# 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): June 10, 2014

## ADVAXIS, INC.

(Exact name of registrant as specified in its charter)

**Delaware** (State or other jurisdiction of incorporation)

**00028489** (Commission File Number)

**02-0563870** (IRS Employer Identification No.)

305 College Road East
Princeton, New Jersey
(Address of principal executive offices)

[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**08540** (Zip Code)

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

	eck 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 ovisions (see General Instruction A.2. below):
]	Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
1	Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

## Item 8.01 Other Events.

On June 10, 2014, Advaxis, Inc. (the "Company") issued a press release to announce that the Company's request for an End-of-Phase 2 meeting with the U.S. Food and Drug Administration has been granted. Additionally, in the press release, the Company also announced its upcoming goals and provided an overview of the Company's clinical programs.

A copy of the Company's press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

## Item 9.01 Financial Statements and Exhibits.

The following exhibit is filed herewith:

(d) Exhibits.

Exhibit No.	Description
EXHIDIT NO.	Description

99.1 Advaxis, Inc. press release dated June 10, 2014.

## **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.

By: /s/ Daniel J. O'Connor

Name: Daniel J. O'Connor
Title: Chief Executive Officer

Date: June 11, 2014

## EXHIBIT INDEX

Exhibit No.	Description
99.1	Advaxis, Inc. press release dated June 10, 2014.

#### ADVAXIS PROVIDES BUSINESS UPDATE

FDA Grants End-of-Phase 2 Type B Meeting to Review Clinical Data and Discuss the Potential Next Phase of the ADXS-HPV Invasive Cervical Cancer
Development Program

<u>Princeton, NJ – June 10, 2014</u> – Advaxis, Inc., (<u>NASDAQ: ADXS</u>), a biotechnology company developing cancer immunotherapies, today announced that its request for an End-of-Phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA) has been granted. The Company will host a conference call today at 10:00 a.m. ET to discuss a business update, including recent milestones and key near-term goals. The call-in number is 844-835-7433.

The purpose of the EOP2 meeting with FDA is to review clinical findings to date of Advaxis's lead immunotherapy product candidate, ADXS-HPV, in order to assess any additional information needed prior to moving ADXS-HPV forward with the next phase of its clinical development. The meeting will establish a dialogue with FDA on ADXS-HPV during which Advaxis can obtain agency recommendations and feedback on the next steps it needs to take in investigating this important immunotherapy product candidate. Advaxis plans to prepare and provide FDA with a comprehensive package detailing its investigational invasive cervical cancer therapy, its phase 1 and 2 clinical findings, its CMC strategy and the Company's plans for a pivotal phase 3 program.

"We have worked to decisively transform Advaxis, financially, clinically and operationally, over the last six months," commented, Daniel J. O'Connor, President and CEO of Advaxis. "Our proprietary immunotherapy platform has been strengthened through licensing agreements with three strategic partners and has been granted four orphan drug designations from the FDA, demonstrating our commitment to develop novel cancer immunotherapies for unmet medical needs even in small underserved patient populations. We have a strong balance sheet, no debt and the resources to continue advancing our technology in clinical trials targeting cervical cancer, pediatric osteosarcoma and prostate cancer. As we prepare for our EOP2 meeting with the FDA and the potential start of a pivotal phase 3 program in recurrent cervical cancer, we look forward to the next transformational phase of our development as a biotech company."

#### **Upcoming Goals:**

- Conduct EOP2 meeting with FDA for ADXS-HPV for recurrent cervical cancer
- Initiate Phase 1/2 high-dose study in recurrent cervical cancer
- Submit IND and initiate Phase 1/2 clinical trial for ADXS-PSA in prostate cancer
- Advance ADXS-cHER2 clinical development program for the treatment of pediatric osteosarcoma towards the filing of an IND in 2014
- Pursue clinical development partners for combination therapy with PD-1 or other appropriate combination therapies

#### **Clinical Programs Overview**

#### **ADXS-HPV for Invasive Cervical Cancer**

ADXS-HPV is Advaxis's lead immunotherapy product candidate for the treatment of human papilloma virus (HPV)-associated cancers. Advaxis was granted Orphan Drug Designation from the FDA for ADXS-HPV for the treatment of Stage II-IV invasive cervical cancer.

Advaxis recently presented at ASCO the final audited data from the Phase 2 study that was conducted in India in 110 women with recurrent cervical cancer. The final results showed that ADXS-HPV was well tolerated and that 22% (24/109) of the patients were long-term survivors (LTS) of greater than 18 months. 18% (16/91) of patients were alive for more than 24 months. Of the 109 patients treated in the study, LTS included not only patients with tumor shrinkage but also patients who had experienced increased tumor burden. 17% (19/109) of the patients in the trial had recurrence of disease after at least two prior treatments for their cervical cancer; these patients comprised 8% (2/24) of LTS. Among the LTS, 25% (3/11) of patients had an ECOG performance status of 2, a patient population that is often times excluded from clinical trials because of their poor survival.

Advaxis has been granted an EOP2 meeting with the FDA to review clinical findings, to date, in order to assess any additional information needed prior to moving ADXS-HPV forward with the next phase of its clinical development. In preparation for the potential initiation of a pivotal phase 3 program in recurrent cervical cancer, the Company has secured inVentiv Health as its global contract research organization.

Advaxis is also on-track to initiate a Phase 1/2 study under the supervision of Dr. Samir Khleif at Georgia Reagents University Cancer Center, in which a high dose ( $1x10^{10}$  cfu) of ADXS-HPV and repeating dosing cycles will be administered to patients with recurrent or refractory cervical cancer to assess safety, efficacy and immunology endpoints for that dosing regimen.

#### **ADXS-cHER2 for Pediatric Osteosarcoma**

Advaxis is developing ADXS-cHER2 to target the HER2 receptor, which is overexpressed in certain solid-tumor cancers, including pediatric bone cancer (osteosarcoma), breast cancer, and gastric cancer. Osteosarcoma will be the initial indication for clinical development of ADXS-cHER2 in HER2 overexpressing cancers.

ADXS-cHER2 is currently being evaluated in pet dogs with canine osteosarcoma. Preliminary results showed that ADXS-cHER2 was able to delay or prevent metastatic disease and prolong overall survival in dogs with osteosarcoma that had minimal residual disease following the standard treatment of amputation and chemotherapy.

Advaxis intends to initiate a clinical development program for ADXS-cHER2 treatment of pediatric osteosarcoma, based on this strong canine data. Canine osteosarcoma is a highly correlative model for human osteosarcoma. Pediatric osteosarcoma affects about 800 children and young adults in the U.S. every year, representing a small but significant unmet medical need that has seen little therapeutic advancement in decades. Advaxis was granted Orphan Drug Designation from the FDA for ADXS-cHER2 for the treatment of osteosarcoma and is currently conducting the necessary toxicology work to support filing an IND in 2014.

#### **ADXS-PSA for Prostate Cancer**

Advaxis is developing ADXS-PSA, which targets prostate specific antigen (PSA) expressing cells, for the treatment of prostate cancer. Prostate cancer affects over 2 million men in the US and is a disease where one immunotherapy has been approved by the FDA. ADXS-PSA has shown promising anti-tumor activity in animal models and the initial clinical research will be conducted in hormone resistant prostate cancer. Advaxis has completed the required toxicology studies, manufactured clinical supplies to GMP specifications, and is on-track to file an IND application with the FDA shortly and to initiate a Phase 1 study in 2014.

#### **PD-1 Synergies**

Dr. Samir N. Khleif and his research team at the Georgia Regents University Cancer Center demonstrated in preclinical mouse models that treatment with the ADXS-HPV immunotherapy combined with an anti-PD-1 antibody significantly improved immune and therapeutic efficacy. The findings suggest that the combination of *Lm*-LLO immunotherapy with an anti-PD-1 antibody could have clinical application and support further development to evaluate synergies. We intend to explore ways we can confirm Dr. Khleif's work in humans by examining clinical trial plans later this year.

Greg Mayes, Chief Operating Officer of Advaxis, commented, "With PD-1 immunotherapeutics taking center stage coming out of ASCO, and the pharmaceutical industry looking for the next great PD-1 combo, Advaxis is actively engaged in partnership discussions. Our awareness is ascending among potential biopharmaceutical partners, as well as the medical/scientific and patient communities, especially in osteosarcoma, where there haven't been any new therapies in 30 years. Patients and doctors alike are particularly energized by our plans to initiate a trial in pediatric osteosarcoma."

#### Head and Neck Cancer

ADXS-HPV is currently being evaluated in head and neck cancer under an investigator-IND. The trial is being conducted at the Icahn School of Medicine at Mount Sinai to evaluate the safety, effectiveness, and immunogenicity of ADXS-HPV in patients with head and neck cancer. Enrollment in the study is progressing slower than anticipated and, as a result, data will not be available by the end of 2014.

Mr. O'Connor continued, "We are executing a business strategy designed to maximize shareholder value by progressing multiple immunotherapies through clinical development with the ultimate goal of providing treatment options for cancer patients in need."

This morning, Advaxis filed with the Securities and Exchange Commission its Quarterly Report on Form 10-Q for the second quarter ended April 30, 2014. Readers are referred to and encouraged to read it in its entirety along with the Company's 10-K, which includes further detail on the Company's business plans and operations, financial condition, and results of operations.

#### **Conference Call Information**

Advaxis will host a conference call today, Tuesday, June 10, 2014, beginning at 10:00 a.m. Eastern Time. The conference call dial-in numbers are 844-835-7433 for domestic callers and 914-495-8521 for international callers. The passcode for the call is 56890711. For those unable to listen in at the designated time, a conference call replay will be available for one week from June 10 through June 17, 2014. The conference call replay numbers for domestic and international callers are 855-859-2056 and 404-537-3406, respectively. The conference ID number for the replay is 56890711.

#### About Advaxis, Inc.

Advaxis is a clinical-stage biotechnology company developing multiple cancer immunotherapies based on its proprietary platform intended to redirect the immune system to kill cancer. The Advaxis technology, using bioengineered live attenuated bacteria, is the only known cancer immunotherapy shown in preclinical studies to neutralize Tregs and MSDCs, that protect the tumor microenvironment from immunologic attack and contribute to tumor growth. Advaxis's lead immunotherapy, ADXS-HPV, targets human papillomavirus (HPV)-associated cancers and is in clinical trials for three 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 Advaxis orphan drug status for each of these three indications. The Company plans to initiate a registrational clinical program for cervical cancer in 2014 and has established licensing partners in India and Asia for commercialization in those regions. Advaxis's second immunotherapy candidate in clinical testing will be ADXS-PSA, which is being developed to address prostate cancer. Advaxis is planning to file an IND with the FDA and initiate a Phase 1 clinical study with ADXS-PSA in 2014. Advaxis is also developing ADXS-cHER2, to target the HER2 receptor, which is overexpressed in certain solid-tumor cancers, including pediatric bone cancer (or osteosarcoma), breast cancer, and gastric cancer. Advaxis is developing ADXS-cHER2 for both human and animal-health, and has seen promising results in canine osteosarcoma, which is considered a model for human bone cancer. Advaxis is pursuing a clinical program in pediatric osteosarcoma and has licensed ADXS-cHER2 and three other immunotherapy constructs to a major animal-health company. Advaxis is planning to file an IND for ADXS-cHER2 in HER2 overexpressing cancers.

For more information please visit www.advaxis.com or connect with us on

• Facebook: <a href="https://www.facebook.com/advaxisinc">https://www.facebook.com/advaxisinc</a>

• Twitter: <a href="https://twitter.com/Advaxis">https://twitter.com/Advaxis</a>

• LinkedIn: <a href="http://www.linkedin.com/company/advaxis-inc.">http://www.linkedin.com/company/advaxis-inc.</a>

• Google+: https://plus.google.com/b/115126287957745987074/115126287957745987074/posts

#### **Forward-Looking Statements**

This news release contains forward-looking statements, including, but not limited to: statements regarding Advaxis's ability to develop the next generation of cancer immunotherapies; the safety and efficacy of Advaxis's proprietary immunotherapy, ADXS-HPV; whether higher doses and multiple treatment cycles of ADXS-HPV can further improve clinical outcomes and quality of life; Advaxis moving forward with a registration program in recurrent cervical cancer; the collaborative efforts of Advaxis's licensing partners; the initiation or a registration clinical trial program for cervical cancer in 2014; Advaxis's development of ADXS-cHER2 for both human and animal health and its pursuit of a clinical program in pediatric osteosarcoma. 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, 2013, which is available at <a href="http://www.sec.gov">http://www.sec.gov</a>. 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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