

Advaxis, Inc.
Form 8-K
March 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): March 19, 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.)

08540

305 College Road East

Princeton, New Jersey

(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 March 19, 2014, Advaxis, Inc. (“Advaxis”) and Aratana Therapeutics Inc. (“Aratana”) entered into a definitive Exclusive License Agreement (the “Agreement”). Pursuant to the Agreement, Advaxis granted Aratana an exclusive, worldwide, royalty-bearing, license, with the right to sublicense, under certain Advaxis proprietary technology that enables the design of an immunotherapy utilizing live attenuated *Listeria monocytogenes* (“Lm”) bioengineered to secrete fusion proteins consisting of antigen and adjuvant molecules, including certain “Constructs” and related “Compounds” (both as defined in the Agreement) in order for Aratana to develop and commercialize animal health products containing or incorporating Compounds (“Products”) for use in non-human animal health applications (the “Aratana Field”) that will be targeted for treatment of osteosarcoma and other cancer indications in animals. The Advaxis technology licensed to Aratana includes certain patents and patent applications, as well as related know-how, data, technical information, results and other information controlled by Advaxis during the term of the Agreement that are reasonably necessary for the development, manufacture or commercialization of any Construct, Compound or Product.

In addition to the Constructs licensed by Aratana upon signing of the Agreement, Aratana also has a right of first refusal to license additional Advaxis constructs in the future if Advaxis develops (on its own or upon request of Aratana) new constructs which are reasonably believed to be suitable for treating osteosarcoma and certain other cancer indications (“Additional Constructs”). If Aratana and Advaxis agree upon the terms pursuant to which such Additional Constructs shall be added as Constructs under the Agreement, such Additional Constructs will be added by virtue of an amendment to the Agreement.

Aratana has granted Advaxis an exclusive, worldwide, royalty-free, fully-paid, irrevocable and perpetual license, with the right to sublicense, under Aratana’s existing technology, and any related sole Aratana development or Aratana’s rights in any joint inventions which may be developed by the parties during the course of the Agreement, solely for Advaxis to develop and commercialize Advaxis products for any and all uses outside of the Aratana Field, including, without limitation, all human health applications. The Aratana technology to be licensed to Advaxis will include any patents or patent applications controlled by Aratana during the term of the Agreement that claim or cover the manufacture, use, sale, offer for sale or import of any Products as well as related know-how, data, technical information, results and other information controlled by Aratana during the term of the Agreement that is necessary or useful in the development, manufacture or commercialization of any Compound, Construct or Product.

Under the terms of the Agreement, Aratana paid an upfront payment to Advaxis of US \$1,000,000 upon signing of the Agreement. Aratana will also pay to Advaxis (a) up to \$36.5 million based on the achievement of milestone relating to the advancement of Products through the approval process with the United States Department of Agriculture (“USDA”) in the United States and the relevant regulatory authorities in the European Union (“E.U.”) in all four therapeutic areas and up to an additional \$15 million in cumulative sales milestones based on achievement of gross sales revenue targets for sales of any and all Products in the Aratana Field (regardless of therapeutic area), and (b) tiered royalties starting at 5% and going up to 10%, which will be paid based on net sales of any and all Products (regardless of therapeutic area) in the Aratana Field in the United States. Royalties for sales of Products outside of the United States will be paid at a rate equal to half of the royalty rate payable by Aratana on net sales of Products in the United States

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(starting at 2.5% and going up to 5%). Royalties will be payable on a Product-by-Product and country-by-country basis from first commercial sale of a Product in a country until the later of (a) the 10th anniversary of first commercial sale of such Product by Aratana, its affiliates or sublicensees in such country or (b) the expiration of the last-to-expire valid claim of an Advaxis patent or joint patent claiming or covering the composition of matter, formulation or method of use of such Product in such country. Aratana will also pay to Advaxis 50% of all sublicensee royalties received by Aratana and its affiliates.

If a determination is made by regulatory authorities in the United States that the regulatory approval of a Product in the Aratana Field will be within the jurisdiction of the United States Food and Drug Administration (“FDA”) and not the USDA, then the parties will negotiate a reduction in the payments due to Advaxis to reflect the increased costs and expenses that Aratana, its affiliates and sublicensees will incur by reason of needing to perform activities in accordance with the FDA regulatory approval process for Products in the Aratana Field.

Aratana is required to use commercially reasonable efforts to (a) conduct such development activities as are necessary to support the filing of an application for regulatory approval in the Aratana Field for at least one Product in each of the United States and three countries in the E.U., and (b) obtain regulatory approval in the Aratana Field for at least one Product in each of the United States and three countries in the E.U. Aratana shall be solely responsible for worldwide Product development expenses in the Aratana Field and shall have the sole responsibility, at its sole expense, for all Aratana regulatory filings. Aratana shall be solely responsible for commercialization of Products in the Aratana Field, and, Aratana will use commercially reasonable efforts to market and sell such Products in the Aratana Field worldwide; in each case, at Aratana’s sole expense.

Each party has the right to terminate the agreement for breach of the other party. Additionally, Advaxis will have the right to terminate the Agreement in the case of a challenge by Aratana to any Advaxis patents. Aratana will have the right to terminate the Agreement at will upon 90 days prior written notice to Advaxis, however, in such case, as well as in the case of a termination by Advaxis for breach or patent challenge by Aratana, Aratana will automatically assign any Aratana regulatory filings for Products to Advaxis and Advaxis will automatically obtain a non-exclusive, royalty-free, fully-paid, irrevocable, perpetual license, with the right to sublicense, under the Aratana technology (including all patents, know-how, data, technical information, results, and other information) practiced by Aratana in connection with any Products, and Aratana’s interest in any patents jointly developed with Advaxis in order to develop Products in the Aratana Field. Further, upon termination of the Agreement for any reason after the effective date, the licenses granted to Aratana will terminate and all such license rights shall revert to Advaxis.

The term of the Agreement begins on the effective date (at signing) and will expire upon expiration of all royalty payment obligations of Aratana under the Agreement.

Item 3.02 Unregistered Sales of Equity Securities.

On March 19, 2014, Advaxis (i) issued and sold 306,122 shares of Advaxis’ common stock to Aratana at a price of \$4.90 per share, which was equal to the closing price of the common stock on the NASDAQ Capital Market on March 19, 2014, and (ii) issued a ten-year warrant to Aratana giving Aratana the right to purchase up to 153,061 additional shares of Advaxis’ common stock at an exercise price of \$4.90 per share. The warrant also contains a provision for cashless exercise if the fair market value of Advaxis’ common stock for the five trading days ending three trading days prior to the exercise date is higher than the exercise price. In connection with the sale of the common stock and warrants, Advaxis received aggregate net proceeds of \$1,500,000. Advaxis issued the shares and warrant in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933.

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: March 24, 2014