
**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): **July 13, 2018**

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 7.01 Regulation FD Disclosure.

A copy of the press release of the Company, dated July 13, 2018, relating to the announcement discussed in Item 8.01 below is attached hereto as Exhibit 99.1.

The information provided pursuant to this Item 7.01, including Exhibit 99.1, is “furnished” and shall not be deemed to be “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that Section or of Sections 11 and 12(a)(2) of the Securities Act, and shall not be incorporated by reference into any filing with the SEC made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01 Other Events.

On July 13, 2018, the Company issued a press release announcing that the U.S. Food and Drug Administration has lifted the clinical hold on the Company’s Investigational New Drug application for its Phase 1/2 study of axalimogene filolisbac in combination with durvalumab for the treatment of patients with advanced, recurrent or refractory cervical cancer and HPV-associated head and neck cancer.

Forward-Looking Statements

This report contains forward-looking statements, including, but not limited to, statements regarding the Company’s ability and strategies to develop and commercialize cancer immunotherapies, timing of planned clinical trials and regulatory milestones, potential partnership opportunities and the safety and efficacy of the Company’s proprietary immunotherapies. These forward-looking statements are subject to a number of risks including the risk factors set forth from time to time in the Company’s SEC filings including, but not limited to, its report on Form 10-K for the fiscal year ended October 31, 2017, which is available at www.sec.gov. Any forward-looking statements set forth in this report speak only as of the date of this report. We do not intend to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof other than as required by law. You are cautioned not to place undue reliance on any forward-looking statements. Information contained on the Company’s website does not constitute part of this report.

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 July 13, 2018.

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: July 13, 2018

By: /s/ Kenneth A. Berlin
Kenneth A. Berlin
President and Chief Executive Officer

ADVAXIS

IMMUNOTHERAPIES

Advaxis Announces FDA Lifts Clinical Hold on Phase 1/2 Combination Study of Axalimogene Filolisbac with Durvalumab

PRINCETON, N.J. (July 13, 2018) – Advaxis, Inc. (NASDAQ:ADXS), a late-stage biotechnology company focused on the discovery, development and commercialization of immunotherapy products, today announced that the U.S. Food and Drug Administration (FDA) has lifted the clinical hold on the Company's Investigational New Drug (IND) application for its Phase 1/2 study of axalimogene filolisbac (AXAL) in combination with durvalumab for the treatment of patients with advanced, recurrent or refractory cervical cancer and HPV-associated head and neck cancer.

The clinical hold for this study was issued on March 9, 2018 following submission by the Company of a safety report to the FDA regarding a patient death that occurred on February 27, 2018, post-dosing, involving acute respiratory failure after nine months of combination therapy. New guidelines for the early detection and treatment of such rare events were agreed to with the FDA and will be implemented for this combination study. Enrollment and dosing in all other Advaxis and durvalumab clinical programs were not affected by the clinical hold.

“We are pleased to have resolved this issue with the FDA and will implement these guidelines across Advaxis’ portfolio as needed, to ensure patient safety. We remain confident in the safety of axalimogene filolisbac based on our experience in treating approximately 400 patients and more than 1200 doses across multiple trials in HPV-associated cancers,” said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis.

About Axalimogene Filolisbac

Axalimogene filolisbac is a targeted *Listeria monocytogenes* (*Lm*)-based immunotherapy that attacks HPV-associated cancers by altering a live strain of *Lm* bacteria to generate cancer-fighting T cells against cancer antigens while neutralizing the tumor's natural protections that guard the tumor microenvironment from immunologic attack. In a Phase 2 trial evaluating axalimogene filolisbac for the treatment of persistent or recurrent metastatic (squamous or non-squamous cell) carcinoma of the cervix (PRmCC), the drug candidate showed a 12-month overall survival rate of 38% in 50 patients. This is a 52% improvement over the 12-month overall survival rate that was expected in the trial's patient population based on prognostic factors.

Axalimogene filolisbac has received Fast Track designation for adjuvant therapy for high-risk locally advanced cervical cancer (HRLACC) and a Special Protocol Assessment for the Phase 3 AIM2CERV trial in HRLACC patients. The immunotherapy has also received orphan drug designation in three clinical indications.

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 the T cells to eliminate tumors. Advaxis has product candidates in various stages of clinical and preclinical development in the following areas: HPV-associated cancers, neoantigen therapy, hotspot/cancer antigens and prostate cancer.

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

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: our ability to develop and commercialize the next generation of cancer immunotherapies; the safety and efficacy of our proprietary immunotherapies; the success and timing of our clinical trials, including patient accrual; our ability to release the clinical hold and reduce the impact to our trials; our ability to obtain and maintain regulatory approval and/or reimbursement of our product candidates for marketing; our plans to develop and commercialize our products; our ability to successfully compete in the potential markets for our product candidates, if commercialized; our ability to obtain additional funding; the success and timing of our preclinical studies including IND enabling studies; and our ability to successfully implement our strategy. These forward-looking statements are subject to a number of risks including the forward-looking statements and risk factors set forth from time to time in Advaxis' SEC filings including, but not limited to, our report on Form 10-K for the fiscal year ended October 31, 2017, and on Form 10-Q for the quarter ended January 31, 2018, which are available at www.sec.gov.

Any forward-looking statements set forth in this press release speak only as of the date of this presentation. We do not intend to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof other than as required by law. You are cautioned not to place undue reliance on any forward-looking statements.

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