

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

FORM 8-K/A

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

Date of Report (Date of earliest event reported): March 25, 2024

Ayala Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)	001-36138 (Commission File Number)	84-1521955 (IRS Employer Identification No.)
9 DEER PARK DRIVE, SUITE K-1 MONMOUTH JUNCTION, New Jersey (Address of principal executive offices)		08852 (Zip code)

Registrant's telephone number, including area code (732) 545-1590

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

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

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

Emerging growth company

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

EXPLANATORY NOTE

On February 5, 2024, Ayala Pharmaceuticals, Inc., a Delaware corporation (the “Ayala”), and Immunome, Inc. (“Immunome”), entered into an Asset Purchase Agreement (the “Asset Purchase Agreement”) pursuant to which Immunome agreed to acquire, and Ayala agreed to sell, certain of Ayala’s assets and liabilities related to its AL101 and AL102 programs (the “Asset Sale”), which constitute substantially all of Ayala’s assets. On March 25, 2024, Ayala and Immunome consummated the Asset Sale pursuant to the Asset Purchase Agreement.

On March 29, 2024, Ayala filed with the Securities and Exchange Commission (the “SEC”) a Current Report on Form 8-K (the “Original Form 8-K”) to report the consummation of the Asset Sale. The Asset Purchase Agreement and additional information on the details of the Asset Sale may be found therein. This Amendment No. 1 to the Original Form 8-K amends and supplements Item 9.01 of the Original Form 8-K to provide the pro forma financial information required under Item 9.01(b) of Form 8-K, which Ayala was not able to complete until it filed its Annual Report on Form 10-K for the year ended December 31, 2023, which it did on April 16, 2024.

Item 9.01 – Financial Statements and Exhibits.

(b) Pro forma financial information.

Ayala’s Pro Forma Financial Information relating to the Asset Sale is as follows:

Overview

On October 18, 2023, Advaxis Israel Ltd., a company organized under the laws of the State of Israel and a wholly owned subsidiary of Ayala (“Merger Sub”) merged (the “Merger”) with and into Biosight, Ltd., a privately-held pharmaceutical company organized under the laws of the State of Israel (“Biosight”) developing innovative therapeutics for hematological malignancies and disorders. Following the Merger, Biosight continued as the surviving company and a wholly-owned subsidiary of Ayala. Ayala and its wholly owned subsidiary Biosight are referred to collectively herein as the “Company”.

On February 5, 2024, Ayala entered into an Asset Purchase Agreement (the “Asset Purchase Agreement”) with Immunome, Inc. (“Immunome”), pursuant to which Immunome agreed to acquire certain of Ayala’s assets and liabilities related to its AL101 and AL102 programs (the “Asset Sale”). The Asset Sale closed (the “Closing”) on March 25, 2024. Pursuant to the Asset Purchase Agreement, Immunome paid to Ayala an aggregate purchase price of \$20,000,000 in cash, 2,175,489 shares (the “Shares”) of Immunome’s common stock, \$0.0001 par value (the “Common Stock”), issued at Closing and up to \$37,500,000 in cash due upon the achievement of certain development and commercial milestone events set forth in the Asset Purchase Agreement.

Basis of Presentation

The following unaudited pro forma condensed combined financial information reflects adjustments to Ayala’s and BioSight’s historical financial results as reported under U.S. Generally Accepted Accounting Principles (“GAAP”) in connection with the Merger and Asset Sale. The unaudited pro forma condensed combined balance sheet data gives effect to the transactions contemplated by the Asset Purchase Agreement as if they had occurred on December 31, 2023. The unaudited pro forma condensed combined statements of operations data gives effect to the Merger and the transactions contemplated by the Asset Purchase Agreement as if they had occurred on January 1, 2023. All dollar amounts, except per share, are in thousands. It is presented as follows:

- The unaudited pro forma condensed balance sheet as of December 31, 2023 has been prepared with the assumption that the transactions contemplated by the Asset Purchase Agreement were completed as of that date.
- The unaudited pro forma condensed combined statement of operations for the year ended December 31, 2023 was prepared based on (i) the historical audited condensed statement of operations of the Company for the year ended December 31, 2023 and (ii) the historical unaudited consolidated statement of operations of Biosight for the period January 1, 2023 through October 18, 2023, which were both then adjusted for the effect of the transactions contemplated by the Asset Purchase Agreement.

The “as reported” column in the unaudited proforma balance sheet and in the unaudited proforma statement of operations reflect the Company’s historical financial statements for the period presented and do not reflect any adjustments related to the events. Assumptions and estimates underlying the proforma adjustments column are described in the accompanying notes.

The unaudited proforma condensed financial statements have been prepared in accordance with the rules and regulations of SEC Regulation S-X. The unaudited proforma consolidated financial information does not purport to be indicative of the results of operations or the financial condition which would have actually resulted if the Merger and Asset Sale actually occurred on the dates presented or to project the Company’s results of operations or financial position for any future period. This financial information may not be predictive of the future results of operations or financial condition of the Company, as the Company’s future results of operation and financial condition may differ significantly from the proforma amounts reflected herein due to a variety of factors.

The unaudited proforma financial information has been prepared by the Company based upon assumptions deemed appropriate by the Company’s management and are based upon information and assumptions available at the time of

filing this Amendment No. 1 to Current Report on Form 8-K. The following unaudited proforma financial information should be read in conjunction with:

- Separate audited financial statements of the Company as of and for the year ended December 31, 2023 and the related notes, included in the Company's Annual Report on Form 10-K filed with the SEC on April 16, 2024.

The pro forma adjustments to the statement of operations do not include the following:

- the non-recurring gain on the Asset Sale or any income tax expense related to the gain on Asset Sale, which will be reflected in the Company's results for the three months ended March 31, 2024.
 - certain non-recurring transaction expenses of the Asset Sale, estimated to be approximately \$1,405,000.
 - amounts paid or to be paid to officers and employees as bonuses and to the directors of the Company following the Asset Sale, in the amount of \$4,400,000.
 - the \$37,500,000 of contingent cash due to the Company upon the achievement of certain milestones.
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Unaudited Pro Forma Condensed Balance Sheet
As of December 31, 2023
(in thousands)

	<u>Condensed Company as Reported</u>	<u>Asset Sale Pro Forma Adjustments</u>	<u>Pro Forma Combined</u>
CURRENT ASSETS:			
Cash and cash equivalents	\$ 4,882	\$ 13,014(1)	\$ 17,896
Restricted marketable securities	-	52,212(2)	52,212
Prepaid expenses and other current assets	2,646	-	2,646
Total current assets	<u>7,528</u>	<u>65,226</u>	<u>72,754</u>
LONG TERM ASSETS:			
Intangible asset, net	3,898	-	3,898
Goodwill	4,500	-	4,500
Operating lease right of use asset	102	-	102
Property and equipment, net	540	-	540
Other assets	11	-	11
Total long-term assets	<u>9,051</u>	<u>-</u>	<u>9,051</u>
Total assets	<u>\$ 16,579</u>	<u>\$ 65,226</u>	<u>\$ 81,805</u>
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIENCY):			
CURRENT LIABILITIES:			
Trade payables	\$ 6,076	\$ (725)(3)	\$ 5,351
Operating lease liabilities	166	-	166
Accrued expenses and other payables	5,554	(2,283)(4)	3,271
Side letter agreements liabilities	8,436	-	8,436
Accrued payroll and employee benefits	786	-	786
Income taxes payable	-	12,974(5)	12,974
Proceeds from Asset Sale	4,000	(4,000)(6)	-
Total current liabilities	<u>25,018</u>	<u>5,966</u>	<u>30,984</u>
LONG TERM LIABILITIES:			
Long-term warrant liability	6,057	-	6,057
Convertible note	8,141	-	8,141
Uncertain tax position	1,771	-	1,771
Long-term operating lease liabilities	9	-	9
Total non-current liabilities	<u>15,978</u>	<u>-</u>	<u>15,978</u>
STOCKHOLDERS' EQUITY (DEFICIENCY):			
Common stock	12	-	12
Additional paid-in capital	172,797	-	172,797
Accumulated deficit	(197,226)	72,195(7) 39(8) (12,974)(5)	(137,966)
Total shareholders' equity (deficiency)	<u>(24,417)</u>	<u>59,260</u>	<u>34,843</u>
Total liabilities and shareholders' equity (deficiency)	<u>\$ 16,579</u>	<u>\$ 65,226</u>	<u>\$ 81,805</u>

**Unaudited Pro Forma Condensed Combined
Statement of Operations
Year ended December 31, 2023**
(in thousands except per share and
share data)

	Company As Reported	Biosight For the Period January		Pro Forma Company Post Merger	Discontinued Operations	Company Post Asset Sale
	For the Year Ended December 31, 2023	1, 2023 through October 18, 2023	Merger Pro Forma Adjustments			
Revenue	\$ 13	\$ -	\$ -	\$ 13	\$ (13)(10)	\$ -
Cost of revenue	(13)	-	-	(13)	13(10)	-
Gross profit	-	-	-	-	-	-
Operating expenses:						
Research and development	24,081	7,114	-	31,195	(20,544)(11)	10,651
General and administrative	12,185	1,686	-	13,871	-	13,871
Total operating expenses	36,266	8,800	-	45,066	(20,544)	24,522
Operating loss	(36,266)	(8,800)	-	(45,066)	20,544	(24,522)
Financial income (expense), net	(15,718)	2,151	(2,236)(9)	(15,803)	-	(15,803)
Loss before income tax	(51,984)	(6,649)	(2,236)	(60,869)	20,544	(40,325)
Income tax benefit	3,912	-	-	3,912	-	3,912
Net loss	<u>\$ (48,072)</u>	<u>\$ (6,649)</u>	<u>\$ (2,236)</u>	<u>\$ (56,957)</u>	<u>\$ 20,544</u>	<u>\$ (36,413)</u>
Net loss per share basic & diluted	<u>\$ (7.99)</u>					<u>\$ (3.39)</u>
Weighted average number of common shares outstanding basic & diluted	<u>6,019,063</u>					<u>10,733,646(12)</u>

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

The pro forma adjustments are based on preliminary estimates and assumptions by management that are subject to change. The following adjustments have been reflected in the unaudited pro forma financial information.

- (1) Pro forma adjustment represents the cash received at Closing from the Asset Sale.

Gross proceeds from sale, excluding contingent consideration	\$ 72,212
Fair value of 2,175,489 shares of Immunome common stock	(52,212)
Net cash proceeds from sale	<u>20,000</u>
Reimbursement of expenses	39
Direct payment of certain vendor invoices	(3,025)
Non-refundable deposit from Immunome	(4,000)
Cash received at Closing	<u>\$ 13,014</u>

- (2) Pro forma adjustments for 2,175,489 shares received from Immunome based on market close price of such shares on the Nasdaq Capital Market of \$24.00 per share. Of the 2,175,489 shares received, the Company has agreed with Immunome that it may not sell more than 50% of the shares in the first six months following the Closing of the Asset Sale, but there are no such restriction on the remaining 50% of the shares. The resale by the Company of the Shares has been registered by Immunome under the Securities Act through the filing of a Registration Statement on Form S-3 (SEC File No. 333-278490), which was effective under the Securities Act upon filing with the SEC on April 3, 2024, and thus the Company can sell the Shares (subject to the contractual restriction described in this paragraph) at any time.

- (3) As part of the cash consideration at Closing, Immunome paid \$3,025 of the Company's liabilities directly to vendors of the Company, at the Company's discretion. Of this amount, \$725 is in trade payables and \$2,300 is in accrued expenses and other payables.

- (4) Pro forma adjustment for estimated net change in accrued expenses and other payables:

Estimated net change in Accrued expenses and other payables

	Amounts
Estimated transaction expenses accrued at Closing	\$ 1,405
Direct payment of certain vendor invoices (3)	(2,300)
Book value of liabilities assumed by Immunome	(1,388)
Net change in accrued expenses and other payables	<u>\$ (2,283)</u>

- (5) Pro forma adjustment to accrue estimated income taxes owed as a result of the Asset Sale:

Net gain on Asset Sale	\$ 72,195
Estimated deductions	(29,072)
	<u>43,123</u>
Estimated income tax rate:	
Federal	21.00%
State	9.09%
	<u>30.09%</u>
Estimated income taxes payable	<u>\$ 12,974</u>

- (6) Pro forma adjustment to remove \$4,000 that had been paid upon entering into an exclusivity agreement with Immunome in December 2023, and has been recorded as a liability until Closing.

- (7) Pro forma adjustment to reflect the estimated net gain from the Asset Purchase Sale:

Gross proceeds from sale, excluding contingent consideration	\$ 72,212
Estimated transaction expenses accrued at Closing	(1,405)
Book value of liabilities assumed by Immunome	1,388
Net gain on Asset Sale	<u>\$ 72,195</u>

- (8) Pro forma adjustment to account for \$39 received in cash for Company expense reimbursements.

- (9) Pro forma adjustment to remove change in fair value of Biosight's warrants to purchase Biosight's common stock. These warrants were cancelled as a result of the Merger.

- (10) Pro forma adjustment to remove licensing agreement revenue and related cost generated from technology sold to Immunome.

- (11) Pro forma adjustment to remove research and development expenses related to assets sold to Immunome.

- (12) Pro forma adjustment to weighted average common shares outstanding related to the Merger:

Weighted average Company shares outstanding - basic and diluted	6,019,063
Adjusted for:	
Shares issued to Biosight shareholders, as if the Merger occurred on January 1, 2023	4,714,583
Pro forma adjusted weighted average shares outstanding – basic and diluted	<u>10,733,646</u>
Pro forma net loss per share – basic and diluted	<u>\$ (36,413)</u>
Pro forma net loss per common share – basic and dilutive	<u>\$ (3.39)</u>

(d) Exhibits

Exhibit Number	Description
<u>2.1</u> [†]	<u>Asset Purchase Agreement, dated as of February 5, 2024, by and between Ayala Pharmaceuticals, Inc. and Immunome, Inc. (incorporated by Reference to Exhibit 2.1 to the Current Report on Form 8-K of the Registrant, filed with the SEC on February 6, 2024).</u>
<u>99.1</u>	<u>Press release dated March 25, 2024 (previously filed).</u>
<u>104</u>	<u>Cover Page Interactive Data File (embedded within the Inline XBRL document).</u>

+ Certain schedules and exhibits to this agreement have been omitted in accordance with Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission on request.

† Certain confidential information contained in this document, marked by ***, has been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both (i) not material and (ii) the type of information that the registrant treats as private or confidential.

SIGNATURES

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

Date: April 19, 2024

AYALA PHARMACEUTICALS, INC.

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