Ayala Pharmaceuticals Reports Financial Results For the Fiscal Year Ended October 31, 2022

February 10, 2023

REHOVOT, Israel and MONMOUTH JUNCTION, N.J., Feb. 10, 2023 (GLOBE NEWSWIRE) -- Ayala Pharmaceuticals, Inc. (f/k/a Advaxis Inc.) (the "Company," "New Ayala," "we," "us" or "our") (OTCQX: ADXS), a clinical-stage oncology company, today announces financial results for the fiscal year ended October 31, 2022.

Management Commentary

"We were pleased to close our previously announced merger in January 2023," said Kenneth A. Berlin, President and Chief Executive Officer of the Company. "Our immediate priorities include executing on Part B of the ongoing registration-enabling RINGSIDE study evaluating AL102 in desmoid tumors. We believe that AL102 has best in class potential and, if approved, may have important clinical advantages including safety, convenient once daily dosing and lower pill burden. For AL101, we expect to gain clarity this year on the development path in recurrent/metastatic adenoid cystic carcinoma (R/M ACC). We also continue to make progress on the development of ADXS-504 for the treatment of early prostate cancer. The dose escalation part of the investigator-sponsored trial at Columbia University has been completed and we are now enrolling patients in an expansion cohort."

Fiscal Year 2022 and Recent Business Highlights:

- **In October 2022, the Company, which was then known as Advaxis, Inc., entered into a definitive agreement to merge with the entity now known as Old Ayala, Inc. (which prior to the merger was named Ayala Pharmaceuticals, Inc.)** The merged company is focused primarily on the development and commercialization AL102 for the treatment of desmoid tumors. The merger closed on January 19, 2023, at which time the Company changed its name to Ayala Pharmaceuticals, Inc.
- **Announced positive interim data from Part A of the Phase 2/3 RINGSIDE study of AL102 in desmoid tumors:** Data showed that AL102 had efficacy across all cohorts, with early responses that deepened over time. AL102 was well tolerated at all three dosing regimens with no dose-limiting toxicities and no Grade 4/5 adverse events. The data were featured in an oral presentation at ESMO 2022 and in a poster at the CTOS 2022 annual meeting.
- **Initiated Part B (Phase 3 segment) of the RINGSIDE study in desmoid tumors:** Part B of RINGSIDE is a double-blind placebo-controlled study enrolling up to 156 patients with progressive desmoid disease, randomized between AL102 or placebo. The primary endpoint is progression free survival with secondary endpoints including objective response rates, duration of response, and patient-reported quality of life measures.
- **Fast Track designation granted for AL102:** The U.S. FDA granted Fast Track designation for AL102 for the treatment of progressing desmoid tumors. The designation holds important advantages that may expedite the development and regulatory review of AL102.
- **Presented data on AL101 in adenoid cystic carcinoma (ACC) at 2022 ASCO annual meeting:** In a poster at ASCO, an update was provided on the ACCURACY study, the only prospective study conducted to date in ACC patients carrying Notch-activating mutations. An overall disease control rate of 66.7% was observed. The median PFS in each of the 4mg and 6mg dose AL101 cohorts was 3.7 months and 6.7 months, respectively, among the patients who had a partial response.
- **Continued progress with Phase 1 clinical trial of ADXS-504 for early prostate cancer:** Dose escalation has been completed and enrollment at second dose level is being expanded at Columbia University. Four out of six patients treated are still on study and PSA values are being followed up. ADXS-504 has been well tolerated with no serious adverse events reported.

New Ayala's Consolidated Financial Results for the Fiscal Year Ended October 31, 2022

Cash position On October 31, 2022, the consolidated cash and cash equivalents position was $25.2 million.

Revenues: Revenues for the fiscal year 2022 were $250,000, compared with $3.2 million for the fiscal year 2021.

R&D expenses: Research and development expenses for fiscal year 2022 were $7.6 million, compared with $10.6 million for fiscal year 2021.

G&A expenses: General and administrative expenses for fiscal year 2021 were $8.9 million, compared to $11.5 million for fiscal year 2021.

Net loss: The net loss for the fiscal year ended October 31, 2022 was approximately $14.4 million or ($8.46) per share based on approximately 1.8

million weighted average shares outstanding. This compares with a net loss for fiscal year 2021 of approximately $17.9 million or ($11.07) per share based on approximately 1.6 million weighted average shares outstanding.

The above financial results, as well as the financial tables included in this press release, reflect the financial performance of the Company, then known as Advaxis Inc., prior to completion of the merger and do not include any contribution from Old Ayala.

For further details on the Company's financial results, refer to our Annual report on Form 10-K for the twelve months ended October 31, 2022, filed with the Securities and Exchange Commission. Old Ayala will report consolidated financial results for the full year ended December 31, 2022 (a period completed prior to the merger) on or about March 31, 2023.

About Ayala Pharmaceuticals, Inc.

Ayala Pharmaceuticals, Inc. is a clinical-stage oncology company primarily focused on developing and commercializing small molecule therapeutics for patients suffering from rare tumors and aggressive cancers and is also developing proprietary *Lm*-based antigen delivery products for patients suffering from more common cancers. The Company's lead candidates under development are the oral gamma secretase inhibitor, AL102, for desmoid tumors; the intravenous gamma secretase inhibitor, AL101, in adenoid cystic carcinoma; and ADXS-504, a *Lm*-based therapy for early-stage prostate cancer. AL102 has received Fast Track Designation from the U.S. FDA and is currently in the Phase 3 portion of a pivotal study for patients with desmoid tumors (RINGSIDE). For more information, visit www.ayalapharma.com.

Contacts:

Ayala Pharmaceuticals:
+1-857-444-0553
info@ayalapharma.com

Media:
Tricia Persad-Bevil
JPA
+44-7792-524442

Tim McCarthy
LifeSci Advisors, LLC
tim@lifesciadvisors.com
917-679-9282

Cautionary Statement Regarding Forward-Looking Statements

Certain statements contained in this filing may be considered forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, including statements regarding the transaction involving Old Ayala, Inc. (f/k/a Ayala Pharmaceuticals, Inc. ("Old Ayala") and Ayala Pharmaceuticals, Inc. (f/k/a Advaxis, Inc.) ("New Ayala" or "we," "us" or "our") and the ability to list the common stock of the Company on Nasdaq. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "anticipate," "plan," "likely," "believe," "estimate," "project," "intend," and other similar expressions among others. Statements that are not historical facts are forward-looking statements. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the success and timing of our clinical trials, including subject accrual; our ability to avoid and quickly resolve any clinical holds; our ability to obtain and maintain regulatory approval and/or reimbursement of our product candidates for marketing; our ability to obtain the appropriate labeling of our products under any regulatory approval; our plans to develop and commercialize our products; the successful development and implementation of our sales and marketing campaigns; the size and growth of the potential markets for our product candidates and our ability to serve those markets; our ability to successfully compete in the potential markets for our product candidates, if commercialized; regulatory developments in the United States and other countries; the rate and degree of market acceptance of any of our product candidates; new products, product candidates or new uses for existing products or technologies introduced or announced by our competitors and the timing of these introductions or announcements; market conditions in the pharmaceutical and biotechnology sectors; our available cash, including to support current and planned clinical activities; uncertainties as to our ability to obtain a listing of our common stock on Nasdaq; our ability to integrate our various business areas successfully and to achieve anticipated synergies following our recent merger and the possibility that other anticipated benefits of the transaction will not be realized; potential litigation relating to the transaction; the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; our ability to obtain additional funding; our ability to obtain and maintain intellectual property protection for our product candidates; the success and timing of our preclinical studies including IND-enabling studies; the timing of our IND submissions; our ability to get FDA approval for study amendments; the timing of data read-outs; the ability of our product candidates to successfully perform in clinical trials; our ability to initiate, enroll, and execute pilots and clinical trials; our ability to maintain our existing collaborations; our ability to manufacture and the performance of third-party manufacturers; the performance of our clinical research organizations, clinical trial sponsors and clinical trial investigators; our ability to successfully implement our strategy; and such other factors as are set forth in our periodic public filings with the SEC, including but not limited to those described under the heading "Risk Factors" in Old Ayala's Form 10-K for the fiscal year ended December 31, 2021, and New Ayala's periodic public filings with the SEC, including but not limited to those described under the heading "Risk Factors" in New Ayala's Form 10-K for the fiscal year ended October 31, 2022. Except as required by applicable law, we undertake no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

AYALA PHARMACEUTICALS, INC.
(formerly known as Advaxis, Inc.)
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	October 31,	
	2022	2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 25,208	$ 41,614
Prepaid expenses and other current assets	551	1,643
Total current assets	25,759	43,257
Property and equipment (net of accumulated depreciation)	38	118
Intangible assets (net of accumulated amortization)	110	3,354
Operating right-of-use asset (net of accumulated amortization)	12	40
Other assets	11	11
Total assets	$ 25,930	$ 46,780
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 22	$ 87
Accrued expenses	2,150	2,836
Current portion of operating lease liability	12	28
Common stock warrant liability	119	4,929
Total current liabilities	2,303	7,880
Operating lease liability, net of current portion	-	12
Total liabilities	2,303	7,892
Contingencies – Note 8	-	-
Series D convertible preferred stock- $0.001 par value; 0 shares authorized, 0 shares issued and outstanding at October 31, 2022 and October 31, 2021.	-	-
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized, 0 shares issued and outstanding at October 31, 2022 and October 31, 2021.	-	-
Common stock - $0.001 par value; 170,000,000 shares authorized, 1,815,951 and 1,820,452 shares issued and outstanding at October 31, 2022 and 2021.	2	2
Additional paid-in capital	466,584	467,486
Accumulated deficit	(442,959)	(428,600)
Total stockholders' equity	23,627	38,888
Total liabilities and stockholders' equity	$ 25,930	$ 46,780

AYALA PHARMACEUTICALS, INC.

(formerly known as Advaxis, Inc.)

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)

	Year Ended October 31,	
	2022	2021
Revenue	$ 250	$ 3,240
Operating expenses:		
Research and development expenses	7,616	10,562
General and administrative expenses	8,891	11,464
Intangible asset impairment	3,053	-
Total operating expenses	19,560	22,026

Loss from operations	(19,310)	(18,786)
Other income (expense):		
Interest income	157	5
Net changes in fair value of derivative liabilities	4,853	970
Other expense	(9)	(1)
Net loss before income taxes	(14,309)	(17,812)
Income tax expense	50	50
Net loss	(14,359)	(17,862)
Accretion of discount and redemption feature of convertible preferred stock	(1,025)	-
Income available to common stockholders	$ (15,384)	$ (17,862)
Net loss per common share, basic and diluted	$ (8.46)	$ (11.07)
Weighted average number of common shares outstanding, basic and diluted	1,818,639	1,613,634