
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): **March 12, 2019**

ADVAXIS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36138
(Commission
File Number)

02-0563870
(IRS Employer
Identification No.)

**305 College Road East
Princeton, New Jersey, 08540**
(Address of Principal Executive Offices)

(609) 452-9813
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act.
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act.
- Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On March 12, 2019, Advaxis, Inc. (the “Company”) issued a press release announcing its financial results for the first quarter ended January 31, 2019 and provided a business update. A copy of that press release is being furnished as Exhibit 99.1 to this report.

The information furnished under this Item 2.02, including the accompanying Exhibit 99.1, shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”), or otherwise subject to the liability of such section, nor shall such information be deemed to be incorporated by reference in any subsequent filing by the Company under the Securities Act of 1933 or the Exchange Act, regardless of the general incorporation language of such filing, except as specifically stated in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished as part of this report:

Exhibit Number	Description
99.1	Press release issued by Advaxis, Inc. dated March 12, 2019

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ADVAXIS, INC.

(Registrant)

Date: March 12, 2019

By: */s/ Molly Henderson*

Molly Henderson

Executive Vice President and Chief Financial Officer

ADVAXIS

IMMUNOTHERAPIES

Advaxis Reports First Quarter Fiscal 2019 Financial Results and Provides Clinical Pipeline Update

PRINCETON, N.J. (March 12, 2019) – Advaxis, Inc. (NASDAQ: ADXS), a late-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 first quarter ended January 31, 2019.

Updates on the progress of the Company’s clinical pipeline include:

- Cancer Type-Focused Hotspot/Off-the-Shelf Neoantigen Therapies (ADXS-HOT)– The Company initiated its first clinical trial using a novel and proprietary approach to cancer immunotherapy that targets hotspot mutations, cancer testis antigens and oncofetal antigens. The first drug candidate from this program, ADXS-503, is designed to treat all types of non-small cell lung cancer and is now enrolling patients. Safety, tolerability and immune correlative data from this Phase1/2 study are anticipated by the end of June 2019.
 - Personalized, Neoantigen-Directed Therapy (ADXS-NEO) – The Company continues to enroll patients in a Phase 1 dose-escalation study with its personalized antigen delivery program using whole-exome sequencing of a patient’s tumor to identify personal neoantigens. Early immune response data from the first cohort of this study were presented last month at the Immuno-Oncology 360^o Conference, and safety, tolerability and immune correlative data from the first two cohorts will be presented at the American Association of Cancer Research (AACR) Annual Meeting on March 31, 2019.
 - Prostate Cancer (ADXS-PSA) – Previously reported data from a Phase 1/2 study of ADXS-PSA in combination with KEYTRUDA[®] (pembrolizumab) demonstrated a manageable safety profile (mostly grade 1-2 treatment-related adverse events), in a cohort of 37 heavily pretreated metastatic castration-resistant prostate cancer patients and showed a greater level of clinical activity compared to monotherapy. The Company will be presenting updated clinical and biomarker data on this program at the AACR Annual Meeting on April 1, 2019.
 - Cervical Cancer (ADXS-HPV) – In January 2019 the Company announced that the U.S. Food and Drug Administration (FDA) placed a partial clinical hold on the Company’s Phase 3 AIM2CERV clinical trial for axalimogene filolisbac (AXAL) in high-risk locally advanced cervical cancer. The partial hold relates to FDA’s request for additional information pertaining to certain AXAL chemistry, manufacturing and controls (CMC) matters. The FDA did not cite any safety issues related to the trial and all currently enrolled patients are continuing to receive treatment. The Company has submitted its initial response to the request for additional CMC information and is currently in discussions with the Agency. In parallel, Advaxis is in discussions with the Agency regarding the Company’s request, made late in 2018, to include a second interim analysis for efficacy. The Company is working diligently to reach a resolution with the Agency on both of these matters.
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Management Commentary

“We reached an important milestone with our ADXS-HOT program last month when we enrolled the first patient in the ADXS-503 Phase 1/2 clinical trial. This is the first clinical trial initiated using a drug construct from our ADXS-HOT program, for which we have designed over 10 different drug constructs for various cancer types,” said Kenneth A. Berlin, president and chief executive officer of Advaxis. “We continue to be very excited about our ADXS-HOT program and anticipate filing two additional INDs for drug constructs from this program during 2019.”

He added, “We expect 2019 will be an important and eventful year for Advaxis due to the amount of information we anticipate generating from our programs and we look forward to reporting data throughout the year. In order to ensure our various programs progress to data readout, we are continually evaluating ways to increase our cash runway by controlling expenses and generating cash from potential out-licensing and/or financing transactions.”

Financial Results for First Quarter Ended January 31, 2019

Research and development expenses for the first quarter of fiscal year 2019 were \$6.7 million, compared with \$16.8 million for the first quarter of fiscal year 2018. The \$10.1 million decrease was primarily attributable to costs incurred during the last fiscal year related to the Company’s Marketing Authorization Application in Europe and cost controls initiated in the latter part of fiscal year 2018. Additionally, there was a decrease in clinical trial expenses resulting from the partial clinical hold on AIM2CERV and winding down of several older studies.

General and administrative expenses for the first quarter of fiscal year 2019 were \$2.7 million, compared with \$5.9 million for the first quarter of fiscal year 2018. The \$3.2 million decrease was primarily attributable to professional and consulting fees relating to external strategy and program assessment work performed for the Company during fiscal year 2018 that did not recur in fiscal year 2019, in addition to improved cost controls initiated in the latter part of fiscal year 2018.

As previously reported, in December 2018 the Company received notice from Amgen of its intent to terminate its collaboration in the ADXS-NEO program. As a result, the Company adjusted its measure of progress for its performance obligations under the collaboration agreement and, based on the modified service period, reported incremental revenue of \$15.6 million in the first quarter of fiscal year 2019. Net income for the first quarter of fiscal year 2019 was \$12.8 million or \$0.18 per share, compared with a net loss for the first quarter of fiscal year 2018 of \$20.5 million or \$0.49 per share. Net cash used during the first quarter ended January 31, 2019 was \$12.4 million.

About Advaxis, Inc.

Advaxis, Inc. is a late-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 four programs in various stages of clinical development: ADXS-HPV for cervical cancer; ADXS-NEO, a personalized neoantigen-directed therapy for multiple cancers; 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.

Advaxis Forward-Looking Statement

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 success and timing of our clinical trials, including subject accrual; our ability to avoid any clinical holds and to resolve FDA's partial clinical hold; 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; 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 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.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, N.J., USA.

CONTACT:

Investors:

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

	<u>January 31, 2018</u>	<u>October 31, 2018</u>
	(Unaudited)	
Cash and cash equivalents	\$ 32,710	\$ 44,141
Restricted cash	\$ -	\$ 977
Total assets	\$ 50,303	\$ 62,267
Total stockholders' equity	\$ 37,500	\$ 24,051

Advaxis, Inc.
Condensed Statements of Operations
(unaudited, in thousands, except per share information)

	<u>Three Months Ended</u>	
	<u>January 31,</u>	
	<u>2019</u>	<u>2018</u>
Revenue	<u>\$ 19,689</u>	<u>\$ 2,056</u>
Operating expenses *		
Research and development expenses	6,707	16,751
General and administrative expenses	2,666	5,852
Total operating expenses	<u>9,373</u>	<u>22,603</u>
Income (loss) from operations	10,316	(20,547)
Net changes in fair value of derivative liabilities	2,409	-
Other income and taxes	192	155
Net income (loss)	<u>\$ 12,817</u>	<u>\$ (20,492)</u>
Net income (loss) per common share, basic and diluted	<u>\$ 0.18</u>	<u>\$ (0.49)</u>
Weighted average number of common shares outstanding, basic	<u>69,640,769</u>	<u>41,428,199</u>
Weighted average number of common shares outstanding, diluted	<u>69,642,251</u>	<u>41,428,199</u>
* Includes stock-based compensation as follows		
Research and development	\$ 323	\$ 1,273
General and administrative	299	1,536
	<u>\$ 622</u>	<u>\$ 2,809</u>

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