
**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): **April 28, 2016**

ADVAXIS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

000-28489
(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.
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Item 7.01 Regulation FD Disclosure.

A copy of the press release of Advaxis, Inc. (the "Company") dated April 28, 2016 relating to the announcement discussed in Item 8.01 below is attached hereto as Exhibit 99.1.

The information furnished pursuant to this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities under that Section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On April 28, 2016, the Company announced that U.S. Food and Drug Administration had granted Fast Track Designation for the company's immunotherapy product candidate ADXS-HER2 for patients with newly-diagnosed, non-metastatic, surgically-resectable osteosarcoma. The FDA established the Fast Track Drug Development Program under the FDA Modernization Act of 1997. The program is designed to facilitate the development and expedite the review of therapies intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. The advantages of Fast Track designation include actions to expedite development, including opportunities for frequent interactions with the FDA review team to discuss all aspects of development to support approval and eligibility for accelerated approval and priority review depending on clinical data at the time of Biologics License Application (BLA) submission.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished as a part of this report

99.1 Press Release dated April 28, 2016.

SIGNATURES

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

ADVAXIS, INC.
(Registrant)

By: /s/ Daniel J. O'Connor

Daniel J. O'Connor
President and Chief Executive Officer

Date: May 2, 2016

INDEX TO EXHIBITS

**Exhibit
Number** **Description**

99.1 Press Release dated April 28, 2016.



FDA Grants Advaxis Fast Track Designation for ADXS-HER2 for Patients with Newly-Diagnosed, Non-Metastatic, Surgically-Resectable Osteosarcoma

PRINCETON, N.J., April 28, 2016 – [Advaxis, Inc.](#) (NASDAQ: ADXS), a clinical stage biotechnology company developing cancer immunotherapies, today announced that the Food and Drug Administration (FDA) has granted Fast Track Designation for the company's immunotherapy product candidate ADXS-HER2 for patients with newly-diagnosed, non-metastatic, surgically-resectable osteosarcoma.

Advaxis' investigational immunotherapies, including ADXS-HER2, are designed to capitalize on the body's ability to recognize and attack bacterial infections. Advaxis' core technology – *Lm* Technology™ – alters a live strain of *Listeria monocytogenes* (*Lm*) bacteria to generate cancer fighting T-cells directed against a cancer antigen and neutralizing factors that protect the tumor microenvironment from immunologic attack and contribute to tumor growth.

The FDA established the Fast Track Drug Development Program under the FDA Modernization Act of 1997. The program is designed to facilitate the development and expedite the review of therapies intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. The advantages of Fast Track designation include actions to expedite development, including opportunities for frequent interactions with the FDA review team to discuss all aspects of development to support approval and eligibility for accelerated approval and priority review depending on clinical data at the time of Biologics License Application (BLA) submission.

"We are pleased that the FDA has granted this important designation for ADXS-HER2," said Daniel O'Connor, Chief Executive Officer of Advaxis. "Currently, there are limited therapeutic treatment options available for this patient population, with no new treatments approved in over 20 years. ADXS-HER2 received orphan drug designation in 2015 from the FDA and EMA for the treatment of osteosarcoma. We believe that with these FDA implemented incentive programs, like Fast Track designation, patients are truly the benefactors."

About ADXS-HER2

ADXS-HER2 is an *Lm* Technology™ immunotherapy product candidate being developed by Advaxis to target HER2 expressing cancers. ADXS-HER2 has received orphan drug designation by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for the treatment of osteosarcoma. Advaxis is developing ADXS-HER2 for both human and animal health, and has seen encouraging data in canine osteosarcoma, which is considered a model for human osteosarcoma.

Dr. Nicola Mason, PhD, BVetMed, Associate Professor of Medicine at the University of Pennsylvania School of Veterinary Medicine, evaluated the immunogenicity, safety, and impact of attenuated, recombinant *Listeria monocytogenes* (*Lm*) transformed with a HER2/Neu fusion protein (ADXS-HER2) on survival in 18 dogs with surgically treated osteosarcoma. In the study, 18 dogs received either 2×10^8 , 5×10^8 , 1×10^9 or 3.3×10^9 CFU of ADXS-HER2 post-completion of surgery and adjuvant chemotherapy with 15 dogs showing an induced antigen-specific response within 6 months of immunotherapy administration. Additionally, treatment with ADXS-HER2 reduced the incidence of metastatic disease and prolonged survival relative to a historical control group. The median survival time for the ADXS-HER2 treated dogs was 956 days which was significantly longer than the 423 day median survival time of the historical control group ($p=0.014$, HR 0.33; 95% CI 0.136-0.802).

Advaxis has licensed ADXS-HER2 to Aratana Therapeutics, Inc. for the development of pet therapeutics and expects that the HER2 construct will be conditionally approved in 2016.

About HER2 Expressing Solid Tumor Cancers

Human epidermal growth factor receptor 2 (HER2) is overexpressed in a percentage of solid tumors such as breast, gastric, bladder, brain, pancreatic, ovarian and pediatric bone cancer (osteosarcoma). The American Cancer Society estimates that in 2015 in the United States alone there will be 231,840 new cases of invasive breast cancer; 24,590 new cases of gastric cancer; 74,000 new cases of bladder cancer; 22,850 new cases of brain/spinal cancer; 48,960 new cases of pancreatic cancer; 21,290 new cases of ovarian cancer; and 207 new cases of pediatric osteosarcoma. HER2 expression is associated with more aggressive disease, increased risk of relapse and decreased overall survival, and is an important target for immunotherapy.

About Advaxis, Inc.

Advaxis, Inc. is a clinical-stage biotechnology company developing multiple cancer immunotherapies based on its proprietary *Lm* Technology™. The *Lm* Technology™, using bioengineered live attenuated *Listeria monocytogenes* (*Lm*) bacteria, is the only known cancer immunotherapy agent shown in preclinical studies to both generate cancer fighting T cells directed against cancer antigens and neutralize Tregs and myeloid-derived suppressor cells (MDSCs) that protect the tumor microenvironment from immunologic attack and contribute to tumor growth. Advaxis' lead *Lm* Technology™ immunotherapy, axalimogene filolisbac, targets human papillomavirus (HPV)-associated cancers and is in clinical trials for three potential indications: Phase 2 in invasive cervical cancer, Phase 1/2 in head and neck cancer, and Phase 1/2 in anal cancer. The U.S. Food and Drug Administration (FDA) has granted axalimogene filolisbac orphan drug designation for each of these three clinical settings. Advaxis has two additional immunotherapy products: ADXS-PSA in prostate cancer and ADXS-HER2 in HER2 expressing solid tumors, in human clinical development.

For additional information on Advaxis, visit www.advaxis.com and connect on [Twitter](#), [LinkedIn](#), [Facebook](#), [YouTube](#) and [Google+](#).

Advaxis Forward-Looking Statement

This media statement contains forward-looking statements, including, but not limited to: statements regarding Advaxis' ability to develop the next generation of cancer immunotherapies; and the safety and efficacy of Advaxis' proprietary immunotherapies. These forward-looking statements are subject to a number of risks, including the risk factors set forth from time to time in Advaxis' SEC filings, including but not limited to its report on Form 10-K for the fiscal year ended October 31, 2015, which is available at <http://www.sec.gov>. Advaxis undertakes no obligation to publicly release the result of any revision to these forward-looking statements, which may be made to reflect the events or circumstances after the date hereof or to reflect the occurrence of unanticipated events, except as required by law. You are cautioned not to place undue reliance on any forward-looking statements.

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