Ayala Pharmaceuticals Announces First Quarter 2023 Financial Results and Provides Corporate Update

May 23, 2023

REHOVOT, Israel and MONMOUTH JUNCTION, N.J., May 23, 2023 (GLOBE NEWSWIRE) -- Ayala Pharmaceuticals, Inc. (OTCQX: ADXS), a clinical-stage oncology company, today announced first-quarter 2023 financial results and provided a corporate update.

“Our immediate priority is to complete enrollment in our ongoing Phase 3 registration-enabling RINGSIDE study in which we are currently evaluating AL102 in desmoid tumors,” said Ken Berlin, President and Chief Executive Officer of the Company. “We also look forward to providing a detailed update from the patients who were enrolled in Phase 2 (Part A) of RINGSIDE at the forthcoming ASCO annual meeting. For AL101, we expect to gain clarity this year on the development path in recurrent/metastatic adenoid cystic carcinoma (R/M ACC).”

First Quarter 2023 and Recent Business Highlights

- **Completed merger between Ayala Pharmaceuticals Inc. and Advaxis, Inc.** The merger closed on January 19, 2023.
- **Continued progress in Phase 3 RINGSIDE trial**: Enrollment continues in Phase 3 of the RINGSIDE trial, a double-blind placebo-controlled study enrolling up to 156 patients globally with progressive desmoid disease, randomized to either 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.

Upcoming Milestones

- **ASCO poster presentation on RINGSIDE:** A poster featuring updated results from the Phase 2 portion of RINGSIDE, evaluating AL102 in desmoid tumors, will be presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting on Saturday, June 3.
- **Data from Phase 1 trial of ADXS-504:** ADXS-504 is being evaluated in a Phase 1 investigator-sponsored study at Columbia University in patients with biochemically recurrent (early) prostate cancer. Readout of initial clinical and PSA data are expected in 2023.
- **Gain clarity on path for future development plan for AL101 in recurrent/metastatic adenoid cystic carcinoma (R/M ACC),** expected in 2023.

Consolidated Financial Results for the Quarter Ended March 31, 2023

Cash position On March 31, 2023, the consolidated cash and cash equivalents position was $16.8 million.

Revenue Collaboration revenue was $4 thousand in the three months ended March 31, 2023, compared with $0.5 million in the comparable period of 2022, mainly as a result of the Novartis Agreement.

R&D Expenses Research and development expenses were $7.3 million for the three months ended March 31, 2023 compared to $7.5 million for the three months ended March 31, 2022, a decrease of $0.2 million.

G&A Expenses General and administrative expenses were $4.6 million for the three months ended March 31, 2023 compared to $2.4 million for the three months ended March 31, 2022, an increase of $2.2 million.

Net Loss The net loss for the three months ended March 31, 2023 was approximately $7.4 million or ($1.67) per share based on approximately 4.4 million weighted average shares outstanding. This compares with a net loss for the three months ended March 31, 2022 of approximately $10.0 million or ($3.47) per share based on approximately 2.9 million weighted average shares outstanding.

For further details on the Company’s financial results, refer to our quarterly report on Form 10-Q for the three months ended March 31, 2023, filed with the Securities and Exchange Commission.

About Ayala Pharmaceuticals, Inc.

Ayala Pharmaceuticals, Inc. is a clinical-stage oncology company primarily focused on developing and commercializing small molecule therapeutics for people living with 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; ADXS-504, a *Lm*-based therapy for early-stage prostate cancer; and the intravenous gamma secretase inhibitor, AL101, for adenoid cystic carcinoma. AL102 has received Fast Track Designation from the U.S. FDA and is currently in the Phase 3 segment of a pivotal study for patients with desmoid

tumors (RINGSIDE). For more information, visit www.ayalapharma.com.

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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 future conduct of our studies and the potential efficacy and success of product candidates. 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 the Form 10-K for the fiscal year ended December 31, 2021 of Old Ayala, Inc. (f/k/a Ayala Pharmaceuticals, Inc.) and the Form 10-K for the fiscal year ended October 31, 2022 of Ayala Pharmaceuticals, Inc. (f/k/a Advaxis, Inc.) ("Ayala" or "we," "us" or "our"), and such entities' periodic public filings with the SEC, including but not limited to those described under the heading "Risk Factors" in 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.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	March 31, 2023	December 31, 2022
	(Unaudited)	
CURRENT ASSETS:		
Cash and cash equivalents	$ 16,839	$ 2,408
Short-term restricted bank deposits	108	110
Trade receivables	4	234
Prepaid expenses and other current assets	1,310	436
Total current assets	18,261	3,188
LONG-TERM ASSETS:		
Deferred issuance costs	-	1,953
Other assets	$ 212	$ 206
Operating lease right of use asset	1,442	1,462
Intangible assets, net	130	-
Property and equipment, net	950	960
Total long-term assets	2,734	4,581
Total assets	**$ 20,995**	**$ 7,769**

LIABILITIES AND STOCKHOLDERS' EQUITY:		
CURRENT LIABILITIES:		
Trade payable	$ 4,140	$ 4,080
Operating lease liabilities	253	419
Accrued expenses	2,026	551
Accrued payroll and employee benefits	1,728	994
Taxes and other accounts payable	1,686	1,492
Total current liabilities	9,833	7,536
LONG TERM LIABILITIES:		
Long-term warrant liability	77	-
Long-term operating lease liabilities	1,410	1,332
Total long-term liabilities	$ 1,487	$ 1,332
STOCKHOLDERS' EQUITY:		
Common Stock of $0.001 par value per share; 170,000,000 and 37,480,000 shares authorized on March 31, 2023 and December 31, 2022, respectively; 4,838,321 and 2,775,906 shares issued on March 31, 2023 and December 31, 2022, respectively; 4,772,740 and 2,695,067 shares outstanding at March 31, 2023 and December 31, 2022, respectively.*	$ 5	$ 3
Additional paid-in capital*	166,185	148,052
Accumulated deficit	(156,515)	(149,154)
Total stockholders' equity	9,675	(1,099)
Total liabilities and stockholders' equity	**$ 20,995**	**$ 7,769**

See accompanying notes to unaudited condensed consolidated financial statements in Form 10Q

* All of the ordinary shares and per share data have been retroactively adjusted for the impact of the merger

AYALA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except share & per share amounts)

	For the Three Months Ended March 31,	
	2023	**2022**
Revenues from license agreement	$ 4	$ 458
Cost of revenue	(4)	(368)
Gross profit	-	90
Operating expenses:		
Research and development	7,265	7,503
General and administrative	4,604	2,433
Operating loss	(11,869)	(9,846)
Financial income, net	301	82
Loss before income tax	(11,568)	(9,746)
Taxes on income	4,207	(189)
Net loss	(7,361)	(9,953)
Net loss per share, basic and diluted	$ (1.67)	$ (3.47)
Weighted average common shares outstanding, basic and diluted*	4,405,286	2,867,420

See accompanying notes to unaudited condensed consolidated financial statements in Form 10Q

* All of the ordinary shares and per share data have been retroactively adjusted for the impact of the merger