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 20, 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)

08540 (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))

Dere-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: <u>/s/ Daniel J. O'Connor</u> Name: Daniel J. O'Connor Title: Chief Executive Officer

Date: January 22, 2014





Press Release

Biocon Collaborates with Advaxis for 'ADXS-HPV' A Novel Cancer Immunotherapy

Bangalore, India and Princeton, New Jersey – January 22, 2014

Biocon Ltd., (BIOCON.BO), Asia's premier biotechnology company, and Advaxis, Inc., (NASDAQ: ADXS), a leader in developing the next generation of cancer immunotherapies, announced today that they have entered into an exclusive licensing agreement for co-development and commercialization of **ADXS**-**HPV**, a novel cancer immunotherapy for the treatment of human papillomavirus (HPV)-associated cervical cancer in women, for India and key emerging markets.

As per the agreement, Biocon will also have access to Advaxis' innovative and proprietary immunotherapy technology that can be leveraged for the development of other novel therapeutics for various unmet medical needs.

Chairperson and Managing Director of Biocon, Kiran Mazumdar-Shaw said, "Biocon is committed to finding solutions for women's health issues. This partnership will enable us to develop **ADXS–HPV** a novel immunotherapy to combat cervical cancer in women. It is a promising technology that has the ability to suppress the tumor inside the micro-environment, and can be leveraged for developing several other novel therapeutics to address various unmet medical needs of patients in India and other emerging markets."

"We are excited to partner with Biocon, one of the world's leading biotechnology companies and the largest biotechnology company in India to bring our innovative cancer immunotherapy for cervical cancer to women with few alternatives," commented **Daniel J. O'Connor, Chief Executive Officer of Advaxis.** "This agreement gives us reach into key markets where the number of patients with HPV-associated cancers is overwhelming."

Dr. Abhijit Barve, President of Research & Development at Biocon said, "The clinical data generated so far with **ADXS-HPV** look very encouraging in patients with advanced metastatic disease who were resistant or refractory to existing therapies. The clinical responses were comparable to prevalent chemotherapy agents and this was achieved with very low incidence of adverse events. Hence **ADXS-HPV** is likely to offer patients a safe and effective alternate to chemotherapeutic agents."

Cervical cancer is one of the most frequent cancers in women in India. Over 366 million women of the age of over 15 years, are at a risk of developing cervical cancer. It is estimated that every year over 134,000 women are diagnosed with cervical cancer in India and nearly 73,000 die from this disease. Approximately 7.9% of women in general are estimated to harbor cervical HPV infection at a given time, and 82.5% of invasive cervical cancers are attributed to high-risk HPV strains.^{*}

According to WHO, in 2008, there were over 530,000 new cases of cervical cancer worldwide, 90% of these were reported in developing countries. While globally there were over 300,000 deaths, the African region recorded over 50,000 deaths and Asian countries reported over 150,000 deaths for the year.

ADXS-HPV has the potential to address this huge challenge in the developing world.

Under the terms of the agreement, Advaxis will provide exclusive commercialization rights for **ADXS-HPV** to Biocon for India, and key emerging markets for all HPV-associated cancers. Advaxis will manufacture and supply **ADXS-HPV** to Biocon.

*Source: WHO/ICO Information Centre on HPV and Cervical Cancer (HPV Information Centre) 2010.

About Biocon Limited

Established in 1978, Biocon Limited, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is India's largest and Asia's leading biotechnology company with a strategic focus on biopharmaceuticals and research services. It is a fully integrated, innovation-driven biopharma enterprise offering affordable solutions for chronic diseases to patient's worldwide. Biocon's robust product portfolio includes the world's first Pichia-based recombinant human Insulin, INSUGEN(R), Glargine, BASALOG[®], India's first biologic BioMAb-EGFR [®] for head and neck cancer and world's first biosimilar trastuzumab, CANMAbTM. It has also successfully developed its second novel biologic Itolizumab, a 'first in class' anti-CD6 monoclonal antibody, introduced as ALZUMAbTM for psoriasis in India. <u>www.biocon.com</u>

About Advaxis, Inc.

Advaxis is a clinical-stage biotechnology company developing the next generation of cancer immunotherapies. Advaxis' 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' lead immunotherapy for the treatment of HPV-associated cancers, has improved survival and objective tumor responses in patients with recurrent cervical cancer. **ADXS-HPV** has Orphan Drug Status for both anal and head and neck 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 an exclusive license for the development and commercialization of **ADXS-HPV** in Asia.

ADXS-cHER2 is an immunotherapy for the treatment of HER2 overexpressing cancers (such as breast, gastric, and other cancers in humans and for osteosarcoma in canines). Advaxis' lead animal-health immunotherapy, ADXS-cHER2, has demonstrated encouraging survival data in a Phase 1 trial in canine osteosarcoma. These data provide the rationale to advance this same immunotherapy into a Phase 1 clinical trial in women with HER2-positive breast cancer. The Company is preparing to submit an IND for ADXS-cHER2 in breast cancer in 2014.

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

For more information please visit www.advaxis.com or connect with us on Facebook, Twitter, Google+ and LinkedIn.

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, 2012, which is available at <u>http://www.sec.gov</u>. 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.

For further information:	
Biocon Media Contacts	
Seema Ahuja	Rumman Ahmed
Head-Corporate Communications	Manager-Corporate Communications
T: +91-80-2808-2222, M:+919972317792	T: +91-80-2808-2223, M:+919845104173
Email: <u>seema.ahuja@biocon.com</u>	Email: <u>rumman.ahmed@biocon.com</u>
Biocon: Investors Contact	Advaxis, Inc
Saurabh Paliwal	Lisa Caperelli
Head Investor Relations	Senior Director of Investor Relations and Corporate Communications
+91 95383 80801	<u>caperelli@advaxis.com</u>
<u>saurabh.paliwal@biocon.com</u>	215.206.1822