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): August 22, 2014

ADVAXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)

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

00028489 (Commission File Number) 02-0563870 (IRS Employer Identification No.)

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))

[] 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 August 22, 2014, Advaxis, Inc. ("Advaxis") and Merck & Co., Inc., through a subsidiary ("Merck") entered into a Clinical Trial Collaboration and Supply Agreement (the "Agreement") pursuant to which the parties will collaborate on a Phase 1/2 dose-escalation and safety study. The Phase 1 portion of the study will evaluate the safety of Advaxis's *Lm*-LLO based immunotherapy for prostate cancer, ADXS31-142 (the "Advaxis Compound") as monotherapy and in combination with Merck's humanized monoclonal antibody against PD-1, pembrolizumab (MK-3475) (the "Merck Compound) to determine a recommended Phase 2 combination dose. The Phase 2 portion will evaluate the safety and efficacy of the Advaxis Compound in combination with the Merck Compound. Both phases of the study will be in patients with previously treated metastatic castration-resistant prostate cancer. A joint development committee, to be comprised of equal representatives from Advaxis and Merck, will be responsible for coordinating all regulatory and other activities under, and pursuant to, the Agreement.

Advaxis and Merck will each be responsible for their own internal costs and expenses to support the study, while Advaxis will be responsible for all third party costs of conducting the study. Merck will be responsible for manufacturing and supplying the Merck Compound. Advaxis will be responsible for manufacturing and supplying the Advaxis Compound. Advaxis will be the sponsor of the study and will hold the investigational new drug application ("IND") relating to the study.

All data and results generated under the study ("Collaboration Data") will be jointly owned by Advaxis and Merck, except that ownership of data and information generated from sample analysis to be performed by each party on its respective compound will be owned by the party conducting such testing. All rights to all inventions and discoveries, which claim or cover the combined use of the Advaxis Compound and the Merck Compound shall belong jointly to Advaxis and Merck. Inventions and discoveries relating solely to the Advaxis Compound, or a live attenuated bacterial vaccine, shall be the exclusive property of Advaxis. Inventions and discoveries relating solely to the Merck Compound, or a PD-1 antagonist, shall be the exclusive property of Merck.

The Agreement shall continue in full force and effect until completion of all of the obligations of the parties or a permitted termination.

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 August 25, 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: August 27, 2014

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Exhibit No.	Description
99.1	Press Release of Advaxis, Inc. dated August 25, 2014.

ADVAXIS AND MERCK FORM COLLABORATION TO EVALUATE INVESTIGATIONAL COMBINATION OF TWO NOVEL IMMUNOTHERAPY CANDIDATES FOR ADVANCED PROSTATE CANCER

PRINCETON, NJ, August 25, 2014 — <u>Advaxis, Inc.</u> (NASDAQ:ADXS), a clinical-stage biotechnology company developing cancer immunotherapies, has entered into a clinical trial collaboration agreement with Merck, known as MSD outside the United States and Canada, through its subsidiaries, to evaluate the combination of Advaxis's *Lm*-LLO cancer immunotherapy, ADXS-PSA, with Merck's investigational anti PD-1 antibody, pembrolizumab. The planned clinical trial will evaluate the safety and efficacy of ADXS-PSA as monotherapy and in combination with pembrolizumab in a Phase 1/2 study of patients with previously treated metastatic, castration-resistant prostate cancer.

Both ADXS-PSA and pembrolizumab are investigational members of a new class of cancer treatments known as immunotherapies that are designed to enhance the body's own defenses in fighting cancer. Preclinical evidence suggests that Advaxis *Lm*-LLO immunotherapies in combination with a PD-1 inhibitor may lead to an enhanced anti-tumor immune response.

"We are excited to be working with Merck. Equally as exciting is the combination potential of our *Lm*-LLO immunotherapy with Merck's anti-PD-1 immune checkpoint inhibitor," commented Daniel J. O'Connor, President and Chief Executive Officer of Advaxis. "We believe the combination of Advaxis *Lm*-LLO cancer immunotherapies and checkpoint inhibitors holds significant promise for the treatment of prostate and other cancers."

Under the terms of the agreement, Advaxis and Merck will collaborate to evaluate the ADXS-PSA/pembrolizumab combination as a treatment for prostate cancer. The Phase 1 part of the trial is designed to establish a recommended dose regimen for ADXS-PSA alone and combined with pembrolizumab, and the Phase 2 portion will assess the safety and efficacy of the combination. Advaxis will sponsor and fund the study and Merck will provide pembrolizumab. The companies will collaboratively oversee the conduct of the study, which is planned to begin in early 2015. Results from the study will be used to determine the path for further clinical development of the combination.

"Collaborations such as this are an integral part of Merck's strategy to evaluate the potential of pembrolizumab in multiple combinations for a broad range of cancers," said Dr. Eric Rubin, vice president Oncology, Merck Research Laboratories. "We look forward to working with Advaxis to evaluate this novel investigational combination immunotherapy for the treatment of advanced prostate cancer."

About Prostate Cancer

According to the American Cancer Society, prostate cancer is the most common type of cancer found in American men, other than skin cancer. Prostate cancer is the second leading cause of cancer death in men, behind only lung cancer. One man in six will get prostate cancer during his lifetime, and one man in 36 will die of this disease.

About ADXS-PSA

ADXS-PSA is an *Lm*-LLO immunotherapy that is designed to target the PSA antigen associated with prostate cancer. ADXS-PSA secretes the PSA antigen, fused to the powerful immunostimulant tLLO, directly inside the antigen presenting cells that are capable of driving a cellular immune response to PSA expressing cells. The Advaxis approach is also designed to inhibit the Treg and MDSC cells that contribute to immunologic tolerance of prostate cancer. In preclinical analysis, ADXS-PSA inhibits the immunosuppression caused by Treg and MDSC cells localized inside tumors that we believe promotes immunologic tolerance of prostate cancer.

About Pembrolizumab

Pembrolizumab (MK-3475) is an investigational, humanized, monoclonal antibody against PD-1 designed to reactivate anti-tumor immunity. Pembrolizumab exerts dual ligand blockade of the PD-1 pathway by inhibiting the interaction of PD-1 on T cells with its ligands PD-L1 and PD-L2.

Pembrolizumab is currently being evaluated across more than 30 types of cancers, as monotherapy and in combination. It is anticipated that by the end of 2014, the pembrolizumab development program will grow to more than 24 clinical trials, enrolling an estimated 6,000 patients at nearly 300 clinical trial sites worldwide. For information about Merck's oncology clinical studies, please visit <u>http://www.merck.com/clinical-trials/index.html</u>.

About Advaxis, Inc.

Advaxis is a clinical-stage biotechnology company developing multiple cancer immunotherapies based on its proprietary platform intended to redirect the immune system to kill cancer. The Advaxis *Lm*-LLO technology, using bioengineered live attenuated *Listeria monocytogenes* bacteria, is the only known cancer immunotherapy agent shown in preclinical studies to both generate cancer fighting T-cells directed against a cancer antigen and neutralize Tregs and MSDCs, that protect the tumor microenvironment from immunologic attack and contribute to tumor growth. Advaxis's lead immunotherapy, ADXS-HPV, targets human papillomavirus (HPV)-associated cancers and is in clinical trials for three indications: Phase 2 in invasive cervical cancer, Phase 1/2 in head and neck cancer, and Phase 1/2 in anal cancer. The FDA has granted Advaxis orphan drug designation for each of these three indications. The Company plans to initiate a registrational clinical program for cervical cancer in 2014 and has established licensing partners in India and Asia for commercialization in those regions. Advaxis is planning to evaluate the combination of ADXS-HPV with an anti-PD-L1 immune checkpoint inhibitor in HPV-associated cancers.

Advaxis's second immunotherapy candidate in clinical testing will be ADXS-PSA, which is being developed to address prostate cancer. Advaxis is planning to file an IND with the FDA and initiate a Phase 1-2 clinical study with ADXS-PSA. Advaxis is also developing ADXS-cHER2, to target the Her2 receptor overexpressing cancers. Her2 is overexpressed in certain solid-tumor cancers, including pediatric bone cancer (or osteosarcoma), breast cancer, esophageal, and gastric cancer. Advaxis is developing ADXS-cHER2 for both human and animal-health, and has seen promising results in canine osteosarcoma, which is considered a model for human osteosarcoma. Advaxis is pursuing a clinical program in pediatric osteosarcoma and has licensed ADXS-cHER2 and three other immunotherapy constructs to a major animal-health company. Advaxis is planning to file an IND for ADXS-cHER2 in Her2 overexpressing cancers.

For more information please visit www.advaxis.com or connect with us on

- Facebook: https://www.facebook.com/advaxisinc
- Twitter: https://twitter.com/Advaxis
- LinkedIn: http://www.linkedin.com/company/advaxis-inc.
- Google+: https://plus.google.com/b/115126287957745987074/115126287957745987074/posts

Forward-Looking Statements

This news release contains forward-looking statements, including, but not limited to: statements regarding Advaxis's ability to develop the next generation of cancer immunotherapies; the safety and efficacy of Advaxis's 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's 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 <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.

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