prior to the Adoption of ASU 2016-02 are as follows:**

The Company leasing expense for the years ended December 2022 and 2021 was \$0.4 million and \$0.4 million, respectively.

**Future minimum lease commitments under non-cancellable operating leases as of December 31, 2021, are as follows:**

<b>Year ended December 31,</b>	<b>(in thousands)</b>
2022	\$ 360
2023	360
2024	120
	<b>\$ 840</b>

## 5. Other account payables

Other account payables consist of the following:

	December 31, 2022	December 31, 2021
	(in thousands)	
Accrued Professional Fees	\$ 487	\$ 291
Accrued Research and Development Expenses	64	56
Tax Provision	1492	1,150
Accrued Payroll and Employee Benefits	994	1,761
Total Accrued Expenses	<u>\$ 3,037</u>	<u>\$ 3,258</u>

## 6. Commitments and Contingent Liabilities

*Asset Transfer and License Agreement with Bristol-Myers Squibb Company.*

In November 2017, the Company entered into a license agreement, or the BMS License Agreement, with Bristol-Myers Squibb Company, or BMS, under which BMS granted the Company a worldwide, non-transferable, exclusive, sublicensable license under certain patent rights and know-how controlled by BMS to research, discover, develop, make, have made, use, sell, offer to sell, export, import and commercialize AL101 and AL102, or the BMS Licensed Compounds, and products containing AL101 or AL102, or the BMS Licensed Products, for all uses including the prevention, treatment or control of any human or animal disease, disorder or condition.

Under the BMS License Agreement, the Company is obligated to use commercially reasonable efforts to develop at least one BMS Licensed Product. The Company has sole responsibility for, and bear the cost of, conducting research and development and preparing all regulatory filings and related submissions with respect to the BMS Licensed Compounds and/or BMS Licensed Products. BMS has assigned and transferred all INDs for the BMS Licensed Compounds to the Company. The Company is also required to use commercially reasonable efforts to obtain regulatory approvals in certain major market countries for at least one BMS Licensed Product, as well as to effect the first commercial sale of and commercialize each BMS Licensed Product after obtaining such regulatory approval. The Company has sole responsibility for, and bear the cost of, commercializing BMS Licensed Products. For a limited period of time, the Company may not, engage directly or indirectly in the clinical development or commercialization of a Notch inhibitor molecule that is not a BMS Licensed Compound.

As consideration of the rights granted by BMS to the Company under the BMS License Agreement, the Company paid BMS a payment of \$6 million and issued to BMS 1,125,929 shares of Series A Preferred Stock valued at approximately \$7.3 million. The payment and transfer of intellectual property occurred in November 2017 at the time the BMS License Agreement was executed (the “Effective Date”).

The Company is required to pay BMS payments upon the achievement of certain development or regulatory milestone events of up to \$95 million in the aggregate with respect to the first BMS Licensed Compound to achieve each such event and up to \$47 million in the aggregate with respect to each additional BMS Licensed Compound to achieve each such event. The Company is also obligated to pay BMS payments of up to \$50 million in the aggregate for each BMS Licensed Product that achieves certain sales-based milestone events and tiered royalties on net sales of each BMS Licensed Product by the Company or its affiliates or sublicensees at rates ranging from a high single-digit to low teen percentage, depending on the total annual worldwide net sales of each such Licensed Product. If the Company sublicenses or assigns any rights to the licensed patents, the BMS Licensed Compounds and/or the BMS Licensed Products, the Company is required to share with BMS a portion of all consideration received from such sublicense or assignment, ranging from a mid-teen to mid-double-digit percentage, depending on the development stage of the most advanced BMS Licensed Compound or BMS Licensed Product that is subject to the applicable sublicense or assignment, but such portion may be reduced based on the milestone or royalty payments that are payable by the Company to BMS under the BMS License Agreement.

Under the terms of the BMS Agreement, the Company was obligated to issue to BMS additional shares of preferred stock as would be required for BMS to maintain its 8% equity ownership in Company, subject to certain exceptions. This right terminated upon the closing of the sale of the Company’s Series B Preferred Stock. The Company estimates the fair value of this anti-dilution commitment using the probability weighted expected return method (“PWERM”). At the date of BMS Agreement, the Company recorded liability associated with the anti-dilution right in the amount of approximately \$0.5 million, according to its fair value. For the year ended December 31, 2018, the Company recorded an income of approximately \$0.5 million for the reassessment of the liability, within financial income, net, in the consolidated statement of operations.

The Company accounted for the acquisition of the rights granted by BMS as an asset acquisition because it did not meet the definition of a business. The Company recorded the total consideration transferred and value of shares issued to BMS as research and development expense in the consolidated statement of operations as incurred since the acquired the rights granted by BMS represented in-process research and development and had no alternative future use.

The Company accounts for contingent consideration payable upon achievement of sales milestones in such asset acquisitions when the underlying contingency is resolved.

The BMS License Agreement remains in effect, on a country-by-country and BMS Licensed Product-by-BMS Licensed Product basis, until the expiration of royalty obligations with respect to a given BMS Licensed Product in the applicable country. Royalties are paid on a country-by-country and BMS Licensed Product-by-BMS Licensed Product basis from the first commercial sale of a particular BMS Licensed Product in a country until the latest of 10 years after the first commercial sale of such BMS Licensed Product in such country, (b) when such BMS Licensed Product is no longer covered by a valid claim in the licensed patent rights in such country, or (c) the expiration of any regulatory or marketing exclusivity for such BMS Licensed Product in such country. Any inventions, and related patent rights, invented solely by either party pursuant to activities conducted under the BMS License Agreement shall be solely owned by such party, and any inventions, and related patent rights, conceived of jointly by the Company and BMS pursuant to activities conducted under the BMS License Agreement shall be jointly owned by the Company and BMS, with BMS’s rights thereto included in the Company’s exclusive license. The Company has the first right—with reasonable consultation with, or participation by, BMS—to prepare, prosecute, maintain and enforce the licensed patents, at the Company’s expense.

BMS has the right to terminate the BMS License Agreement in its entirety upon written notice to the Company (a) for insolvency-related events involving the Company, (b) for the Company’s material breach of the BMS License Agreement if such breach remains uncured for a defined period of time, for the Company’s failure to fulfill its obligations to develop or commercialize the BMS Licensed Compounds and/or BMS Licensed Products not remedied within a defined period of time following written notice by BMS, or (d) if the Company or its affiliates commence any action challenging the validity, scope, enforceability or patentability of any of the licensed patent rights. The Company has the right to terminate the BMS License Agreement for convenience upon prior written notice to BMS, the length of notice dependent on whether a BMS Licensed Project has received regulatory approval, (b) upon immediate written notice to BMS for insolvency-related events involving BMS, (c) for BMS’s material breach of the BMS License Agreement if such breach remains uncured for a defined period of time, or (d) on a BMS Licensed Compound-by-BMS Licensed Compound and/or BMS Licensed Product-by-BMS Licensed Product basis upon immediate written notice to BMS if the Company reasonably determine that there are unexpected safety and public health issues relating to the applicable BMS Licensed Compounds and/or BMS Licensed Products.

Upon termination of the BMS License Agreement in its entirety by the Company for convenience or by BMS, the Company grants an exclusive, non-transferable, sublicensable, worldwide license to BMS under certain of its patent rights that are necessary to develop, manufacture or commercialize BMS Licensed Compounds or BMS Licensed Products. In exchange for such license, BMS must pay the Company a low single-digit percentage royalty on net sales of the BMS Licensed Compounds and/or BMS Licensed Products by it or its affiliates, licensees or sublicensees, provided that the termination occurred after a specified developmental milestone for such BMS Licensed Compounds and/ or BMS Licensed Products.

*Option and License Agreement with Novartis International Pharmaceutical Ltd.*

In December 2018, the Company entered into an evaluation, option and license agreement, or the Novartis Option Agreement, with Novartis International Pharmaceutical Limited, or Novartis, pursuant to which Novartis agreed to conduct certain studies to evaluate AL102 in combination with its B-cell maturation antigen, or BCMA, therapies in multiple myeloma, and the Company agreed to supply AL102 for such studies. All supply and development costs associated with such evaluation studies are fully borne by Novartis.

Under the Novartis Option Agreement, the Company granted Novartis an exclusive option to obtain an exclusive (including as to the Company and its affiliates), sublicensable (subject to certain terms and conditions), worldwide license and sublicense (as applicable) under certain patent rights and know-how controlled by the Company (including applicable patent rights and know-how that are licensed from BMS pursuant to the BMS License Agreement) to research, develop, manufacture (subject to the Company's non-exclusive right to manufacture and supply AL102 or the Novartis Licensed Product for Novartis) and commercialize AL102 or any pharmaceutical product containing AL102 as the sole active ingredient, or the Novartis Licensed Product, for the diagnosis, prophylaxis, treatment, or prevention of multiple myeloma in humans. The Company also granted Novartis the right of first negotiation for the license rights to conduct development or commercialization activities with respect to the use of AL102 for indications other than multiple myeloma. Additionally, from the exercise by Novartis of its option until the termination of the Novartis Option Agreement, the Company may not, either itself or through its affiliates or any other third parties, directly or indirectly research, develop or commercialize certain BCMA-related compounds for the treatment of multiple myeloma.

According to the agreement, Novartis shall pay the Company a low eight figure option exercise fee in order to exercise its option and activate its license, upon which the Company will be eligible to receive development, regulatory and commercial milestone payments of up to \$245 million in the aggregate and tiered royalties on net sales of Novartis Licensed Products by Novartis or its affiliates or sublicensees at rates ranging from a mid-single-digit to low double-digit percentage, depending on the total annual worldwide net sales of Novartis Licensed Products. Royalties will be paid on a country-by-country and Novartis Licensed Product-by-Novartis Licensed Product basis from the first commercial sale of a particular Novartis Licensed Product in a country until the latest of (a) 10 years after the first commercial sale of such Novartis Licensed Product in such country, (b) when such Novartis Licensed Product is no longer covered by a valid claim in the licensed patent rights in such country, or (c) the expiration of any regulatory or marketing exclusivity for such Novartis Licensed Product in such country. Contemporaneously with the Novartis Option Agreement, the Company entered into a stock purchase agreement and associated investment agreements, or the SPA, with Novartis' affiliate, Novartis Institutes for BioMedical Research, Inc., or NIBRI, pursuant to which NIBRI acquired a \$10 million equity stake in the Company.

Novartis shall own any inventions, and related patent rights, invented solely by it or jointly with the Company in connection with activities conducted pursuant to the Novartis Option Agreement. The Company will maintain first right to prosecute and maintain any patents licensed to Novartis, both before and after its exercise of its option. The Company maintain the first right to defend and enforce its patents prior to Novartis's exercise of its option, upon which Novartis gains such right with respect to patents included in the license.

The option granted to Novartis will remain in effect until the earlier of (a) 60 days following the last visit of the last subject in the evaluation studies, the termination of the Novartis Option Agreement, or (c) 36 months following the delivery by the Company to Novartis of sufficient amounts of clinical evaluation materials to conduct the anticipated clinical studies. The Novartis Option Agreement remains in effect until such time as no Novartis Licensed Product is being developed or commercialized by Novartis, its affiliates, or sublicensees (including distributors or commercial partners), unless terminated earlier. The Company has the right to terminate the Novartis Option Agreement (a) for Novartis's material breach if such breach remains uncured for 60 days (such cure period shall be extended for an additional period during which Novartis is making good faith efforts to cure such breach) or (b) for Novartis's failure to use commercially reasonable efforts to develop or commercialize AL102 and/or the Novartis Licensed Product not remedied within four months following written notice to Novartis. Novartis has the right to terminate the Novartis Option Agreement (a) in its entirety or on a country-by-country basis for convenience, upon 60 days written notice to us, (b) for Company's material breach if such breach remains uncured for 60 days (such cure period shall be extended for an additional period during which Novartis is making good faith efforts to cure such breach) or (c) upon immediate written notice to the Company for insolvency-related events involving the Company.

On June 2, 2022, Novartis informed the Company that Novartis does not intend to exercise its option to obtain an exclusive license for AL102, thereby terminating the agreement.



## 7. Fair Value Measurements

As of December 31, 2022, the Company had no financial liabilities measured at fair value.

The following tables summarize the fair value measurements of our financial instruments as of December 31, 2022:

	<b>Fair Value Measurements at December 31, 2022</b>			
	<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>	<b>Total</b>
	<b>(\$in thousands)</b>			
Cash equivalents:				
Money market funds	\$ 1,200	\$ —	\$ —	\$ 1,200
Total cash equivalents	\$ 1,200	\$ —	\$ —	\$ 1,200

The following tables summarize the fair value measurements of our financial instruments as of December 31, 2021:

	<b>Fair Value Measurements at December 31, 2021</b>			
	<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>	<b>Total</b>
	<b>(\$in thousands)</b>			
Cash equivalents:				
Money market funds	\$ 32,900	\$ —	\$ —	\$ 32,900
Total cash equivalents	\$ 32,900	\$ —	\$ —	\$ 32,900

## 8. Common Stock

The Common Stock confer upon the holders the right vote in annual and special meetings of the Company, and to participate in the distribution of the surplus assets of the Company upon liquidation of the Company, after the distribution of the preferred stock liquidation preference. No dividends have been declared as of December 31, 2022 and 2021.

On February 19, 2021, we entered into a Securities Purchase Agreement (the “2021 Purchase Agreement”) with the purchasers named therein (the “Investors”). Pursuant to the 2021 Purchase Agreement, we agreed to issue (i) an aggregate of 333,333 shares of our common stock (the “Private Placement Shares”), par value \$0.01 per share, together with warrants to purchase an aggregate of 116,666 shares of our common stock with an exercise price of \$18.10 per share (the “Common Warrants”), for an aggregate purchase price of \$4,999,995.00 and (ii) pre-funded warrants to purchase an aggregate of 1,333,333 shares of our common stock with an exercise price of \$0.01 per share (the “Pre-Funded Warrants” and collectively with the Common Warrants, the “Private Placement Warrants”), together with an aggregate of 466,666 Common Warrants, for an aggregate purchase price of \$19,986,661.67 (collectively, the “Private Placement”). The Private Placement closed on February 23, 2021. The Company had issuance costs of approximately \$1.715 million. The Private Placement closed on February 23, 2021. The warrants were classified as a component of permanent equity pursuant to ASC 480 “Distinguishing Liabilities from Equity” and ASC 815 “Derivatives and Hedging.” As of December 31, 2021, the 1,799,999 warrants are all outstanding.

In June 2021, we entered into an Open Market Sales Agreement, or the Sales Agreement, with Jefferies LLC, or Jefferies, as sales agent, pursuant to which we may, from time to time, issue and sell common stock with an aggregate value of up to \$200.0 million in “at-the-market” offerings, under our Registration Statement on Form S-3 (File No. 333-256792) filed with the SEC on June 4, 2021 (the “ATM”). Sales of common stock, if any, pursuant to the Sales Agreement, may be made in sales deemed to be an “at the market offering” as defined in Rule 415(a) of the Securities Act, including sales made directly through The Nasdaq Global Market or on any other existing trading market for our common stock. Pursuant to the Sales Agreement, during the twelve months ended December 31, 2021, the Company issued a total of 827,094 shares of common stock for total gross proceeds of approximately \$10.4 million.

Total shares of Common Stock reserved for issuance are summarized as follows:

	December 31, 2022	December 31, 2021
Options Outstanding	1,056,015	900,789
Warrants for common shares of the company.	1,799,999	1,799,999
Shares available for future option grants	547,085	593,040
Total shares of Common Stock reserved for Issuance	<u>3,403,099</u>	<u>3,293,828</u>

Composition of Capital Stock:

	December 31, 2022		December 31, 2021	
	<u>Authorized</u>	<u>Issued and outstanding</u>	<u>Authorized</u>	<u>Issued and outstanding</u>
Shares of USD 0.01 par value:				
Common Stock	200,000,000	14,381,361*	200,000,000	13,956,035*

\* Does not include 431,376 and 124,348 shares of restricted Common Stock issued but not outstanding in 2022 and 2021, respectively.

## 9. Stock-Based Plans

In 2017, the Company's board of directors adopted the 2017 Stock Incentive Plan (the "Plan"). According to the Plan, share awards, including restricted stock, restricted stock units or other stock-based awards, or options to purchase shares may be granted to employees, directors, consultants and other service providers of the Company or any affiliate of the Company.

As of December 31, 2022, a total of 2,404,255 shares of Common Stock were authorized for issuance in accordance with the provisions of the 2017 Plan, of which 547,085 shares were then available for future awards (whether as share awards or as options to purchase shares of common stock of the Company). Each option granted under the Plan expires no later than 10 years from the date of grant. The options vest primarily over four to five years of employment.

The following table set forth the parameters used in the computation of the fair value of options granted to employees:

	Year ended December 31,	
	<u>2022</u>	<u>2021</u>
Expected volatility	80%	80%
Expected dividends	0%	0%
Expected term (in years)	6.34	6.34
Risk free rate	0.98%-3.53%	0.50%-1.08%

### *Expected Volatility:*

As the Company was privately owned in part of 2020, there was not sufficient historical volatility for the expected term of the stock options. Therefore, the Company used an average historical share price volatility based on an analysis of reported data for a peer group of comparable publicly traded companies which were selected based upon industry similarities.

*Expected term (years):*

Expected term represents the period that the Company's option grants are expected to be outstanding. There is not sufficient historical share exercise data to calculate the expected term of the stock options. Therefore, the Company elected to utilize the simplified method to value option grants. Under this approach, the weighted-average expected life is presumed to be the average of the shortest vesting term and the contractual term of the option.

*Risk-free interest rate:*

The Company determined the risk-free interest rate by using a weighted-average equivalent to the expected term based on the U.S. Treasury yield curve in effect as of the date of grant.

*Expected dividend yield:*

The Company does not anticipate paying any dividends in the foreseeable future.

The Company recorded stock-based compensation for the period indicated as follows (in thousands):

	Year ended December 31, 2022	Year ended December 31, 2021
Research and Development	\$ 717	\$ 1,097
General and Administrative	1,527	1,587
Total Stock-Based Compensation	<u>\$ 2,244</u>	<u>\$ 2,684</u>

The Company recognizes compensation expenses for the value of its awards granted based on the accelerated method over the requisite service period of each of the awards.

A summary of the Company's stock option activity granted to employees under the Plan is as follows:

	Year ended December 31, 2022			
	Number of options	Weighted average exercise price	Weighted average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at Beginning of Year	900,789	\$ 7.41	7.25	\$ 1,695,276
Granted	318,830	8.37		
Forfeited	(107,943)	6.28		
Expired	(55,661)	7.58		
Outstanding, December 31, 2022	<u>1,056,015</u>	<u>\$ 7.53</u>	<u>4.91</u>	<u>\$ -</u>
Exercisable Options, December 31, 2022	550,850	\$ 6.34	5.92	\$ -

The weighted-average grant date per-share fair value of stock options granted during 2022 and 2021 was \$5.74 and \$7.98, respectively. The aggregate intrinsic value of stock options exercised during the year ended December 31, 2022 and 2021 was \$ 0 and \$55, respectively. As of December 31, 2022, there was approximately \$1.2 million of total unrecognized compensation cost related to non-vested stock-based compensation arrangements granted under the Plan. That cost is expected to be recognized over a weighted-average period of 0.94 years.

*Company's restricted shares:*

In January 2021, the Company granted 71,253 restricted shares to officers and employees of the Company. The restricted shares vest over three years starting January 4, 2022.

In May 2022, the Company granted 427,160 restricted shares to officers and employees of the Company. The restricted shares vest over three years starting May 15, 2022.

In August 2022, the Company granted 26,400 restricted shares to employees of the Company. The restricted shares vest over four years starting Aug 14, 2022.

The following table summarizes information relating to restricted shares, as well as changes to such awards during the fiscal years ended December 31, 2022 and 2021:

	<b>Year ended December 31, 2022</b>	<b>Year ended December 31, 2021</b>
Outstanding at beginning of Year	124,348	101,929
Granted	453,560	71,253
Forfeited	(31,623)	-
Vested	(114,909)	(48,834)
Outstanding at end of Year	<u>431,376</u>	<u>124,348</u>

The weighted average fair values at grant date of restricted shares granted for the years ended December 31, 2022 and 2021 was \$2.00 and \$11.26, per share respectively.

The total fair value of shares vested during each of 2022 and 2021 was approximately \$0.7 million and \$0.6 million, respectively. As of December 31, 2022, the Company had approximately \$0.6 million of unrecognized compensation expense related to non-vested restricted shares, expected to be recognized over a weighted average period of 0.84 years.

Restricted shares are subject to a repurchase right by the Company on certain occasions. Under the repurchase right, the Company may reacquire restricted shares, for no consideration, if certain conditions occur including the employees' end of service with the Company.

## **10. Taxes on Income**

The Company records income tax expense related to profits realized in the United States and realized by its subsidiary in Israel.

*United States:*

On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act (the "U.S. Tax Reform"); a comprehensive tax legislation that includes significant changes to the taxation of business entities. These changes, most of which are effective for tax years beginning after December 31, 2017, include several key tax provisions that might impact the Company, among others: (i) a permanent reduction to the statutory federal corporate income tax rate from 35% (top rate) to 21% (flat rate) effective for tax years beginning after December 31, 2017 (ii) a new tax deduction in the amount of 37.5% of "foreign derived intangible income" that effectively reduces the federal corporate tax on certain qualified foreign derived sales/licenses/leases and service income in excess of a base amount to 13.125% (as compared to the regular corporate income tax rate of 21%); (iii) stricter limitation on the tax deductibility of business interest expense; (iv) a shift of the U.S. taxation of multinational corporations from a tax on worldwide income to a territorial system (along with certain rules designed to prevent erosion of the U.S. income tax base) (v) a one-time deemed repatriation tax on accumulated offshore earnings held in cash and illiquid assets, with the latter taxed at a lower rate and (vi) an expansion of the U.S. controlled foreign corporation ("CFC") anti deferral starting with the CFC's first tax year beginning in 2018 intended to tax in the U.S. "global intangible low-taxed income" ("GILTI").

The Company recorded loss from continuing operations, before taxes on income for the period indicated as follows (in thousands):

	Year ended December 31, 2022	Year ended December 31, 2021
United States	\$ (36,674)	\$ (39,018)
Israel	(755)	(460)
Net loss before tax	<u>\$ (37,429)</u>	<u>\$ (39,478)</u>

Income tax expense is summarized as follows (in thousands):

	Year ended December 31, 2022	Year ended December 31, 2021
Current :		
Domestic	\$ 57	\$ -
Foreign	527	776
	<u>\$ 584</u>	<u>\$ 776</u>
Income tax expense	<u>\$ 584</u>	<u>\$ 776</u>

The effective income tax rate differed from the amount computed by applying the federal statutory rate to our loss before income taxes as follows:

	Year ended December, 31 2022	Year ended December, 31 2021
U.S. federal tax provision at statutory rate	21.00%	21.00%
State and local tax, net of federal benefit	0.72	4.01
Foreign rate differences	(0.06)	(0.09)
Non-deductible stock compensation	(1.26)	(1.43)
Section 951A GILTI	0.00	0.00
Effect of other permanent differences	(0.01)	(0.07)
Uncertain tax positions	(1.15)	(0.66)
Change in valuation allowance	(25.51)	(34.39)
Federal Tax Reform Rate Change	0.00	0.00
Tax Credits	4.14	6.01
Provision to Return	1.67	3.95
Other adjustments	(1.10)	(0.30)
Effective tax rate	(1.56)%	(1.97)%

## Deferred Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows (in thousands):

	(\$ in thousands)	
	As of December 31,	
	2022	2021
Deferred tax assets:		
Federal net operating loss carry forwards	\$ 27,592	\$ 22,614
Tax credit carry forwards	4,862	3,402
Intangible and other related assets	2,990	3,011
Research and Development Costs	3,074	-
Accrued expenses	72	169
Lease Liability	410	-
Total deferred tax assets before valuation allowance	39,000	29,196
Valuation allowance	(38,652)	(29,196)
Total deferred tax assets	348	-
Deferred tax liabilities:		
Right of Use Asset	348	-
Total deferred tax liabilities	348	-
Net deferred tax assets	\$ -	\$ -

As of December 31, 2022, the Company has provided a valuation allowance of approximately \$38.7 million in respect of the Company's deferred tax assets resulting from tax loss carryforwards, tax credits and other temporary differences. Realization of deferred tax assets is dependent upon future earnings, if any, the time and amount of which are uncertain. As the Company is still in its development stage and has not yet generated revenues, it is more likely than not that sufficient taxable income will not be available for the tax losses to be utilized in the future. Therefore, a valuation allowance was recorded to reduce the deferred tax assets to their recoverable amounts.

### Available Carryforward Tax Losses

As of December 31, 2022, we had net operating loss carryforwards, or NOLs, of \$114.3 million for federal income tax purposes and \$69.4 million for state income tax purposes, which may be available to offset our future taxable income, if any, and begin to expire in various amounts in 2037 and 2038, respectively, provided that NOLs generated in tax years ending after December 31, 2017 will not be subject to expiration. In general, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to use its pre-change NOLs to offset future taxable income. If the U.S. Internal Revenue Service challenges our determinations with respect to the existence of previous ownership changes or the effects thereof, or if we undergo an ownership change, our ability to use our NOLs could be limited by Section 382 of the Code. Future changes in our stock ownership, some of which are outside of our control, could also result in an ownership change under Sections 382 and 383 of the Code. In addition, for taxable years beginning after December 31, 2020, utilization of federal NOLs generated in tax years beginning after December 31, 2017 are limited to a maximum of 80% of the taxable income for such year, after taking into account utilization of NOLs generated in years beginning before January 1, 2018 and determined without regard to such NOL deduction. Furthermore, our ability to use NOLs of companies that we may acquire in the future may be subject to limitations. For these reasons, we may not be able to use a material portion of the NOLs, even if we attain profitability. The reduction of the corporate tax rate under recently-enacted U.S. tax legislation may cause a reduction in the economic benefit of our NOLs and other deferred tax assets available to us.

In addition, as of December 31, 2022, the Company had federal Orphan Drug research and development credit carryforwards of approximately \$4,619 thousand and \$66, respectively. If not utilized, the federal tax carryforwards which expire in 2039. The Company also had state research and development credit carryforward of approximately \$0.1 million and will begin to expire in 2037 if not utilized.

### Uncertain Tax Positions

The Company has reviewed the tax positions taken, or to be taken, in our tax returns for all tax years currently open to examination by a taxing authority. As of December 31, 2022, and 2021, the Company has recorded an uncertain tax position liability exclusive of interest and penalties of approximately \$1.3 million, and \$0.9 million, respectively. As of December 31, 2022, the Company has not accrued penalties for uncertain tax positions. A reconciliation of the Company's unrecognized tax benefits is below:

	2022	2021
	(in thousands)	(in thousands)
Uncertain tax position at the beginning of year	\$ 858	\$ 581
Additions for uncertain tax position of prior years (foreign exchange and interest)	36	17
Additions for tax positions of current year	429	260
Uncertain tax position at the end of the year	\$ 1,323	\$ 858

The Company remains subject to examination until the statute of limitations expires for each respective tax jurisdiction. The statute of limitations is currently open for 2017, 2018, 2019, 2020, 2021 and 2022 for all tax jurisdictions.

*Israel:*

In December 2016, the Israeli Parliament approved the Economic Efficiency Law (Legislative Amendments for Applying the Economic Policy for the 2017 and 2018 Budget Years) which reduces the corporate income tax rate from 25% to 24% effective from January 1, 2017, and to 23% effective from January 1, 2018.

The Israeli corporate income tax rate was 23% in 2022 and 2021. Income not eligible for Preferred Enterprise benefits is taxed at the regular corporate tax rates as described above.

## 11. Net Loss Per Share Attributable to Common Stockholders

The following table sets forth the computation of the loss per share for the period presented (in thousands, except for share data):

	<u>Year ended December 31, 2022</u>	<u>Year ended December 31, 2021</u>
<b>Numerator:</b>		
Net loss	\$ 38,013	\$ 40,254
<b>Denominator:</b>		
Weighted-average number of shares used to compute net loss per share, basic and diluted	15,448,931	14,398,905

The calculation of basic and diluted Loss Per Share includes 1,333,333 and 1,155,555 weighted average warrants with an exercise price of \$0.01 for the year ended December 31, 2022 and 2021, respectively.

The following potentially dilutive common stock equivalents have been excluded from the calculation of diluted net loss per share for the period presented due to their anti-dilutive effect: 466,666 shares of common stock and 1,056,015 options outstanding to purchase common stock as of December 31, 2022.

The following potentially dilutive common stock equivalents have been excluded from the calculation of diluted net loss per share for the period presented due to their anti-dilutive effect: 466,666 shares of common stock and 900,789 options outstanding to purchase common stock as of December 31, 2021.

## 12. Subsequent Events

On October 18, 2022, the Company entered into an Agreement of Merger (the “Merger Agreement”) with Advaxis, Inc., a Delaware corporation (“Advaxis”). The Merger Agreement provides, among other things, that on the terms and subject to the conditions set forth therein: (i) each share of the common stock, par value \$0.01 per share, of the Company (the “Ayala Common Stock”) issued and outstanding immediately prior to the Merger shall be automatically converted into the right to receive 0.1874 shares (as such amount may be adjusted as provided in the Merger Agreement “Exchange Ratio”) of the common stock, par value \$0.001 per share, of Advaxis (the “Advaxis Common Stock”), (iii) each outstanding option to purchase shares of the Ayala Common Stock (each, an “Ayala Option”) were substituted and converted automatically into an option (each, an “Advaxis Replacement Option”) to purchase the number of shares of Advaxis Common Stock equal to the product obtained by multiplying (a) the number of shares of Ayala Common Stock subject such Ayala Option immediately prior to the effective time of the Merger, by (b) the Exchange Ratio, with any fractional shares rounded down to the nearest whole share, with each such Advaxis Replacement Option to have an exercise price per share of Advaxis Common Stock equal to (x) the per share exercise price for the shares of Ayala Common Stock subject to the corresponding Ayala Option immediately prior to the effective time of the Merger, divided by (y) the Exchange Ratio, rounded up to the nearest whole cent, and (iv) each restricted stock unit of the Company (each, an “Ayala RSU”) outstanding immediately prior to the effective time of the Merger, whether or not vested or issuable, were substituted and converted automatically into a restricted stock unit award of Advaxis with respect to a number of shares of Advaxis Common Stock equal to the product obtained by multiplying (i) the total number of shares of Ayala Common Stock subject to such Ayala RSU immediately prior to the effective time of the Merger by (ii) the Exchange Ratio, with any fractional shares rounded down to the nearest whole share.

Upon completion of the Merger, the Company’s stockholders owned approximately 62.5 % of the combined company’s outstanding common stock and Advaxis stockholders will own approximately 37.5%.

As a result of the merger, the Company incurred issuance costs of 1,953 through the balance sheet date that are directly related to the Merger. The costs are accounted for as deferred issuance costs that will be charged to shareholder equity upon the completion of the transaction.

Closing of the Merger occurred on January 19th, 2023.



**UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS**

On October 18, 2022, Ayala Pharmaceuticals, Inc. (formerly known as Advaxis, Inc.) (“Ayala Pharmaceuticals”), a Delaware corporation, Doe Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Ayala Pharmaceuticals (“Merger Sub”), and Old Ayala (formerly known as Ayala Pharmaceuticals, Inc.), a Delaware corporation (“Old Ayala”) entered into an Agreement and Plan of Merger (the “Merger Agreement”). On January 19, 2023, pursuant to the Merger Agreement, Merger Sub merged with and into Old Ayala, with Old Ayala continuing as the surviving company and a wholly-owned subsidiary of Ayala Pharmaceuticals.

Ayala Pharmaceuticals and Old Ayala had different fiscal years. Ayala Pharmaceuticals’ fiscal year ended on October 31, whereas Old Ayala’s fiscal year end on December 31. The unaudited pro forma condensed combined balance sheet and statements of operations 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.

The following unaudited pro forma condensed combined financial information is presented to illustrate the effect of the merger of Ayala Pharmaceuticals and Old Ayala based on the historical financial position and historical results of operations of Ayala Pharmaceuticals and Old Ayala. It is presented as follows:

- The unaudited pro forma condensed combined balance sheet as of December 31, 2022 was prepared based on (i) the historical audited condensed consolidated balance sheet of Ayala Pharmaceuticals as of October 31, 2022 and (ii) the historical audited condensed consolidated balance sheet of Old Ayala as of December 31, 2022.
- The unaudited pro forma condensed combined statement of operations for the year ended December 31, 2022 was prepared based on (i) the historical audited consolidated statement of operations of Ayala Pharmaceuticals for the year ended October 31, 2022 and (ii) the historical audited consolidated statement of operations of Old Ayala for the year ended December 31, 2022.

The unaudited pro forma condensed combined financial information set forth below primarily gives effect to the following:

- the consummation of the merger;
- the fair value adjustment of Ayala Pharmaceuticals’ assets and liabilities assumed in connection with the reverse merger in accordance with U.S. GAAP;
- the cashless exercise of Old Ayala’s pre-funded warrants;
- transaction costs incurred in connection with the merger.

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 combined balance sheet data gives effect to the Merger as if it had occurred on December 31, 2022. The unaudited pro forma combined statement of operations data gives effect to the Merger as if it had occurred on November 1, 2021.

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Because most of the value of the assets of Ayala Pharmaceuticals is in cash and cash equivalents, the merger is treated primarily as a financing transaction for accounting purposes with a small component as a business acquisition, with Old Ayala as the deemed accounting acquirer and Ayala Pharmaceuticals as the deemed accounting acquiree. Therefore, no gain or loss is recorded as a result of the merger. Old Ayala's transaction costs were capitalized and offset against the proceeds from the merger, but Ayala Pharmaceutical's transaction costs were expensed as merger costs. The historical basis of Old Ayala's assets and liabilities will not be remeasured as a result of the merger. In identifying Old Ayala 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 for the minor business acquisition 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. For pro forma purposes, the enterprise value of Ayala Pharmaceuticals is based on, among other things, the cash value of Ayala Pharmaceuticals plus the fair value of its other assets and liabilities assumed. The assets and liabilities of Ayala Pharmaceuticals and other pro forma adjustments have been measured based on various preliminary estimates using assumptions that Ayala Pharmaceuticals and Old Ayala 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 Old Ayala. Upon completion of the Merger, the combined company will perform a detailed review of Ayala Pharmaceuticals' 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 Old Ayala and Ayala Pharmaceuticals 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 Ayala Pharmaceuticals and Old Ayala:

- Separate historical audited consolidated financial statements of Old Ayala as of and for the year ended December 31, 2022 and the related notes included in this Form 8-K; and
  - Separate historical audited consolidated financial statements of Ayala Pharmaceuticals as of and for the year ended October 31, 2022 and the related notes included in Ayala Pharmaceuticals' Annual Report on Form 10-K filed on February 10, 2023.
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**Unaudited Pro Forma Condensed Combined Balance Sheet**
**As of December 31, 2022**

(in thousands, except for per share amounts)

	Old Ayala, Inc. December 31, 2022	Ayala Pharmaceuticals, Inc. October 31, 2022	Transaction Accounting Adjustments		Pro Forma Combined
<b>ASSETS</b>					
Current Assets:					
Cash and cash equivalents	\$ 2,408	\$ 25,208	\$ (2,823)	<b>5B</b>	\$ 24,793
Short-term restricted bank deposits	110	-	-		110
Trade receivables	234	-	-		234
Prepaid expenses and other current assets	436	551	-		987
Total Current Assets	<u>3,188</u>	<u>25,759</u>	<u>(2,823)</u>		<u>26,124</u>
Property and equipment (net of accumulated depreciation)	960	38	-		998
Intangible assets (net of accumulated amortization)	-	110	20	<b>5A</b>	130
Deferred issuance costs	1,953	-	(1,953)	<b>5H</b>	-
Operating right-of-use asset	1,462	12	-		1,474
Other assets	206	11	-		217
<b>TOTAL ASSETS</b>	<u>\$ 7,769</u>	<u>\$ 25,930</u>	<u>\$ (4,756)</u>		<u>\$ 28,943</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>					
Current Liabilities:					
Trade payables	\$ 4,080	\$ 22	\$ -		\$ 4,102
Other accounts payables	3,037	-	-		3,037
Accrued expenses	-	2,150	1,023	<b>5C</b>	3,173
Current portion of operating lease liability	419	12	-		431
Common stock warrant liability	-	119	84	<b>5F</b>	203
Total Current Liabilities	<u>7,536</u>	<u>2,303</u>	<u>1,107</u>		<u>10,946</u>
Long term rent liability	1,332	-	-		1,332
<b>Total Liabilities</b>	<u>8,868</u>	<u>2,303</u>	<u>1,107</u>		<u>12,278</u>
Commitments and Contingencies					
Shareholders' Equity:					
Preferred stock	-	-	-		-
Common stock	139	2	(136)	<b>5D</b>	5
Additional paid-in capital	147,916	466,584	(444,076)	<b>5D</b>	168,265
			1,428	<b>5G</b>	
			(1,570)	<b>5B</b>	
			(1,953)	<b>5H</b>	
			(64)	<b>5E</b>	
Accumulated deficit	(149,154)	(442,959)	444,212	<b>5D</b>	(151,605)
			(1,253)	<b>5B</b>	
			(1,023)	<b>5C</b>	
			(1,428)	<b>5G</b>	
<b>Total stockholders' equity</b>	<u>(1,099)</u>	<u>23,627</u>	<u>(5,863)</u>		<u>16,665</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 7,769</u>	<u>\$ 25,930</u>	<u>\$ (4,756)</u>		<u>\$ 28,943</u>

**Unaudited Pro Forma Condensed Combined Statement of Operations**  
**Year ended December 31, 2022**

(in thousands)

	<b>Old Ayala, Inc.</b> <b>For the year ended</b> <b>December 31, 2022</b>	<b>Ayala Pharmaceuticals,</b> <b>Inc.</b> <b>For the year ended</b> <b>October 31, 2022</b>	<b>Transaction</b> <b>Accounting</b> <b>Adjustments</b>	<b>Pro Forma</b> <b>Combined</b>
Revenue	\$ 692	\$ 250	\$ -	\$ 942
Cost of revenue	(602)	-	-	(602)
Gross profit	90	250	-	340
Operating expenses				
Research and development expenses	27,851	7,616	-	35,467
General and administrative expenses	9,742	8,891	(359)	21,978
			1,253	6A
			1,023	6D
			1,428	6E
Intangible asset impairment		3,053	(3,053)	6B
Total Operating Expenses	<u>37,593</u>	<u>19,560</u>	<u>292</u>	<u>57,445</u>
Loss from operations	(37,503)	(19,310)	(292)	(57,105)
Other income (expense):	-	-	-	
Interest income (expense)	74	157	-	231
Net changes in fair value of derivative liabilities	-	4,853	-	4,853
Loss on shares issued in settlement of warrants	-	-	-	-
Other expense	-	(9)	-	(9)
Net Loss Before Benefit for Income Taxes	<u>(37,429)</u>	<u>(14,309)</u>	<u>(292)</u>	<u>(52,030)</u>
Income Tax Expense	584	50	-	634
Net loss	(38,013)	(14,359)	(292)	(52,664)
Accretion of discount and redemption feature of convertible preferred stock	-	(1,025)	-	(1,025)
Income available to common stockholders	<u>\$ (38,013)</u>	<u>\$ (15,384)</u>	<u>\$ (292)</u>	<u>\$ (53,689)</u>
Net loss per common share basic & diluted	<u>\$ (2.46)</u>	<u>\$ (8.46)</u>	<u>\$ -</u>	<u>\$ (10.83)</u>
Weighted average number of common shares outstanding Basic & Diluted	<u>15,448,931</u>	<u>1,818,639</u>		<u>4,957,273</u>

**Notes to the Unaudited Pro Forma Financial Statements:**  
**(dollars in thousands, except per share amounts)**

**1. Description of the Merger**

On October 18, 2022, Old Ayala entered into the Merger Agreement with Ayala Pharmaceuticals and Merger Sub, pursuant to which Merger Sub will merge with and into Old Ayala, with Old Ayala as the surviving corporation and becoming a wholly-owned subsidiary of Ayala Pharmaceuticals. The merger closed on January 13, 2023. Upon closing, Ayala Pharmaceuticals issued an aggregate of 3,022,370 shares of its common stock to existing shareholders and prefunded warrant holders of Old Ayala, which resulted in pre-merger Ayala Pharmaceutical stockholders owning approximately 37.5% of the combined company and Old Ayala stockholders owning approximately 62.5% of the combined company.

**2. Basis of Presentation**

The preceding unaudited pro forma condensed combined financial information has been prepared in accordance with Article 8 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 the option to 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 primarily as a financing transaction for accounting purposes with a small component as a business acquisition, with Old Ayala as the deemed accounting acquirer and Ayala Pharmaceuticals as the deemed accounting acquiree. Since the business acquisition component is very immaterial and is an integral part of this merger, management deems it to have occurred at fair value; therefore, no gain or loss is recorded. Old Ayala’s transaction costs were capitalized and offset against the proceeds, but Ayala Pharmaceutical’s transaction costs were expensed as merger costs. The historical basis of Old Ayala’s assets and liabilities will not be remeasured as a result of the merger. In identifying Old Ayala 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 for the business acquisition 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 Old Ayala and Ayala Pharmaceuticals management, and a preliminary valuation of Ayala Pharmaceuticals’ assets and liabilities using January 19, 2023, as the measurement date.

For pro forma purposes, the enterprise value of Ayala Pharmaceuticals is based on, among other things, the cash value of Ayala Pharmaceuticals plus the fair value of its other assets and liabilities assumed. Refer to Note 4 for additional information. This is used for pro forma purposes only.

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The unaudited pro forma combined balance sheet data gives effect to the Merger as if it had occurred on December 31, 2022. The unaudited pro forma combined statement of operations data gives effect to the Merger as if it had occurred on November 1, 2021.

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 Old Ayala. Following the Merger, the combined company will conduct a review of accounting policies of Ayala Pharmaceuticals 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 Old Ayala'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 Fair Value Allocation

#### *Fair Value Allocation*

The following is a preliminary estimate of the fair value of acquired identifiable assets and assumed liabilities of Ayala Pharmaceuticals, which includes preliminary adjustments to reflect the fair value of intangible assets acquired:

	<b>Amounts</b>
Cash and cash equivalents	\$ 25,208
Prepaid expenses and other current assets	551
Property and equipment, net	38
Intangible assets	130
Operating right-of-use asset	12
Other assets	11
<b>Total assets</b>	<b>25,950</b>
Common stock warrant liability	(203)
Other current liabilities	(2,184)
<b>Total liabilities</b>	<b>(2,387)</b>
Estimated enterprise value of Ayala Pharmaceuticals	23,563
Total stockholders' equity of Ayala Pharmaceuticals at October 31, 2022	23,627
Fair value adjustment of Ayala Pharmaceuticals	\$ (64)

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). 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.

	Ayala Pharmaceuticals Historical Carrying Value	January 19, 2023 Estimated Fair Value	Incremental Amortization and Abandonment of Intangible Expense for the Year Ended October 31, 2022
Patents	\$ 95	\$ -	\$ (392)
License agreements	15	130	33
<b>Total</b>	<b>\$ 110</b>	<b>\$ 130</b>	<b>\$ (359)</b>

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 the estimated enterprise value of Ayala Pharmaceuticals by approximately \$13 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.

## 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 to increase historical Ayala Pharmaceuticals intangible assets by \$20 as of January 19, 2023 to estimated fair value. Refer to Note 4 for a discussion of this reverse merger and fair value allocation.
- B. Represents \$2,823 of transaction costs incurred after year-end in connection with the Merger, of which approximately \$1,253 were costs of Ayala Pharmaceuticals and recorded as an increase in accumulated deficit. The remaining transaction costs were cost of Old Ayala of \$1,570 were reflected in additional paid-in capital as a reduction in proceeds. See also note 6C.
- C. Represents severance to be paid to three executives of Old Ayala of \$1,023 as a result of the Merger recorded as an increase in accrued expenses and an increase to accumulated deficit.
- D. Represents the elimination of Ayala Pharmaceuticals common stock, paid-in capital and accumulated deficits as well as the adjustments to reflect the capital structure of the combined company and the cashless exercise of warrants to purchase 1,333,333 shares of common stock of Old Ayala for \$0.01 per share (246,192 net shares of Ayala Pharmaceuticals Common Stock). See the following explanation of the adjustments:
  - i. Adjustments to common stock: a decrease in common stock of \$136 represents the adjustment to the aggregate historical par value of Old Ayala and Ayala Pharmaceuticals of \$136, to reflect 4,838,321 shares outstanding at a total par value of \$5 (\$0.001 par value per share) calculated as follows:

	Amounts
Shares of Ayala Pharmaceuticals common stock outstanding on October 31, 2022	1,815,951
Ayala Pharmaceuticals common stock issued to Old Ayala shareholders as of closing of Merger	2,776,178
Ayala Pharmaceuticals common stock issued to Old Ayala prefunded warrant holders as of closing of Merger	246,192
Total shares of Ayala Pharmaceuticals common stock outstanding as of merger close	4,838,321
Par value per common share	\$ 0.001
Common stock total par value at merger	5
Common stock total par value of Ayala Pharmaceuticals prior to closing of Merger	(2)
Common stock total par value of Old Ayala prior to closing of Merger	(139)
<b>Total pro forma merger adjustments</b>	<b>\$ (136)</b>

ii. Adjustments to paid-in capital are as follows:

	<b>Amounts</b>
Fair value of Ayala Pharmaceuticals	\$ 23,563
Elimination of Ayala Pharmaceuticals historical additional paid-in capital	(466,584)
Merger costs expensed after October, 31, 2022	(1,253)
Fair value adjustment of Ayala Pharmaceuticals	64
Par value of Ayala Pharmaceuticals common stock on October 31, 2022	(2)
Par value adjustment of common stock	136
<b>Total pro forma merger adjustments</b>	<b>\$ (444,076)</b>

iii. Adjustments to accumulated deficit are as follows:

	<b>Amounts</b>
<b>Pro forma merger adjustments:</b>	
Elimination of historical Ayala Pharmaceuticals accumulated deficit	\$ 442,959
Merger costs expensed after October, 31, 2022	1,253
<b>Total pro forma merger adjustments</b>	<b>\$ 444,212</b>

- E. Represents an adjustment to reduce additional paid-in capital by \$64 for the estimated adjustment of Ayala Pharmaceuticals' assets and liabilities to fair value. See Note 4.
- F. Represents an increase in the common stock warrant liability of \$84 of Ayala Pharmaceuticals to update the fair value of the warrant liability. See Note 4.
- G. Represents stock-based compensation to be recognized for the acceleration of vesting of options of three executives of Old Ayala of \$1,428 as an increase to additional paid in capital and accumulated deficit.
- H. Represents an adjustment to reduce Old Ayala's deferred issuance costs and reduce additional paid-in capital by \$1,953.

#### **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 and abandonment of intangible asset expense of \$359 for the year ended October 31, 2022, related to the fair value adjustments to intangible assets discussed above in Note 4.
- B. Represents a decrease in intangible asset impairment expense of \$3,053 for the year ended October 31, 2022, related to the fair value adjustments to intangible assets discussed above in Note 4. If the intangible assets had been revalued as of the beginning of the period presented, no impairment expense would have been required.
- C. Represents \$1,253 of additional transaction costs for the year ended October 31, 2022 incurred by the Ayala Pharmaceuticals in conjunction with this reverse merger for transaction related fees and expenses.
- D. Represents severance to be paid to three executives of Old Ayala of \$1,023 to be expensed as a result of the merger.
- E. Represents stock-based compensation to be recognized for the acceleration of vesting of options of three executives of Old Ayala of \$1,428.



## 7. Loss per Share

The unaudited pro forma weighted average number of basic and diluted shares outstanding is calculated as follows:

	<b>For the year ended December 31, 2022</b>
Weighted average Old Ayala shares outstanding - basic	15,448,931
Merger exchange ratio	0.1874
	<u>2,895,130</u>
Adjusted for:	
Ayala Pharmaceuticals shares outstanding as if the merger occurred on November 1, 2021	1,815,951
Ayala Pharmaceuticals shares issued to Old Ayala warrant holders as if the Merger occurred on November 1, 2021	246,192
Pro forma adjusted weighted average shares outstanding – basic and dilutive	<u>4,957,273</u>
Pro forma net loss attributable to common shareholders – basic and dilutive	<u>\$ (53,689)</u>
Pro forma net loss per common share – basic and dilutive	<u>\$ (10.83)</u>

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