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): July 5, 2022

Ayala Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**001-39279**	**82-3578375**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

Oppenheimer 4
Rehovot, Israel 7670104
(Address of Principal Executive Offices) (Zip Code)

Registrant's Telephone Number, Including Area Code: (857) 444-0553
(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:

☐ 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:

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

Indicate by check mark whether the registrant 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. ☐

Item 8.01. Other Events.

On July 5, 2022, Ayala Pharmaceuticals, Inc. announced interim data results from Part A of its ongoing RINGSIDE pivotal Phase 2/3 clinical trial evaluating AL102 in desmoid tumors. In February 2022, Part A completed enrollment of 42 patients with progressive desmoid tumors in three study arms across three doses of AL102: 1.2 mg daily, 2 mg twice weekly, and 4 mg twice weekly with initial follow up to evaluate safety, tolerability and tumor volume by MRI after 16 weeks.

As of the cut-off date of May 1, 2022, 13 patients had reached the 16-week time point of which 10 had a completed central reading of their MRI scans. Of these 10 patients, nine showed a decrease in tumor size. In addition, one patient showed an unconfirmed partial response as measured by RECIST 1.1. AL102 was observed to be well tolerated at all dose levels with no dose-limiting toxicities and no Grade 4 or 5 adverse events observed. The most common treatment-related adverse events were Grade 1 and 2 and included diarrhea, fatigue, skin rash and nausea.

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.

Ayala Pharmaceuticals, Inc.

Date: July 5, 2022

By: /s/ Roni Mamluk
Roni Mamluk, Ph.D.
Chief Executive Officer and President