

Advaxis, Inc.
Form 8-K
July 24, 2014

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 21, 2014

ADVAXIS, INC.

(Exact name of registrant as specified in its charter)

| | | |
|---|-----------------------------|--------------------------------------|
| Delaware | 00028489 | 02-0563870 |
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

305 College Road East
Princeton, New Jersey **08540**
(Address of principal executive offices) (Zip Code)

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

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 under 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 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))

Item 1.01 Entry into a Material Definitive Agreement.

On July 21, 2014, Advaxis, Inc. (“Advaxis”) and MedImmune, LLC (“MedImmune”), the global biologics research and development arm of AstraZeneca, entered into a Clinical Trial Collaboration Agreement (the “Agreement”) pursuant to which the parties intend to initiate Phase I and Phase II clinical trials in the United States to evaluate the safety and efficacy of MedImmune’s investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736, in combination with Advaxis’s investigational *Lm*-LLO cancer immunotherapy, ADXS-HPV, as a combination treatment for patients with advanced, recurrent or refractory human papillomavirus (HPV) associated cervical cancer and HPV-associated head and neck cancer. A joint steering committee, to be composed of equal numbers of Advaxis and MedImmune representatives, will be responsible for various matters associated with the clinical trials, including approving protocols for the trials, as well as reviewing and monitoring the progress of the trials.

MedImmune will be responsible for providing MEDI4736 for the clinical trials at no cost. Advaxis will be the sponsor of the clinical trials and be responsible for the submission of all regulatory filings to support the trials, the negotiation and execution of the clinical trial agreements associated with each study site, and the packaging and labelling of the Advaxis and MedImmune product candidates to be used in the clinical trials and the costs associated therewith.

For a period beginning upon the completion of the clinical trials and the receipt by MedImmune of the last final report for the trials and ending one hundred twenty (120) days thereafter (unless extended), MedImmune will be granted first right to negotiate in good faith in an attempt to enter into an agreement with Advaxis with respect to the development, regulatory approval and commercialization of ADXS-HPV and MEDI4736 to be used in combination with each other for the treatment or prevention of cancer. Neither party is obligated to enter into such an agreement. In the event the parties do not enter an agreement and Advaxis obtains regulatory approval for ADXS-HPV in combination with any PD-1 antibody or PD-L1 antibody, Advaxis shall pay MedImmune a royalty obligation and one-time payment.

All intellectual property rights made, conceived or generated through the clinical trials that relate solely to a MedImmune development product shall be owned solely by MedImmune. All intellectual property rights made, conceived or generated through the clinical trials that relate solely to an Advaxis development product shall be owned solely by Advaxis. All intellectual property rights made, conceived or generated through the clinical trials that relate to the combination of one or more MedImmune development product and one or more Advaxis development product shall be jointly owned by MedImmune and Advaxis; provided, however that in the event the parties do not enter into a clinical development and commercialization agreement, Advaxis will not exploit, commercialize or license the joint inventions, except for the performance of its obligations under the Agreement. MedImmune has the sole right to prosecute and enforce all patents and other intellectual property rights covering all joint inventions and all associated costs will be shared by the parties.

The Agreement shall remain in effect until the earlier of (i) permitted termination, (ii) the parties entering into a clinical development and commercialization agreement or expiration of the negotiation period (unless extended),

except with respect to rights that survive termination. Either party may terminate the Agreement upon thirty (30) days written notice upon material breach of the other party, unless the breach is cured in such period or reasonable actions to cure the breach are initiated and pursued (if the breach is not capable of being cured during the 30-day notice period). In addition, either party may terminate the Agreement immediately if the party determines in good faith that the trials may unreasonably affect the safety of trial subjects.

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

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

99.1 Press Release of Advaxis, Inc. dated July 22, 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 and President

Date: July 24, 2014

EXHIBIT INDEX

Exhibit No. Description

99.1 Press Release of Advaxis, Inc. dated July 22, 2014.

