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 March 31, 2023

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: 001-36138

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

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

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

(Former name, former address and former fiscal year, if changed since last report):

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

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 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 ☒

The registrant had 4,838,321 shares of common stock, par value $0.001 per share, outstanding as of May 23, 2023.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. All statements other than statements of historical facts contained in this Quarterly Report, including without limitation statements relating to 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, and the timing and results of any clinical trials or readouts, 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 the factors described under the sections in this Quarterly Report titled and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

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.

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)

	March 31, 2023	December 31, 2022
	(Unaudited)	
CURRENT ASSETS:		
Cash and cash equivalents	$ 16,839	$ 2,408
Short-term restricted bank deposits	108	110
Trade receivables	4	234
Prepaid expenses and other current assets	1,310	436
Total current assets	18,261	3,188
LONG-TERM ASSETS:		
Deferred issuance costs	-	1,953
Other assets	$ 212	$ 206
Operating lease right of use asset	1,442	1,462
Intangible assets, net	130	-
Property and equipment, net	950	960
Total long-term assets	2,734	4,581
Total assets	**$ 20,995**	**$ 7,769**
LIABILITIES AND STOCKHOLDERS' EQUITY:		
CURRENT LIABILITIES:		
Trade payable	$ 4,140	$ 4,080
Operating lease liabilities	253	419
Accrued expenses	2,026	551
Accrued payroll and employee benefits	1,728	994
Other accounts payable	1,686	1,492
Total current liabilities	9,833	7,536
LONG TERM LIABILITIES:		
Long-term warrant liability	77	-
Long-term operating lease liabilities	1,410	1,332
Total long-term liabilities	$ 1,487	$ 1,332
STOCKHOLDERS' EQUITY:		
Common Stock of $0.001 par value per share; 170,000,000 and 37,480,000 shares authorized on March 31, 2023 and on December 31, 2022, respectively; 4,838,321 and 2,775,906 shares issued and on March 31, 2023 and December 31, 2022, respectively;* 4,772,740 and 2,695,067 shares outstanding at March 31, 2023 and December 31, 2022, respectively.	$ 5	$ 3
Additional paid-in capital*	166,185	148,052
Accumulated deficit	(156,515)	(149,154)
Total stockholders' equity	9,675	(1,099)
Total liabilities and stockholders' equity	**$ 20,995**	**$ 7,769**

See accompanying notes to unaudited condensed consolidated financial statements.

* Common Stock, additional paid-in capital and per share data have been retroactively adjusted for the impact of the merger, see note 1.

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

	For the Three Months Ended March 31,	
	2023	**2022**
Revenues from license agreement	$ 4	$ 458
Cost of revenue	(4)	(368)
Gross profit	-	90
Operating expenses:		
Research and development	7,265	7,503
General and administrative	4,604	2,433
Operating loss	(11,869)	(9,846)
Financial income, net	301	82
Loss before income tax	(11,568)	(9,764)
Taxes on income	4,207	(189)
Net loss	(7,361)	(9,953)
Net loss per share, basic and diluted	$ (1.67)	$ (3.47)
Weighted average common shares outstanding, basic and diluted*	4,405,286	2,867,420

See accompanying notes to unaudited condensed consolidated financial statements.

* Common Stock, additional paid-in capital and per share data have been retroactively adjusted for the impact of the merger, see note 1.

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, 2021	2,615,360	$ 3	$ 145,296	$ (111,141)	$ 34,158
Share based compensation	2,219	*	643	-	643
Proceeds from issuance of common stock and warrants, net of issuance cost of $3	918	*	44	-	44
Net Loss	-	-	-	(9,953)	(9,953)
Balance as of March 31, 2022	**2,618,497**	**$ 3**	**145,983**	**$ (121,094)**	**$ 24,892**
Balance as of December 31, 2022	**2,695,067**	**3**	**148,052**	**(149,154)**	**(1,099)**
Share based compensation	15,530	*	1,186	-	1,186
Issuance of shares upon Merger, net of issuance costs of $3,153	2,062,143	2	16,947	-	16,949
Net Loss	-	-	-	(7,361)	(7,361)
Balance as of March 31, 2023	**4,772,740**	**$ 5**	**$ 166,185**	**$ (156,515)**	**$ 9,675**

See accompanying notes to unaudited condensed consolidated financial statements.

* Represents an amount lower than $1.
** All of the Common Stocks and per share data have been retroactively adjusted for the impact of the merger, see note 1.

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

(In thousands)

	Three Months Ended	
	March 31, 2023	**March 31 2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (7,361)	$ (9,953)
Adjustments to reconcile net loss to net cash used in operating activities:		
Shared based compensation	1,186	643
Depreciation	44	30
Remeasurement of long term warrant liability	(126)	-
Foreign currency loss, net	36	-
(Increase) decrease in prepaid expenses and other assets	(574)	1,184
Decrease (increase) in trade receivables	230	(638)
Decrease in trade payables	(892)	(651)
Decrease in operating lease right-of-use assets	89	72
Decrease in operating lease liabilities	(158)	(207)
Increase (decrease) accrued expenses	(1,351)	(55)
Increase in accrued payroll and employee benefits	1,689	79
Increase (decrease) in other accounts payable	447	(488)
Net cash used in operating activities	(6,741)	(9,984)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Net cash used in investing activities	-	-
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of shares, net of issuance cost of $3	-	44
Issuance of shares upon merger, net of issuance costs	21,201	-
Net cash provided by financing activities	21,201	44
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(36)	-
Increase (decrease) in cash and cash equivalents and restricted cash	14,424	(9,940)
Cash and cash equivalents and restricted cash at beginning of the period	2,724	37,339
Cash and cash equivalents and restricted cash at end of the period	$ 17,148	$ 27,399
SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING ACTIVITIES		
Non-cash issuance costs in relation to the merger	$ 1,200	$ -
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION		
Tax paid in cash	$ 202	$ 64

Reconciliation of cash, cash equivalents and restricted cash

	March 31, 2023	**March 31, 2022**
Cash and cash equivalents	$ 16,839	$ 27,050
Restricted bank deposits	108	122
Restricted bank deposits in other assets	201	227
Cash and cash equivalents and restricted cash at end of the period	$ 17,148	$ 27,399

See accompanying notes to unaudited condensed consolidated financial statements

NOTE 1—SIGNIFICANT ACCOUNTING POLICIES

In these financial statements, unless otherwise stated or the context otherwise indicates, references to "New Ayala," the "Company," "we," "us," "our" and similar references refer to Ayala Pharmaceuticals, Inc., a Delaware corporation, which prior to the change of its name effected on January 19, 2023, was known as Advaxis, Inc. The name change was affected in connection with the Merger, as described below. References to "former Advaxis" refer to our company solely in the period prior to the Merger.

Prior to the Merger, we were a clinical-stage biotechnology company focused on the development and commercialization of proprietary *Listeria monocytogenes* ("*Lm*")-based antigen delivery products. These efforts utilized our *Lm* platform directed against tumor-specific targets in order to engage the patient's immune system to destroy tumor cells. Through a license from the University of Pennsylvania, we have exclusive access to this proprietary formulation of attenuated *Lm* called *Lm* Technology™.

Following the Merger, we are primarily 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. We also continue to conduct certain operations relating to former Advaxis' operations as a clinical-stage biotechnology company focused on the development and commercialization of proprietary *Listeria monocytogenes* ("*Lm*")-based antigen delivery products. These efforts are primarily focused on the development of ADXS-504, a *Lm*-based therapy for early-stage prostate cancer.

In 2017, the Company entered into an exclusive worldwide license agreement with respect to AL101 and AL102. See note 5.

Merger with Ayala Pharmaceuticals, Inc.

On October 18, 2022, the Company, which at the time was named Advaxis, Inc., entered into a Merger Agreement (the "Merger Agreement"), with an entity then known as Ayala Pharmaceuticals, Inc., with the Ayala Pharmaceuticals, Inc. shortly prior to the closing of the merger in January 2023 changing its name to Old Ayala, Inc., ("Old Ayala") and Doe Merger Sub, Inc. ("Merger Sub"), a direct, wholly-owned subsidiary of the Company. Under the terms of the Merger Agreement, Merger Sub merged with and into Old Ayala, with Old Ayala continuing as the surviving company and a wholly-owned subsidiary of the Company (the "Merger"). Immediately after the Merger, former Advaxis stockholders as of immediately prior to the Merger own approximately 37.5% of the outstanding shares of the combined Company and former Old Ayala shareholders own approximately 62.5% of the outstanding shares of the combined Company.

At the effective time of the Merger (the "Effective Time"), each share of share capital of Old Ayala issued and outstanding immediately prior to the Effective Time was converted into the right to receive a number of shares of the Company's common stock, par value $0.001 per share, equal to the exchange ratio, 0.1874 shares of the Company's common stock per Old Ayala share.

The Merger has been accounted for as a reverse merger with Old Ayala as the accounting acquirer and former Advaxis as the accounting acquiree. In identifying Old Ayala as the accounting acquirer, the companies considered ASC 805-10-55 including the structure of the Merger, relative outstanding share ownership at closing and the composition of the combined Company's board of directors and senior management. The financial reporting reflects the accounting from the perspective of Old Ayala ("accounting acquirer"), except for the legal capital, which has been retroactively adjusted to reflect the capital of former Advaxis ("accounting acquiree") in accordance with ASC 805-40-45. As such, the historical financial information presented is that of Old Ayala as the accounting acquirer in the Merger.

Because most of the value of the assets of former Advaxis was in cash and cash equivalents, the Merger is treated primarily as a financing transaction for accounting purposes with a small component as a business acquisition. Therefore, no gain or loss is recorded as a result of the Merger. Old Ayala's transaction costs were capitalized and offset against the shareholder's equity upon the Merger, and former Advaxis' transaction costs were expensed as merger costs. The consolidated financial statements from the closing date of the Merger include the assets, liabilities, and results of operations of the combined company.

NOTE 1—SIGNIFICANT ACCOUNTING POLICIES (continued):

Fair Value Allocation

The following is a preliminary estimate of the fair value of acquired identifiable assets and assumed liabilities of former Advaxis which includes preliminary adjustments to reflect the fair value of intangible assets acquired (in thousands) as of January 19, 2023:

	Amounts
Cash and cash equivalents	$ 22,539
Prepaid expenses and other current assets	300
Property and equipment, net	34
Intangible assets	130
Operating right-of-use asset	5
Other assets	11
Total assets	23,019
Common stock warrant liability	(203)
Other current liabilities and trade payables	(2,714)
Total liabilities	(2,917)
Net assets acquired	$ 20,102

The fair value estimate for all identifiable assets and liabilities assumed is preliminary and is based on assumptions that market participants would use in pricing an asset, based on the most advantageous market for the asset (i.e., its highest and best use). This preliminary fair value estimate could include assets that are not intended to be used, may be sold, or are intended to be used in a manner other than their best use. Such estimates are subject to change during the measurement period, which is not expected to exceed one year. Any adjustments identified during the measurement period will be recognized in the period in which the adjustments are determined.

The Company recognized intangible assets related to the Merger, which consist of the Patents and License agreements valued at $130 thousand with an estimated useful life of four years. Acquired identifiable finite-lived intangible assets are amortized on a straight-line basis over the estimated useful lives of the assets. The basis of amortization approximates the pattern in which the assets are utilized, over their estimated useful lives. The Company routinely reviews the remaining estimated useful lives of finite-lived intangible assets. In case the Company reduces the estimated useful life for any asset, the remaining unamortized balance is amortized or depreciated over the revised estimated useful life.

These intangible assets are classified as Level 3 measurements within the fair value hierarchy.

The following unaudited table provides certain pro forma financial information for the Company as if the Merger occurred on January 1, 2022 (in thousands except per share amounts):

	Three months ended March 31, 2023	Three months ended March 31, 2022
	Unaudited	Unaudited
Revenue	$ 4	$ 458
Net loss	$ (6,892)	$ (11,666)

The pro forma numbers above are derived from historical numbers of the Company and Old Ayala. The results of operations for the three months ended March 31, 2022 include the operations of the Company for the period from November 1, 2021 to January 31, 2022, which was the first quarter of fiscal year 2022 prior to the change in our fiscal year end from October 31 to December 31, which change was effected in January 2023.

The unaudited pro forma results have been prepared based on estimates and assumptions, which we believe are reasonable; however, they are not necessarily indicative of the consolidated results of operations had the acquisition occurred on January 1, 2022, or of future results of operations.

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 $156.5 million as of March 31, 2023. For the three months ended March 31, 2023, the Company used approximately $6.7 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 March 31, 2023, the Company had approximately $16.8 million in cash and cash equivalents, which, without additional funding, the Company believes will not be sufficient to meet its obligations within the next twelve months from the date of issuance of these 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 months ended March 31, 2023, 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, 2022, included in the Annual Report on Form 10-K of Old Ayala filed for the year ended December 31, 2022 (the "Old Ayala 2022 Form 10-K") with the Securities and Exchange Commission (the "SEC") on March 31, 2023 and the Annual Report on Form 10-K of the Company filed for the year ended October 31, 2022 (the "Form 10-K") with the SEC on February 10, 2023. 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, 2022, included in the Old Ayala 2022 Form 10-K and the Form 10-K, unless otherwise stated.

Use of estimates

The preparation of the unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the amounts reported in the unaudited condensed 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 unaudited condensed consolidated financial statements. Actual results could differ from those estimates.

NOTE 1—SIGNIFICANT ACCOUNTING POLICIES (continued):

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 249,867 pre-funded warrants, which as part of Merger converted to common stock, for the three months ended March 31, 2023.

The calculation of basic and diluted loss per share includes 249,867 pre-funded warrants for the three months ended March 31, 2022.

All of the Common Stock, exercise prices and per share data have been retroactively adjusted for the impact of the Merger. The shares have been adjusted to the merger ratio of 0.1874.

Fair value of financial instruments

The Company measures and discloses the fair value of financial assets and liabilities in accordance with ASC Topic 820, “Fair Value Measurement.” Fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Restricted bank deposits, trade receivables, trade payables are stated at their carrying value, which approximates fair value due to the short time to the expected receipt or payment date. Warrants liabilities are stated at fair value on a recurring basis.

Recently Adopted Accounting Pronouncements

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 new guidance was effective for the Company on January 1, 2023 and the adoption did not have a material impact on the Company’s consolidated 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.

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.

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 amount of approximately $4 thousand was recognized in the three months ended March 31, 2023.

Revenue associated with the research and development services in the amount of approximately $0.5 million was recognized in the three months ended March 31, 2022.

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 March 31, 2023 and December 31, 2022, the Company has recorded an uncertain tax position liability exclusive of interest and penalties of $1.6 million and $1.3 million, respectively, which were classified as other accounts payable. As of March 31, 2023 and December 31, 2022, the Company accrued interest related to uncertain tax positions of $90 thousand and $79 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:

	Three months ended March 31, 2023	Year ended December 31, 2022
	(In thousands)	(In thousands)
Uncertain tax position at the beginning of the period	$ 1,323	$ 858
Additions for uncertain tax position of prior years (foreign exchange and interest)	11	36
Subtractions for tax positions of previous period	(7)	
Additions for tax positions of current period	251	429
Uncertain tax position at the end of the period	$ 1,578	$ 1,323

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 2018 and subsequent tax years remain subject to examination by the applicable taxing authorities as of March 31, 2023.

In March 2023, the Company received $4,675 proceeds from the sale of our Net Operating Losses ("NOLs") under the State of New Jersey NOL Transfer Program. This was recorded as a tax benefit and offset against income tax expense in the consolidated statement of operations.

NOTE 4 – COMMON STOCK PURCHASE WARRANTS AND WARRANT LIABILITY

Common Stock Rights

The Common Stock confer upon the holders the right vote in annual and special meetings of the Company, and to participate in the distribution of the surplus assets of the Company upon liquidation of the Company, after the distribution of the preferred stock liquidation preference.

Warrants

As of March 31, 2023, there were 465,271 warrants outstanding of which 290,206 were exercisable warrants to purchase shares of our common stock, with exercise prices ranging from $2.79 to $224.00 per share. As of December 31, 2022, there were outstanding and exercisable warrants to purchase 337,320*, shares of our common stock with exercise prices ranging from $0.05* to $96.58* per share. Information on the outstanding warrants as of March 31, 2023 is as follows:

Exercise Price	Number of Shares Underlying Warrants	Expiration Date	Type of Financing
$ 2.79	879	September 2024	September 2018 Public Offering
$ 224.00	4,092	July 2024	July 2019 Public Offering
$ 28.00	57,230	November 2025	November 2020 Public Offering
$ 56.00	140,552	April 2026	April 2021 Registered Direct Offering (Accompanying Warrants)
$ 56.00	175,065	5 years after the date such warrants become exercisable, if ever	April 2021 Private Placement (Private Placement Warrants)
$ 96.58	87,453*	February 2024	February 2021 Private Placement (issued by Old Ayala)
Grand Total	465,271		

*Exercise price and warrant numbers of Old Ayala's warrants have been retroactively adjusted for the impact of the Merger, see note 1.

As of March 31, 2023, the Company had 289,327 of its total 465,271 outstanding warrants classified as equity (equity warrants). As of December 31, 2022, all outstanding warrants were classified as equity (equity warrants). At issuance, equity warrants are recorded in Additional Paid-In Capital in the shareholders equity section of the consolidated balance sheets.

A summary of warrant activity was as follows (In thousands, except share and per share data):

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life In Years	Aggregate Intrinsic Value
Outstanding and exercisable warrants at December 31, 2022	337,320	$ 25.08	1.14	$ 86,613
Issuance of warrants upon Merger	377,818*	53.45*		
Exercised	(249,867)*	0.05*		
Outstanding warrants at March 31, 2023	465,271*	$ 61.56*	3.15	$ -
Exercisable warrants at March 31, 2023	290,206	$ 64.92	2.29	$ -

* Exercise price and warrant numbers have been retroactively adjusted for the impact of the Merger, see note 1.

Shares Issued for Warrants Exercises

During the three months ended March 31, 2023, pre-funded warrant holders from the Old Ayala's February 2019 Offering automatically net exercised 249,867 warrants in exchange for 246,192 shares of the Company's common stock in accordance with their terms.

Warrant Liability

The warrants issued in the April 2021 Private Placement will become exercisable only on such day, if ever, that is 14 days after the Company files an amendment to the Company's Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock, $0.001 par value per share from 170,000,000 shares to 300,000,000 shares. These warrants expire five years after the date they become exercisable. As of March 31, 2023, the Company did not have sufficient authorized common stock to allow for the issuance of common stock underlying these warrants. Accordingly, based on certain indemnification provisions of the securities purchase agreement, the Company concluded that liability classification is warranted. The Company utilized the Black Scholes model to calculate the fair value of these warrants at the merger and reporting date.

The September 2018 Public Offering warrants contain a down round feature, except for exempt issuances as defined in the warrant agreement, in which the exercise price would immediately be reduced to match a dilutive issuance of common stock, options, convertible securities and changes in option price or rate of conversion. As of March 31, 2023, the down round feature was triggered five times and the exercise price of the warrants were reduced from $1,800.00 to $2.79. The warrants require liability classification as the warrant agreement requires the Company to maintain an effective registration statement and does not specify any circumstances under which settlement in other than cash would be permitted or required. In addition, the contract contains an unpermitted adjustment to the exercise price, and therefore preclude an equity classification. As a result, net cash settlement is assumed and liability classification is warranted. The Company utilized the Black Scholes model to calculate the fair value of these warrants at the merger and reporting date.

In measuring the warrant liability for the warrants issued in the April 2021 Private Placement and September 2018 Public Offering at March 31, 2023, the Company used the following inputs in its Black Scholes model:

	March 31, 2023	January 19, 2023
Exercise Price	$ 55.73	$ 55.73
Stock Price	$ 1.25	$ 2.95
Expected Term	4.98 years	4.98 years
Volatility %	119%	117%
Risk Free Rate	3.61%	3.60%

For the three months ended March 31, 2023, the Company reported a gain of approximately $126 due to changes in the fair value of the warrant liability.

NOTE 5—COMMITMENTS AND CONTINGENT LIABILITIES

In January 2019, the Company's wholly owned Israeli subsidiary, Ayala-Oncology Israel Ltd. (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 an amount of approximately $0.5 million paid in arrears for leasehold improvements. The amount was recorded as an incentive and is taken into account when computing the Right of Use ("ROU") asset.

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

On March 25, 2021, the Company entered into a one-year lease agreement for its corporate office/lab with base rent of approximately $29 per year, plus other expenses. In September 2021, the Company exercised its option to renew the lease, extending the lease term until March 31, 2023. On March 25, 2023 the Company signed an extension up to March 31, 2025, with base rent of approximately $36 per year. The Company recorded an ROU asset and liability of approximately $65.

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

	March 31, 2023	
	ROU assets	Lease liabilities
Offices	$ 1,312	$ 1,550
Cars	130	113
Total operating leases	**$ 1,442**	**$ 1,663**

	December 31, 2022	
	ROU assets	Lease liabilities
Offices	$ 1,273	$ 1,612
Cars	189	139
Total operating leases	**$ 1,462**	**$ 1,751**

	March 31, 2023	December 31, 2022
	Lease liabilities	Lease liabilities
Current lease liabilities	$ 253	$ 419
Non-current lease liabilities	1,410	1,332
Total lease liabilities	**$ 1,663**	**$ 1,751**

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

	March 31, 2023	March 31, 2022
Operating lease cost	$ 126	$ 112
Variable lease cost	2	-
Total lease cost	**$ 128**	$ 112

As of March 31, 2023, the weighted-average remaining lease term and weighted-average discount rate for operating leases are 3.16 years and 7.5%, respectively. The following table presents supplementary cash flow information regarding the Company's operating leases:

	March 31, 2023	March 31, 2022
Cash paid for amounts included in the measurement of lease liabilities	$ 109	$ 109
Right of use assets obtained in exchange for operating lease liabilities	$ 65	$ 1,751

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

	March 31, 2023
2023	$ 319
2024	345
2025	309
2026	308
2027	308
After 2027	308
Total undiscounted lease payments	$ 2,000
Less: Interest	337
Total lease liabilities - operating	**$ 1,663**

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 5—COMMITMENTS AND CONTINGENT LIABILITIES (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 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 5—COMMITMENTS AND CONTINGENT LIABILITIES (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.

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 maintained first right to prosecute and maintained 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.

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.

Purported Stockholder Claims

Purported Stockholder Claims Related to Biosight Transaction

Between September 16, 2021, and November 4, 2021, the Company received demand letters on behalf of six purported stockholders of the Company, alleging that the Company failed to disclose certain matters in the Registration Statement, and demanding that the Company disclose such information in a supplemental disclosure filed with the SEC. On October 14, 2021, the Company filed an amendment to the Registration Statement and on November 8, 2021, the Company made certain other additional disclosures that mooted the demands asserted in the above-referenced letters. The six plaintiffs have made settlement demands. On May 20, 2022, the Company and one of the plaintiffs have reached a settlement agreement. At this time, the Company is unable to predict the likelihood of an unfavorable outcome.

In addition, the Company received certain additional demands from stockholders asserting that the proxy materials filed by the Company in connection with the Previously Proposed Merger contained alleged material misstatements and/or omissions. Certain stockholders also demanded books and records of the Company pursuant to Delaware law. In response to these demands, the Company agreed to make, and did make, certain supplemental disclosures to the proxy materials. The stockholders have made settlement demands. On July 18, 2022, the Company and the plaintiffs consummated settlement agreements.

Purported Stockholder Claims Related to Series D Convertible Preferred Stock Offering

On February 17, 2022, the Company received a letter on behalf of purported stockholders of the Company, demanding certain books and records pursuant to Delaware law regarding the proposed issuance of super voting preferred stock. The Company agreed to provide certain books and records to the stockholders and agreed to make, and did make, a supplemental disclosure to the proxy materials. The stockholders have made settlement demands. On July 18, 2022, the Company and the plaintiffs consummated settlement agreements.

Purported Stockholder Claims Related to Merger with Old Ayala

On December 15, 2022, a purported stockholder of Old Ayala filed a complaint in the U.S. District Court for the Southern District of New York against Old Ayala and the members of its Board, captioned Stephen Bushansky v. Ayala Pharmaceuticals, Inc., Case No.1:22-cv-10621 (S.D.N.Y.) (the "Complaint").

The Complaint asserts claims against all defendants under Section 14(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and Rule 14a-9 promulgated thereunder for omitting or misrepresenting material information from Old Ayala's Proxy Statement and against the individual defendants under Section 20(a) of the Exchange Act for alleged "control person" liability with respect to such alleged omissions and misrepresentations. The allegations in the Complaint include that the Proxy Statement omitted material information regarding Old Ayala's financial projections and the financial analyses of Old Ayala's financial advisor for the Merger. The Complaint seeks, among other relief, (1) to enjoin defendants from consummating the Merger; (2) to enjoin a vote on the Merger; (3) to rescind the Merger Agreement or recover damages, if the Merger is completed; (4) a declaration that defendants violated Sections 14(a) or 20(a) and Rule 14a-9 of the Exchange Act; and (5) attorneys' fees and costs.

In addition, approximately nine purported stockholders of Old Ayala sent letters to those noted in the above-referenced Complaint alleging similar deficiencies in Old Ayala's Proxy Statement (collectively, the "Demand Letters").

At this time, the Company is unable to predict the likelihood of an unfavorable outcome with respect to the Complaint and the Demand Letters.

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 October 31, 2022 and the Annual Report of Old Ayala, Inc. on Form 10-K for the fiscal year ended December 31, 2022 (the "Old Ayala 2022 Form 10-K"), 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.

Merger with Old Ayala

On October 18, 2022, the Company, which at the time was named Advaxis, Inc., entered into a Merger Agreement (the "Merger Agreement"), subject to shareholder approval, with the entity then known as Ayala Pharmaceuticals, Inc., with the Ayala Pharmaceuticals, Inc. shortly prior to the closing of the merger in January 2023 changing its name to Old Ayala Inc., ("Old Ayala") and Doe Merger Sub, Inc. ("Merger Sub"), our direct, wholly-owned subsidiary. Under the terms of the Merger Agreement, Merger Sub merged with and into Old Ayala, with Old Ayala continuing as the surviving company and our wholly-owned subsidiary (the "Merger"). Immediately after the Merger, our stockholders as of immediately prior to the Merger owned approximately 37.5% of the outstanding shares of the combined company and former Old Ayala shareholders owned approximately 62.5% of the outstanding shares of the combined company. The Merger was accounted for a reverse acquisition pursuant to ASC 805-40.

At the effective time of the Merger (the "Effective Time"), each share of common stock of Old Ayala issued and outstanding immediately prior to the Effective Time was converted into the right to receive a number of shares of the our common stock equal to the exchange ratio, 0.1874 shares of our common stock per Old Ayala share**.**

Overview

Following the Merger we are primarily 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. We also continue to conduct certain operations relating to former Advaxis' operations as clinical-stage biotechnology company focused on the development and commercialization of proprietary *Listeria monocytogenes* ("*Lm*")-based antigen delivery products. These efforts are primarily focused on the development of ADXS-504, a *Lm*-based therapy for early-stage prostate cancer.

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 originally incorporated in the State of Colorado on June 5, 1987 and later reorganized as a Delaware corporation in 2006. Our principal executive offices are located at 9 Deer Park Drive, Suite K-1, Monmouth Junction, New Jersey 08852. Old Ayala, the accounting acquirer in the Merger, was incorporated as a Delaware corporation on November 14, 2017. 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 $7.4 million and $10.0 million for the three months ended March 31, 2023 and 2022, respectively. As of March 31, 2023, we had an accumulated deficit of $156.5 million. We anticipate that our expenses will increase significantly as we:

- 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 March 31, 2023, we had cash and cash equivalents of approximately $16.8 million. Due to the uncertainty in securing additional funding, and the insufficient amount of cash and cash equivalent resources on March 31, 2023, 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.

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 fulfil 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.

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 the Old Ayala 2022 Form 10-K.

Results of Operations

Comparison of the three months ended March 31, 2023 and 2022

The following table summarizes our results of operations for three months ended March 31, 2023 and 2022. The results of operations for the three months ended March 31, 2023, reflect the operations of the post-Merger combined company for the period from January 20, 2023 to March 31, 2023. The results of operations for the three months ended March 31, 2022, reflect the operations solely of Old Ayala, which was the accounting acquirer in the Merger.

	For the Three Months Ended March 31,		
	2023	**2022**	
	(in thousands except share and per share data)		***Change***
Revenues from licensing agreement and others	$ 4	$ 458	(454)
Cost of revenues	(4)	(368)	364
Gross profit	—	90	(90)
Operating expenses:			
Research and development	7,265	7,503	(238)
General and administrative	4,604	2,433	2,171
Operating loss	(11,869)	(9,846)	(2,023)
Financial income, net	301	82	219
Loss before income tax	(11,568)	(9,764)	(1,804)
Taxes on income	4,207	(189)	4,396
Net loss attributable to common stockholders	(7,361)	(9,953)	2,592
Net Loss per share attributable to common stockholders, basic and diluted	$ (1.67)	$ (3.47)	
Weighted average common shares outstanding, basic and diluted	4,405,286	$ 2,867,420	

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 March 31, 2023 and 2022, we recognized approximately $4 thousand in revenue and $0.5 million in revenue, respectively, mainly as a result 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, and 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.
- Conduct certain operations relating to former Advaxis' operations as clinical-stage biotechnology company focused on the development and commercialization of proprietary *Listeria monocytogenes* ("*Lm*")-based antigen delivery products.

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 March 31,			
	2023	2022	$ Change	% Change
	($ in thousands)			
Research and development	$ 7,265	$ 7,503	$ (238)	(3)%

Research and development expenses were $7.3 million for the three months ended March 31, 2023 compared to $7.5 million for the three months ended March 31, 2022, an decrease of $0.2 million. The increase was due to the termination of the TENACITY trial and winding down of the ACCURACY trial offset by expenses occurred by the programs of former Advaxis.

The following table summarizes our research and development expenses by product candidate or development program for the three months ended March 31, 2023 and 2022:

	Three Months Ended	
	March 31 2023	March 31, 2022
Program-Specific Costs:		
AL 101		
ACC	741	962
TNBC [1]	1,390	1,334
General expenses	716	702
AL 102		
General expenses	170	119
Desmoid	2,664	4,386
OTHER R&D EXPENSES	1,584	-
Total research and development expenses	$ 7,265	7,503

(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 cease 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.

General and Administrative Expenses

	Three Months Ended March 31,			
	2023	2022	$ Change	% Change
	($ in thousands)			
General and Administrative	$ 4,604	$ 2,433	$ 2,171	89%

General and administrative expenses were $4.6 million for the three months ended March 31, 2023 compared to $2.4 million for the three months ended March 31, 2022, an increase of $2.2 million. The increase was mainly due to severance agreement obligation recognized in the period to former executives of $863 thousand in salary compensation and $929 thousand in stock-based compensation due to acceleration of options as part of severance agreement.

Financial Loss, net

Financial income, net was $301 thousand for the three months ended March 31, 2023 compared to the financial income, net of $82 thousand for the three months ended March 31, 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 $7.4 million for the three months ended March 31, 2023. As March 31, 2023, we had an accumulated deficit of $156.5 million.

On May 12, 2020, Old Ayala completed the sale of shares of its common stock in its IPO. In connection with the IPO, Old Ayala issued and sold 738,485* shares of common stock, including 51,352* 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 $80.04* per share, resulting in net proceeds to Old Ayala of approximately $52.2 million after deducting underwriting discounts and commissions and estimated offering expenses payable by Old Ayala. 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, Old Ayala entered into a Securities Purchase Agreement (the "2021 Purchase Agreement") with the purchasers named therein (the "Investors"). Pursuant to the 2021 Purchase Agreement, Old Ayala agreed to sell (i) an aggregate of 62,467* shares of our common stock (the "Private Placement Shares"), par value $0.01 per share, together with warrants to purchase an aggregate of 21,863* shares of Old Ayala's common stock with an exercise price of $96.58* 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 249,866* shares of our common stock with an exercise price of $0.05* per share (the "Pre-Funded Warrants" and collectively with the Common Warrants, the "Private Placement Warrants"), together with an aggregate of 87,453*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, Old Ayala entered into an Open Market Sales Agreement, or the Sales Agreement, with Jefferies LLC, or Jefferies, as sales agent, pursuant to which Old Ayala was able to, 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 a registration statement on Form S-3 filed with the SEC. Sales of common stock, if any, pursuant to the Sales Agreement, could 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. During the three months ended March 31, 2022, Old Ayala sold a total of 918 shares of its common stock for total gross proceeds of approximately $47 thousand.

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").

On October 18, 2022, the Company, which at the time was named Advaxis, Inc., entered into a Merger Agreement (the "Merger Agreement"), with entity then known as Ayala Pharmaceuticals, Inc. following its January 2023 name change to Old Ayala, Inc., ("Old Ayala") and Doe Merger Sub, Inc. ("Merger Sub"), a direct, wholly-owned subsidiary of the Company. Under the terms of the Merger Agreement, Merger Sub merged with and into Old Ayala, with Old Ayala continuing as the surviving company and a wholly-owned subsidiary of the Company (the "Merger"). Immediately after the Merger, former Advaxis stockholders as of immediately prior to the Merger own approximately 37.5% of the outstanding shares of the combined Company and former Old Ayala shareholders own approximately 62.5% of the outstanding shares of the combined Company.

At the effective time of the Merger (the "Effective Time"), each share of share capital of Old Ayala issued and outstanding immediately prior to the Effective Time was converted into the right to receive a number of shares of the Company's common stock, par value $0.001 per share, equal to the exchange ratio, 0.1874 shares of the Company's common stock per Old Ayala share.

As of March 31, 2023, we had cash and cash equivalents of approximately $16.8 million.

Cash Flows

The following table summarizes our cash flow for the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31,	
	2023	**2022**
	($ in thousands)	
Cash flows provided by (used in):		
Operating activities	(6,741)	(9,984)
Investing activities	-	-
Financing activities	21,201	44
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(36)	-
Increase (decrease) in cash and cash equivalents and restricted cash	14,424	(9,940)

*Common Stock, Common Stock, warrant exercise price and per share data have been retroactively adjusted for the impact of the merger, see note 1 of Finical Statements.

Operating Activities

Net cash used in operating activities during the three months ended March 31, 2023 of approximately $6.7 million was primarily attributable to our net loss of $7.4 million, adjusted for non-cash expenses of $1.2 million, which includes stock-based compensation of $1.2 million, and a net increase in working capital of $0.7 million.

Net cash used in operating activities during the three months ended March 31, 2022 of approximately $10 million was primarily attributable to our net loss of $10.0 million, which was further increased due to decrease in prepaid expenses of $1.2 million and decrease of $0.7 million in trade payables and partially offset by stock-based compensation of $0.6 million.

Investing Activities

We did not have any cash provided by investing activities during the three months ended March 31, 2023 and 2022.

Financing Activities

Net cash provided by financing activities during the three months ended March 31, 2023 of $21.2 million is attributable to the merger between the Company and Old Ayala.

Net cash provided by financing activities during the three months ended March 31, 2022 of $44 thousand was attributable to sales of securities by Old Ayala.

Funding Requirements

Our future capital requirements are difficult to forecast and will depend on many factors, including our ability to raise additional funding. 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 March 31, 2023, we had cash and cash equivalents of $16.8 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 unaudited condensed consolidated financial statements are issued. Due to the uncertainty in securing additional funding, and the insufficient amount of cash and cash equivalent resources at March 31, 2023, 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 AL102;
- the cost of manufacturing additional material for future clinical trials of 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;

- 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 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 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 the Old Ayala 2022 Form 10-K.

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 condensed 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 the Old Ayala 2022 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.

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 March 31, 2023, 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 March 31, 2023 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.

See the matters set forth in note 4, “Commitments and Contingent Liabilities – Purported Stockholder Claims” in the Notes to Condensed Consolidated Financial Statements included herein.

Item 1A. Risk Factors.

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 October 31, 2022.

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

None.

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
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)					*

* 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: May 23, 2023

By: */s/ Kenneth Berlin*

Kenneth Berlin
President Chief Executive Officer
(principal executive officer)

Date: May 23, 2023

By: */s/ Igor Gitelman*

Igor Gitelman
Interim Chief Financial Officer
(principal financial and accounting officer)

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18.U.S.C. 7350
(SECTION 302 OF THE SARBANES OXLEY ACT OF 2002)

I, Kenneth A. Berlin, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the fiscal quarter ended March 31, 2023 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)) for the registrant 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.

May 23, 2023

By: */s/ Kenneth A. Berlin*
Kenneth A. Berlin
President and Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18.U.S.C. 7350
(SECTION 302 OF THE SARBANES OXLEY ACT OF 2002)

I, Igor Gitelman, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the fiscal quarter ended March 31, 2023 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)) for the registrant 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.

May 23, 2023

By: */s/ Igor Gitelman*
Igor Gitelman
Interim Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
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 of Ayala Pharmaceuticals, Inc., a Delaware corporation (the "Company"), on Form 10-Q for the fiscal quarter ended March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, the President and Chief Executive Officer, hereby certifies pursuant to 18 U.S.C. Sec. 1350 as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002 that, to the undersigned's knowledge:

(1) the Report of the Company filed today fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Date: May 23, 2023

By: */s/ Kenneth A. Berlin*
Kenneth A. Berlin
President and Chief Executive Officer

EXHIBIT 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
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 of Ayala Pharmaceuticals, Inc., a Delaware corporation (the "Company"), on Form 10-Q for the fiscal quarter ended March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, the Interim Chief Financial Officer, hereby certifies pursuant to 18 U.S.C. Sec. 1350 as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002 that, to the undersigned's knowledge:

(1) the Report of the Company filed today fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Date: May 23, 2023

By: */s/ Igor Gitelman*
Igor Gitelman
Interim Chief Financial Officer