UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2022

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from_____ to _____

Commission File Number: 001-39279

AYALA PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	82-3578375
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

Oppenheimer 4
Rehovot, Israel 7670104
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (857) 444-0553

Not applicable
(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value per share	AYLA	The Nasdaq Global Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 1, 2022, the registrant had 14,820,727 shares of common stock, $0.01 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Quarterly Report, including without limitation statements relating to the potential Merger (as defined herein), our development of AL101 and AL102, our ability to continue as a going concern, our future capital needs and our need to raise additional funds, the promise and potential impact of our preclinical or clinical trial data, the timing of and plans to initiate additional clinical trials of AL101 and AL102, the timing and results of any clinical trials or readouts, and the anticipated impact of COVID-19 on our business, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential", or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements are identified by these terms or expressions. The forward-looking statements in this Quarterly Report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of important factors that could cause actual results to differ materially from those in the forward-looking statements, including but not limited to: the announcement and pendency of the Merger (as defined herein) could have an adverse effect on our business; failure to consummate the Merger within the expected timeframe or at all could have a material adverse impact on our business, financial condition and results of operations; certain provisions of the Merger Agreement (as defined herein) may discourage third parties from submitting competing proposals, including proposals that may be superior to the transactions contemplated by the Merger Agreement; failure to consummate the Merger may result in the terminating party paying a termination fee to the non-terminating party and could harm the terminating party's common stock price and its future business and operations; if we do not successfully consummate the Merger with Advaxis (as defined herein), our board of directors may dissolve or liquidate our assets to pursue a dissolution and liquidation; our directors and executive officers have interests in the Merger that are different from our stockholders, and that may influence them to support or approve the Merger without regard to our stockholders' interests; if the Merger is not completed, our stock price may fluctuate significantly; the announcement and pendency of the Merger, whether or not consummated, adversely affected the trading price of our common stock and may continue to adversely affect the trading price of our common stock; the failure to successfully integrate the businesses and operations of Ayala and Advaxis in the expected time frame may adversely affect the combined company's future results; we have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future; we are not currently profitable, and we may never achieve or sustain profitability; we will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of AL101 and AL102; our recurring losses from operations raise substantial doubt regarding our ability to continue as a going concern; we have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability; we are heavily dependent on the success of AL101 and AL102, our most advanced product candidates, which are still under clinical development, and if either AL101 or AL102 does not receive regulatory approval or is not successfully commercialized, our business may be harmed; due to our limited resources and access to capital, we must prioritize development of certain programs and product candidates; these decisions may prove to be wrong and may adversely affect our business; the outbreak of COVID-19, may adversely affect our business, including our clinical trials; our ability to use our net operating loss carry forwards to offset future taxable income may be subject to certain limitations; our product candidates are designed for patients with genetically defined cancers, which is a rapidly evolving area of science, and the approach we are taking to discover and develop product candidates is novel and may never lead to marketable products; we were not involved in the early development of our lead product candidates; therefore, we are dependent on third parties having accurately generated, collected and interpreted data from certain preclinical studies and clinical trials for our product candidates; enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control; if we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of our product candidates may be delayed and our business will be harmed; our product candidates may cause serious adverse events or undesirable side effects, which may delay or prevent marketing approval, or, if approved, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales; the market opportunities for AL101 and AL102, if approved, may be smaller than we anticipate; we may not be successful in developing, or collaborating with others to develop, diagnostic tests to identify patients with Notch-activating mutations; we have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any of our product candidates; even if we obtain approval from the U.S. Food and Drug Administration, or the FDA, for our product candidates in the United States, we may never obtain approval for or commercialize them in any other jurisdiction, which would limit our ability to realize their full market potential; we have been granted Orphan Drug Designation for AL101 for the treatment of ACC and may seek Orphan Drug Designation for other indications or product candidates, and we may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity, and may not receive Orphan Drug Designation for other indications or for our other product candidates; although we have received fast track designation for AL101 and AL102, and may seek fast Track designation for our other product candidates, such designations may not actually lead to a faster development timeline, regulatory review or approval process; we face significant competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively; we are dependent on a small number of suppliers for some of the materials used to manufacture our product candidates, and on one company for the manufacture of the active pharmaceutical ingredient for each of our product candidates; and any future collaborations will be, important to our business. If we are unable to maintain our existing collaboration or enter into new collaborations, or if these collaborations are not successful, our business could be adversely affected; enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates, if approved, and may affect the prices we may set; if we are unable to obtain, maintain, protect and enforce patent and other intellectual property protection for our technology and products or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and we may not be able to compete effectively in our markets; we may engage in acquisitions or in-licensing transactions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources; risks related to our operations in Israel could materially adversely impact our business, financial condition and results of operations; and the other factors described under the section entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2021.

Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Our forward-looking statements also do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

You should read this Quarterly Report and the documents that we reference in this Quarterly Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

PART I—FINANCIAL INFORMATION

Item 1: Financial Statements

AYALA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	September 30, 2022 (Unaudited)	December 31, 2021
CURRENT ASSETS:		
Cash and Cash Equivalents	$ 11,195	$ 36,982
Short-term Restricted Bank Deposits	110	122
Trade Receivables	129	-
Prepaid Expenses and other Current Assets	1,598	2,636
Total Current Assets	13,032	39,740
LONG-TERM ASSETS:		
Other Assets	$ 229	$ 267
Property and Equipment, Net	999	1,120
Total Long-Term Assets	1,228	1,387
Total Assets	**$ 14,260**	**$ 41,127**
LIABILITIES AND STOCKHOLDERS' EQUITY:		
CURRENT LIABILITIES:		
Trade Payables	$ 2,326	$ 3,214
Other Accounts Payables	3,379	3,258
Total Current Liabilities	5,705	6,472
LONG TERM LIABILITIES:		
Long-term Rent Liability	396	497
Total Long-Term Liabilities	$ 396	$ 497
STOCKHOLDERS' STOCKHOLDERS' EQUITY:		
Common Stock of $0.01 par value per share; 200,000,000 shares authorized at December 31, 2021 and September 30, 2022; 14,820,727 and 14,080,383 shares issued at September 30, 2022 and December 31, 2021, respectively; 14,301,984 and 13,956,035 shares outstanding at September 30, 2022 and December 31, 2021, respectively	$ 139	$ 139
Additional Paid-in Capital	147,586	145,160
Accumulated Deficit	(139,566)	(111,141)
Total Stockholders' Equity	8,159	34,158
Total Liabilities and Stockholders' Equity	**$ 14,260**	**$ 41,127**

See accompanying notes to unaudited condensed consolidated financial statements.

AYALA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except share & per share amounts)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenues from licensing agreement	$ 91	$ 625	$ 587	$ 2,360
Cost of services	(91)	(625)	(497)	(2,360)
Gross profit	-	-	90	-
Operating expenses:				
Research and development	7,196	7,368	20,279	22,414
General and administrative	2,885	2,198	7,586	7,037
Operating loss	(10,081)	(9,566)	(27,775)	(29,451)
Financial Income (Loss), net	(1)	(63)	(141)	(177)
Loss before income tax	(10,082)	(9,629)	(27,916)	(29,628)
Taxes on income	(106)	(167)	(509)	(577)
Net loss	(10,188)	(9,796)	(28,425)	(30,205)
Net Loss per share, basic and diluted	$ (0.66)	$ (0.68)	$ (1.85)	$ (2.14)
Weighted average common shares outstanding, basic and diluted	**15,482,809**	**14,483,629**	**15,365,342**	**14,130,993**

See accompanying notes to unaudited condensed consolidated financial statements.

AYALA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)
(In thousands, except share and per share amounts)

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Number	Amount	Capital	Deficit	Equity
Balance as of December 31, 2020	12,728,446	$ 128	$ 109,157	$ (70,887)	$ 38,398
Share based compensation	36,990	-	1,964	-	1,964
Exercise of stock options	8,186	-	54	-	54
Proceeds from Issuance of common stocks and warrants, net of Issuance Cost of $1,665	333,333	3	23,319	-	23,322
Proceeds from Issuance of common stocks, net of Issuance Cost of $337	442,407	4	5,847		5,851
Net Loss	-	-	-	(30,205)	(30,205)
Balance as of September 30, 2021	**13,549,362**	**$ 135**	**140,341**	**$ (101,092)**	**$ 39,384**
Balance as of June 30, 2021	**13,092,925**	**131**	**133,925**	**(91,296)**	**42,760**
Share based compensation	11,844	-	545	-	545
Exercise of stock options	2,186	-	24	-	24
Proceeds from Issuance of common stocks net of Issuance Cost of $337	442,407	4	5,847	-	5,851
Net Loss	-	-	-	(9,796)	(9,796)
Balance as of September 30, 2021	**13,549,362**	**$ 135**	**$ 140,341**	**$ (101,092)**	**$ 39,384**
Balance as of December 31, 2021	**13,956,034**	**139**	**145,160**	**(111,141)**	**34,158**
Share based compensation	35,533	-	1,914	-	1,914
Proceeds from issuance of common stock, net of issuance costs of $16	310,417		512		512
Net Loss	-	-		(28,425)	(28,425)
Balance as of September 30, 2022	**14,301,984**	**$ 139**	**$ 147,586**	**$ (139,566)**	**$ 8,159**
Balance as of June 30, 2022	**13,984,622**	**139**	**146,602**	**(129,378)**	**17,363**
Share based compensation	11,845	-	516	-	516
Proceeds from issuance of common stock, net of issuance costs of $14	305,517	-	468	-	468
Net Loss	-	-	-	(10,188)	(10,188)
Balance as of September 30, 2022	**14,301,984**	**$ 139**	**$ 147,586**	**$ (139,566)**	**$ 8,159**

See accompanying notes to unaudited condensed consolidated financial statements.

AYALA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS
(Unaudited)
(In thousands)

	Nine Months Ended	
	September 30, 2022	**September 30, 2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net Loss	$ (28,425)	$ (30,205)
Adjustments to Reconcile Net Loss to Net Cash used in Operating Activities:		
Shared Based Compensation	$ 1,914	$ 1,964
Depreciation	121	140
(Increase) decrease in Prepaid Expenses and Other Assets	1,045	(1,546)
(Increase) decrease in Trade Receivables	(129)	308
Decrease in Trade Payables	(888)	(993)
Increase (Decrease) in other Accounts Payable	20	(232)
Net Cash used in Operating Activities	(26,342)	(30,564)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of Property and Equipment	-	(5)
Net Cash provided by (used in) Investing Activities	-	(5)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from Issuance of Shares, net	-	6,007
Issuance of shares and warrants, net	512	23,322
Exercise of Stock Options	-	54
Net Cash provided by Financing Activities	512	29,383
Decrease in Cash and Cash Equivalents and Restricted Bank Deposits	25,830	1,186
Cash and Cash Equivalents and Restricted Bank Deposits at Beginning of the period	37,339	42,370
Cash and Cash Equivalents and Restricted Bank Deposits at End of the period	11,509	$ 41,184
SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING ACTIVITIES		
Non-cash deferred issuance costs	$ -	$ 156
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION		
Cash Received for Interest	$ 63	$ -
Tax Paid in Cash	$ 182	$ 128

Reconciliation of cash, cash equivalents and restricted bank deposits

	September 30, 2022	**September 30, 2021**
Cash and Cash Equivalents	$ 11,195	$ 40,840
Restricted Bank Deposits	110	120
Restricted Bank Deposits in Other Assets	204	224
Cash and Cash Equivalents and Restricted Bank Deposits at End of the Period	$ 11,509	$ 41,184

See accompanying notes to unaudited condensed consolidated financial statements

NOTE 1—SIGNIFICANT ACCOUNTING POLICIES

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 4.

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.

Certain Transactions

On February 19, 2021, the Company entered into a Securities Purchase Agreement (the "2021 Purchase Agreement") with the purchasers named therein (the "Investors"). Pursuant to the 2021 Purchase Agreement, the Company agreed to sell (i) an aggregate of 333,333 shares of the Company's common stock (the "Common Stock"), par value $0.01 per share (the "Private Placement Shares"), together with warrants to purchase an aggregate of 116,666 shares of its 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 its 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.

In June 2021, the Company entered into an Open Market Sales Agreement, or the Sales Agreement, with Jefferies LLC, or Jefferies, as sales agent, pursuant to which the Company 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 (the "ATM"), under its registration statement on Form S-3 (File No. 333-256792) filed with the SEC on June 4, 2021 (the "ATM Registration Statement"). 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 its Common Stock. Pursuant to the Sales Agreement, during the year ended December 31, 2021, the Company sold a total of 827,094 shares of Common Stock for total net proceeds of approximately $10.0 million. During the three and nine months ended September 30, 2022, the Company sold a total of 305,517 and 310,417 shares of Common Stock for total net proceeds of approximately $468 thousand and $512 thousand, respectively.

NOTE 1—SIGNIFICANT ACCOUNTING POLICIES (continued):

Going Concern

The Company has incurred recurring losses since inception as a research and development organization and has an accumulated deficit of $139.6 million as of September 30, 2022. For the nine months ended September 30, 2022, the Company used approximately $26.3 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 September 30, 2022, the Company had approximately $11.5 million in cash and cash equivalents and restricted bank deposits, 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 condensed 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 unaudited condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern. Therefore, the unaudited condensed consolidated financial statements for the three and nine months ended September 30, 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.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") for interim financial information. Accordingly, they do not include all the information and notes required by GAAP for annual financial statements. In the opinion of management, all adjustments (of a normal recurring nature) considered necessary for a fair statement of the results for the interim periods presented have been included. Operating results for the interim period are not necessarily indicative of the results that may be expected for the full year.

These unaudited condensed consolidated financial statements should be read in conjunction with the consolidated financial statements for the year ended December 31, 2021, included in the Company's Annual Report on Form 10-K filed for the year ended December 31, 2021 (the "Annual Report") with the Securities and Exchange Commission (the "SEC").. The Company's significant accounting policies have not changed materially from those included in Note 2 of the Company's consolidated financial statements for the year ended December 31, 2021, included in the Company's Annual Report, unless otherwise stated.

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.

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.

The calculation of basic and diluted loss per share includes 1,333,333 warrants with an exercise price of $0.01 for the three and nine months ended September 30, 2022.

The calculation of basic and diluted loss per share includes 1,333,333 and 1,091,158 weighted average warrants with an exercise price of $0.01 for the three and nine month ended September 30, 2021, respectively.

NOTE 1—SIGNIFICANT ACCOUNTING POLICIES (continued):

The calculation of diluted loss per share does not include 583,332 Warrants and 1,141,927 options outstanding to purchase common stock with anti-dilutive effect for the three and nine months ended September 30, 2022.

The calculation of diluted loss per share does not include 583,332 Warrants and 913,194 options outstanding to purchase common stock with anti-dilutive effect for the three and nine month ended September 30, 2021.

Newly Issued Accounting Pronouncements

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 February 2016, the FASB issued ASU 2016-02—Leases, requiring the recognition of lease assets and liabilities on the balance sheet. The standard:

(a)clarifies the definition of a lease; (b) requires a dual approach to lease classification similar to current lease classifications; and (c) causes lessees to recognize leases on the balance sheet as a lease liability with a corresponding right-of-use asset for leases with a lease-term of more than 12 months. The standard is effective for the Company for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. The Company estimates the change in liabilities of $4.3 million and change in assets of $4.2 million.

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. Early adoption is permitted. The Company believes Adoption of the standard will 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 believes Adoption of the standard will not have a material impact on the financial statements.

Recently issued and adopted pronouncements

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 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), which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. This guidance also eliminates the treasury stock method to calculate diluted earnings per share for convertible instruments and requires the use of the if-converted method. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. Early adoption is permitted for fiscal years beginning after December 15, 2020. The Company elected to early adopt ASU 2020-06 on January 1, 2022. Adoption of the standard did not have a material impact on the financial statements.

NOTE 2—REVENUES

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 must 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 expects to be entitled to receive in exchange for those goods or services.

In December 2018, the Company entered into an evaluation, option and license agreement (the “Novartis Agreement”) with Novartis International Pharmaceutical Limited (“Novartis”) for which the Company is paid for its research and development costs.

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

Revenue associated with the research and development services in the amounts of approximately $91 thousand and $0.6 million were recognized in the three months ended September 30, 2022, and 2021, respectively and $0.6 million and $2.4 million were recognized in the nine months ended September 30, 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 relative to the total estimated expenses. The Company periodically reviews and updates its estimates, when appropriate, which may adjust revenue recognized for the period. Most of the company's revenues derive from the Novartis Agreement, for which revenues consist of reimbursable research and development costs. 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.

NOTE 3—TAX

The Company has reviewed the tax positions taken, or to be taken, in its tax returns for all tax years currently open to examination by a taxing authority. As of September 30, 2022 and 2021, the Company has recorded an uncertain tax position liability exclusive of interest and penalties of $1.3 million and $0.9 million, respectively, which were classified as other long-term liabilities. As of September 30, 2022 and 2021, the Company accrued interest related to uncertain tax positions of $71 thousand and $46 thousand, respectively. The interest is recorded as part of financial expenses. These uncertain tax positions would impact the Company's effective tax rate, if recognized. A reconciliation of the Company's unrecognized tax benefits is below:

	Nine months ended September 30, 2022	Year ended December 31, 2021
	(in thousands)	
Uncertain tax position at the beginning of the period	$ 858	$ 581
Additions for uncertain tax position of prior years (foreign exchange and interest)	19	17
Additions for tax positions of current period	470	260
Uncertain tax position at the end of the period	$ 1,347	$ 858

The Company files U.S. federal, various U.S. state and Israeli income tax returns. The associated tax filings remain subject to examination by applicable tax authorities for a certain length of time following the tax year to which those filings relate. In the United States and Israel, the 2017 and subsequent tax years remain subject to examination by the applicable taxing authorities as of September 30, 2022.

NOTE 4—COMMITMENTS AND CONTINGENT

Liabilities Lease

In January 2019, the Subsidiary 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 with finance in in the amount of approximately $0.5 million paid in arrears for of leasehold improvements. The financing was recorded as a Long-Term Rent Liability. In September 2020, the Company signed a new lease agreement. The term of the lease is for 30 months. The minimum rental payments under operating leases as of September 30, 2022, are as follows (in thousands):

Year ended December 31,	
2022	103
2023	409
2024	145
	$ 657

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

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 affect 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.

NOTE 4—COMMITMENTS AND CONTINGENT (continued):

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.

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 (a) 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 were fully borne by Novartis.

NOTE 4—COMMITMENTS AND CONTINGENT (continued):

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 was not able to, 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 was obligated to pay the Company a low eight figure option exercise fee in order to exercise its option and activate its license, upon which the Company would have been 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 were 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 owned 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 maintain first right to prosecute and maintain any patents licensed to Novartis, both before and after its exercise of its option. The Company maintained 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.

NOTE 5—SUBSEQUENT EVENTS

Agreement and Plan of Merger

On October 18, 2022, the Company entered into an Agreement and Plan 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") will be 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, will be 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 will own approximately 62.5 % of the combined company's outstanding common stock and Advaxis stockholders will own approximately 37.5%, subject to the terms of the Merger Agreement.

Consummation of the Merger is subject to certain closing conditions, including, among other things, (i) approval of the Merger Agreement and the Transactions by the Company's stockholders (the "Ayala Stockholder Approval"); (ii) the effectiveness of a registration statement on Form S-4 filed by Advaxis registering the shares of Advaxis Common Stock to be issued in connection with the Merger; (iii) receipt of all required state securities or "blue sky" authorizations for the issuance of such shares of Advaxis Common Stock, except for such authorizations the lack of receipt of which would not reasonably be expected to have a material adverse impact on any of the parties to the Merger Agreement or their respective affiliates; (iv) the absence of any law or judgment of a governmental entity of competent jurisdiction that is in effect and restrains, enjoins, or otherwise prohibits consummation of the Merger; (v) the absence of a material adverse effect on the business, financial condition or results of operations of, respectively, (a) the Company and its subsidiaries, taken as a whole or (b) Advaxis and its subsidiaries, taken as a whole; (vi) the accuracy of the Company's and Advaxis's representations and warranties, subject to specified materiality qualifications; (vii) compliance by the Company and Advaxis with its respective covenants in the Merger Agreement in all material respects; and (viii) delivery of customary closing documents, including a customary officer certificate from the Company and Advaxis.

The Merger Agreement provides that the payment of a $600,000 termination fee will be payable to either sides if the merger does not go through.

Closing of the Merger is expected to occur during the first quarter of 2023. The representations, warranties, agreements and covenants of the parties set forth in the Merger Agreement will terminate at the Closing.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (the "Annual Report"), our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage oncology company focused on developing and commercializing small molecule therapeutics for patients suffering from rare and aggressive cancers, primarily in genetically defined patient populations. Our differentiated development approach is predicated on identifying and addressing tumorigenic drivers of cancer, through a combination of our bioinformatics platform and next-generation sequencing to deliver targeted therapies to underserved patient populations. Our current portfolio of product candidates, AL101 and AL102, targets the aberrant activation of the Notch pathway using gamma secretase inhibitors. Gamma secretase is the enzyme responsible for Notch activation and, when inhibited, turns off the Notch pathway activation. Aberrant activation of the Notch pathway has long been implicated in multiple solid tumor and hematological cancers and has often been associated with more aggressive cancers. In cancers, Notch is known to serve as a critical facilitator in processes such as cellular proliferation, survival, migration, invasion, drug resistance and metastatic spread, all of which contribute to a poorer patient prognosis. AL101 and AL102 are designed to address the underlying key drivers of tumor growth, and our initial Phase 2 clinical data of AL101 suggest that our approach may address shortcomings of existing treatment options. We believe that our novel product candidates, if approved, have the potential to transform treatment outcomes for patients suffering from rare and aggressive cancers.

Our product candidates, AL101 and AL102, are being developed as potent, selective, small molecule gamma secretase inhibitors, or GSIs. We obtained an exclusive, worldwide license to develop and commercialize AL101 and AL102 from Bristol-Myers Squibb Company, or BMS, in November 2017. BMS evaluated AL101 in three Phase 1 studies involving more than 200 total subjects and AL102 in a single Phase 1 study involving 36 subjects with various cancers who had not been prospectively characterized for Notch activation, and to whom we refer to as unselected subjects. While these Phase 1 studies did not report statistically significant overall results, clinical activity was observed across these studies in cancers in which Notch has been implicated as a tumorigenic driver.

We are currently evaluating AL102, our oral GSI for the treatment of desmoid tumors, in our RINGSIDE Phase 2/3 pivotal study. In February 2022, Part A completed enrollment of 42 patients with progressive desmoid tumors in three study arms across three doses of AL102. We reported initial interim data from Part A in July 2022 with additional data released at a medical conference in September 2022, showing efficacy across all cohorts, with early tumor responses that deepened over time. AL102 was well tolerated. We have initiated Part B of RINGSIDE (Phase 3), and are enrolling patients in an open label extension study. Part B of the study is a double-blind placebo-controlled study enrolling up to 156 patients with progressive disease, randomized between AL102 or placebo. The study's primary endpoint will be progression free survival, or PFS with secondary endpoints including ORR, duration of response, or DOR and patient reported QOL measures. On September 27, 2022, we announced that FDA has granted Fast Track designation for AL102 for the treatment of progressing desmoid tumors. The FDA grants Fast Track designation to facilitate development and expedite the review of therapies with the potential to treat a serious condition where there is an unmet medical need. A therapeutic that receives Fast Track designation can benefit from early and frequent communication with the agency, in addition to a rolling submission of the marketing application, with potential pathways for expedited approval that have the objective of getting important new therapies to patients more quickly.

In addition, we collaborated with Novartis International Pharmaceutical Limited, or Novartis, to develop AL102 for the treatment of multiple myeloma, or MM, in combination with Novartis' B-cell maturation antigen, or BCMA, targeting therapies. 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.

We are currently concluding a Phase 2 ACCURACY trial for the treatment of recurrent/metastatic adenoid cystic carcinoma, or R/M ACC, in subjects with progressive disease and Notch-activating mutations. We refer to this trial as the ACCURACY trial. We use next-generation sequencing, or NGS, to identify patients with Notch-activating mutations, an approach that we believe will enable us to target the patient population with cancers that we believe are most likely to respond to and benefit from AL101 treatment. We chose to initially target R/M ACC based on our differentiated approach, which is comprised of: data generated in a Phase 1 study of AL101 in unselected, heavily pretreated subjects conducted by BMS, our own data generated in patient-derived xenograft models, our bioinformatics platform and our expertise in the Notch pathway.

If approved, we believe that AL101 has the potential to be the first therapy approved by the FDA for patients with R/M ACC and address the unmet medical need of these patients. AL101 was granted Orphan Drug Designation in May 2019 for the treatment of adenoid cystic carcinoma, or ACC, and fast track designation in February 2020 for the treatment of R/M ACC. We reported interim data regarding the most recent safety efficacy, pharmacokinetics, and pharmacodynamics data from Phase 2 of the ACCURACY trial in June 2022.

As part of our efforts to focus our resources on the more advanced programs and studies including the RINGSIDE study in desmoid tumors and the ACCURACY study for ACC, we elected to discontinue the TENACITY trial, which was evaluating AL101 as a monotherapy in an open-label Phase 2 clinical trial for the treatment of patients with Notch-activated R/M TNBC.

We were incorporated as a Delaware corporation on November 14, 2017, and our headquarters is located in Rehovot, Israel. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital and conducting research and development activities for our product candidates. To date, we have funded our operations primarily through the sales of common stock and convertible preferred stock.

We have incurred significant net operating losses in every year since our inception and expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year and could be substantial. Our net losses were approximately $10.2 million and $28.4 million for the three and nine months ended September 30, 2022, respectively. As nine months ended September 30, 2022, we had an accumulated deficit of $139.6 million. We anticipate that our expenses will increase significantly as we:

- pay for transaction costs and expenses related to our potential Merger;
- advance our development of AL101 for the treatment of R/M ACC;
- advance our Phase 2/3 RINGSIDE pivotal trial of AL102 for the treatment of desmoid tumors, or obtain and conduct clinical trials for any other product candidates;
- assuming successful completion of our Phase 2 ACCURACY trial of AL101 for the treatment of R/M ACC, may be required by the FDA to complete Phase 3 clinical trials to support submission of a New Drug Application, or NDA, of AL101 for the treatment of R/M ACC;
- establish a sales, marketing and distribution infrastructure to commercialize AL101 and/or AL102, if approved, and for any other product candidates for which we may obtain marketing approval;
- maintain, expand, protect and enforce our intellectual property portfolio;
- hire additional staff, including clinical, scientific, technical, regulatory operational, financial, commercial and other personnel, to execute our business plan; and
- add clinical, scientific, operational, financial and management information systems and personnel to support our product development and potential future commercialization efforts, and to enable us to operate as a public company.

We do not expect to generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for a product candidate. Additionally, we currently use contract research organizations, or CROs, to carry out our clinical development activities. Furthermore, we incur additional costs associated with operating as a public company. As a result, we will need substantial additional funding to support our continuing operations, pursue our growth strategy and continue as a going concern. Until such time as we can generate significant revenue from product sales, if ever, we expect to fund our operations through public or equity offerings or debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. We may, however, be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our current or any future product candidates.

Because of the numerous risks and uncertainties associated with therapeutics product development, we are unable to predict accurately the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we can generate revenue from product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of September 30, 2022, we had cash and cash equivalents and restricted bank deposits of approximately $11.5 million. Due to the uncertainty in securing additional funding, and the insufficient amount of cash and cash equivalent resources on December 31, 2021, we have concluded that substantial doubt exists with respect to our ability to continue as a going concern within one year after the date of the filing of this Quarterly Report on Form 10-Q. See “— Liquidity and Capital Resources.” Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock, and it may be more difficult for us to obtain financing. If potential collaborators decline to do business with us or potential investors decline to participate in any future financings due to such concerns, our ability to increase our cash position may be limited. We will need to generate significant revenues to achieve profitability, and we may never do so. Because of the numerous risks and uncertainties associated with the development of our current and any future product candidates, the development of our platform and technology and because the extent to which we may enter into collaborations with third parties for development of any of our product candidates is unknown, we are unable to estimate the amounts of increased capital outlays and operating expenses required for completing the research and development of our product candidates.

If we raise additional funds through marketing and distribution arrangements and other collaborations, strategic alliances, and licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, intellectual property, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate product candidate development programs or future commercialization efforts, grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves or discontinue operations.

Agreement and Plan of Merger

On October 18, 2022, we entered into an Agreement and Plan of Merger, or the Merger Agreement, with Advaxis, Inc., a Delaware corporation, or Advaxis, and Doe Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of Advaxis, or Merger Sub, pursuant to which Merger Sub will merge with and into us, with us as the surviving corporation and a wholly-owned subsidiary of Advaxis, or the Merger, and, collectively with the other transactions contemplated by the Merger Agreement, the Transactions. As a result of the Merger, Advaxis will be renamed "Ayala Pharmaceuticals, Inc." Closing of the Merger is expected to occur during the first quarter of 2023. The representations, warranties, agreements and covenants of the parties set forth in the Merger Agreement will terminate at the Closing.

Voting and Support Agreements

On October 18, 2022, concurrently with the execution of the Merger Agreement, Advaxis entered into voting and support agreements, each a Voting Agreement, and together the Voting Agreements, with each of Israel Biotech Fund I, L.P. and aMoon Growth Fund Limited Partnership (each in its capacity as our stockholder), pursuant to which, among other things and subject to the terms and conditions therein, each such stockholder agreed to vote all shares of our capital stock that it beneficially owns, representing approximately 22.4 % and 20.3 %, respectively, of our total current outstanding voting power, in favor of, among other things, the approval and adoption of the Merger Agreement and the Transactions, including the Merger. The Voting Agreements provide that, in the event of a Company Change in Recommendation (as defined in the Merger Agreement), the number of shares of our capital stock subject to the Voting Agreements shall only be 30% of our total current outstanding voting power, and the number of shares of our capital stock of each of Israel Biotech Fund I, L.P. and aMoon Growth Fund Limited Partnership subject to the Voting Agreements shall be reduced proportionately based on the number of shares of our capital stock of subject thereto.

Bristol-Myers Squibb License Agreements

In November 2017, we entered into an exclusive worldwide license agreement with Bristol-Myers Squibb Company, or BMS, for AL101 and AL102, each a small molecule gamma secretase inhibitor in development for the treatment of cancers. Under the terms of the license agreement, we have licensed the exclusive worldwide development and commercialization rights for AL101 (previously known as BMS-906024) and AL102 (previously known as BMS-986115).

We are responsible for all future development and commercialization of AL101 and AL102. In consideration for the rights granted under the agreement, we 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, which converted to 562,964 shares of common stock in connection with our initial public offering, or IPO. We are obligated to pay BMS up to approximately $142 million in the aggregate upon the achievement of certain clinical development or regulatory milestones and up to $50 million in the aggregate upon the achievement of certain commercial milestones by each product containing the licensed BMS compounds. In addition, we are obligated to pay BMS tiered royalties ranging from a high single-digit to a low teen percentage on worldwide net sales of all products containing the licensed BMS compounds.

BMS has the right to terminate the BMS License Agreement in its entirety upon written notice to us (a) for insolvency-related events involving us, (b) for our material breach of the BMS License Agreement if such breach remains uncured for a defined period of time, (c) for our failure to fulfill our 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 we or our affiliates commence any action challenging the validity, scope, enforceability or patentability of any of the licensed patent rights. We have the right to terminate the BMS License Agreement (a) for convenience upon prior written notice to BMS, the length of notice dependent on whether a BMS Licensed Product 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 we 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 us for convenience or by BMS, we grant an exclusive, non-transferable, sublicensable, worldwide license to BMS under certain of our 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 us 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.

Novartis License Agreements

In December 2018, we entered into an evaluation, option and license agreement, or the Novartis Agreement, with Novartis International Pharmaceutical Limited, or Novartis, pursuant to which we granted Novartis an exclusive option to obtain an exclusive license to research, develop, commercialize and manufacture AL102 for the treatment of multiple myeloma.

We supplied Novartis quantities of AL102, products containing AL102 and certain other materials for purposes of conducting evaluation studies not comprising human clinical trials during the option period, together with our know-how as may have been reasonably be necessary in order for Novartis to conduct such evaluation studies. Novartis agreed to reimburse us for all such expenses.

At any time during the option term, Novartis may have exercised its option by payment of a low eight figure option exercise fee. If Novartis exercised its option, it would have been obligated to pay us up to an additional $245 million upon the achievement of certain clinical development and commercial milestones. In addition, Novartis was obligated to pay us tiered royalties at percentages ranging from a mid-single digit to a low double-digit percentage on worldwide net sales of products licensed under the agreement.

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.

Financial Overview

Except as described below, there have been no material changes from the disclosure provided under the caption “Components of Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2021.

Results of Operations

Comparison of the three months and nine months ended September 30, 2022, and 2021

The following table summarizes our results of operations for three and nine months ended September 30, 2022, and 2021

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenues from licensing agreement	$ 91	$ 625	$ 587	$ 2,360
Cost of services	(91)	(625)	(497)	(2,360)
Gross profit	—	—	90	—
Operating expenses:				
Research and development	7,196	7,368	20,279	22,414
General and administrative	2,885	2,198	7,586	7,037
Operating loss	(10,081)	(9,566)	(27,775)	(29,451)
Financial Income (Loss), net	(1)	(63)	(141)	(177)
Loss before income tax	(10,082)	(9,629)	(27,916)	(29,628)
Taxes on income	(106)	(167)	(509)	(577)
Net loss	(10,188)	(9,796)	(28,425)	(30,205)
Net Loss per share, basic and diluted	$ (0.66)	$ (0.68)	$ (1.85)	$ (2.14)
Weighted average common shares outstanding, basic and diluted	**15,482,809**	**14,483,629**	**15,365,342**	**14,130,993**

Revenue

To date, we have not generated any revenue from product sales, and we do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for our product candidates are successful and result in regulatory approval and successful commercialization efforts, we may generate revenue from product sales in the future. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates.

For the three months ended of September 30, 2022 and 2021, we recognized approximately $ 91 thousand and $0.6 million in revenue, respectively, mainly as a result of the termination of the Novartis Agreement.

For the nine months ended of September 30, 2022 and 2021, we recognized approximately $0.6 million and $2.4 million in revenue, respectively, mainly as a result of the termination of the Novartis Agreement.

Refer to Note 2 to our unaudited condensed consolidated financial statements for information regarding our recognition of revenue under the Novartis Agreement.

Research and Development

Research and development expenses consist primarily of costs incurred for our research activities, including the development of and pursuit of regulatory approval of our lead product candidates, AL101 and AL102, which include:

- employee-related expenses, including salaries, benefits and stock-based compensation expense for personnel engaged in research and development functions;
- expenses incurred in connection with the preclinical and clinical development of our product candidates, including under agreements with CROs, investigative sites and consultants;
- costs of manufacturing our product candidates for use in our preclinical studies and clinical trials, as well as manufacturers that provide components of our product candidates for use in our preclinical and current and potential future clinical trials;
- costs associated with our bioinformatics platform;
- consulting and professional fees related to research and development activities;
- costs related to compliance with clinical regulatory requirements; and
- Facility costs and other allocated expenses, which include expenses for rent and maintenance of our facility, utilities, depreciation and other supplies.

We expense research and development costs as incurred. Our external research and development expenses consist primarily of costs such as fees paid to consultants, contractors and CROs in connection with our preclinical and clinical development activities. We typically use our employee and infrastructure resources across our development programs and we do not allocate personnel costs and other internal costs to specific product candidates or development programs with the exception of the costs to manufacture our product candidates.

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2022	2021	$ Change	% Change	2022	2021	$ Change	% Change
	($ in thousands)							
Research and Development	7,196	7,368	(172)	(2)%	20,279	22,414	(2,135)	(10)%

Research and development expenses were $7.2 million for the three months ended September 30, 2022 compared to $7.4 million for the three months ended September 30, 2021, an decrease of $0.2 million. Research and development expenses were $20.3 million for the nine months ended September 30, 2022 compared to $22.4 million for the nine months ended September 30, 2021, a decrease of $2.1 million. The decrease was due to the termination of the TENACITY trial and winding down of the ACCURACY trial.

The following table summarizes our research and development expenses by product candidate or development program for the three and nine months ended September 30, 2022 and 2021:

	Three Months Ended		Nine Months Ended	
	September 30, 2022	September 30, 2021	September 30, 2022	September 30, 2021
Program-Specific Costs:				
AL 101				
ACC	940	3,415	2,703	11,351
TNBC[(1)]	926	1,966	3,460	5,926
General Expenses	728	693	1,904	1,496
AL 102				
General Expenses	71	8	251	32
Desmoid	4,531	1,286	11,961	3,609
Total Research and Development Expenses	$ 7,196	$ 7,368	$ 20,279	$ 22,414

(1) As part of our efforts to focus our resources on the more advanced programs and studies including the RINGSIDE study in desmoid tumors and the ACCURACY study for ACC, we elected to discontinue the TENACITY trial, which was evaluating AL101 as a monotherapy in an open-label Phase 2 clinical trial for the treatment of patients with Notch-activated R/M TNBC.

We expect our research and development expenses to increase for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, including investments in manufacturing, as our programs advance into later stages of development and as we conduct additional clinical trials.

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2022	2021	$ Change	% Change	2022	2021	$ Change	% Change
	($ in thousands)							
General and Administrative	2,885	2,198	687	31%	7,586	7,037	549	8%

General and administrative expenses were $2.9 million for the three months ended September 30, 2022 compared to 2.2 million for the three months ended September 30, 2021, an increase of $0.7 million. General and administrative expenses were $7.6 million for the nine months ended September 30, 2022 compared to $7.0 million for the nine months ended September 30, 2021, an increase of $0.5 million.

Financial Loss, net

Financial loss, net was $63 thousand for the three months ended September 30, 2021 compared to the financial income, net of $1 thousand for the three months ended September 30, 2022. Financial loss, net was $177 thousand for the nine months ended September 30, 2021 and $141 thousand for the same period in 2022.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. Our net losses were approximately $10.2 million and $28.4 million for the three and nine months ended September 30, 2022, respectively. As of September 30, 2022, we had an accumulated deficit of $139.6 million.

On May 12, 2020, we completed the sale of shares of our common stock in our IPO. In connection with the IPO, we issued and sold 3,940,689 shares of common stock, including 274,022 shares associated with the partial exercise on June 4, 2020 of the underwriters' option to purchase additional shares, at a price to the public of $15.00 per share, resulting in net proceeds to us of approximately $52.2 million after deducting underwriting discounts and commissions and estimated offering expenses payable by us. All shares issued and sold were registered pursuant to a registration statement on Form S-1 (File No. 333-236942), as amended, declared effective by the SEC, on May 7, 2020 (the "IPO Registration Statement").

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 sell (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.

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 (the "ATM"), under our registration statement on Form S-3 (File No. 333-256792) filed with the SEC on June 4, 2021 (the "ATM Registration Statement"). 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 year ended December 31, 2021, we sold a total of 827,094 shares of common stock for total net proceeds of approximately $10.0 million. During the three and nine months ended September 30, 2022, the Company sold a total of 305,517 and 310,417 shares of Common Stock for total net proceeds of approximately $468 thousand and $517 thousand, respectively.

The exercise price and the number of shares of common stock issuable upon exercise of each Private Placement Warrant are subject to adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the common stock. In addition, in certain circumstances, upon a fundamental transaction, a holder of Common Warrants will be entitled to receive, upon exercise of the Common Warrants, the kind and amount of securities, cash or other property that such holder would have received had they exercised the Private Placement Warrants immediately prior to the fundamental transaction. The Pre-Funded Warrants will be automatically exercised on cashless basis upon the occurrence of a fundamental transaction. Each Common Warrant is exercisable from the date of issuance and has a term of three years and each Pre-Funded Warrant is exercisable from the date of issuance and has a term of ten years. Pursuant to the 2021 Purchase Agreement, we registered the Private Placement Shares and Private Placement Warrants for resale by the Investors on a registration statement on Form S-3 (the "Private Placement Registration Statement").

As of September 30, 2022, we had cash and cash equivalents and restricted bank deposits of approximately $11.5 million.

Cash Flows

The following table summarizes our cash flow for the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,	
	2022	2021
Cash Flows provided by (used in):	($ in thousands)	
Operating Activities	(26,342)	(30,564)
Investing Activities	-	(5)
Financing Activities	512	29,383
Net increase (decrease) in cash and cash equivalents and short-term restricted bank deposits	(25,830)	(1,186)

Operating Activities

Net cash used in operating activities during the nine months ended September 30, 2022 of approximately $26.3 million was primarily attributable to our net loss of $29.7 million, the decrease in our prepaid expenses of $1.5 million, and the decrease in other accounts payables of $0.4 million, partially offset by stock-based compensation of $1.9 million.

Net cash used in operating activities during the nine months ended September 30, 2021 of $30.6 million was primarily attributable to our net loss of $30.2 million, adjusted for non-cash expenses of $0.8 million.

Investing Activities

We did not have any cash provided by investing activities during the nine months ended September 30, 2022. Net cash used by investing activities of $5 thousand as of September 30, 2021 was primarily to purchase property and equipment.

Financing Activities

Net cash provided by financing activities during the nine months ended September 30, 2022 of $512 thousand was attributable to the Private Placement, net of issuance costs, and sales pursuant to the ATM.

Net cash provided by financing activities during the nine months ended September 30, 2021 of $ 29.4 million was primarily attributable to the Private Placement, net of issuance costs.

Funding Requirements

Our future capital requirements are difficult to forecast and will depend on many factors, including our ability to consummate the Merger; if the Merger is not completed, the timing and nature of any other strategic transactions that we undertake. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development for, initiate later-stage clinical trials for, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. Furthermore, we incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

As of September 30, 2022, we had cash and cash equivalents and restricted cash equivalents of $11.5 million. We evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the audited consolidated financial statements are issued. Due to the uncertainty in securing additional funding, and the insufficient amount of cash and cash equivalent resources at September 30, 2022, we have concluded that substantial doubt exists with respect to our ability to continue as a going concern within one year after the date of the filing of this Report on Form 10-Q. Our future capital requirements will depend on many factors, including:

- the costs of consummating the Merger and our ability to consummate the Merger;
- the costs of conducting future clinical trials of AL101 and AL102;
- the cost of manufacturing additional material for future clinical trials of AL101 and AL102;

- the scope, progress, results and costs of discovery, preclinical development, laboratory testing and clinical trials for other potential product candidates we may develop or acquire, if any;

- the costs, timing and outcome of regulatory review of our product candidates;

- the achievement of milestones or occurrence of other developments that trigger payments under any current or future license, collaboration or other agreements;

- the costs and timing of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;

- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;

- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining, protecting and enforcing our intellectual property rights and defending intellectual property-related claims;

- the severity, duration and impact of the COVID-19 pandemic, which may adversely impact our business and clinical trials;

- our headcount growth and associated costs as we expand our business operations and our research and development activities; and

- the costs of operating as a public company.

Conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interests may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect your rights as a common stockholder. Any debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business.

If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, such as our former agreement with Novartis, we may have to relinquish valuable rights to our technologies, intellectual property, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favourable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations

There have been no material changes to our contractual obligations from those described in our Annual Report on Form 10-K for the year ended December 31, 2021.

Critical Accounting Policies

Our management's discussion and analysis of financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience, known trends and events, and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions.

There have been no significant changes in our critical accounting policies as discussed in our Form 10-K, except as described in Note 1 to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Emerging Growth Company Status

The Jumpstart Our Business Start-ups Act of 2012, or the JOBS Act, permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have elected to use this extended transition period under the JOBS Act. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of our financials to those of other public companies more difficult.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, or December 31, 2025, (b) in which we have total annual gross revenues of $1.235 billion or more, or (c) in which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value of our outstanding common stock held by non-affiliates exceeds $700 million as of last business day of our most recently completed second fiscal quarter, and (2) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

Not applicable.

Item 4. Controls and Procedures.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our principal executive officer and principal financial officer concluded that, as of September 30, 2022, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended September 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not subject to any material legal proceedings.

Item 1A. Risk Factors.

Other than as set forth below, there have been no material changes to our risk factors as previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021.

The announcement and pendency of the Merger could have an adverse effect on our business.

On October 18, 2022, we entered into the Merger Agreement with Advaxis and Merger Sub, pursuant to which Merger Sub will merge with and into us, with us as the surviving corporation and a wholly-owned subsidiary of Advaxis. Uncertainty about the effect of the Merger on our employees, independent contractors, principal investigators, contract research organizations, or CROs, consultants, vendors, and any other third parties that we engage may have an adverse effect on our business, financial condition and results of operations regardless of whether the Merger is consummated. These risks to the business include the following, all of which could be exacerbated by a delay in the completion of the Merger:

- the diversion of significant management time and resources towards the completion of the Merger;
- difficulties with maintaining relationships with principal investigators, CROs, consultants, vendors, and any other third parties;
- diminished ability to retain and hire key personnel;
- the inability to pursue alternative business opportunities or make appropriate changes to our business because of requirements in the Merger Agreement that we conduct our business in the ordinary course consistent with past practice and not engage in certain kinds of transactions prior to the completion of the Merger;
- litigation related to the Merger and the costs related thereto; and
- the incurrence of significant costs, expenses and fees for professional services and other transaction costs in connection with the Merger.

Failure to consummate the Merger within the expected timeframe or at all could have a material adverse impact on our business, financial condition and results of operations.

There can be no assurance that the Merger will occur. Consummation of the Merger is subject to certain conditions and there can be no assurance that these conditions will be satisfied in a timely manner or at all. The Merger Agreement also contains termination rights for both us and Advaxis. If we are required to make these payments, doing so may materially adversely affect our business, financial condition and results of operations. See "*– Failure to consummate the Merger may result in the terminating party paying a termination fee to the non-terminating party and could harm the terminating party's common stock price and its future business and operations.*" In addition, if the Merger is not completed, and there are no other parties willing and able to acquire us or we are unable to obtain funding sufficient for us to continue our current operations, we will have to delay, reduce or discontinue our product development programs and may have to wind-down our operations. Also, we will continue to incur significant costs, expenses and fees for professional services and other transaction costs in connection with the Merger for which we will have received little or no benefit if the Merger is not completed. Many of the fees will be payable by us even if the Merger is not completed and may relate to activities that we would not have undertaken other than to complete the Merger. Further, a failed transaction may result in negative publicity and a negative impression of us in the investment community. Finally, any disruption to our business resulting from the announcement and pendency of the Merger, including any adverse changes in our relationships with our employees, independent contractors, principal investigators, CROs, consultants, vendors, and any other third parties, could continue or accelerate in the event of a failed transaction.

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

The terms of the Merger Agreement prohibit each of us and Advaxis from soliciting or engaging in discussions with third parties regarding alternative acquisition proposals, except in limited circumstances when such party's board of directors determines in good faith that an unsolicited acquisition proposal constitutes or could reasonably be expected to lead to a superior proposal and that failure to take such action would reasonably be expected to be inconsistent with its fiduciary duties under applicable law. In addition, if the Merger Agreement is terminated by us or Advaxis under certain circumstances, including because of a decision by either company's board of directors to accept a superior proposal, such company would be required to pay the other a termination fee of $600,000. This termination fee may discourage third parties from submitting alternative takeover proposals to either company or its stockholders and may cause such company's board of directors to be less inclined to recommend an alternative proposal.

Failure to consummate the Merger may result in the terminating party paying a termination fee to the non-terminating party and could harm the terminating party's common stock price and its future business and operations.

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

- if the Merger Agreement is terminated under certain circumstances, the terminating party will be required to pay the non-terminating party a termination fee of $600,000; and

- the price of the terminating party's common stock may decline and remain volatile.

If the Merger does not close for any reason, our board of directors may elect to, among other things, attempt to complete another strategic transaction, attempt to sell or otherwise dispose of our various assets, dissolve or liquidate our assets, declare bankruptcy or seek to continue to operate our business. If we seek another strategic transaction or attempt to sell or otherwise dispose of our various assets, there is no assurance that we will be able to do so, that the terms would be equal to or superior to the terms of the Merger or as to the timing of such transaction. If we decide to dissolve and liquidates our assets, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurance as to the amount or timing of available cash left to distribute to stockholders after paying our debts and other obligations and setting aside funds for reserves. If we were to seek to continue our business, we would need to obtain funds sufficient to continue our operations and planned development of our product candidates. We cannot guarantee that we will be able to obtain any or sufficient funding or that such funding, if available, will be obtainable on terms satisfactory to us.

If the Merger is not consummated, we may be unable to retain the services of key remaining members of our management teams and, as a result, may be unable to seek or consummate another strategic transaction, properly dissolve and liquidate our assets, raise funds or continue our business.

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

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

In the event of a dissolution and liquidation, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision since the amount of cash available for distribution continues to decrease as we fund our operations and incur professional services and other transaction costs in preparation for the consummation of the Merger. Further, the Merger Agreement contains certain termination rights for each party, and provides that, upon termination under specified circumstances, either party may be required to pay the other a termination fee of $600,000, which would further decrease such company's available cash resources. If our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. Our commitments and contingent liabilities may include (i) regulatory and clinical obligations remaining under our clinical trials; (ii) obligations under our employment, separation and retention agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control; and (iii) potential litigation against us, and other various claims and legal actions arising in the ordinary course of business. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of our liquidation, dissolution or winding up.

Our directors and executive officers have interests in the Merger that are different from our stockholders, and that may influence them to support or approve the Merger without regard to our stockholders' interests.

Our directors and executive officers have interests in the Merger that are different from, or in addition to, the interests of other Ayala stockholders generally. These interests with respect to our directors and executive officers may include, among others, that certain of our directors and executive officers have options, subject to vesting, to purchase shares of Ayala common stock which, at the effective time of the Merger, will be converted into and become fully vested options to purchase shares of the common stock of the combined company; certain of our excutive officers will be entitled to severance benefits in connection with the Merger; and all of our directors and executive officers are entitled to certain indemnification and liability insurance coverage pursuant to the terms of the Merger Agreement. Further, certain current members of our board of directors will continue as directors of the combined company after the effective time of the Merger, and, following the closing of the Merger, will be eligible to be compensated as non-employee directors of the combined company pursuant to the Advaxis non-employee director compensation policy that is expected to remain in place following the effective time of the Merger. As a result of these interests, our directors and executive officers may have a greater interest in supporting or approving the Merger than our other stockholders.

The members of our board of directors were aware of and considered those interests, among other matters, in reaching their decisions to approve and adopt the Merger Agreement, approve the Merger, and recommend the approval of the Merger Agreement to Ayala stockholders. These interests, among other factors, may have influenced our directors and executive officers to support or approve the Merger.

If the Merger is not completed, our stock price may fluctuate significantly.

The market price of our common stock is subject to significant fluctuations. During the 12-month period from November 2, 2021 through November 1, 2022, the closing sales price of our common stock on The Nasdaq Global Market ranged from a high of $12.45 on November 10, 2021, to a low of $0.63 on October 21, 2022. Market prices for securities of pharmaceutical, biotechnology and other life science companies have historically been particularly volatile. In addition, the market price of our common stock will likely be volatile based on whether stockholders and other investors believe that we or Advaxis can complete the Merger or otherwise raise capital if the Merger is not consummated and another strategic transaction cannot be identified, negotiated and consummated in a timely manner, if at all. The volatility of the market price of our common stock is exacerbated by low trading volume. Additional factors that may cause the market price of our common stock to fluctuate include:

- the initiation of, material developments in, or conclusion of litigation to enforce or defend our intellectual property rights or defend against claims involving the intellectual property rights of others;
- the entry into, or termination of, key agreements, including commercial partner agreements;
- announcements by commercial partners or competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- the introduction of technological innovations or new therapies that compete with our future products;
- the loss of key employees;
- future sales of our common stock;
- general and industry-specific economic conditions that may affect our research and development expenditures;
- the failure to meet industry analyst expectations; and
- period-to-period fluctuations in financial results.

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

The announcement and pendency of the Merger, whether or not consummated, adversely affected the trading price of our common stock and may continue to adversely affect the trading price of our common stock.

On October 18, 2022, the closing sales price of our common stock on The Nasdaq Global Market was $0.91, and on October 19, 2022, after announcing the Merger, the closing sales price of our common stock was $0.71. The announcement and pendency of the Merger, whether or not consummated, may continue to adversely affect the trading price of our common stock, which may affect our business prospects. In the event that the Merger is not completed, the announcement of the termination of the Merger Agreement may also adversely affect the trading price of our common stock and our business prospects.

The failure to successfully integrate the businesses and operations of Ayala and Advaxis in the expected time frame may adversely affect the combined company's future results.

We and Advaxis have operated independently and there can be no assurances that the businesses can be integrated successfully. It is possible that the integration process could result in the loss of key Ayala or Advaxis employees, independent contractors, principal investigators, CROs, consultants, vendors, and any other third parties, the disruption of our ongoing businesses, inconsistencies in standards, controls, procedures and policies, unexpected integration issues, higher than expected integration costs and an overall integration process that takes longer than originally anticipated. Specifically, the following issues, among others, must be addressed in integrating the operations of Ayala and Advaxis in order to realize the anticipated benefits of the Merger so the combined company performs as expected:

- combining the companies' operations and corporate functions;
- combining the businesses of Ayala and Advaxis and meeting the capital requirements of the combined company, in a manner that permits the combined company to achieve any cost savings or other synergies anticipated to result from the Merger, the failure of which would result in the anticipated benefits of the Merger not being realized in the time frame currently anticipated or at all;
- integrating personnel from the two companies, especially in the COVID-19 environment which has required many people to work remotely in many locations;
- integrating and unifying Ayala's and Advaxis' pipeline of product candidates in development;
- identifying and eliminating redundant and underperforming functions and assets;
- harmonizing the companies' operating practices, employee development and compensation programs, internal controls and other policies, procedures and processes;
- maintaining existing agreements with employees, independent contractors, principal investigators, CROs, consultants, vendors, and any other third parties, avoiding delays in entering into new agreements with prospective employees, independent contractors, principal investigators, CROs, consultants, vendors, and any other third parties, and leveraging relationships with such third parties for the benefit of the combined company;
- addressing possible differences in business backgrounds, corporate cultures and management philosophies;
- consolidating the companies' administrative and information technology infrastructure;
- coordinating research, commercialization, and marketing efforts;
- coordinating geographically dispersed organizations; and
- effecting actions that may be required in connection with obtaining regulatory or other governmental approvals.

In addition, at times the attention our management may be focused on the integration of the businesses of the two companies and diverted from day-to-day business operations or other opportunities that may have been beneficial to us, which may disrupt our ongoing business.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

On May 12, 2020, we completed our IPO and issued and sold 3,666,667 shares of our common stock at a price to the public of $15.00 per share. On June 9, 2020, in connection with the partial exercise of the underwriters' option to purchase additional shares, we issued and sold 274,022 additional shares of common stock at a price of $15.00 per share.

The offer and sale of all of the shares in the offering was registered under the Securities Act pursuant to the IPO Registration Statement (File No. 333-236942), which was declared effective by the SEC on May 7, 2020. The offering terminated after the sale of all securities registered pursuant to the Registration Statement. The net proceeds of approximately $52.2 million have been invested in short- and intermediate-term investments in accordance with our investment policy. These investments may include money market funds and investment securities consisting of U.S. Treasury notes, and high quality, marketable debt instruments of corporations and government sponsored enterprises. There has been no material change in the expected use of the net proceeds from our IPO as described in the final prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on May 11, 2020 in connection with the IPO.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
2.1	Agreement and Plan of Merger, dated as of October 18, 2022, by and among Advaxis, Inc., Doe Merger Sub, Inc., and Ayala Pharmaceuticals, Inc.#	8-K	001-39279	2.1	10/19/2022	
3.1	Restated Certificate of Incorporation of Ayala Pharmaceuticals, Inc.	8-K	001-39279	3.1	5/12/2020	
3.2	Amended and Restated Bylaws of Ayala Pharmaceuticals, Inc.	8-K	001-39279	3.2	5/12/2020	
10.1	Voting and Support Agreement, dated as of October 18, 2022, by and between Advaxis, Inc. and Israel Biotech Fund I, L.P.	8-K	001-39279	10.1	10/19/2022	
10.2	Voting and Support Agreement, dated as of October 18, 2022, by and between Advaxis, Inc. and a Moon Growth Fund Limited Partnership	8-K	001-39279	10.2	10/19/2022	
10.3	Letter Agreement, dated as of October 18, 2022, by and between Ayala-Oncology Israel Ltd. and Roni Mamluk	8-K	001-39279	10.3	10/19/2022	
10.4	Letter Agreement, dated as of October 18, 2022, by and between Ayala-Oncology Israel Ltd. and Yossi Maimon	8-K	001-39279	10.4	10/19/2022	
10.5	Letter Agreement, dated as of October 18, 2022, by and between Ayala Pharmaceuticals, Inc. and Gary Gordon	8-K	001-39279	10.5	10/19/2022	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d- 14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					*
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d- 14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					*
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					**
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					**
101.INS	Inline XBRL Instance Document—the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document					*
101.SCH	Inline XBRL Taxonomy Extension Schema Document					*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					*

The schedules to the Agreement and Plan of Merger have been omitted from this filing pursuant to Item 601(b)(2) of Regulation S-K. Ayala will furnish copies of any such schedules to the SEC upon request.

* Filed herewith.

** Furnished herewith.

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 thereunto duly authorized.

AYALA Pharmaceuticals, Inc.

Date: November 3, 2022

By: /s/ Roni Mamluk

Roni Mamluk, Ph.D.
Chief Executive Officer
(principal executive officer)

Date: November 3, 2022

By: /s/ Yossi Maimon

Yossi Maimon, CPA, M.B.A.
Chief Financial Officer
(principal financial and accounting officer)

Exhibit 31.1

CERTIFICATION

I, Roni Mamluk, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ayala Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2022

By: /s/ Roni Mamluk

Roni Mamluk, Ph.D.
Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION

I, Yossi Maimon, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ayala Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2022

By: /s/ Yossi Maimon

Yossi Maimon, CPA, M.B.A.
Chief Financial Officer
(principal financial officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Ayala Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 3, 2022

By: /s/ Roni Mamluk
Roni Mamluk, Ph.D.
President and Chief Executive Officer
(principal executive officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Ayala Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 3, 2022

By: /s/ Yossi Maimon
Yossi Maimon, CPA, M.B.A.
Chief Financial Officer
(principal financial officer)