
**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): **January 8, 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 Disclosures.

A copy of the press release of Advaxis, Inc. (the “Company”) dated January 8, 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 January 8, 2016, the Company issued a press release announcing its 2016 business outlook. The press release also outlined various regulatory, clinical, business and operational milestones for 2015.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibits are furnished as a part of this report:

Exhibit Number	Description
99.1	Press Release dated January 8, 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: January 11, 2016

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press release issued by the Company on January 8, 2016.



Advaxis Provides 2016 Business Outlook

11 Trials Evaluating Lm Technology™ Advance to Hit Multiple Development Milestones

PD-1 and PD-L1 Checkpoint Combination Trials Advance to Second Phases of Evaluation

Phase 3 AIM2CERV Trial to Commence in mid-2016

MINE™ (My Immunotherapy Neo-Epitopes) Progresses to Clinical Evaluation

PRINCETON, N.J., January 8, 2016 — **Advaxis, Inc.** (NASDAQ:ADXS), a clinical-stage biotechnology company developing cancer immunotherapies, announced today its 2016 business outlook. The outlook is intended to provide Advaxis investors with an overview of anticipated events and key milestones for the coming year.

Advaxis made significant strides in its clinical development programs in 2015. Positive data was presented at the 2015 American Gynecological & Obstetrical Society Annual Meeting from a Phase 2 study of lead compound axalimogene filolisbac in metastatic cervical cancer patients (GOG 0265). Axalimogene filolisbac exceeded historical survival rates in a refractory and heterogeneous patient population and, on the basis of this data, allowed the study to move forward into stage two. Advaxis commenced dosing of a Phase 1/2 trial of axalimogene filolisbac in combination with MedImmune's durvalumab (anti-PD-L1 immune checkpoint inhibitor) for metastatic cervical cancer and head and neck cancer. The Company also began dosing of a Phase 1/2 trial of ADXS-PSA in combination with Merck's Keytruda® (pembrolizumab; anti-PD-1 immune checkpoint inhibitor) for metastatic prostate cancer. A third product candidate, ADXS-HER2, targeting HER2 positive cancers, moved into the clinic and commenced dosing.

Advaxis made significant progress in its business operations, including raising more than \$100M in capital. Presented with the challenge of a clinical hold on all of its programs, Advaxis worked closely with the U.S. Food and Drug Administration (FDA) to have the hold lifted in a timely manner.

2016 OPERATIONAL MILESTONES

Advaxis anticipates the following operational milestones in 2016:

Clinical Operations

Axalimogene Filolisbac

- Finish the Special Protocol Assessment (SPA) process and initiate enrollment in a Phase 3 trial for the treatment of high-risk, locally advanced cervical cancer (AIM2CERV) in mid-2016.
- Complete enrollment of stage 2 of GOG 0265 study in patients with metastatic cervical cancer in 2016.
- Initiate Phase 2 study in combination with Incyte's epacadostat (IDO-1 inhibitor) for the treatment of early stage cervical cancer in the first half of 2016.
- Commence enrollment of Phase 2 trial in metastatic anal cancer (FAWCETT) in the first half of 2016.
- Complete enrollment in the combination Phase 1/2 study with MedImmune's durvalumab (anti-PD-L1 immune checkpoint inhibitor) for the treatment of HPV-associated head and neck and cervical cancer in late 2016.
 - Following the successful completion of cohort 1 of the combination, which occurred in 2015, fully enroll cohort 2 (with a higher dose of durvalumab).
 - Following completion of cohort 2, a dose determination will be made and enrollment in the expansion phase of the study will commence in the first half of 2016, with completion of enrollment by the end of 2016.
- Commence and complete enrollment of the Phase 2 dose-escalation study in recurrent cervical cancer (at 1×10^{10} cfu) in the first half of 2016.
- Present data from a Phase 1/2 window of opportunity trial in HPV-positive head and neck cancer in the first half of 2016 at a major medical meeting.
- Commence enrollment of Phase 2 study in patients with HPV-positive, non-squamous, non-small cell lung cancer following first-line induction chemotherapy via partner in the first half of 2016.
- Commence investigator initiated studies, including for other HPV-associated cancers (e.g., penile and vaginal cancers).

ADX-PSA

- Complete enrollment of Phase 1/2 study in combination with Merck's Keytruda® (pembrolizumab), an anti-PD-1 immune checkpoint inhibitor, for the treatment of advanced, metastatic castrate-resistant prostate cancer.
 - Following the successful completion of dose escalation cohorts 1 and 2, which occurred in 2015, fully enroll cohort 3 (highest dose at 1×10^{10}) in the first half of 2016.
 - Once a dose determination is made, enrollment in the Part B combination arm with ADXS-PSA and Keytruda® will commence in the first half of 2016, with completion of enrollment by the end of 2016.
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ADXS-HER2

- Complete enrollment of Phase 1b dose-escalation study of ADXS-HER2 in patients with HER2-driven malignancies in the first half of 2016.
 - Fully enroll Part A, which is designed to establish safe dosing levels in preparation for the expansion phase of the study in HER2-driven malignancies.
 - Once a dose is selected from Part A, enrollment in a Part B expansion phase will commence in the second half of 2016.
- Following completion of Part A in the Phase 1b dose escalating study, commence collaboration and cooperative group trial with the Children's Oncology Group in osteosarcoma.
- Initiate commercialization via Aratana Therapeutics (NASDAQ:PETX) (using the name AT-014) for the treatment of canine osteosarcoma following approval from the U.S. Department of Agriculture (USDA).

Expanding Pipeline

ADXS-NEO

- MINE™ (My Immunotherapy Neo-Epitopes), a collaboration with Memorial Sloan Kettering Cancer Center, will progress toward the filing of an IND in 2016. MINE™ uses Advaxis's *Lm* Technology™ to develop neoepitope immunotherapies based on an individual patient's tumor.

ADXS-TNBC

- Preclinical work will be finalized for ADXS-TNBC, a multiple-antigen construct for Triple Negative Breast Cancer (TNBC) with the goal of filing an IND in 2016.

Enhanced Manufacturing Capabilities

- Advaxis will continue to enhance its internal process/analytical development, quality systems, manufacturing and quality control infrastructure with the goal of accelerating and advancing its pipeline. The company plans to broaden its capabilities through the completion of a new pilot plant, GMP manufacturing facility, research and development labs, and quality control labs. In addition, Advaxis plans to undertake several technology transfers with its partners and install new innovative technologies to reduce lead times and to improve the overall supply chain.
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Business Development

- Advaxis will continue to pursue partnerships for its cancer immunotherapy platform to enable additional research in combination with other cancer therapies and novel immunotherapies.
- Advaxis also continues to explore options for retaining a Latin American partner for axalimogene filolisbac to collaborate on co-development and registration in this important region.

SECOND HALF 2015 REVIEW

Since issuing [its first half 2015 business update](#) in June, Advaxis achieved several regulatory, clinical, business and operational milestones during the second half of 2015.

Clinical Milestones

Axalimogene Filolisbac

- August 20: Advaxis and MedImmune commenced enrollment in Phase 1/2 trial. First patient was enrolled in a Phase 1/2 study of axalimogene filolisbac in combination with MedImmune's investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab (MEDI4736), for the treatment of patients with advanced, recurrent or refractory HPV-associated cervical cancer and HPV-associated head and neck cancer.
- September 14: U.S. Food and Drug Administration's (FDA) Office of Orphan Products Development awarded a three-year \$1.1 million grant to Baylor College of Medicine for an ongoing Phase 2 trial in HPV-associated oropharynx (throat) cancer.
- September 17: Data from stage 1 of Phase 2 Study (GOG-0265) of ADXS-HPV were presented at 2015 American Gynecological & Obstetrical Society Annual Meeting. In patients with persistent or recurrent metastatic (squamous or non-squamous cell) carcinoma of the cervix (PRMCC), who have progressed on at least one prior line of systemic therapy, treatment with axalimogene filolisbac resulted in a 38.5 percent 12-month overall survival rate in 26 patients.
- November 9: Poster at the Society for Immunotherapy Cancer annual meeting showed that axalimogene filolisbac may be safely administered with prophylactic antibiotics up to 1×10^{10} cfu in patients with PRMCC, a tenfold increase from prior studies.
- December 14: Advaxis receives Orphan Drug Status from the European Medicines Agency for axalimogene filolisbac for the treatment of anal cancer.

ADXS-PSA

- August 5: Movember Foundation and Prostate Cancer Foundation each awarded grants of \$1 million to two research projects in metastatic, treatment-resistant prostate cancer.
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ADX-HER2

- September 28: First patient treated in Phase 1b dose-escalation study of Advaxis's ADXS-HER2 in HER2-expressing solid tumors. The study is the first in-human study of the *Lm* Technology™ immunotherapy product for HER2 expressing cancers.
- December 1: Company receives Orphan Drug Status from the European Medicines Agency for axalimogene filolisbac for the treatment of anal cancer.

Business & Operations

Advaxis achieved the following operational milestones in the second half of 2015:

- The company significantly expanded its IP portfolio of new products including ADXS-NEO (neoepitopes) and PSA-2.0. In addition, Advaxis down-scaled its manufacturing process to enable rapid turn-around of ADXS-NEO for clinical use.
 - Over the course of 2015, Advaxis expanded its leadership team, deepening its medical, clinical operations, manufacturing and regulatory affairs functions:
 - Mayo Pujols, Vice President, Manufacturing
 - Thomas W. Hare, Vice President, Clinical Operations
 - Bob Ashworth, Vice President, Regulatory Affairs
 - June 29: Daniel J. O'Connor received the 2015 Ernst & Young New Jersey Entrepreneur of the Year award.
 - July 21: Advaxis received two patents from the United States Patent and Trademark Office (USPTO) of patents with composition of matter claims for ADXS-PSA and methods of use claims for ADXS-HER2.
 - August 13: Advaxis appointed Tom Ridge, first Secretary of Homeland Security and 43rd Governor of Pennsylvania, to its board of directors.
 - August 26: Advaxis announced a \$25M licensing agreement with Knight Therapeutics to help commercialize its three lead drug candidates in Canada.
 - September 10: Advaxis was the inaugural recipient of the Medical Visionary Angel Award from the Farrah Fawcett Foundation.
 - October 27: Launched Research Collaboration with Memorial Sloan Kettering Cancer Center to develop neo-epitope immunotherapies based on an individual patient's tumor (MINE™).
 - November 17: Received \$1.6M Tax Credit from New Jersey Technology Business Tax Program.
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About Advaxis, Inc.

Located in Princeton, N.J., 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 a cancer antigen and neutralize Tregs and myeloid-derived suppressor cells (MDSCs) that protect the tumor microenvironment from immunologic attack and contribute to tumor growth. Advaxis's 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 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+](#).

Forward-Looking Statements

This media statement contains forward-looking statements, including, but not limited to: statements regarding Advaxis's ability to develop the next generation of cancer immunotherapies (including our ability to enroll patients in our studies and successfully complete such studies, our ability to expand our product pipeline, and our ability to enter into partnerships with others); and statements regarding the safety and efficacy of Advaxis's proprietary immunotherapies. 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. These forward-looking statements are subject to a number of risks, including the risk factors set forth from time to time in Advaxis's 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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