# 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): June 22, 2020**

# AYALA PHARMACEUTICALS, INC.
**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-39279** | **82-3578375** |
|---|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(Commission File Number)** | **(I.R.S. Employer Identification No.)** |

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

**+972-8-373-1541**
**(Registrant's telephone number, include area code)**

**N/A**
**(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 Symbols | 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 2.02 Results of Operations and Financial Condition**

On June 22, 2020, Ayala Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 2020, and provided a business update on recent corporate and clinical developments. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits**

**(d) Exhibits**

99.1 Press release dated June 22, 2020

**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: June 22, 2020

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

# Ayala Pharmaceuticals Reports First Quarter 2020 Financial Results and Provides Business Update

*– Completed upsized initial public offering raising a total of $59.1 million in gross proceeds*

*– Current cash balance expected to fund operations into second half of 2022*

*– Fast Track Designation granted for lead candidate, AL101 for the treatment of R/M ACC; additional Phase 2 data expected in 2H20*

*– Dosing commenced in the R/M ACC study in the 6mg cohort*

*– IND accepted by FDA for Phase 2 study in AL101 for the treatment of TNBC; study on track to initiate in 2H20*

REHOVOT, Israel & WILMINGTON, Del., June 22, 2020 – (GLOBE NEWSWIRE) – Ayala Pharmaceuticals, Inc. (Nasdaq: AYLA), 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, today reported financial results for the first quarter ended March 31, 2020 and highlighted recent progress and upcoming milestones for its pipeline programs.

“Despite the challenges presented by the COVID-19 pandemic, Ayala continues to operate from a position of strength both clinically and operationally. We remain on track to report additional data from our ongoing Phase 2 ACCURACY study in R/M ACC and to initiate our Phase 2 AL101 study of TNBC before year end,” said Roni Mamluk, Ph.D., Chief Executive Officer of Ayala. “In addition, in May 2020, we completed our upsized IPO, providing us the financial stability to further develop both AL101 and AL102 across a wide range of genetically defined cancer indications, as well as in multiple myeloma in collaboration with Novartis.”

**Key Business and Clinical Highlights**

- **Completed Upsized Initial Public Offering:** In May 2020, Ayala successfully completed its initial public offering (IPO) of 3,666,667 shares of common stock and additional 274,022 shares in connection with the partial exercise of the underwriters’ option to purchase additional shares, at a public offering price of $15.00 per share. The total gross proceeds from the IPO were approximately $59.1 million. Through this offering Ayala broadened its shareholder base with a number of U.S. healthcare dedicated funds.
- **Received Fast Track Designation for AL101 for the Treatment of Recurrent/Metastatic Adenoid Cystic Carcinoma (R/M ACC):** In March 2020, Ayala received Fast Track designation from the U.S. Food and Drug Administration (FDA) for AL101 for the treatment of R/M ACC with Notch-activating mutations. Ayala’s lead product candidate, AL101 is a potent, selective, injectable small molecule gamma secretase inhibitor (GSI) and was granted Orphan Drug Designation in May 2019 for the treatment of R/M ACC.
- **Commenced Dosing of Patients in 6mg Cohort of R/M ACC Study:** Ayala commenced dosing of the second patient cohort in its ACCURACY study for the treatment of R/M ACC with Notch-activating mutations at the higher dose of 6mg. In the first cohort of the study, 45 patients were dosed at 4mg where clear signs of clinical activity were observed along with a favorable safety profile. The study is expected to dose 42 patients in the 6mg cohort.
- **Investigational New Drug (IND) Accepted by FDA for Phase 2 Study of AL101 For Treatment of TNBC:** In April 2020, the FDA accepted the IND for the Phase 2 study of AL101 for treatment of triple negative breast cancer (TNBC.) The FDA approved the dosing to commence at 6mg in a monotherapy study to evaluate TNBC patients bearing Notch activating mutations who have undergone 3 prior lines of therapies or less.

**Upcoming Milestones**

- **On Track to Report Additional Phase 2 Data of AL101 in Patients with R/M ACC Data in The Second Half of 2020:** Ayala plans to report additional data from its ongoing Phase 2 ACCURACY study of AL101 for the treatment of patients with R/M ACC with Notch-activating mutations, a rare malignancy of the secretory glands, at an upcoming medical meeting in the second half of 2020. Initial data demonstrating a 15% response rate and 69% disease control rate were previously reported out of the first 39 evaluable patients in the 4mg cohort.

- **On Track to Initiate Phase 2 Study of AL101 in Patients with Recurrent/Metastatic Triple Negative Breast Cancer** (R/M TNBC) **in The Second Half of 2020:** Ayala plans to initiate a Phase 2 clinical trial of AL101 for the treatment of patients with R/M TNBC with Notch-activating mutations in the second half of 2020, subject to the impact of COVID-19.

**First Quarter 2020 Financial Results**

- **Cash Position:** Cash and cash equivalents were $10.1 million as of March 31, 2020, as compared to $16.7 million as of December 31, 2019. Total cash, cash equivalents and marketable securities at March 31, 2020 did not include total net proceeds of approximately $55.0 million, after deducting underwriting discounts and commissions, from the Company's IPO of 3,940,689 shares of common stock, including the partial exercise of the underwriters' option to purchase additional shares, in May 2020. We expect the cash balance to fund operations into the second half of 2022 through potentially multiple key clinical and development milestones.
- **Collaboration Revenue:** Collaboration revenue was $1.0 million for the first quarter of 2020, compared to $0.3 million for the same period in 2019. The increase in revenue was due to the advancement of our collaboration with Novartis on AL102 in combination with Novartis' anti BCMA agent.
- **R&D Expenses:** Research and development expenses were $5.1 million for the first quarter of 2020, compared to $2.8 million for the same period in 2019. The increase was primarily driven by higher costs related to the advancement of our ongoing Phase 2 study of AL101 in ACC and preparations for the initiation of the Phase 2 study in our TNBC trial.
- **G&A Expenses:** General and administrative expenses were $1.3 million for the first quarter of 2020, compared to $0.8 million for the same period in 2019. The increase was primarily related to higher professional services and personnel costs to support the growth of the company.
- **Net Income/Loss:** Net loss was $6.6 million, or $1.32 loss per share, for the first quarter of 2020, compared to $3.5 million, or $0.71 loss per share, for the same period in 2019, attributable mainly to the increase in our clinical operations.

**About Ayala Pharmaceuticals**

Ayala Pharmaceuticals, Inc. is 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. Ayala's approach is focused on predicating, identifying and addressing tumorigenic drivers of cancer through a combination of its bioinformatics platform and next-generation sequencing to deliver targeted therapies to underserved patient populations. The company has two product candidates under development, AL101 and AL102, targeting the aberrant activation of the Notch pathway with gamma secretase inhibitors to treat a variety of tumors including Adenoid Cystic Carcinoma, Triple Negative Breast Cancer (TNBC), T-cell Acute Lymphoblastic Leukemia (T-ALL), Desmoid Tumors and Multiple Myeloma (MM) (in collaboration with Novartis). Ayala's lead product candidate, AL101, has received Fast Track Designation and Orphan Drug Designation from the U.S. FDA and is currently in a Phase 2 clinical trial for patients with ACC (ACCURACY) bearing Notch activating mutations. For more information, visit www.ayalapharma.com

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**Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including statements relating to our development of AL101 and AL102, 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, upcoming milestones, including without limitation the timing and results of any clinical trials or readouts, and the sufficiency of cash to fund operations. These forward-looking statements are based on management's current expectations. The words "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "estimate," "believe," "predict," "potential" or "continue" or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These statements are neither promises nor guarantees, but 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, including, but not limited to, the following: the impact of the COVID-19 pandemic on our operations, including our preclinical studies and clinical trials, and the continuity of our business; we have incurred significant losses, are not currently profitable and may never become profitable; our need for additional funding; our cash runway; our limited operating history and the prospects for our future viability; the lengthy, expensive, and uncertain process of clinical drug development, including potential delays in regulatory approval; our requirement to pay significant payments under product candidate licenses; the approach we are taking to discover and develop product candidates and whether it will lead to marketable products; the expense, time-consuming nature and uncertainty of clinical trials; enrollment and retention of patients; potential side effects of our product candidates; our ability to develop or to collaborate with others to develop appropriate diagnostic tests; protection of our proprietary technology and the confidentiality of our trade secrets; potential lawsuits for, or claims of, infringement of third-party intellectual property or challenges to the ownership of our intellectual property; risks associated with international operations; our ability to retain key personnel and to manage our growth; the potential volatility of our common stock; costs and resources of operating as a public company; unfavorable or no analyst research or reports; and securities class action litigation against us. These and other important factors discussed under the caption "Risk Factors" in Quarterly Report on Form 10-Q for the three months ended March 31, 2020 filed with the U.S. Securities and Exchange Commission (SEC) on June 22, 2020 and our other filings with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. New risk factors and uncertainties may emerge from time to time, and it is not possible to predict all risk factors and uncertainties. While we may elect to update such forward-looking statements at some point in the future, except as required by law, we disclaim any obligation to do so, even if subsequent events cause our views to change. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

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

| | March 31, 2020 (unaudited) | December 31, 2019 |
|---|---|---|
| **CURRENT ASSETS:** | | |
| Cash and cash equivalents | $ 10,055 | $ 16,725 |
| Short-term restricted bank deposits | 81 | 83 |
| Trade receivables | 1,001 | 469 |
| Prepaid expenses and other current assets | 313 | 417 |
| Total current assets | 11,450 | 17,694 |
| **LONG-TERM ASSETS:** | | |
| Other assets | $ 274 | $ 283 |
| Deferred offering costs | 2,050 | 656 |
| Property and equipment, net | 1,388 | 1,421 |
| Total long-term assets | 3,712 | 2,360 |
| Total current assets | $ 15,162 | $ 20,054 |
| **LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS DEFICIT:** | | |
| **CURRENT LIABILITIES:** | | |
| Trade payables | $ 3,362 | $ 2,922 |
| Other Accounts payables | 3,104 | 2,380 |
| Total current liabilities | 6,466 | 5,302 |
| **LONG TERM LIABILITIES:** | | |
| Long-term rent liability | 548 | 299 |
| Total long-term liabilities | $ 548 | $ 299 |
| Convertible preferred stock, $0.01 par value: | | |
| Series A Preferred Stock of $0.01 par value per share; 3,700,000 shares authorized at December 31, 2019 and March 31, 2020; 3,679,778 issued and outstanding shares at December 31, 2019 and March 31, 2020; aggregate liquidation preference value of $23,919 at December 31, 2019 and March 31, 2020 | $ 23,823 | $ 23,823 |
| Series B Preferred Stock of $0.01 par value per share; 4,500,000 shares authorized at December 31, 2019 and March 31, 2020; 3,750,674 issued and outstanding shares at December 31, 2019 and March 31, 2020; aggregate liquidation preference value of $29,668 at December 31, 2019 and March 31, 2020 | 29,550 | 29,550 |
| Total convertible preferred stock | $ 53,373 | $ 53,373 |
| **STOCKHOLDERS' (DEFICIT) EQUITY:** | | |
| Common Stock of $0.01 par value per share; 20,000,000 shares authorized at December 31, 2019 and March 31, 2020; 5,064,722 shares issued at December 31, 2019 and March 31, 2020; 4,998,874 and 5,003,380 shares outstanding at December 31, 2019 and March 31, 2020, respectively | $ 51 | $ 51 |
| Additional paid-in capital | 2,063 | 1,770 |
| Accumulated deficit | (47,339) | (40,741) |
| Total stockholders' deficit (no ()) | (45,225) | (38,920) |
| Total liabilities, convertible preferred stock, and stockholders' deficit (no ()) | $ 15,162 | $ 20,054 |

**AYALA PHARMACEUTICALS, INC.**
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**
**(Unaudited)**
(in thousands, except share and per share amounts)

| | Three months ended | |
|---|---|---|
| | **March 31, 2020** | **March 31, 2019** |
| Revenues from license agreement | $ 1,001 | $ 265 |
| Cost of revenue | (1,001) | (265) |
| Gross profit | — | — |
| Research and development | 5,128 | 2,752 |
| General and administrative | 1,311 | 848 |
| Operating loss | (6,439) | (3,600) |
| Financial (loss) income, net | (38) | 136 |
| Loss before income tax | (6,477) | (3,464) |
| Taxes on income | (121) | (75) |
| Net loss attributable to common stockholders | $ (6,598) | $ (3,539) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (1.32) | $ (0.71) |
| Weighted average common shares outstanding, basic and diluted | **4,999,563** | **4,960,936** |