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

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): April 5, 2023

AYALA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

Emerging growth company

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

EXPLANATORY NOTE

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

Although Old Ayala is now a direct subsidiary of the Registrant, for accounting purposes the Merger is treated as a “reverse acquisition” and Old Ayala is considered the accounting acquirer. Accordingly, as of the closing of the Merger, Old Ayala’s historical financial condition and results of operations replace the Registrant’s historical financial condition and results of operations for all periods prior to the Merger and, for all periods ending after the Merger, the financial condition and results of operations of both companies will be included in the Registrant’s financial statements.

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

Item 4.01 Changes in Registrant’s Certifying Accountant.

The financial statements of Old Ayala as of and for the years ended December 31, 2022 and 2021 were audited by Kost, Forer, Gabbay & Kasierer, a Member of EY Global (“KFGK”). The financial statements of Pre-Merger Advaxis as of and for the years ended October 31, 2022 and 2021 were audited by Marcum LLP (“Marcum”).

After the completion of the Merger, the audit committee of the Registrant’s board of directors (the “Audit Committee”), which has the responsibility to engage and dismiss the Registrant’s auditor under Rule 10A-3(b)(2), made the decision to continue the engagement of both KFGK and Marcum, KFGK to serve as the independent registered public accounting firm to audit the consolidated financial statements of Old Ayala (the accounting acquirer in the Merger) for the year ended December 31, 2022 and Marcum to serve as the independent registered public accounting firm to audit the consolidated financial statements of Pre-Merger Advaxis (the accounting acquiree in the Merger) for the year ended October 31, 2022.

Dismissal of Independent Registered Public Accounting Firm

On April 5, 2023, the Audit Committee determined to discontinue the engagement of Marcum as the Registrant’s independent registered public accounting firm. Marcum’s audit report on the consolidated financial statements of the Registrant for the fiscal years ended October 31, 2022 and October 31, 2021 did not contain an adverse opinion or a disclaimer of opinion, and was not qualified or modified as to uncertainty, audit scope or accounting principles, except for an explanatory paragraph as to the Company’s ability to continue as a going concern. In connection with the audits of the Registrant’s consolidated financial statements for each of the two fiscal years ended October 31, 2022 and October 31, 2021, and in the subsequent interim period through the date of the termination of Marcum, there were no disagreements with Marcum on any matters of accounting principles or practices, financial statement disclosure, or auditing scope or procedures, which disagreements, if not resolved to the satisfaction of Marcum, would have caused Marcum to make reference to the subject matter of the disagreement in its report on such financial statements.

The Registrant provided Marcum with a copy of this disclosure and requested that Marcum furnish it with a letter addressed to the SEC stating whether it agrees with the above statements. Such letter is filed hereunder as Exhibit 16.1.

Engagement of Independent Registered Public Accounting Firm

On April 5, 2023, the Audit Committee approved the engagement of KFGK as the Registrant’s independent registered public accounting firm to audit the consolidated financial statements of the Registrant for the fiscal year ending December 31, 2023.

During the two most recent fiscal years of the Registrant and through April 5, 2023, the date of the engagement of KFGK, neither the Registrant nor any person on its behalf has consulted with KFGK with respect to either (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Registrant’s consolidated financial statements or (ii) any matter that was either the subject of a “disagreement” or a “reportable event” as such terms are described in Items 304(a)(1)(iv) or 304(a)(1)(v), respectively, of Regulation S-K promulgated under the under the Securities Exchange Act of 1934, as amended (the “Exchange Act”).

(d) *Exhibits.*

<u>Exhibit No.</u>	<u>Description</u>
16.1	Letter from Marcum LLP to the SEC regarding change in certifying accountants
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

April 7, 2023

AYALA PHARMACEUTICALS, INC.

By: /s/ Kenneth A. Berlin

Name: Kenneth A. Berlin

Title: President and Chief Executive Officer

April 7, 2023

Securities and Exchange Commission
100 F Street, N.E.
Washington, DC 20549

Commissioners:

We have read the statements made by Ayala Pharmaceuticals, Inc. under Item 4.01 of its Form 8-K dated April 5, 2023. We agree with the statements concerning our Firm in such Form 8-K; we are not in a position to agree or disagree with other statements of Ayala Pharmaceuticals, Inc. contained therein.

Very truly yours,

/s/ Marcum LLP

Marcum LLP
