# 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): May 5, 2014

### ADVAXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware		00028489	02-0563870			
	(State or other jurisdiction	(Commission	(IRS Employer			
of incorporation)		File Number)	Identification No.)			
	305 College Road East					
	Princeton, New Jersey		08540			
	(Address of principal executive office	rs)	(Zip 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 (see General Instruction A.2. below):						
. ]	Written communications pursuant to Rule 425 unc	der the Securities Act (17 CFR 230.425)				
[]	Soliciting material pursuant to Rule 14a-12 under	the Exchange Act (17 CFR 240.14a-12)				
]	Pre-commencement communications pursuant to l	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 2	240.13e-4(c))			

### Item 7.01 Regulation FD Disclosure.

On May 5, 2014, Advaxis, Inc. (the "Company") issued a press release announcing that the Company intends to initiate a clinical development program with its product candidate, ADXS-cHER2, for the treatment of pediatric osteosarcoma. A copy of the Company's press release 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.

### **Exhibit No. Description**

99.1 Press Release dated May 5, 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: May 6, 2014

### EXHIBIT INDEX

Exhibit No.	Description

99.1 Press Release issued by the Company on May 5, 2014.



# ADVAXIS TO INITIATE CLINICAL DEVELOPMENT OF ADXS-cHER2 IMMUNOTHERAPY TO TREAT PEDIATRIC BONE CANCER

Clinical Data in Canine Osteosarcoma Presented at Sarcoma Foundation of America Annual Conference

**PRINCETON, NJ, May 5, 2014** — <u>Advaxis, Inc.</u> (NASDAQ:ADXS), a biotechnology company developing cancer immunotherapies, announced it intends to initiate a clinical development program with its product candidate, ADXS-cHER2, for the treatment of pediatric osteosarcoma. ADXS-cHER2 is an immunotherapy that targets the HER2 oncogene, which is overexpressed in certain solid-tumor cancers, including pediatric bone cancer and breast cancer. In a veterinarian clinical study, pet dogs with naturally occurring osteosarcoma treated with ADXS-cHER2 after the standard of care showed a statistically significant prolonged overall survival benefit compared with dogs that received standard of care without ADXS-cHER2. Both veterinary and human osteosarcoma specialists consider canine osteosarcoma to be the best model for human osteosarcoma.

Building on these data, Advaxis now intends to initiate a clinical development program in pediatric patients with osteosarcoma. Pediatric osteosarcoma affects about 400 children and teens in the U.S. every year, representing a small but significant unmet medical need that has seen little therapeutic improvement in decades. Pediatric osteosarcoma is considered a rare disease and may qualify for regulatory incentives including, but not limited to, orphan drug designation, patent term extension, market exclusivity, and development grants. Given the limited availability of new treatment options for pediatric osteosarcoma, and that it is an unmet medical need affecting a very small number of patients in the U.S. annually, the Company believes that, subject to regulatory approval, the potential to be on the market may be accelerated.

"The clinical activity seen with ADXS-cHER2 in preventing recurrence of osteosarcoma in pet dogs provides a strong rationale that this treatment has the potential to benefit pediatric osteosarcoma," said Robert Petit, Ph.D., Advaxis Chief Scientific Officer. "We are grateful to the Sarcoma Foundation of America for this opportunity to present these data in canine osteosarcoma and look forward to working with them as we translate what we have learned from the canine study into developing ADXS-cHER2 for the treatment of osteosarcoma in pediatric patients."

"The parallel between canine and pediatric bone cancer, along with our data in pet dogs, strongly supports our decision to pursue a clinical program with ADXS-cHER2 in pediatric osteosarcoma," said Daniel J. O'Connor, Advaxis CEO. "Success with ADXS-cHER2 in osteosarcoma will provide Advaxis with a high degree of confidence to rapidly pursue larger markets in HER2 overexpressing cancers. We intend to move forward with the clinical development of ADXS-cHER2 for the treatment of pediatric osteosarcoma as expeditiously as possible. Osteosarcoma in children is a small and tragically underserved market in which Advaxis immunotherapy could provide a significant advancement."

Advaxis is conducting the required pre-IND activities to support the development of ADXS-cHER2 in HER2 overexpressing cancers.

At the 2014 Sarcoma Foundation of America Annual Patient Educational Conference, Nicola Mason DVM, Assistant Professor of Medicine & Pathobiology, University of Pennsylvania School of Veterinary Medicine and lead investigator in the ADXS-cHER2 canine osteosarcoma study, presented updated statistically significant survival data from this ongoing study. In her presentation, Dr. Mason reiterated the strong connection between canine osteosarcoma and osteosarcoma in humans.

### **About Pediatric Osteosarcoma**

Osteosarcoma is the most common type of bone cancer. In children and young adults, osteosarcoma usually develops in areas where the bone is growing quickly, such as near the ends of the long bones. Each year, about 800 new cases of osteosarcoma are diagnosed in the United States. About 400 of these are in children and teens. Most osteosarcomas occur in children and young adults between the ages of 10 and 30. Osteosarcomas account for about 3% of childhood cancers, but they make up a much smaller percentage of adult cancers, according to the American Cancer Society.

### About Advaxis, Inc.

Advaxis is a clinical-stage biotechnology company developing cancer immunotherapies. Advaxis's immunotherapies are based on a novel platform technology using live, attenuated bacteria to stimulate the immune system to selectively target cancer cells while reducing tumor defenses.

ADXS-HPV, Advaxis's lead immunotherapy is under investigation for the treatment of HPV-associated cancers and has demonstrated improved survival and objective tumor responses in a Phase 2 trial in 110 patients with recurrent cervical cancer. Advaxis is now planning the registrational program for ADXS-HPV. ADXS-HPV is also being evaluated in other HPV-associated cancers including a Phase 2 trial in advanced cervical cancer, a Phase 1/2 trial in head and neck cancer, and a Phase 1/2 trial in anal cancer. ADXS-HPV has orphan drug status for invasive cervical, head and neck, and anal cancers. As part of its global commercialization strategy to enter into regional licensing deals with other market dominant biopharmaceutical companies in territories where there is a high prevalence of HPV-associated cancers, Advaxis has granted exclusive licenses for the development and commercialization of ADXS-HPV in Asia and India.

ADXS-cHER2 is an immunotherapy under investigation for the treatment of HER2 overexpressing cancers (such as breast, gastric, esophageal, pediatric osteosarcoma, and other cancers in humans and for osteosarcoma in canines). While still early in the study, Advaxis's lead animal-health immunotherapy, ADXS-cHER2, has demonstrated statistically significant survival data in a Phase 1 trial in canine osteosarcoma. Advaxis recently granted exclusive rights to Aratana Therapeutics (NASDAQ: PETX) to develop and commercialize ADXS-cHER2 for the treatment of osteosarcoma in dogs.

Advaxis has created more than 15 distinct immunotherapies based on its platform, either directly or through strategic collaborations with recognized cancer centers of excellence such as: the University of Pennsylvania, Brown University, the Georgia Regents University Cancer Center, the Icahn School of Medicine at Mount Sinai, and others.

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

This news release contains forward-looking statements, including, but not limited to: statements regarding Advaxis' ability to develop the next generation of cancer immunotherapies; the safety and efficacy of Advaxis' proprietary immunotherapy, ADXS-HPV; whether Advaxis immunotherapies can redirect the powerful immune response all human beings have to the bacterium to cancers. 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, 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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