# 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

June 3, 2009

(Date of Earliest Event Reported)

### 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.)

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

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

(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 (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 8.01 Other Events**

On June 3, 2009, Advaxis, Inc. issued a press release regarding the response from the Food & Drug Administration's denial for its request for Orphan Drug Designation in invasive cervix cancer.

A copy of the press release is attached as Exhibit 99.1 to this Current Report and is incorporated herein by this reference.

## Item 9.01 Financial Statements and Exhibits

99.1 Advaxis, Inc. press release, dated June 3, 2009

## **SIGNATURE**

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

Dated: June 3, 2009

# Advaxis, Inc.

By: /s/ Thomas A. Moore

Name: Thomas A. Moore
Title: Chief Executive Officer



### Exhibit 99.1

## ADVAXIS RECEIVES FDA RESPONSE TO ORPHAN DRUG FILING

**North Brunswick, NJ** – **June 2, 2009** – **Advaxis, Inc. (OTCBB: ADXS)** received the FDA letter late on June 1 denying the company's request for Orphan Drug Designation (ODD) for the use of ADXS11-001 in invasive cervix cancer. The FDA stated their market definition for invasive cervical cancer prevalence (including all those who had been cured) is over the 200,000 person cutoff. Further, the applicability of ADXS11-01 for a precursor condition, cervical intraepithelial neoplasia (CIN) was considered by the ODD as an early manifestation of the disease. No prevalence estimate for CIN was provided in our original application. There was no issue raised about efficacy.

Advaxis Chairman and CEO Thomas Moore commented, "When we announced this ODD filing, we said it was historically a 50% probability of getting approved. With an annual incidence of only 10,000 patients in the US diagnosed with invasive cervical cancer and a very poor prognosis if standard therapies fail, which they do for about half these patients, this appeared to be just what Orphan Drug was designed to encourage. The FDA Office of Orphan Products Development was very cooperative with us but we are naturally disappointed."

"We have pending study activity in cervical cancer in collaboration with NCI and plan to conduct at least one additional off-shore study. Our Phase I results showed great promise. We will likely seek another regulatory route for this indication, Fast Track designation, for which we can apply in the near term. If approved, Fast Track provides similar advantages in regulatory acceleration, but provides no market exclusivity or the possibility of grant support from FDA."

## About Advaxis, Inc.

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.

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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