

Edgar Filing: Advaxis, Inc. - Form 8-K

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.

Advaxis, Inc. (“Advaxis”) and Biocon Limited, a company incorporated under the laws of India (“Biocon”) entered into a Distribution and Supply Agreement effective as of January 20, 2014 (the “Agreement”).

Pursuant to the Agreement, Advaxis granted Biocon an exclusive license (with a right to sublicense) to (i) use Advaxis’ data from clinical development activities, regulatory filings, technical, manufacturing and other information and know-how to enable Biocon to submit regulatory filings for ADXS-HPV in the following territories: India, Malaysia, Kenya, Bangladesh, Bhutan, Maldives, Myanmar, Nepal, Pakistan, Sri Lanka, Bahrain, Jordan, Kuwait, Oman, Saudi Arabia, Qatar, United Arab Emirates, Algeria, Armenia, Egypt, Eritrea, Iran, Iraq, Lebanon, Libya, Sudan, Syria, Tunisia and Yemen (collectively, the “Territory”) and (ii) import, promote, market, distribute and sell pharmaceutical products containing ADXS-HPV. ADXS-HPV is based on a novel platform technology using live, attenuated bacteria that are bio-engineered to secrete an antigen/adjuvant fusion protein(s) that is designed to redirect the powerful immune response all human beings have to the bacterium against their cancer.

Under the Agreement, Biocon has agreed to use its commercially reasonable efforts to obtain regulatory approvals for ADXS-HPV in India. In the event Phase II or Phase III clinical trials are required, Advaxis shall conduct such trials at its cost, provided that if Advaxis is unable to commence such clinical trials, Biocon may conduct such clinical trials, subject to reimbursement of costs by Advaxis. Biocon has agreed to commence commercial distribution of ADXS-HPV no later than 9 months following receipt of regulatory approvals in a country in the Territory. Biocon will be responsible for the costs of obtaining and maintaining regulatory approvals in the Territory.

Advaxis will have the exclusive right to supply ADXS-HPV to Biocon and Biocon will be required to purchase its requirements of ADXS-HPV exclusively from Advaxis at the specified contract price, as such price may be adjusted from time to time. In addition, Advaxis will be entitled to a six-figure milestone payment if net sales of ADXS-HPV for the contract year following the initiation of clinical trials in India exceed certain specified thresholds.

Biocon will also have a right of first refusal relating to the licensing of any new products in the Territory that Advaxis may develop during the term of the Agreement.

The term of the Agreement will be the later of twenty years or the last to expire patent or patent application. In addition, the Agreement may be terminated by either party upon thirty days’ written notice (i) in the event of a material breach by the other party of its obligations under the Agreement, (ii) if the other party becomes bankrupt or insolvent or (iii) if the other party undergoes a change in control.

Item 7.01 Regulation FD Disclosure.

On January 22, 2014, the Company issued a press release announcing the Agreement. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The information contained in Exhibit 99.1 shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Exhibit No. Description

99.1 Press Release dated January 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

Date: January 22, 2014