Advaxis Reports Fiscal Third Quarter 2019 Financial Results and Provides Pipeline Update

September 9, 2019

PRINCETON, N.J.--(BUSINESS WIRE)--Advaxis, Inc. (Nasdaq: ADXS), a clinical-stage biotechnology company focused on the discovery, development and commercialization of immunotherapy products, today announced an update on its clinical pipeline and financial results for the fiscal third quarter ended July 31, 2019.

"Safety and Immunogenicity of a Personalized Neoantigen-Listeria Vaccine in Cancer Patients"

Key corporate and clinical pipeline updates include:

- Completed enrollment of the first dose level in Part A of the Phase 1/2 trial with ADXS-503 monotherapy ("HOT Lung") being studied in patients with non-small cell lung cancer and set to begin enrolling patients simultaneously in the second dose level of Part A as well as Part B, a combination arm consisting of ADXS-503 plus a checkpoint inhibitor.
- Received $17 million in gross proceeds from an underwritten public offering.
- Presented early immune response and clinical data from the Phase 1 ADXS-NEO study, an open-label, dose-escalation, multicenter clinical trial. Preliminary direct ELISpot data showed that CD8+ T cell reactivity was generated in >90% of neoantigen pools from four patients so far treated (i.e., 1X 10^9 colony forming units (CFU) (n=2) and 1X10^8 CFU (n=2)) as well as antigen spreading. Initial deconvoluted ELISpot data from the second patient treated at 1X 10^9 CFU showed a hit rate of up to 90% of personalized antigen targets in the ADXS-NEO vectors. In addition, hotspot mutations were identified in all four patients treated in this study with CD8+ T cells generated against the hotspot mutations in the two evaluated patients' tumors serving as an important proof-of-mechanism for the Company's HOT program. To date, dosing of ADXS-NEO at 1x10^8 CFU has been safe, tolerable and immunogenic in two patients. ADXS-NEO dosed at 1x10^9 CFU was beyond the maximum tolerated dose with reversible Grade 3 hypoxia (n=2) and Grade 3 hypotension (n=1) dose-limiting toxicities.
- Presented two posters at the Frontiers in Cancer Immunotherapy conference at the New York Academy of Sciences with updated data from previous presentations at the recent American Association for Cancer Research (AACR) Annual Meeting. Findings from the first poster, "*Effects of ADXS-PSA With or Without Pembrolizumab on Survival and Antigen Spreading in Metastatic, Castration-Resistant Prostate Cancer Patients (Results from KEYNOTE-046)*," showed prolonged survival in prostate cancer patients with advanced and microsatellite-stable (MSS) disease, a subset of patients that are unlikely to respond to checkpoint inhibitors. The combination of ADXS-PSA and pembrolizumab appeared safe and tolerable in this heavily pretreated population of patients with metastatic castration-resistant prostate cancer. The majority of treatment-related adverse events consisted of transient and reversible Grade 1-2 chills/rigors, fever, hypotension, nausea and fatigue with no additive toxicity. Data from the second poster, *"Safety and Immunogenicity of a Personalized Neoantigen-Listeria Vaccine in Cancer Patients*" include further data from ADXS-NEO showing two MSS colorectal cancer patients dosed with ADXS-NEO at 1x10^8 CFU demonstrating increased CD8+ T cell infiltration in the tumor microenvironment after three doses of ADXS-NEO. Both patients had MSS metastatic colorectal cancer, which is considered to be a "cold" tumor that typically exhibits little CD8+ T cell infiltration along with resistance to immunotherapy, yet the preliminary results from both suggested a successful transition from "cold" tumors into "hot" tumors with ADXS-NEO therapy. An estimated 80-85% of colorectal cancer patients are MSS.
- Reduced operating expenses for the nine months ended July 31, 2019 by $24.6 million, or 46%, compared to the prior year's comparable period.

Management Commentary

"We believe the data generated from our ADXS-NEO program has provided valuable immunological insight that will be applicable across our neoantigen programs," said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. "Specifically, we are increasingly excited by the potential of our investigational ADXS-HOT program to provide a rapidly available, off-the-shelf immunotherapy to patients and believe that the generation of CD8+ T cells against hotspot mutations in the NEO program serves as an important proof-of-mechanism for this approach. In addition, we are thrilled to see consistent antigen spreading across our programs which is an important driver of clinical response."

Mr. Berlin continued, "We have continued our efforts to reduce cash burn and increase efficiencies, and with our improved cash position we will continue to focus our efforts on those programs most likely to improve patient outcomes and create shareholder value. We look forward to providing a more detailed pipeline update next month with important details relevant to the advancement of our innovative immunotherapy clinical programs."

Fiscal Third Quarter Ended July 31, 2019 Financial Results

Research and development expenses for the third quarter of fiscal year 2019 were $7.1 million, compared with $10.6 million for the third quarter of fiscal year 2018. The decrease is largely attributable to the wind down of its Phase 3 clinical trial in high-risk, locally advanced cervical cancer, as announced in June 2019.

General and administrative expenses for the three months ended July 31, 2019 decreased approximately $1.7 million, or 35%, compared to the same three-month period in 2018. In June 2018, the Company began instituting measures to control costs for non-essential items in areas that do not support the strategic direction of the company. The decrease in expenses in these areas is a direct result of these cost control measures.

As of July 31, 2019, the Company had approximately $41.8 million in cash and cash equivalents. The Company believes this is sufficient capital to fund its obligations, as they become due, in the ordinary course of business until at least September 2020.

About Advaxis, Inc.

Advaxis, Inc. is a clinical-stage biotechnology company focused on the discovery, development and commercialization of proprietary *Lm*-based antigen delivery products. These immunotherapies are based on a platform technology that utilizes live attenuated Listeria monocytogenes (*Lm*) bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm*-based strains are believed to be a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy and are designed to access and direct antigen presenting cells to stimulate anti-tumor T cell immunity, activate the immune system with the equivalent of multiple adjuvants, and simultaneously reduce tumor protection in the tumor microenvironment to enable T cells to eliminate tumors. Advaxis has three programs in various stages of clinical development: ADXS-NEO, a personalized neoantigen-directed therapy designed, in principle, for any solid tumor; ADXS-503 for non-small cell lung cancer, from its ADXS-HOT off-the-shelf neoantigen-directed program and ADXS-PSA for prostate cancer.

To learn more about Advaxis, visit www.advaxis.com and connect on Twitter, LinkedIn, Facebook and YouTube.

Forward-Looking Statements

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are any statements that express the current beliefs and expectations of management, including but not limited to statements related to the expected use of proceeds from the proposed offering. These and other risks are discussed in the Company's filings with the SEC, including, without limitation, its Annual Report on Form 10-K, filed on January 11, 2019, and its periodic reports on Form 10-Q and Form 8-K, as well as the risks identified in the registration statement and the preliminary prospectus supplement relating to the offering. Any statements contained herein that do not describe historical facts are forward-looking statements that are subject to risks and uncertainties that could cause actual results, performance and achievements to differ materially from those discussed in such forward-looking statements. The Company cautions readers not to place undue reliance on any forward-looking statements, which speak only as of the date they were made. The Company undertakes no obligation to update or revise forward-looking statements, except as otherwise required by law, whether as a result of new information, future events or otherwise.

Advaxis, Inc.

Selected Balance Sheet Data

(In thousands)

	July 31, 2019 (Unaudited)	October 31, 2018
Cash and cash equivalents	$ 41,755	$ 44,141
Restricted cash	$ -	$ 977
Total assets	$ 56,133	$ 62,267
Total stockholders' equity	$ 49,269	$ 24,051

STATEMENTS OF OPERATIONS

(unaudited, in thousands, except share and per share data)

	Three Months Ended July 31,		Nine Months Ended July 31,	
	2019	2018	2019	2018
Revenue	$ 6	$ 1,131	$ 20,883	$ 4,934
Operating expenses*				
Research and development expenses	7,060	10,560	19,735	37,679
General and administrative expenses	3,076	4,735	8,834	15,519
Total operating expenses	10,136	15,295	28,569	53,198
Loss from operations	(10,130)	(14,164)	(7,686)	(48,264)
Interest income, net	95	149	354	439
Net changes in fair value of derivative liabilities	177	-	2,572	-
Loss on shares issued in settlement of warrants	-	-	(1,607)	-
Income tax expense and other expense	-	(2)	(57)	(92)
Net loss	$ (9,858)	$ (14,017)	$ (6,424)	$ (47,917)
Net loss per common share, basic and diluted	$ (1.00)	$ (3.99)	$ (0.94)	$ (14.98)
Weighted average number of common shares outstanding, basic and diluted	9,870,461	3,511,261	6,813,494	3,197,778
* Includes stock-based compensation as follows:				
Research and development	$ 241	$ 543	$ 822	$ 2,342
General and administrative	223	1,409	743	3,645

	$ 464	$ 1,952	$ 1,565	$ 5,987

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