Ayala Pharmaceuticals Reports Full-Year 2021 Financial Results and Provides Corporate Update

March 28, 2022

- Part A of AL102 RINGSIDE study fully enrolled; interim data expected mid-2022 –

REHOVOT, Israel and WILMINGTON, Del., March 28, 2022 (GLOBE NEWSWIRE) -- Ayala Pharmaceuticals, Inc. (Ayala or the Company) (Nasdaq: AYLA), a clinical-stage oncology company focused on developing and commercializing small molecule therapeutics for patients suffering from rare and aggressive cancers today announced full-year 2021 financial results and provided a corporate update.

“2022 is off to a very promising start for Ayala, following a number of important accomplishments across our pipeline of innovative gamma-secretase inhibitors in 2021,” said Roni Mamluk, Ph.D., Chief Executive Officer of Ayala. “We are pleased with the progress of our AL102 program in desmoid tumors, having recently completed enrollment in Part A of the open label RINGSIDE study. We are encouraged by initial positive feedback received from investigators so far. We plan to announce initial interim data from Part A around mid-year 2022 and intend to move into Part B, the randomized portion of the study, immediately thereafter. We look forward to announcing additional data readouts and updates on our other clinical programs throughout 2022 including further data on AL101 in adenoid cystic carcinoma.”

2021 and Recent Business and Clinical Highlights

- **Completed enrollment of Part A of the Phase 2/3 RINGSIDE study of AL102 in desmoid tumors:** 36 patients have been enrolled in Part A of the RINGSIDE study, which is evaluating the safety and tolerability of AL102, as well as tumor volume by MRI at 16 weeks. Ayala expects to report an initial interim data read-out around mid-2022, with Part B of the study commencing immediately thereafter.
- **Initiated “Window of Opportunity” study of AL101 in adenoid cystic carcinoma (ACC):** The study is focused on determining the effects of AL101 for the treatment of ACC and other cancers. The goals of the study are to better understand the mechanism of AL101, determine the best treatment regime and generate data for the future development strategy. The study is being conducted in collaboration with M.D. Anderson Cancer Center and the Adenoid Cystic Carcinoma Research Foundation.
- **Presented positive preliminary clinical data from the ongoing ACCURACY trial in ACC:** Updated interim data from the 6mg cohort of the Phase 2 ACCURACY study of AL101 in recurrent/metastatic adenoid cystic carcinoma (R/M ACC) were presented at the European Society for Medical Oncology (ESMO) Congress 2021 demonstrating partial responses in three subjects (9%) and stable disease in 20 subjects (61%). At ESMO, the Company also presented preclinical proof of concept data on AL101 in combination with approved cancer therapies in patient-derived ACC tumor models
- **Initiated Phase 1 trial of AL102 in combination with Novartis’ B-cell maturation antigen** (**BCMA**) **targeting agent WVT078 in relapsed/refractory multiple myeloma (MM)**: inhibition of gamma-secretase with AL102 prevents the cleavage and shedding of BCMA, which is ubiquitously expressed on MM cells. Preclinical data have demonstrated that treatment with AL102 increases the expression of membrane-bound BCMA on the surface of MM cells and could enhance the activity of WVT078. Ongoing patient enrollment continues as planned.
- **AL101 in Notch-activated triple negative breast cancer:** The Company has elected to discontinue the Phase 2 TENACITY study as part of its efforts to focus its resources on the more advanced programs and studies including the RINGSIDE study in desmoid tumors and the ACCURACY study for ACC.

Upcoming Milestones

- **Initial interim data from the pivotal Phase 2/3 RINGSIDE trial in desmoid tumors (Mid-2022):** Ayala expects to report an initial interim data read-out from Part A of the Phase 2/3 RINGSIDE trial of AL102 in desmoid tumors around mid-2022. Part B of the study will be a double-blind placebo-controlled study and will start immediately after dose selection from Part A.
- **Additional data from the Phase 2 ACCURACY trial of AL101 in ACC:** The ongoing ACCURACY trial is an open-label, single-arm Phase 2 clinical trial evaluating AL101 as monotherapy for the treatment of R/M ACC patients with Notch-activated mutations. The first cohort of the trial included 45 subjects dosed at 4 mg of AL101 IV once weekly. Final data from the 4 mg cohort and additional data from the 6 mg cohort,which includes 42 subjects are expected to be reported in the second half of 2022.
- **Initiate Phase 2 Clinical Trial Evaluating AL102 in T-cell Acute Lymphoblastic Leukemia (T-ALL)**: Ayala plans to begin a Phase 2 clinical trial evaluating AL101 in R/R T-ALL in the second half of 2022.

Full Year 2021 Financial Results

Cash Position: Cash and cash equivalents were $37.3 million as of December 31, 2021, as compared to $42.4 million as of December 31, 2020.

Collaboration Revenue: Collaboration revenue was $3.5 million for the full year of 2021, as compared to $3.7 million for the full year of 2020.

R&D Expenses: Research and development expenses were $29.9 million for the full year 2021, compared to $22.4 million in 2020. The increase was primarily driven by additional costs in connection with the initiation and advancement of the Phase 2/3 RINGSIDE pivotal study for desmoid tumors.

G&A Expenses: General and administrative expenses were $9.3 million as of December 31, 2021, compared to $7.4 million as of December 31, 2020. The increase was primarily due to higher expenses in connection with our operations as a public company, including director and officer insurance, increased headcount, and stock-based compensation.

Net Loss: Net loss was $40.3 million for the full year 2021, resulting in basic and diluted net loss per share of ($2.80). This compares with a net loss was $30.1 million for the full year of 2020, equivalent to basic and diluted net loss per share of ($3.06).

For further details on the Company's financial results, refer to our Annual Report on Form 10-K, for the year ended December 31, 2021 filed with the U.S. Securities and Exchange Commission (SEC) on March 28, 2022.

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,. 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, T-cell Acute Lymphoblastic Leukemia (T-ALL), Desmoid Tumors and Multiple Myeloma (MM) (in collaboration with Novartis). 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 and other gene rearrangements. AL102 is currently in a pivotal Phase 2/3 clinical trial for patients with desmoid tumors (RINGSIDE) and is being evaluated in a Phase 1 clinical trial in combination with Novartis' BMCA targeting agent, WVT078, in patients with relapsed/refractory Multiple Myeloma. 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, the timing and results of any clinical trials or readouts, the sufficiency of cash to fund operations, and the anticipated impact of COVID-19, on our business. 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: we have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We are not currently profitable, and we may never achieve or sustain profitability; we will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of AL101 and AL102; we have identified conditions and events that raise substantial doubt about our ability to continue as a going concern; we have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability; we are heavily dependent on the success of AL101 and AL102, our most advanced product candidates, which are still under clinical development, and if either AL101 or AL102 does not receive regulatory approval or is not successfully commercialized, our business may be harmed; due to our limited resources and access to capital, we must prioritize development of certain programs and product candidates; these decisions may prove to be wrong and may adversely affect our business; the outbreak of COVID-19, may adversely affect our business, including our clinical trials; our ability to use our net operating loss carry forwards to offset future taxable income may be subject to certain limitations; our product candidates are designed for patients with genetically defined cancers, which is a rapidly evolving area of science, and the approach we are taking to discover and develop product candidates is novel and may never lead to marketable products; we were not involved in the early development of our lead product candidates; therefore, we are dependent on third parties having accurately generated, collected and interpreted data from certain preclinical studies and clinical trials for our product candidates; enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control; if we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of our product candidates may be delayed and our business will be harmed; our product candidates may cause serious adverse events or undesirable side effects, which may delay or prevent marketing approval, or, if approved, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales; the market opportunities for AL101 and AL102, if approved, may be smaller than we anticipate; we may not be successful in developing, or collaborating with others to develop, diagnostic tests to identify patients with Notch-activating mutations; we have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any of our product candidates; even if

we obtain FDA approval for our product candidates in the United States, we may never obtain approval for or commercialize them in any other jurisdiction, which would limit our ability to realize their full market potential; we have been granted Orphan Drug Designation for AL101 for the treatment of ACC and may seek Orphan Drug Designation for other indications or product candidates, and we may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity, and may not receive Orphan Drug Designation for other indications or for our other product candidates; although we have received Fast Track designation for AL101, and may seek Fast Track designation for our other product candidates, such designations may not actually lead to a faster development timeline, regulatory review or approval process; we face significant competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively; we are dependent on a small number of suppliers for some of the materials used to manufacture our product candidates, and on one company for the manufacture of the active pharmaceutical ingredient for each of our product candidates; our existing collaboration with Novartis is, and any future collaborations will be, important to our business. If we are unable to maintain our existing collaboration or enter into new collaborations, or if these collaborations are not successful, our business could be adversely affected; enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates, if approved, and may affect the prices we may set; if we are unable to obtain, maintain, protect and enforce patent and other intellectual property protection for our technology and products or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and we may not be able to compete effectively in our markets; we may engage in acquisitions or in-licensing transactions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources; and risks related to our operations in Israel could materially adversely impact our business, financial condition and results of operations.

These and other important factors discussed under the caption “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 29, 2022 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

U.S. dollars in thousands (except share and per share data)

	December 31, 2021	December 31, 2020
Assets		
Current Assets:		
Cash and Cash Equivalents	$ 36,982	$ 42,025
Short-Term Restricted Bank Deposits	122	90
Trade Receivables	-	681
Prepaid Expenses and Other Current Assets	2,636	1,444
Total Current Assets	39,740	44,240
Long-Term Assets:		
Other Assets	267	305
Property and Equipment, Net	1,120	1,283
Total Long-Term Assets	1,387	1,588
Total Assets	$ 41,127	$ 45,828
Liabilities and Stockholders’ Equity:		
Current Liabilities:		
Trade Payables	$ 3,214	$ 3,726
Other Accounts Payables	3,258	3,151
Total Current Liabilities	6,472	6,877
Long-Term Liabilities:		
Long-Term Rent Liability	497	553
Total Long-Term Liabilities	$ 497	$ 553
Stockholders’ Equity:		
Common Stock of $0.01 par value per share; 200,000,000 shares authorized at December 31, 2021 and 2020; 14,080,383 and 12,824,463 shares issued at December 31, 2021 and 2020, respectively; 13,956,035 and 12,728,446 shares outstanding at December 31, 2021 and 2020, Respectively.	$ 139	$ 128
Additional Paid-in Capital	145,160	109,157
Accumulated Deficit	(111,141)	(70,887)
Total Stockholders’ Equity	34,158	38,398
Total Liabilities and Stockholders’ Equity	$ 41,127	$ 45,828

AYALA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

U.S. dollars in thousands (except shares and per shares data)

	Year ended December 31, 2021	Year ended December 31, 2020
Revenue from License Agreement	$ 3,506	$ 3,708
Cost of Revenue	(3,506)	(3,708)
Gross Profit	—	—
Research and Development	$ 29,941	$ 22,406
General and Administrative	9,277	7,371
Operating Loss	(39,218)	(29,777)
Financial income (expenses), net	(260)	56
Loss before taxes on income	(39,478)	(29,721)
Taxes on Income	(776)	(425)
Net Loss	$ (40,254)	$ (30,146)
Net Loss per Share attributable to Common Stockholders, Basic and Diluted	$ (2.80)	$ (3.06)
Weighted Average Shares Used to Compute Net Loss per Share, Basic and Diluted	14,398,905	9,860,610