Advaxis Reports Fiscal Year 2019 Financial Results and Provides a Business Update

December 20, 2019

PRINCETON, N.J.--(BUSINESS WIRE)--Dec. 20, 2019-- Advaxis, Inc. (Nasdaq:ADXS), a clinical-stage biotechnology company focused on the development and commercialization of immunotherapy products, today announces its financial results for the fiscal year ended October 31, 2019 and provides a business update.

Fiscal Year 2019 and Recent Key Accomplishments

- Completed enrollment in the first and second dose levels in Part A of the ongoing Phase 1/2 trial evaluating ADXS-503, the Company's ADXS-HOT drug candidate in non-small cell lung cancer, with immune response data anticipated in early 2020.
- Completed manufacturing of ADXS-506, the Company's ADXS-HOT drug candidate for bladder cancer, enabling future potential clinical development.
- Reported early immune response data from the Phase 1 ADXS-NEO study demonstrating the generation of CD8+ T cells against hotspot neoantigen mutations. These results serve as an important proof-of-mechanism for the Company's off-the-shelf ADXS-HOT program which targets common hotspot mutations found in tumors.
- Announced updated overall survival from the KEYNOTE-046 Phase 1/2 trial evaluating ADXS-PSA in combination with KEYTRUDA® in metastatic castrate resistant prostate cancer. Median overall survival increased to 33.6 months from the previously reported 21.1 months.
- Entered collaborative research agreement with University of California, Los Angeles to investigate anti-tumor immunity and responses generated by *Lm* vaccines targeting glioblastoma neoantigens.
- Continued pipeline prioritization efforts enabling the reduction of operating expenses and extension of cash runway into early 2021.

Management Commentary

"Fiscal year 2019 has been marked with continued progress in the strategic advancement of our most promising clinical programs," said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. "With encouraging clinical proof-of-concept data, we are focused on developing and expanding our off-the-shelf neoantigen program, ADXS-HOT, and look forward to sharing immunogenicity data in early 2020. In addition, the announcement of significant improvements in overall survival from our KEYNOTE-046 study in prostate cancer further bolsters our confidence in the power of our *Lm* technology to improve patient outcomes and potentially shift the immunotherapy treatment paradigm. These promising data, in combination with our successful efforts to reduce cash burn and increase efficiencies, leave us positioned to execute on our innovative immunotherapy clinical pipeline."

Balance Sheet Highlights

As of October 31, 2019, Advaxis had cash and cash equivalents of $32.4 million. The Company used $36.1 million in cash to fund operations during fiscal year 2019, mainly attributed to funding research and development and general and administrative activities. Throughout fiscal year 2019, the Company continued a strategic pipeline prioritization across all programs and reduced its annual expenses by approximately $37.6 million, or nearly 50%.

Fiscal Year 2019 Financial Information

Research and development expenses for fiscal year 2019 were $26.7 million, compared with $57.0 million for fiscal year 2018**.** The $30.3 million decrease was primarily attributable to decreases in clinical trial costs, laboratory costs, drug manufacturing process validation and drug stability studies.

General and administrative expenses for fiscal year 2019 were $12.2 million, compared to $19.5 million for fiscal year 2018. The $7.3 million decrease was primarily attributable to the institution of control cost measures for non-essential items in areas that did not support the strategic direction of the Company, as well as a reduction in external costs associated with strategy, business consulting and regulatory in fiscal year 2018 that did not recur in fiscal year 2019.

The net loss for the fiscal year ended October 31, 2019 was $16.6 million or $1.09 per share based on 15.2 million weighted average shares outstanding. This compares with a net loss for fiscal year 2018 of $66.5 million or $19.36 per share based on 3.4 million weighted average shares outstanding.

About Advaxis, Inc.

Advaxis, Inc. is a clinical-stage biotechnology company focused on the 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.

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

Forward-Looking Statements

Some of the statements included in this press release may be forward-looking statements that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. The factors that could cause our actual results to differ materially include: the impact of the discontinuation on relationships related to the AIM2CERV Study; 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; 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 and IND filings; 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, other risk factors identified from time to time in our reports filed with the SEC. Any forward-looking statements set forth in this press release speak only as of the date of this press release. We do not intend to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof.

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Advaxis, Inc.
Selected Balance Sheet Data
(In thousands)

	October 31, 2019	October 31, 2018
Cash and cash equivalents	$ 32,363	$ 44,141
Restricted cash	$ -	$ 977
Total assets	$ 45,257	$ 62,267
Total stockholders' equity	$ 39,531	$ 24,051

STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	Year Ended October 31, 2019	Year Ended October 31, 2018
Revenue	$ 20,884	$ 6,063
Operating expenses*		
Research and development expenses	26,677	56,970
General and administrative expenses	12,179	19,472
Total operating expenses	38,856	76,442
Loss from operations	(17,972)	(70,379)
Other income	1,410	3,914
Net loss	$ (16,562)	$ (66,465)
Net loss per common share, basic and diluted	$ (1.09)	$ (19.36)
Weighted average number of common shares outstanding, basic and diluted	15,207,637	3,434,824

* Includes stock-based compensation as follows:

Research and development	$ 1,036	$ 2,836
General and administrative	966	4,147
	$ 2,002	$ 6,983

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