Advaxis, Inc.
Form DEFA14A
April 30, 2013

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

SCHEDULE 14A

(Rule 14a-101)

Proxy Statement Pursuant to Section 14(a) of the
Securities Exchange Act of 1934
(Amendment No.)

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¨Preliminary Proxy Statement

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Advaxis, Inc.

(Name of Registrant as Specified in Its Charter)

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April 30, 2013

Dear Fellow Shareholders,

The last 18 months have been very productive for Advaxis. During this time, we have expanded our clinical program for our lead product candidate, ADXS-HPV (cervical, anal, and head and neck cancer), into five clinical trials in four indications; furthered our preclinical development for ADXS-PSA (prostate cancer); and generated positive canine osteosarcoma data with ADXS-cHER2 (canine osteosarcoma, human breast cancer). In addition, we engaged our first potential licensing partner, strengthened our management team, and made significant improvements to our balance sheet.

We are pleased with our recent achievements and we are excited for the next stage of our company as we continue to lead the development of immunotherapies to treat cancer and infectious disease.

ADXS-HPV- cervical, anal, and head and neck cancer

ADXS-HPV is emerging as an active agent in recurrent/refractory cervical cancer with encouraging preliminary data in safety, survival, tumor response, and disease stabilization. In our March business outlook conference call, we discussed our plans to advance ADXS-HPV toward a registrational clinical program. We intend to analyze our Phase 2 data as they become available, and work to optimize the dose and schedule of this immunotherapy in future studies. We will consult with global thought leaders to finalize our clinical plan, consult with regulatory authorities on the proposed path forward, and plan to move ADXS-HPV to registrational Phase 3 trials in 2014.

Our Phase 2 study being conducted in India in 110 patients with recurrent/refractory cervical cancer began enrollment in November 2010 and completed enrollment in May 2012. Preliminary efficacy data from this study include apparent prolonged survival, complete and partial tumor reductions, as well as stable disease with ADXS-HPV alone or in combination with cisplatin. Less than 3% of patients have reported serious adverse events associated with ADXS-HPV as compared to a rate of 130% or more in published studies of active chemotherapy regimens in this disease setting. The final 12-month survival data from this study will be reported at the 2013 American Society of Clinical Oncology Annual Meeting (ASCO) in June. The data continue to compare favorably to published reports for 12 month survival with single agents that are active in this disease setting. It will exceed the previous best for this study.

The Gynecologic Oncology Group (GOG) of the National Cancer Institute (NCI) continues to conduct their single arm Phase 2 study of ADXS-HPV in 67 patients with recurrent/refractory cervical cancer. Nine patients have been enrolled in the safety lead-in portion of the study and the GOG has decided to open the study to additional sites. GOG will present a poster at the ASCO June 2013 annual meeting. NCI is funding about 90% of study costs.

Our Phase 2 dose escalation study being conducted in the United States in 120 patients with cervical intraepithelial neoplasia (CIN) 2/3 commenced in March 2010 to assess the safety and efficacy of ADXS-HPV in women with this pre-cancerous condition. Given that we had no prior experience with ADXS-HPV in otherwise healthy subjects, our strategy was to go for the lowest possible dose, and we started with a dose that was $1/20^{th}$ of that used in all other studies. Enrollment was completed in the low-dose Cohort (41 patients) in September 2011 and although statistical significance was not reached, clinical benefit was observed that warranted further investigation. We completed enrollment of the mid-dose Cohort (40 patients) in June 2012 with a dose that was six times higher than Cohort 1 but 1/3 of the dose at which clinical activity has been observed in other studies ($1x10^9$cfu). The data from this Cohort were significantly delayed due to study challenges, one of which was a high rate of discontinuation with 6 patients failing to complete the study. While incomplete, the second Cohort did not demonstrate significant clinical efficacy. Based on the results from Cohorts 1 and 2, we have not yet identified a dose that can deliver a statistically significant benefit. We are therefore evaluating our options for this indication.

Cancer Research UK (CRUK) is continuing its Phase 1/2 study to evaluate the use of ADXS-HPV for the treatment of 27 patients with HPV positive head and neck cancer. This trial is being conducted at the Aintree Hospital at the University of Liverpool, the Royal Marsden Hospital at the University of London, and the Cardiff Hospital at the University of Wales. To date, 12 patients have enrolled. CRUK is sponsoring the study and assuming almost all of the associated costs.

This month we announced that the Brown University Oncology Group (BrUOG) dosed the first patient in a Phase 1/2 study of ADXS-HPV in 25 patients with HPV-associated anal cancer funded and coordinated by Brown University.

ADXS-cHER2- canine osteosarcoma, human breast cancer

ADXS-cHER2 is a construct developed for the treatment of human breast cancer. In advance of human trials, we identified a veterinary opportunity that could build our clinical experience quickly and efficiently.

Dr. Nicola Mason, Chair in Companion Animal Medicine at the University of Pennsylvania School of Veterinary Medicine, continues to conduct the Phase 1 dose escalation study to determine the maximum tolerated dose of ADXS-cHER2 for the treatment of dogs with osteosarcoma. In this trial, dogs with HER-2/neu overexpressing tumors that have received standard of care treatment for osteosarcoma (limb amputation and follow up chemotherapy) are then treated with ADXS-cHER2. This study was initiated in 2011. Preliminary data from the first two dose groups show a significant survival advantage in dogs that received ADXS-cHER2 compared to dogs whose owners elected not to participate in the trial but who were followed for survival (p=0.01). Treatment with ADXS-cHER2 has been well tolerated. Dr. Mason plans to expand the trial to three additional sites in the United States to further evaluate the effectiveness of ADXS-cHER2 maintenance immunotherapy.

These preliminary data represent a significant achievement. We have demonstrated clinical benefit against a totally different kind of cancer with a different Advaxis *Lm*-LLO immunotherapy in a different market that has significant commercial potential. This study further validates the versatility of our technology platform and constructs.

Dr. Nicola Mason and Dr. Yvonne Paterson, scientific founder of Advaxis, received the inaugural University of Pennsylvania One Health Award in March 2013 for their research of ADXS-cHER2 for the treatment of canine osteosarcoma.

ADXS-PSA- prostate cancer

We continue to move our constructs from preclinical development to clinical evaluation. Our next *Lm*-LLO immunotherapy that we intend to progress to human trials is our ADXS-PSA for the treatment of prostate cancer. In June 2011, we conducted a pre-IND meeting with the FDA to discuss the CMC, pharmacology, toxicology, and clinical plan for ADXS-PSA. The required toxicology studies have been completed and GMP drug product for the Phase 1 clinical study has been manufactured. We expect to file an IND with the FDA for ADXS-PSA in the first half of 2014.

Licensing Activities

This month we announced that we have a Memorandum of Understanding to license ADXS-HPV to FusionVax, a Taiwan-based company developing treatments for HPV-associated cancers. Upon completing a definitive agreement, FusionVax will develop ADXS-HPV clinically and commercially in Asia (excluding India) across multiple HPV-associated cancers. Other discussions are ongoing.

Other Developments and Activities

We are continuing development of a more temperature stable formulation to eliminate the need for -70 C shipping and storage. Allergy research continues at the Karolinska Institutet and we will continue to explore the apparent synergy between ADXS *Lm*-LLO immunotherapies and radiation that was published by Dr. Chandon Guha in the treatment of prostate cancer. Research describing the use of radioactive *listeria* to treat pancreatic cancer was recently published and used an Advaxis construct.

Expanded Management Team

In January of 2013 we welcomed Daniel J. O'Connor to Advaxis as our Senior Vice President, Chief Legal and Business Development Officer. Dan was a senior vice president, general counsel and secretary at ImClone Systems where he played a key leadership role in the clinical development, launch, and commercialization of ERBITUX®. Dan joins our other dedicated employees as an energetic catalyst for future licensing negotiations and business development. With the departure of Dr. John Rothman, Dr. Robert Petit, who managed the U.S. Oncology Program for Bristol Myers Squibb has stepped in to take 100% responsibility for both Advaxis clinical and development activities.

Financial Improvements

In 2012, we made progress toward simplifying our balance sheet and strengthening the financial health of the company. Specifically, we reduced non-affiliated debt by approximately $7.2M or 80% from 2011. We also secured a $10M committed equity line. We have also significantly reduced our payables over the past six months. In 2013, our goal is to build on this momentum, continue to simplify our balance sheet, including actively exploring multiple strategic licensing agreements and efficient financing paths to enable an extension of our cash runway sufficient to achieve the Advaxis mission.

Looking forward

The coming year will be transformational for Advaxis. Our research achievements, expanded management team, and improved balance sheet set the stage for a progressive 2013. We intend to advance our lead product candidate, ADXS-HPV, toward a registration program and continue to significantly strengthen our financial position.

Your Board has submitted certain proposals in the proxy that would allow Advaxis to make future financial moves we believe can, at the appropriate time, help secure additional funding and broaden the appeal of Advaxis' stock. I want to draw your attention to the proxy information provided and personally, as a major cash investor in Advaxis as well as CEO, urge your approval of these proposals.

We are pleased to see the medical community increasingly committed to the future of immunotherapy in the treatment of cancer. We believe the Advaxis technology, which offers clinical benefits, a well-tolerated safety profile and lower cost of manufacturing will be a big part of this revolution in treating unmet needs in cancer.

We are thankful for our supportive and resilient shareholders and our Board. We look forward to realizing Advaxis' potential as an excellent investment.

Thank you,

Tom Moore

Chairman and CEO, Advaxis