Ayala Pharmaceuticals Reports Second Quarter 2020 Financial Results and Provides Business Update

August 13, 2020

– New interim data from Phase 2 ACCURACY study of AL101 for the treatment of R/M ACC to be presented at ESMO 2020 –

– On track to initiate patient dosing in Phase 2 TENACITY study of AL101 for the treatment of TNBC in 2020 –

REHOVOT, Israel and WILMINGTON, Del., Aug. 13, 2020 (GLOBE NEWSWIRE) -- Ayala Pharmaceuticals, Inc. (Nasdaq: AYLA) (the Company or Ayala), 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 second quarter ended June 30, 2020 and highlighted recent progress and upcoming milestones for its pipeline programs.

"Our successful IPO in the second quarter represents an important step for Ayala as we work to make meaningful strides across our exciting programs. With a well-capitalized foundation on which to further develop our novel pipeline of therapies for genetically defined cancers, we are poised to execute across multiple milestones in the remainder of 2020 and through the first half of 2021," said Roni Mamluk, Ph.D., Chief Executive Officer of Ayala. "We are looking forward to presenting new interim data from our Phase 2 ACCURACY study of AL101 for the treatment of ACC in September 2020, while also continuing to dose patients in the 6mg dose cohort of the study. Now more than ever, the need for innovation and drug development is evident and we are pleased by the additional clinical progress we have made to-date. This quarter our IND was accepted for our Phase 2 TENACITY study of AL101 monotherapy in patients with recurrent or metastatic triple negative breast cancer who have undergone up to three prior lines of therapy and we are on track to begin dosing patients this year."

Key Business and Clinical Highlights

- **Phase 2 TENACITY Study of AL101 For Treatment of Triple Negative Breast Cancer:** In April 2020, the U.S. Food and Drug Administration (FDA) accepted the investigational new drug application (IND) for the Phase 2 TENACITY study of AL101 for the 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 or fewer prior lines of therapy. Ayala has opened its first U.S. clinical site for the study.

Upcoming Milestones

- **New Interim Data from Phase 2 ACCURACY Study of AL101 for the Treatment of Recurrent/Metastatic Adenoid Cystic Carcinoma to be Presented at European Society for Medical Oncology (ESMO) Virtual Congress 2020:** Ayala will provide an oral presentation of new interim data from its ongoing Phase 2 ACCURACY study of AL101 for the treatment of recurrent/metastatic adenoid cystic carcinoma (R/M ACC) harboring Notch activating mutations at the upcoming ESMO Virtual Congress 2020 on September 18, 2020, at 03:55 CEST.

- **On Track to Begin Patient Dosing in Phase 2 TENACITY Study of AL101 for the Treatment of TNBC:** Ayala expects to initiate patient dosing before year-end 2020 in the Phase 2 TENACITY study of AL101 for the treatment of TNBC harboring Notch activating mutations.

- **On Track to Initiate Two Phase 2 Clinical Trials in 2021:**

    - **Phase 2 Study of AL102 for the Treatment of Desmoid Tumors:** Ayala expects to initiate a Phase 2 study of AL102, a potent, selective, oral gamma secretase inhibitor, in patients with desmoid tumors, a category of rare, disfiguring and often debilitating soft tissue tumors, in the first half of 2021.

    - **Phase 2 Study of AL101 for the Treatment of Relapsed or Refractory T-cell Acute Lymphoblastic Leukemia:** Based on findings from Ayala's Phase 1 study of AL101 and supporting data from its preclinical studies, Ayala expects to initiate a Phase 2 study of AL101 for the treatment of relapsed or refractory T-cell acute lymphoblastic leukemia (R/R T-ALL), an aggressive and rare form of T-cell specific leukemia, in the first half of 2021.

Second Quarter 2020 Financial Results

- **Cash Position:** Cash and cash equivalents were $57.4 million as of June 30, 2020, as compared to $16.7 million as of

December 31, 2019. Ayala expects its existing cash balance to fund operations through multiple potential key clinical and development milestones into the second half of 2022.

- **Collaboration Revenue:** Collaboration revenue was $1.0 million for the second quarter of 2020 compared to $0.9 million for the same period in 2019. The increase in revenue was attributed to the advancement of Ayala's collaboration with Novartis for the development of AL102 in combination with Novartis' anti-B-cell maturation antigen agent.

- **R&D Expenses:** Research and development expenses were $5.1 million for the second quarter of 2020, compared to $3.4 million for the same period in 2019. The increase was primarily driven by additional costs in connection with the advancement of AL101 trials and other preclinical development.

- **G&A Expenses:** General and administrative expenses were $1.5 million for the second quarter of 2020, compared to $1.0 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 $6.7 million, or $0.74 loss per share, for the second quarter of 2020, compared to $3.8 million, or $0.76 loss per share, for the same period in 2019, mainly attributable to the advancement of the clinical trials and other preclinical development.

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, the sufficiency of cash to fund operations, and upcoming events and presentations. 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 six months ended June 30, 2020 filed with the U.S. Securities and Exchange Commission (SEC) on August 12, 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.

PART I—FINANCIAL INFORMATION

Item 1: Financial Statements

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

	June 30, 2020 (Unaudited)	December 31, 2019
CURRENT ASSETS:		
Cash and Cash Equivalents	$ 57,355	$ 16,725
Short-term Restricted Bank Deposits	83	83
Trade Receivables	836	469
Prepaid Expenses and other Current Assets	353	417
Total Current Assets	58,627	17,694
LONG-TERM ASSETS:		
Other Assets	$ 283	$ 283
Deferred Offering Costs	—	656
Property and Equipment, Net	1,365	1,421
Total Long-Term Assets	1,648	2,360
Total Assets	$ 60,275	$ 20,054
LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS EQUITY (DEFICIT):		
CURRENT LIABILITIES:		
Trade Payables	$ 3,565	$ 2,922
Other Accounts Payables	2,220	2,380
Total Current Liabilities	5,785	5,302
LONG TERM LIABILITIES:		
Long-term Rent Liability	534	299
Total Long-Term Liabilities	$ 534	$ 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 none on June 30, 2020 respectively; 3,679,778 issued and outstanding shares at December 31, 2019 and none on June 30, 2020; aggregate liquidation preference value of $23,919 and $0 at December 31, 2019 and June 30, 2020 respectively		$ 23, 823
Series B Preferred Stock of $0.01 par value per share; 4,500,000 shares authorized at December 31, 2019 and none on June 30, 2020 respectively; 3,750,674 issued and outstanding shares at December 31, 2019 and none on June 30, 2020; aggregate liquidation preference value of $29,668 and $0 at December 31, 2019 and June 30, 2020 respectively	—	29,550
Total Convertible Preferred Stock	$ —	$ 53,373
STOCKHOLDERS' DEFICIT:		
Common Stock of $0.01 par value per share; 20,000,000 shares authorized at December 31, 2019 and June 30, 2020; 5,064,722 and 12,779,284 shares issued at December 31, 2019 and June 30, 2020, respectively; 4,998,874 and 12,660,841 shares outstanding at December 31, 2019 and June 30, 2020, respectively	$ 128	51
Additional Paid-in Capital	107,879	1,770
Accumulated Deficit	(54,051)	(40,741)
Total Stockholders' Equity (Deficit)	53,956	(38,920)
Total Liabilities, Convertible Preferred Stock, and Stockholders' Equity (Deficit)	$ 60,275	$ 20,054

See accompanying notes to unaudited condensed consolidated financial statements.

AYALA PHARMACEUTICAL, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)

(In thousands, except share & per share amounts)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
	(in thousands except share and per share data)			
Revenues from licensing agreement	$ 1,045	$ 852	$ 2,046	$ 1,117
Cost of services	1,045	160	2,046	425
Gross profit	—	692	—	692
Operating expenses:				
Research and development	5,067	3,439	10,195	6,191
General and administrative	1,546	1,021	2,857	1,869
Operating loss	(6,613)	(3,768)	(13,052)	(7,368)
Financial Income, net	40	98	2	234
Loss before income tax	(6,573)	(3,670)	(13,050)	(7,134)
Taxes on income	(139)	(113)	(260)	(188)
Net loss attributable to common stockholders	(6,712)	(3,783)	(13,310)	(7,322)
Net Loss per share attributable to common stockholders, basic and diluted	$ (0.74)	$ (0.76)	$ (1.90)	$ (1.47)
Weighted average common shares outstanding, basic and diluted	**9,018,637**	**4,974,839**	**6,989,762**	**4,969,735**

See accompanying notes to unaudited condensed consolidated financial statements.