## 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): December 15, 2009

## 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 Number)

Technology Centre of New Jersey 675 Rt. 1, Suite B113 North Brunswick, N.J. 08902 (Address of principal executive offices)

Registrant's telephone number, including area code: (732) 545-1590

## Not applicable

(Former Name or Former Address, if Changed Since Last Report)

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:
☐ 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 8.01. Other Events.

On December 15, 2009, Advaxis, Inc. (the "Company") issued a press release regarding its planned collaboration with the National Cancer Institute's Gynecological Oncology Group in a Phase II clinical trial of the Company's drug candidate ADXS11-001. A copy of the press release, which is attached as Exhibit 99.1 to this Current Report, is incorporated herein by reference.

# Item 9.01 Financial Statements and Exhibits.

# (c) Exhibits

99.1 Advaxis, Inc. press release, dated December 15, 2009.

# **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: December 15, 2009 Advaxis, Inc.

By: /s/ Thomas A. Moore

Thomas A. Moore Chief Executive Officer

# EXHIBIT INDEX

Exhibit No.

**Document Description** 

99.1

Advaxis, Inc. press release, dated December 15, 2009.



## FOR IMMEDIATE RELEASE

#### ADVAXIS ANNOUNCES PHASE II TRIAL COLLABORATION

#### WITH THE NATIONAL CANCER INSTITUTE

### Gynecologic Oncology Group to Study ADXS11-001 in Sixty-Patient Study

**North Brunswick, NJ - December 15, 2009 -** <u>Advaxis, Inc.</u>, **(OTCBB: ADXS)**, the live, attenuated *Listeria monocytogenes* (*Lm*) vaccine company, will collaborate with the Gynecologic Oncology Group (GOG), a collaborative research group of the National Cancer Institute (NCI), in a multicenter, Phase II clinical trial of the Company's lead drug candidate, ADXS1 1-001 in the treatment of advanced cervix cancer in women who have failed prior cytotoxic therapy.

This Phase II trial will be conducted by GOG investigators and largely underwritten by the NCI. The study's patient population – a very sick and rapidly progressive patient population for whom no therapy has been found to be effective – will be the same patient population that was treated in Advaxis Phase I trial of ADXS1 1-001.

Advaxis will contribute the study drug and some funds to the cost of the trial, including the translational clinical immunology research. Advaxis will update its IND and file the final protocol with FDA before the study begins.

In an Advaxis Phase I clinical trial, it was found that multiple doses of the agent were safely administered to this patient population at two (2) different dose levels and that the side effect profile, comprised of a flu-like syndrome, was consistent with strong immune stimulation. Although this firstin-human trial was not powered for efficacy, it was observed that the response rate and survival data compared favorably with historical controls. The new study will investigate this response with greater statistical power. The Phase I trial results were published earlier this year in *Vaccine* (*Vaccine*. 2009, 27 3975–3983).

Advaxis has separately announced its plans of Phase II studies of cervical cancer and cervical intraepithelial neoplasia (CIN), which are anticipated to begin dosing shortly.

## About the ADXS11-001 Immunotherapy

ADXS11-001 is a therapeutic vaccine that treats human papilloma virus (H PV) related tumors. Unlike marketed prophylactic vaccines that require treatment prior to exposure to the virus, A DX S1 1-001 treats patients who have already developed cancer as a result of HPV infection. Today, HPV is the most prevalent sexually transmitted disease in the US and the cause of cervix cancer, 40% of head and neck cancer, as well as penile, vulvar and anal cancer. Other clinical trials are planned for this agent in 2010, including a trial in cervical intraepithelial neoplasia (CIN). For additional information please see <a href="https://www.advaxis.com">www.advaxis.com</a>.

#### Advaxis, Incorporated

Based in North Brunswick, New Jersey, Advaxis is developing proprietary *Listeria monocytogenes* (*Lm*) cancer vaccines based on technology developed by Dr. Yvonne Paterson, professor of microbiology at the University of Pennsylvania and chairperson of Advaxis' scientific advisory board. Advaxis is developing attenuated live *Lm* vaccines that deliver engineered tumor antigens, which stimulate multiple simultaneous immunological mechanisms to fight cancer.

In a recent Advaxis Phase I clinical trial, a live *Lm* vaccine directed against the tumor-associated antigen HPV-16-E7 was safely administered to fifteen (15) women with advanced metastatic cancer of the cervix. Although this first trial of an *Lm* vaccine in humans was not designed or powered to prove efficacy, Advaxis believes an efficacy signal was observed that will be further explored in two (2) planned Phase II trials in the US and India in cervical cancer and its predecessor condition, cervical intraepithelial neoplasia (CIN). Advaxis now has nine (9) distinct cancer fighting constructs in various stages of development, both directly and with academic collaborators. For further information on the Company, please visit: www.advaxis.com.

#### **Forward-Looking Statements**

Certain statements contained in this press release are forward-looking statements that involve risks and uncertainties. The statements contained herein that are not purely historical are forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements deal with the Company's current plans, intentions, beliefs and expectations and statements of future economic performance. Forward-looking statements involve known and unknown risks and uncertainties that may cause the Company's actual results in future periods to differ materially from what is currently anticipated. Factors that could cause or contribute to such differences include those discussed from time to time in reports filed by the Company with the Securities and Exchange Commission. The Company cannot guarantee its future results, levels of activity, performance or achievements.

#### For Further Information:

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