

Advaxis, Inc.  
Form 424B5  
March 26, 2014

The information in this preliminary prospectus supplement is not complete and may be changed. This preliminary prospectus supplement and the accompanying prospectus are part of an effective registration statement filed with the Securities and Exchange Commission under the Securities Act of 1933, as amended. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell these securities and are not soliciting an offer to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

**PRELIMINARY PROSPECTUS  
SUPPLEMENT**

**SUBJECT TO COMPLETION**

**DATED MARCH 26,  
2014**

**(To the Prospectus dated March 4, 2014)**

**Filed Pursuant to Rule 424(b)(5)  
Registration No. 333-194009**

## Shares

### Common Stock

We are offering      shares of our common stock, par value \$0.001 per share, pursuant to this prospectus supplement and the accompanying prospectus.

Our common stock is listed on the NASDAQ Capital Market under the symbol    ADXS.    The last reported sale price of our common stock on March 26, 2014 was \$4.07 per share.

**Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page S-13 of this prospectus supplement and page 5 of the accompanying prospectus for a discussion of information that you should consider in connection with an investment in our common stock.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or determined if this prospectus supplement or any accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

	Per Share	Total
Public offering price	\$	\$
Underwriting discounts and commissions <sup>(1)</sup>	\$	\$
Proceeds, before expenses, to us	\$	\$

(1) Does not include a non-accountable expense allowance equal to 1% of the gross proceeds of this offering payable to Aegis Capital Corp., the representative of the underwriters. There will be additional items of value paid in connection with this offering that are viewed by the Financial Regulatory Authority, Inc. as underwriting compensation. Payment of this additional underwriting compensation will reduce the proceeds to us, before

expenses. See Underwriting beginning on page S-35 of this prospectus supplement for a description of the compensation payable to the underwriters.

We have granted a 30-day option to the representative of the underwriters to purchase up to an additional shares of common stock solely to cover over-allotments, if any.

The underwriters expect to deliver the shares against payment therefor on or about April , 2014.

## **Aegis Capital Corp**

April ,2014

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## **ABOUT THIS PROSPECTUS SUPPLEMENT**

This prospectus supplement and the accompanying prospectus are part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC, utilizing a shelf registration process. Under this process, we may sell from time to time in one or more offerings up to an aggregate of \$50,000,000 in our securities described in the accompanying prospectus.

This document is in two parts. The first part is this prospectus supplement, which describes the specific terms of this offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. The second part, the accompanying prospectus, gives more general information about the common stock we may offer from time to time. Generally, when we refer to this prospectus, we are referring to both parts of this document combined together with all documents incorporated by reference. If the description of the offering varies between this prospectus supplement and the accompanying prospectus, you should rely on the information contained in this prospectus supplement. However, if any statement in one of these documents is inconsistent with a statement in another document having a later date—for example, a document incorporated by reference into this prospectus supplement or the accompanying prospectus—the statement in the document having the later date modifies or supersedes the earlier statement.

You should rely only on the information contained in or incorporated by reference into this prospectus supplement or contained in or incorporated by reference into the accompanying prospectus to which we have referred you. We have not, and the underwriters have not, authorized anyone to provide you with information that is different. If anyone provides you with different or inconsistent information, you should not rely on it. The information contained in, or incorporated by reference into, this prospectus supplement and contained in, or incorporated by reference into, the accompanying prospectus is accurate only as of the respective dates thereof, regardless of the time of delivery of this prospectus supplement and the accompanying prospectus or of any sale of securities. Our business, financial condition, results of operations and prospects may have changed since those dates.

It is important for you to read and consider all information contained in this prospectus supplement and the accompanying prospectus, including the documents incorporated by reference herein and therein, in making your investment decision. You should also read and consider the information in the documents to which we have referred you under the captions *Where You Can Find More Information* and *Incorporation of Documents by Reference* in this prospectus supplement and in the accompanying prospectus.

We are offering to sell, and are seeking offers to buy, the common stock only in jurisdictions where such offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of the common stock in certain jurisdictions or to certain persons within such jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about and observe any restrictions relating to the offering of the common stock and the distribution of this prospectus supplement and the accompanying prospectus outside the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

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## **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus supplement and any accompanying prospectus, including the documents incorporated by reference, contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on our management's current beliefs, expectations and assumptions about future events, conditions and results and on information currently available to us.

Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but not always, made through the use of words or phrases such as anticipate, estimate, plan, project, continuing, believe, expect, future and intent expressions to identify forward-looking statements, but are not the exclusive means of identifying forward-looking statements in this prospectus supplement. Additionally, statements concerning future matters such as our interpretation of the trials for our product candidates, the ability to successfully complete additional clinical trials on a timely basis and obtain regulatory approvals for one or more of our product candidates, the potential biological effects and indications for our product candidates, the market opportunity for our product candidates, our ability to complete additional discovery and development activities for drug candidates, our ability to timely raise additional funds to support our operations and the period of time for which our existing cash will enable us to fund our operations and other statements regarding matters that are not historical in nature are forward-looking statements.

Such statements are based on currently available operating, financial and competitive information and are subject to various risks, uncertainties and assumptions that could cause actual results to differ materially from those anticipated or implied in our forward-looking statements due to a number of factors including, but not limited to, those set forth in the section entitled "Risk Factors" in this prospectus supplement. Given these risks, uncertainties and other factors, many of which are beyond our control, you should not place undue reliance on these forward-looking statements.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to revise any forward-looking statements to reflect events or developments occurring after the date of this prospectus, even if new information becomes available in the future.

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## PROSPECTUS SUPPLEMENT SUMMARY

*This summary highlights information contained elsewhere or incorporated by reference into this prospectus supplement and the accompanying prospectus. This summary does not contain all of the information that you should consider before deciding to invest in our securities. You should read this entire prospectus supplement and the accompanying prospectus carefully, including the Risk Factors section contained in this prospectus supplement and our consolidated financial statements and the related notes and the other documents incorporated by reference into this prospectus supplement and the accompanying prospectus. Unless we have indicated otherwise or the context otherwise requires, references in this prospectus supplement, the accompanying prospectus or the documents incorporated by reference herein and therein to the Company, Advaxis, we, us and our refer to Advaxis, Inc.*

### Business Overview

We are a clinical development stage biotechnology company focused on the discovery, development and commercialization of our proprietary *Lm*-LLO cancer immunotherapies. These immunotherapies are based on a platform technology that utilizes live attenuated *Listeria monocytogenes*, which we refer to as *Listeria* or *Lm*, that have been bioengineered to secrete antigen/adjuvant fusion proteins. We believe that these *Lm*-LLO strains are a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy because they access and direct antigen presenting cells, or APC, to stimulate anti-tumor T-cell immunity, stimulate and activate the immune system with the equivalent of multiple adjuvants, and simultaneously reduce tumor protection in the tumor microenvironment to enable the T-cells to eliminate tumors. Other immunotherapies may employ individual elements of our comprehensive approach, but, to our knowledge, none combine all of these elements together in a single, easily administered, well-tolerated yet comprehensive immunotherapy.

The effectiveness of our approach has been validated by numerous publications in multiple models of human disease.

In the clinic, ADXS-HPV, our lead *Lm*-LLO immunotherapy for the treatment of HPV-associated cancers, is well-tolerated and has been administered to both young patients with pre-malignant dysplasia, as well as patients with advanced disease. Clinical efficacy has been demonstrated by apparent prolonged survival, complete and partial tumor responses, and the prolonged stabilization of advanced cancer. The preliminary data from our completed Phase 2 clinical trial of ADXS-HPV in patients with recurrent cervical cancer demonstrate that ADXS-HPV is an active agent in this disease setting with a manageable safety profile. We achieved proof of concept with this Phase 2 study, and over the next two to five years, we plan to advance ADXS-HPV through a registrational program and regulatory approval(s) in the United States and relevant markets for the treatment of women with cervical cancer. We are currently evaluating this same *Lm*-LLO immunotherapy in Phase 1/2 clinical trials for two other HPV-associated cancers: head and neck cancer and anal cancer. In addition, we plan to advance ADXS-PSA, our second *Lm*-LLO immunotherapy, into a Phase 1 dose escalation trial to determine the maximum tolerated dose for the treatment of prostate cancer in the first half of 2014. A third *Lm*-LLO immunotherapy, ADXS-cHER2, is being evaluated for safety and efficacy in the treatment of companion dogs with HER2 over-expressing osteosarcoma. We plan to advance ADXS-cHER2 into a Phase 1 dose escalation trial to determine the maximum tolerated dose for the treatment of HER2 overexpressing cancers such as breast and others.

We own or have an exclusive license to a robust and extensive patent portfolio relating to our core *Lm*-LLO immunotherapy technology. Our current patent portfolio includes 43 issued patents granted in the United States and

foreign jurisdictions, and 52 pending patent applications in the United States and foreign jurisdictions. To develop our technology, we may enter into commercial partnerships, joint ventures, or other arrangements with competitive or complementary companies, including pharmaceutical or biotechnology companies or universities during the preclinical or clinical stages. Our current collaborations include the preclinical development of *Lm*-LLO immunotherapies for a number of indications. We currently have over 15 distinct immunotherapies in various stages of development, developed directly by us and through strategic collaborations with recognized centers of excellence.

These include but are not limited to the following Advaxis immunotherapy and corresponding tumor antigen:

ADXS11-001/HPV16-E7, ADXS31-142/Prostate Specific Antigen, ADXS31-164/HER2/neu Chimera, Lm-LLO-HMW-MAA/HMW-MAA, C-terminus fragment, Lm-LLO-ISG15/ISG15, Lm-LLO CD105/Endoglin, Lm-LLO-flk/VEGF and Bivalent Therapy, HER-2-Chimera/HMW-MAA-C. We will continue to conduct preclinical research to develop additional *Lm*-LLO

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constructs to expand our platform technology and may develop additional distinct immunotherapies in the future. We are exploring potential development and commercialization collaborations for certain product candidates in our development pipeline.

We recently entered into strategic global partnerships with Global BioPharma, Inc. and Biocon, Ltd. for the development and commercialization of ADXS-HPV in territories where there is a high prevalence of HPV-associated cancers:

### *Global BioPharma, Inc.*

On December 9, 2013, we entered into an exclusive licensing agreement, or the GBP Agreement, for the development and commercialization of ADXS-HPV with Global BioPharma, Inc., or GBP, a Taiwanese based biotech company funded by a group of investors led by Taiwan Biotech Co., Ltd., or TBC.

GBP plans to conduct registration trials with ADXS-HPV for the treatment of advanced cervical cancer and will explore the use of Advaxis' lead product candidate in several other indications including lung, head and neck, and anal cancer.

GBP will pay us event-based financial milestones, an annual development fee, and annual net sales royalty payments in the high single to double digits. In addition, as an upfront payment, GBP made an investment in us by purchasing shares of our common stock at market price. GBP has an option to purchase additional shares of our stock at a 150% premium to the stock price on the effective date of the GBP Agreement.

GBP will be responsible for all clinical development and commercialization costs in the GBP territory. In collaboration with us, GBP will also identify and pay the clinical trial costs for up to 150 patients with cervical cancer for enrollment in our U.S. and GBP's Asia registrational programs for cervical cancer. GBP is committed to establishing manufacturing capabilities for its own territory and to serving as a secondary manufacturing source for us in the future. Under the terms of the GBP Agreement, we will exclusively license the rights to ADXS-HPV to GBP for the Asia, Africa, and former USSR territory, exclusive of India and certain other countries, for all HPV-associated indications. We will retain exclusive rights to ADXS-HPV for the rest of the world.

### *Biocon Limited*

On January 20, 2014, we entered into a Distribution and Supply Agreement, or the Biocon Agreement, with Biocon Limited, or Biocon, a company incorporated under the laws of India.

Pursuant to the Biocon Agreement, we granted Biocon an exclusive license (with a right to sublicense) to (i) use our data from clinical development activities, regulatory filings, technical, manufacturing and other information and know-how to enable Biocon to submit regulatory filings for ADXS-HPV in the following territories: India, Malaysia, Kenya, Bangladesh, Bhutan, Maldives, Myanmar, Nepal, Pakistan, Sri Lanka, Bahrain, Jordan, Kuwait, Oman, Saudi Arabia, Qatar, United Arab Emirates, Algeria, Armenia, Egypt, Eritrea, Iran, Iraq, Lebanon, Libya, Sudan, Syria, Tunisia and Yemen, collectively referred to as the Territory, and (ii) import, promote, market, distribute and sell pharmaceutical products containing ADXS-HPV.

Under the Biocon Agreement, Biocon has agreed to use its commercially reasonable efforts to obtain regulatory approvals for ADXS-HPV in India. In the event Phase II or Phase III clinical trials are required, we will conduct such



trials at our cost, provided that if we are unable to commence such clinical trials, Biocon may conduct such clinical trials, subject to reimbursement of costs by us. Biocon has agreed to commence commercial distribution of ADXS-HPV no later than 9 months following receipt of regulatory approvals in a country in the Territory. Biocon will be responsible for the costs of obtaining and maintaining regulatory approvals in the Territory.

We will have the exclusive right to supply ADXS-HPV to Biocon and Biocon will be required to purchase its requirements of ADXS-HPV exclusively from us at the specified contract price, as such price may be adjusted from time to time. In addition, we will be entitled to a six-figure milestone payment if net sales of ADXS-HPV for the contract year following the initiation of clinical trials in India exceed certain specified thresholds.

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Biocon will also have a right of first refusal relating to the licensing of any new products in the Territory that we may develop during the term of the Biocon Agreement.

### **Our Results of Operations and Financial Position**

We have sustained losses from operations in each fiscal year since our inception, and we expect these losses to continue for the indefinite future, due to the substantial investment in research and development. As of January 31, 2014, we had an accumulated deficit of \$75,653,215, and stockholders' equity of \$14,859,802. We had net losses of \$19,986,826 and \$5,187,392 for the fiscal year ended October 31, 2013 and three months ended January 31, 2014, respectively. We incurred research and development expenses of \$5,621,989 and \$1,559,867 for the fiscal year ended October 31, 2013 and three months ended January 31, 2014, respectively.

### **Our *Lm*-LLO Immunotherapy Platform Technology**

Our *Lm*-LLO immunotherapies are based on a platform technology under exclusive license from the Trustees of the University of Pennsylvania, or Penn, that utilizes live attenuated *Lm* bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm* strains use a fragment of the protein listeriolysin, or LLO, fused to a tumor associated antigen, or TAA, or other antigen of interest and we refer to these as *Lm*-LLO immunotherapies. Regardless of which antigen(s) is fused to *LLO*, the proposed mechanism of action is basically the same. We believe these *Lm*-LLO immunotherapies redirect the potent immune response to *Lm* that is inherent in humans, to the TAA or other antigen of interest.

*Lm*-LLO immunotherapies stimulate the immune system to induce antigen-specific anti-tumor immune responses involving both innate and adaptive arms of the immune system. In addition, our technology facilitates the immune response by altering the tumor microenvironment to reduce immunologic tolerance in the tumors but leaves normal tissues unchanged. This makes the tumor more susceptible to immune attack by inhibiting the T-cells, or Tregs, and myeloid-derived suppressor cells, or MDSC, that we believe promote immunologic tolerance of cancer cells in the tumor.

The field of immunotherapy is a relatively new area of cancer treatment development that holds tremendous promise to generate more effective and better tolerated treatments for cancer than the more traditional, high dose chemotherapy and radiation therapies that have been the mainstay of cancer treatment thus far. There are many approaches toward immunotherapy that have been recently approved or are in development. We believe *Lm*-LLO immunotherapies will offer a more comprehensive immunotherapy in a single, well-tolerated, easy to administer treatment than other alternative immunotherapy treatments.

The following diagram illustrates how the live attenuated *Lm* in our immunotherapies are phagocytosed and processed by an APC leading to the stimulation of CD4+ T cell, or helper T cells, and CD8+ T cells, or killer T cells.

Live attenuated *Lm* bioengineered to secrete an antigen-adjuvant fusion protein (antigen + tLLO) stimulate a profound innate immune response and are phagocytized by APC. Fragments from *Lm* are processed via the major histocompatibility complex, or MHC, class II generating antigen specific CD4+ T cells. Some *Lm* escapes into the cytosol and secretes antigen-LLO fusion proteins.

Fusion protein antigens are presented via MHC class I pathway to generate activated CD8+ T cells. The activated T cells will then find and infiltrate tumors and destroy the tumor cells. Immunologic tolerance in the tumor microenvironment mediated by regulatory T cells, or Tregs, and myeloid-derived suppressor cells, or MDSC, is reduced. Thus we believe Lm-LLO immunotherapies may stimulate innate and adaptive tumor-specific immunity while simultaneously reducing immune tolerance to tumors.

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We believe our *Lm*-LLO immunotherapies integrate all four of what we consider to be the essential elements of a cancer immunotherapy into a comprehensive, single, well-tolerated, easy to manufacture and administer immunotherapy.

### **Our Preclinical and Clinical Development Pipeline**

Our most advanced product candidates in clinical development are ADXS-HPV, ADXS-PSA and ADXS-CHER2:

**ADXS-HPV.** ADXS-HPV is an *Lm*-LLO immunotherapy directed against HPV. ADXS-HPV is designed to target cells expressing the HPV gene E7. Expression of the E7 gene from high-risk HPV strains is responsible for the transformation of infected cells into dysplastic and malignant tissues and in the laboratory, was more effective than ADXS vectors targeting HPV E6. Eliminating these cells can eliminate the dysplasia or malignancy. ADXS-HPV is designed to direct antigen-presenting cells to generate powerful innate and cellular immune responses to HPV transformed cells resulting in the infiltration of cytotoxic T cells and attack on tumors. At the same time, we believe ADXS-HPV treatment may cause a reduction in the number and function of immunosuppressive regulatory Tregs and MDSC in the tumors that are protecting tumors from immune attack. In October 2013, we completed the randomized Phase 2 study evaluating the safety and efficacy of ADXS-HPV (1 cycle of three doses at  $1 \times 10^9$  cfu) with and without cisplatin (40 mg/m<sup>2</sup>, weekly x5) in 110 patients in India with recurrent cervical cancer. Updated preliminary results were presented in November 2013 at the 2013 Society for Immunotherapy of Cancer (SITC) Annual Meeting in National Harbor, MD. Patients continue to be followed for overall survival. ADXS-HPV is being evaluated in three ongoing clinical trials for HPV-associated diseases: locally advanced cervical cancer (with the Gynecologic Oncology Group, largely underwritten by the NCI, U.S.); head and neck cancer (Icahn School of Medicine at Mount Sinai, U.S.) and anal cancer (Brown University Oncology Group, U.S.). Our next goal is to conduct Phase 1/2 trials to optimize the dose and

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schedule of ADXS-HPV, which we believe may further increase efficacy with respect to both clinical response and survival. On February 5, 2014, we expanded our relationship with the Georgia Health Sciences University Cancer Center by entering into a master clinical trial, or the GRU Clinical Trial Agreement, agreement to conduct four clinical trials relating to ADXS-HPV. Four clinical trials will be designed to assess: (i) high dose, repeating cycles of ADXS-HPV in recurrent or refractory cervical cancer; (ii) the optimal combination of ADXS-HPV and PD-1 antibody in patients with recurrent or refractory cervical cancer; (iii) safety and efficacy of ADVX-HPV in HER2 overexpressing cancers and (iv) ADXS-HPV prior to surgery in patients with surgically treatable cervical cancer. Additional studies will investigate how best to combine ADXS-HPV with existing cytotoxic treatments. We plan to advance ADXS-HPV through a registrational program and regulatory approval in the United States and relevant markets for the treatment of cervical cancer. We also plan to evaluate ADXS-HPV in Phase 1/2 clinical trials for the treatment of patients with HPV-positive head and neck cancer and HPV-positive anal cancer. On December 5, 2013, we entered into a clinical trial agreement with Icahn School of Medicine at Mount Sinai, U.S. to evaluate the safety, effectiveness and immunogenicity of ADXS-HPV in 25 patients with head and neck cancer. The clinical trial will be the first study to evaluate the effects of ADXS-HPV in patients when they are initially diagnosed with HPV-associated head and neck cancer, prior to receiving any standard of care (surgery, chemotherapy, radiation or a combination thereof) to remove and/or treat their tumors. Future plans for the ADXS-HPV franchise are contingent upon a number of variables including available resources, types and number of studies, study initiation, patient enrollment, clinical and safety data generated, regulatory interactions and changing competitive landscape.

**ADXS-PSA.** ADXS-PSA is an *Lm-LLO* immunotherapy directed against PSA. ADXS-PSA is designed to target cells expressing PSA. ADXS-PSA secretes the PSA antigen, fused to LLO, directly inside the APC, that are capable of driving a cellular immune response to PSA expressing cells. In preclinical analysis, the localized effect is the inhibition of the Treg and MDSC cells that we believe may promote immunologic tolerance of the PSA cancer cells of the tumor. We have conducted a pre-Investigational New Drug application (IND) meeting with the FDA to discuss the chemistry, manufacturing and controls, pharmacology, toxicity and clinical plans for ADXS-PSA. We will finalize the toxicology and good manufacturing practice (GMP), documentation required for the IND, which we plan to submit to the FDA in order to advance ADXS-PSA into a Phase 1 dose escalation trial to determine the maximum tolerated dose for the treatment of prostate cancer. Future plans for the ADXS-PSA clinical program are contingent upon a number of variables including available resources, types and number of studies, study initiation, patient enrollment, clinical and safety data generated, regulatory interactions and changing competitive landscape.

**ADXS-cHER2.** ADXS-cHER2 is an *Lm-LLO* immunotherapy for HER2 overexpressing cancers (such as breast and other cancers in humans and for osteosarcoma in canines). ADXS-cHER2 secretes the cHER2 antigen, fused to LLO, directly inside APC that are capable of driving a cellular immune response to cHER2 overexpressing cells. In preclinical analysis, localized effect is the inhibition of the Treg and MDSC cells that we believe may promote immunologic tolerance of the HER2 overexpressing cancer cells of the tumor. ADXS-cHER2 was validated based on interim data from an ongoing unblinded clinical study in 13 client-owned dogs with osteosarcoma, conducted at the University of Pennsylvania School of Veterinary Medicine and sponsored by Advaxis. In the study, dogs treated with ADXS-cHER2 immunotherapy after the standard of care had a statistically significant prolonged overall survival benefit compared with dogs that received standard of care without ADXS-cHER2. Under the GRU Clinical Trial Agreement, a Phase 1/2 clinical trial will be designed to assess the safety and efficacy of ADXS-cHER2 in patients with HER2 over-expressing cancers such as breast and others with measurable disease who have progressed after prior standard therapy. Future plans for the ADXS-cHER2 program are contingent upon a number of variables including available resources, types and number of studies, study initiation, patient enrollment, clinical and safety data generated, regulatory interactions and changing competitive landscape.

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The following table summarizes the stage of development of ADXS-HPV, ADXS-PSA and ADXS-cHER2:

*ADXS-HPV Phase 2 Data*

In October 2013, we completed *Lm-LLO-E7-15*, a Phase 2 randomized trial designed to assess the safety and efficacy of ADXS-HPV ( $1 \times 10^9$  cfu) with and without cisplatin (40 mg/m<sup>2</sup>, weekly x5). 110 patients were randomized to one of two treatment arms with 55 patients per treatment. The primary endpoint of the study is overall survival.

As reported at the SITC Annual Meeting in November 2013, 110 patients received 264 doses of ADXS11-001. The final 18-month survival was 28% (31/110) and the final 12-month survival was 36% (39/110). The National Comprehensive Cancer Network Guidelines and/or Gynecologic Oncology Group published studies cite historical 12-month survival data of 0-22% with single agent therapy in recurrent cervical cancer.

Both treatment arms included ADXS-HPV, but one treatment arm added cisplatin chemotherapy. The addition of cisplatin did not significantly improve overall survival or tumor responses over ADXS-HPV treatment alone, but was associated with increased toxicity. In addition, survival outcomes and tumor responses were not affected by Eastern Cooperative Oncology Group performance status (0-2); type of prior therapy (radiation alone, chemotherapy alone, or a combination of both); or aggressiveness of disease (defined as recurrence 2 years from initial diagnosis) versus non-aggressive disease (defined as recurrence >2 years from initial diagnosis).

Tumor responses have been observed in both treatment arms with six complete responses and six partial responses. 41% (45/110) of patients (35/66) had durable stable disease for at least 3 months. Tumor reductions have been observed against all high-risk HPV strains detected, including HPV 16, 18, 31, 33 and 45. Average duration of response after 12 month minimum follow-up was 10.5 months for both treatment groups. In those

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patients treated with ADXS-HPV alone who had stable disease, the average duration of response was 6 months compared to 4.1 months in patients treated with ADXS-HPV plus cisplatin.

Published Phase 2 single agent trials report 12 months survival of 0 22%\*  
\* NCCN Guidelines:  
Plaxe SC, et. al., 2002, Cancer Chemother Pharmacol; 50: 151-4.

Garcia AA, et. al., 2007, Am J Clin Oncol; 30: 428-431.

ADXS-HPV continues to demonstrate a well-tolerated and manageable safety profile with 42% ( 46/110) of patients reporting predominately cytokine-release syndrome (CRS) Grade 1 or 2 transient, non-cumulative side effects related/possibly related to ADXS-HPV. Side effects either responded to symptomatic treatment or self-resolved. Less than 2% of patients reported serious adverse events associated with ADXS-HPV (1 Grade 3 CRS with dyspnea and 1 Grade 4 CRS with fever).

## **Business Strategy**

Our strategy is to maintain and fortify a leadership position in the discovery, acquisition and development of *Lm-LLO* cancer immunotherapies. The fundamental goals of our business strategy include the following:

***Be the first immunotherapy company to commercialize a therapeutic HPV-associated oncology drug.*** Because we believe ADXS-HPV is the most clinically advanced cervical cancer immunotherapy, we aim to fortify our leadership position and be the first to commercialize our *Lm-LLO* immunotherapy for this unmet medical need.

***Develop and commercialize ADXS-HPV in multiple HPV-associated cancers.*** We plan to advance ADXS-HPV through a registrational program and regulatory approval in the United States and relevant markets for the treatment of cervical cancer. If successful, we plan to submit a Biologics

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License Application, or BLA, to the FDA as the basis for marketing approval in the United States of ADXS-HPV for the treatment of cervical cancer. HPV, the target for ADXS-HPV, is expressed on a wide variety of cancers including cervical, head and neck, anal, vulva, vaginal, and penile. Accordingly, we believe that ADXS-HPV should be active in these HPV-associated cancers and these indications could represent significant market opportunities for ADXS-HPV.

***Obtain Orphan Drug Designation with the FDA and the EMEA for ADXS-HPV for use in the treatment of invasive cervical cancer, head and neck cancer and anal cancer.*** In June 2013, we filed three applications for Orphan Drug Designation, or ODD, with the FDA for ADXS-HPV for the treatment of anal cancer (granted August 2013), head and neck cancer (granted November 2013), invasive cervical cancer (denied in October 2013 as the target population estimate exceeded the statutory maximum allowed). In January 2014, a teleconference meeting was conducted with the FDA to discuss the orphan drug designation request and subsequent denial for ADXS-HPV for invasive cervical cancer. Based on these discussions, we submitted a new ODD application in February 2014.) Orphan status is granted by the FDA to promote the development of products that demonstrate promise for the treatment of rare diseases affecting fewer than 200,000 individuals in the United States annually, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation would entitle our company to a seven-year period of marketing exclusivity in the United States to the extent our request is approved by the FDA, and would enable us to apply for research funding, tax credits for certain research expenses, and a waiver from the FDA's application user fee. Orphan drug status in the European Union has similar but not identical benefits in that jurisdiction.

***Develop ADXS-PSA in prostate cancer.*** We plan to advance ADXS-PSA into a Phase 1 dose escalation trial in the first half of 2014 to determine the maximum tolerated dose for the treatment of patients with prostate cancer.

***Develop ADXS-cHER2 in -HER2 overexpressing cancers.*** We plan to advance ADX-cHER2 into a Phase 1 dose escalation trial in the second half of 2014 to determine the maximum tolerated dose for the treatment of patients with HER2 overexpressing cancers such as breast and others.

***Develop scale-up and commercial manufacturing processes.*** We plan to develop scale-up and commercial manufacturing processes, including the development of a lyophilized dosage form.

***Leverage our proprietary discovery platform to identify new therapeutic immunotherapies.*** We intend to conduct research relating to the development of the next generations of our *Lm*-LLO immunotherapies using new antigens of interest; improving the *Lm*-LLO based platform technology by developing new strains of *Listeria* that may be more suitable as live vaccine vectors; developing bivalent *Lm*-LLO immunotherapies; further evaluating synergy of *Lm*-LLO immunotherapies with cytotoxic therapies and continuing to develop the use of LLO as a component of a fusion protein based immunotherapy. We currently have over 15 distinct immunotherapies in various stages of development, developed directly by us and through strategic collaborations with recognized centers of excellence. These include but are not limited to the following Advaxis immunotherapy and corresponding tumor antigen: ADXS11-001/HPV16-E7, ADXS31-142/Prostate Specific Antigen, ADXS31-164/HER2/neu Chimera, *Lm*-LLO-HMW-MAA/HMW-MAA, C-terminus fragment, *Lm*-LLO-ISG15/ISG15, *Lm*-LLO CD105/Endoglin, *Lm*-LLO-flk/VEGF and Bivalent Therapy, HER-2-Chimera/HMW-MAA-C. We will continue to conduct preclinical research to develop additional *Lm*-LLO constructs to expand our platform technology and may develop additional distinct immunotherapies in the future. Our growth strategy is to expand from the ADXS-HPV franchise into larger cancer indications such as prostate and breast cancer to further validate the robustness and versatility of the platform technology and to develop immunotherapies that we believe to be of interest to big pharmaceutical partners. We also intend to further expand the research and development programs to provide multiple biomarker-specific products with applications across multiple tumor types that express those biomarkers. Additionally, we plan to partner with or acquire a target discovery company, develop multiple constructs targeting numerous biomarker targets to deliver the promise of biomarker driven

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multi-targeted immunotherapies. The overall goal with each patient is to: biopsy the patient's tumor; identify which biomarkers are expressed; treat the patient with our immunotherapies that hit multiple targets simultaneously, adding in the ability to adjust an individual's immunotherapy over time based on changes in the tumor. We believe that if successful, this has the potential to revolutionize the treatment of cancer.

***Enter into commercialization collaborations for ADXS-HPV.*** If ADXS-HPV is approved by the FDA and other regulatory authorities for first use, we plan to either enter into commercial partnerships, joint ventures, or other arrangements with competitive or complementary companies, including pharmaceutical companies or commercialize these products ourselves in North America and Europe through direct sales and distribution. On December 9, 2013, we entered into an exclusive licensing agreement with Global BioPharm Inc. for the development and commercialization of ADXS-HPV. On January 20, 2014, we entered into an exclusive licensing agreement for co-development and commercialization with Biocon Ltd.

***Develop commercialization capabilities in India, China, South America, North America and Europe.*** We believe that the infrastructure required to commercialize our oncology products is relatively limited, which may make it cost-effective for us to internally develop a marketing effort and sales force. If ADXS-HPV is approved by the FDA and other regulatory authorities for first use and we do not enter into commercial partnerships, joint ventures, or other arrangements with competitive or complementary companies, including pharmaceutical companies, we plan to commercialize these products ourselves in North America and Europe through direct sales and distribution. However, we will remain opportunistic in seeking strategic partnerships in these and other markets when advantageous.

***Continue to both leverage and strengthen our intellectual property portfolio.*** We plan to continue to leverage our Lm-LLO immunotherapies intellectual property portfolio to create value. We intend to file new patent applications, in-license new intellectual property and take other steps to strengthen, leverage, and expand our intellectual property position.

## Short-Term Strategic Goals and Objectives

During the next 12 months, our strategic goals and objectives include the following:

Report final results from the completed Phase 2 clinical trial conducted in India with ADXS-HPV for the treatment of recurrent cervical cancer;

Initiate Phase 1/2 high-dose clinical trial in patients with recurrent cervical cancer;

Seek an end of Phase 2 meeting with the FDA and submit a Special Protocol Assessment for ADXS-HPV;

Initiate global registrational study in recurrent cervical cancer with ADXS-HPV;

Initiate Phase 1 study with ADXS-PSA in prostate cancer;

Initiate Phase 1 study with ADXS-cHER2 in overexpressing cancers;

Continue to support the Phase 2 clinical trial of ADXS-HPV in the treatment of advanced cervical cancer with the Gynecologic Oncology Group, largely underwritten by the NCI;

Continue our collaboration with the Brown University Oncology Group, U.S., to support the Phase 1/2 clinical trial of ADXS-HPV in the treatment of anal cancer, entirely underwritten by the Brown University Oncology Group, U.S.;

Continue our collaboration with Icahn School of Medicine at Mount Sinai, U.S. to support the Phase 1/2 study with ADXS-HPV in patients with head and neck cancer; seek to conduct Advisory Board with key opinion leaders;

Seek Orphan Drug Designation for ADXS-HPV for the treatment of invasive cervical cancer;

Submit IND for ADXS-PSA for the treatment of prostate cancer;

Submit IND for ADXS-cHER2 for the treatment of HER2 overexpressing cancers;

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Continue to work with our contract manufacturing organization to develop GMP scale-up and commercial manufacturing processes;

Continue the preclinical development of additional *Lm*-LLO constructs as well as research to expand our platform technology;

Continue to develop and maintain strategic and development collaborations with academic laboratories, clinical investigators and potential commercial partners; and

Continue to actively pursue our global commercialization strategy by executing a second ex-US ADXS-HPV regional licensing deal with another market dominant biopharmaceutical company.

## **Recent Developments**

### **Exclusive License Agreement with Aratana Therapeutics Inc.**

On March 19, 2014, we entered into a definitive Exclusive License Agreement, or the Aratana License, with Aratana Therapeutics Inc., or Aratana. Pursuant to the Aratana License, we granted Aratana an exclusive, worldwide, royalty-bearing, license, with the right to sublicense, under certain of our proprietary technology that enables the design of an immunotherapy utilizing live attenuated *Listeria monocytogenes* bioengineered to secrete fusion proteins consisting of antigen and adjuvant molecules, including certain constructs and related compounds in order for Aratana to develop and commercialize animal health products containing or incorporating certain compounds for use in non-human animal health applications that will be targeted for treatment of osteosarcoma and other cancer indications in animals. Our 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 us during the term of the Aratana License that are reasonably necessary for the development, manufacture or commercialization of any construct, compound or product.

Aratana granted us 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 Aratana License, solely for us to develop and commercialize our products for any and all uses outside of the use in non-human animal health applications.

Aratana paid an upfront payment to us of US \$1,000,000 upon signing of the Aratana License. Aratana will also pay us, among other things, (a) up to \$36.5 million based on the achievement of certain regulatory milestones and up to an additional \$15 million in cumulative sales milestones based on achievement of certain gross sales revenue targets, and (b) tiered royalties starting at 5% and going up to 10%, which will be paid based on net sales of certain products in the United States. Royalties for sales of certain 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 certain products in the United States (starting at 2.5% and going up to 5%). Aratana will also pay us 50% of all sublicensee royalties received by Aratana and its affiliates.

### **Unregistered Sales of Equity Securities**

On March 19, 2014, we (i) issued and sold 306,122 shares of our 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 our 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 the our 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, we received aggregate net proceeds of \$1,500,000. We issued the shares and warrant in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended.

### **Appointment of New Chief Financial Officer**

On March 24, 2014, Mark J. Rosenblum, our former Senior Vice President, Chief Financial Officer and Secretary resigned, effective immediately. Our board of directors appointed Sara Bonstein to serve as our new Chief Financial Officer, effective as of March 24, 2014.

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Ms. Bonstein, age 33, has a decade of financial leadership experience in the biopharmaceutical industry, including preclinical and clinical development, manufacturing, quality, regulatory and medical affairs, sales, and marketing.

On March 24, 2014, we entered into an employment agreement, or the Employment Agreement, with Ms. Bonstein, that provides for Ms. Bonstein's appointment as Chief Financial Officer, which took effect as of such date. The Employment Agreement provides for, among other terms, an initial term of one year and, a base salary of \$225,000 per year (plus annual cost-of-living adjustments). The Employment Agreement also includes provisions with respect to bonus and equity participation, which are consistent with the terms of our employment agreements with our other executive officers, as well as other customary covenants regarding non-solicitation, non-compete, confidentiality and works for hire.

In connection with Mr. Rosenblum's resignation, we entered into a separation agreement with Mr. Rosenblum effective as of March 24, 2014 that provides for certain severance benefits, including, one year's salary of \$275,000 and accelerated vesting of all unvested stock and options awards held by Mr. Rosenblum.

### **Iliad Research and Trading, L.P. Complaint**

On March 24, 2014, Iliad Research and Trading, L.P., or Iliad, filed a complaint, or Complaint, against us in the Third Judicial District Court of Salt Lake County, Utah. Although we have not been served with the Complaint, we understand that in the Complaint, Iliad alleges that we granted a participation right to Tonaquint, Inc., or Tonaquint, in a securities purchase agreement, or the Purchase Agreement, dated as of December 13, 2012, between Tonaquint and us, pursuant to which Tonaquint was entitled to participate in any transaction that we structured in accordance with Section 3(a)(9) or Section 3(a)(10) of the Securities Act of 1933, as amended. We also understand that Iliad further alleges that the settlement that we entered into with Ironridge Global IV, Ltd., or Ironridge, pursuant to which we issued certain shares of our common stock to Ironridge in reliance on the Section 3(a)(10) exemption, occurred without adequate notice for Tonaquint to exercise its participation right. In addition, we understand that Iliad alleges that it acquired all of Tonaquint's rights under the Purchase Agreement in April 2013, and that Iliad claims approximately \$4,502,490 in damages plus interest, attorneys' fees and costs. We intend to defend ourselves vigorously.

### **Corporate Information**

We were originally incorporated in the State of Colorado on June 5, 1987 under the name Great Expectations, Inc. We were a publicly-traded shell company without any business until November 12, 2004 when we acquired Advaxis, Inc., a Delaware corporation, through a Share Exchange and Reorganization Agreement, dated as of August 25, 2004, which we refer to as the Share Exchange, by and among Advaxis, the stockholders of Advaxis and us. As a result of the Share Exchange, Advaxis became our wholly-owned subsidiary and our sole operating company. On December 23, 2004, we amended and restated our articles of incorporation and changed our name to Advaxis, Inc. On June 6, 2006, our stockholders approved the reincorporation of our company from Colorado to Delaware by merging the Colorado entity into our wholly-owned Delaware subsidiary. Our date of inception, for financial statement purposes, is March 1, 2002.

Our principal executive offices are located at 305 College Road East, Princeton, New Jersey 08540 and our telephone number is (609) 452-9813. We maintain a website at [www.advaxis.com](http://www.advaxis.com) which contains descriptions of our technology, our drugs and the trial status of each drug. The information on our website is not incorporated into this prospectus



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## The Offering

Common stock offered by us

shares of common stock.

Over-allotment option

We have granted the underwriters a 30-day option to purchase up to additional shares of our common stock from us at the public offering price less underwriting discounts and commissions.

Common stock to be outstanding after this offering

shares or shares of common stock, if the underwriters exercise in full their option to purchase up to additional shares of common stock.

Use of Proceeds

We intend to use the net proceeds of this offering to fund our continued research and development initiatives in connection with expanding our product line and for other general corporate purposes. See Use of Proceeds on page S-31 for further information.

Risk Factors

See Risk Factors beginning on page S-13 of this prospectus supplement and other information included or incorporated by reference into this prospectus supplement and the accompanying prospectus for a discussion of factors you should carefully consider before investing in our securities.

NASDAQ Capital Market trading symbol

ADXS

Unless we indicate otherwise, all information in this prospectus supplement is based on 14,322,466 shares of common stock outstanding as of March 25, 2014 and:

assumes no exercise by the underwriters of their option to purchase up to an additional shares of common stock to cover over-allotments, if any;

excludes 473,923 shares of our common stock issuable upon exercise of outstanding stock options under our equity incentive plans at a weighted average exercise price of \$15.71 per share, with 15,514 shares remaining available for future grant under such plans;

excludes 4,513,502 shares of our common stock issuable upon exercise of outstanding warrants at a weighted average exercise price of \$6.60 per share;

excludes 3,354 shares of our common stock underlying the warrants to be issued to the underwriters in connection with this offering; and

excludes shares of our common stock underlying the warrants to be issued to the underwriters in connection with this offering.

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## **Risk Factors**

*Investing in our securities involves a high degree of risk. You should carefully consider and evaluate all of the information included and incorporated by reference or deemed to be incorporated by reference in this prospectus supplement and the accompanying prospectus, including the risk factors contained herein and those incorporated by reference herein from our Annual Report on Form 10-K for the fiscal year ended October 31, 2013, as updated by annual, quarterly and other reports and documents we file with the SEC after the date of this prospectus supplement. Our business, results of operations or financial condition could be adversely affected by any of these risks or by additional risks and uncertainties not currently known to us or that we currently consider immaterial.*

### **Risks Related to our Business and Industry**

#### **We are a development stage company.**

We are an early development stage biotechnology company with a history of losses and can provide no assurance as to future operating results. As a result of losses that will continue throughout our development stage, we may exhaust our financial resources and be unable to complete the development of our products. We anticipate that our ongoing operational costs will increase significantly as we continue conducting our clinical development program. Our deficit will continue to grow during our drug development period. Since our inception, we have had no revenue, and do not expect to have any revenue for another three to five years, depending on when we can commercialize our immunotherapies, if at all.

We have sustained losses from operations in each fiscal year since our inception, and we expect losses to continue for the indefinite future due to the substantial investment in research and development. As of January 31, 2014, we had an accumulated deficit of \$75,653,215 and shareholders' equity of \$14,859,802. We expect to spend substantial additional sums on the continued administration and research and development of proprietary products and technologies with no certainty that our immunotherapies will become commercially viable or profitable as a result of these expenditures. If we fail to raise a significant amount of capital, we may need to significantly curtail operations or cease operations in the near future. If any of our product candidates fails in clinical trials or does not gain regulatory approval, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

#### **Our limited operating history does not afford investors a sufficient history on which to base an investment decision.**

We commenced our *Lm*-LLO based immunotherapy development business in February 2002 and have existed as a development stage company since such time. Prior thereto we conducted no business. Accordingly, we have a limited operating history. We have no approved products or products pending approval and therefore have not derived any revenue from the sales of products and have not yet demonstrated ability to obtain regulatory approval, formulate and manufacture commercial scale products, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, there is limited information for investors to use as a basis for assessing our future viability. Investors must consider the risks and difficulties we have encountered in the rapidly evolving vaccine and immunotherapy industry. Such risks include the following:

difficulties, complications, delays and other unanticipated factors in connection with the development of new drugs;  
competition from companies that have substantially greater assets and financial resources than we have;

need for acceptance of our immunotherapies;  
ability to anticipate and adapt to a competitive market and rapid technological developments;  
need to rely on multiple levels of complex financing agreements with outside funding due to the length of drug development cycles and governmental approved protocols associated with the pharmaceutical industry; and  
dependence upon key personnel including key independent consultants and advisors.

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We cannot be certain that our strategy will be successful or that we will successfully address these risks. In the event that we do not successfully address these risks, our business, prospects, financial condition and results of operations could be materially and adversely affected. We may be required to reduce our staff, discontinue certain research or development programs of our future products and cease to operate.

### **We may face legal claims; Litigation is expensive and we may not be able to afford the costs.**

We may face legal claims involving stockholders, consumers, competitors, and other issues. Litigation and other legal proceedings are inherently uncertain, and adverse rulings could occur, including monetary damages, or an injunction stopping us from engaging in business practices, or requiring other remedies, such as compulsory licensing of patents.

The costs of litigation or any proceeding relating to our intellectual property or contractual rights could be substantial even if resolved in our favor. Some of our competitors or financial funding sources have far greater resources than we do and may be better able to afford the costs of complex litigation. Also, a law suit for infringement or contractual breaches, even if frivolous, will require considerable time commitments on the part of management, its attorneys and consultants. Defending these types of proceedings or legal actions involve considerable expense and could negatively affect our financial results.

On March 24, 2014, Iliad filed the Complaint against us in the Third Judicial District Court of Salt Lake County, Utah. Although we have not been served with the Complaint, we understand that in the Complaint, Iliad alleges that we granted a participation right to Tonaquint, Inc. in a securities purchase agreement dated as of December 13, 2012 between Tonaquint and us, pursuant to which Tonaquint was entitled to participate in any transaction that we structured in accordance with Section 3(a)(9) or Section 3(a)(10) of the Securities Act of 1933, as amended. We also understand that Iliad further alleges that the settlement that we entered into with Ironridge Global IV, Ltd. pursuant to which we issued certain shares of our common stock to Ironridge in reliance on the Section 3(a)(10) exemption, occurred without adequate notice for Tonaquint to exercise its participation right. In addition, we understand that Iliad alleges that it acquired all of Tonaquint's rights under the Purchase Agreement in April 2013, and that Iliad claims approximately \$4,502,490 in damages plus interest, attorneys' fees and costs. While we intend to defend ourselves against such claims, there can be no assurance that additional claims will not be made by Iliad or that we will be successful in our defense against any such claims. Even if we are successful against Iliad, we may incur significant legal fees and our management and attorneys may be required to spend considerable time in relation to our defense of the claims. Our defense and the outcome of the claims could negatively affect our financial results.

### **We can provide no assurance of the successful and timely development of new products.**

Our immunotherapies are at various stages of research and development. Further development and extensive testing will be required to determine their technical feasibility and commercial viability. We will need to complete significant additional clinical trials demonstrating that our product candidates are safe and effective to the satisfaction of the FDA and other non-U.S. regulatory authorities. The drug approval process is time-consuming, involves substantial expenditures of resources, and depends upon a number of factors, including the severity of the illness in question, the availability of alternative treatments, and the risks and benefits demonstrated in the clinical trials. Our success will depend on our ability to achieve scientific and technological advances and to translate such advances into licensable, FDA-approved, commercially competitive products on a timely basis. Failure can occur at any stage of the process. If such programs are not successful, we may invest substantial amounts of time and money without developing revenue-producing products. As we enter a more extensive clinical program for our product candidates, the data

generated in these studies may not be as compelling as the earlier results.

Immunotherapies and vaccines that we may develop are not likely to be commercially available until five to ten or more years. The proposed development schedules for our immunotherapies may be affected by a variety of factors, including technological difficulties, clinical trial failures, regulatory hurdles, competitive products, intellectual property challenges and/or changes in governmental regulation, many of which will not be within our control. Any delay in the development, introduction or marketing of our products could result either in such products being marketed at a time when their cost and performance characteristics would not be competitive in the marketplace or in the shortening of their commercial lives. In light of the long-term nature

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of our projects, the unproven technology involved and the other factors described elsewhere in this section, there can be no assurance that we will be able to successfully complete the development or marketing of any new products.

### **Drug discovery and development is a complex, time-consuming and expensive process that is fraught with risk and a high rate of failure.**

Product candidates are subject to extensive pre-clinical testing and clinical trials to demonstrate their safety and efficacy in humans. Conducting pre-clinical testing and clinical trials is a lengthy, time-consuming and expensive process that takes many years. We cannot be sure that pre-clinical testing or clinical trials of any of our product candidates will demonstrate the safety, efficacy and benefit-to-risk profile necessary to obtain marketing approvals. In addition, product candidates that experience success in pre-clinical testing and early-stage clinical trials will not necessarily experience the same success in late-stage clinical trials, which are required for marketing approval.

Even if we are successful in advancing a product candidate into the clinical development stage, before obtaining regulatory and marketing approvals, we must demonstrate through extensive human clinical trials that the product candidate is safe and effective for its intended use. Human clinical trials must be carried out under protocols that are acceptable to regulatory authorities and to the independent committees responsible for the ethical review of clinical studies. There may be delays in preparing protocols or receiving approval for them that may delay the start or completion of the clinical trials. In addition, clinical practices vary globally, and there is a lack of harmonization among the guidance provided by various regulatory bodies of different regions and countries with respect to the data that is required to receive marketing approval, which makes designing global trials increasingly complex. There are a number of additional factors that may cause our clinical trials to be delayed, prematurely terminated or deemed inadequate to support regulatory approval, such as:

- unforeseen safety issues (including those arising with respect to trials by third parties for compounds in a similar class as our product or product candidate), inadequate efficacy, or an unacceptable risk-benefit profile observed at any point during or after completion of the trials;
- slower than expected rates of patient enrollment, which could be due to any number of factors, including failure of our third-party vendors, including our CROs, to effectively perform their obligations to us, a lack of patients who meet the enrollment criteria or competition from clinical trials in similar product classes or patient populations;
- the risk of failure of our clinical investigational sites and related facilities to maintain compliance with the FDA's cGMP regulations or similar regulations in countries outside of the U.S., including the risk that these sites fail to pass inspections by the appropriate governmental authority, which could invalidate the data collected at that site or place the entire clinical trial at risk;
- any inability to reach agreement or lengthy discussions with the FDA, equivalent regulatory authorities, or ethical review committees on trial design that we are able to execute;
- changes in laws, regulations, regulatory policy or clinical practices, especially if they occur during ongoing clinical trials or shortly after completion of such trials.

Any deficiency in the design, implementation or oversight of our development programs could cause us to incur significant additional costs, experience significant delays, prevent us from obtaining marketing approval for any product candidate or abandon development of certain product candidates, any of which could harm our business and cause our stock price to decline.

### **Our research and development expenses are subject to uncertainty.**

Factors affecting our research and development expenses include, but are not limited to:

Drug discovery and development is a complex, time-consuming and expensive process that is fraught with risk and

competition from companies that have substantially greater assets and financial resources than we have;  
need for acceptance of our immunotherapies;

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ability to anticipate and adapt to a competitive market and rapid technological developments; amount and timing of operating costs and capital expenditures relating to expansion of our business, operations and infrastructure; need to rely on multiple levels of outside funding due to the length of drug development cycles and governmental approved protocols associated with the pharmaceutical industry; and dependence upon key personnel including key independent consultants and advisors.

There can be no guarantee that our research and development expenses will be consistent from period to period. We may be required to accelerate or delay incurring certain expenses depending on the results of our studies and the availability of adequate funding.

### **We are subject to numerous risks inherent in conducting clinical trials.**

We outsource the management of our clinical trials to third parties. Agreements with clinical investigators and medical institutions for clinical testing and with other third parties for data management services, place substantial responsibilities on these parties that, if unmet, could result in delays in, or termination of, our clinical trials. For example, if any of our clinical trial sites fail to comply with FDA-approved good clinical practices, we may be unable to use the data gathered at those sites. If these clinical investigators, medical institutions or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for, or successfully commercialize, agents such as ADXS-HPV. We are not certain that we will successfully recruit enough patients to complete our clinical trials nor that we will reach our primary endpoints. Delays in recruitment, lack of clinical benefit or unacceptable side effects would delay or prevent the initiation of the registrational program of ADXS-HPV.

We or our regulators may suspend or terminate our clinical trials for a number of reasons. We may voluntarily suspend or terminate our clinical trials if at any time we believe they present an unacceptable risk to the patients enrolled in our clinical trials or do not demonstrate clinical benefit. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the patients enrolled in our clinical trials.

Our clinical trial operations are subject to regulatory inspections at any time. If regulatory inspectors conclude that we or our clinical trial sites are not in compliance with applicable regulatory requirements for conducting clinical trials, we may receive reports of observations or warning letters detailing deficiencies, and we will be required to implement corrective actions. If regulatory agencies deem our responses to be inadequate, or are dissatisfied with the corrective actions we or our clinical trial sites have implemented, our clinical trials may be temporarily or permanently discontinued, we may be fined, we or our investigators may be precluded from conducting any ongoing or any future clinical trials, the government may refuse to approve our marketing applications or allow us to manufacture or market our products, and we may be criminally prosecuted.

The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval for ADXS-HPV or our other product candidates, which would materially harm our business, results of operations and prospects.

## **The successful development of immunotherapies is highly uncertain.**

Successful development of biopharmaceuticals is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Immunotherapies that appear promising in the early phases of development may fail to reach the market for several reasons including:

preclinical study results that may show the immunotherapy to be less effective than desired (e.g., the study failed to meet its primary objectives) or to have harmful or problematic side effects;

clinical study results that may show the immunotherapy to be less effective than expected (e.g., the study failed to meet its primary endpoint) or to have unacceptable side effects;

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failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis, or Biologics License Application preparation, discussions with the FDA, an FDA request for additional preclinical or clinical data, or unexpected safety or manufacturing issues; manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make the immunotherapy uneconomical; and the proprietary rights of others and their competing products and technologies that may prevent the immunotherapy from being commercialized.

Success in preclinical and early clinical studies does not ensure that large-scale clinical studies will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical studies and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one immunotherapy to the next, and may be difficult to predict.

Even if we are successful in getting market approval, commercial success of any of our product candidates will also depend in large part on the availability of coverage and adequate reimbursement from third-party payers, including government payers such as the Medicare and Medicaid programs and managed care organizations, which may be affected by existing and future health care reform measures designed to reduce the cost of health care. Third-party payers could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other health care payers were not to provide adequate coverage and reimbursement levels for one any of our products once approved, market acceptance and commercial success would be reduced.

In addition, if one of our products is approved for marketing, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply (or ensure that our third party providers) comply with cGMPs, and GCPs, for any clinical trials that we conduct post-approval. In addition, there is always the risk that we or a regulatory authority might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our product candidates post-market approval could have a material adverse effect on our business, financial condition and results of operations.

### **We must comply with significant government regulations.**

The research and development, manufacture and marketing of human therapeutic and diagnostic products are subject to regulation, primarily by the FDA in the United States and by comparable authorities in other countries. These national agencies and other federal, state, local and foreign entities regulate, among other things, research and development activities (including testing in animals and in humans) and the testing, manufacturing, handling, labeling, storage, record keeping, approval, advertising and promotion of the products that we are developing. If we obtain approval for any of our product candidates, our operations will be directly or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statue and the federal False Claims Act, and privacy laws. Noncompliance with applicable laws and requirements can result in various adverse consequences, including delay in approving or refusal to approve product licenses or other applications, suspension or termination of clinical investigations, revocation of approvals previously granted, fines, criminal prosecution, civil and criminal penalties, recall or seizure of products, exclusion from having our products reimbursed by federal health care programs, the curtailment or restructuring of our operations, injunctions against shipping products and total or partial suspension of production and/or refusal to allow a company to enter into

governmental supply contracts.

The process of obtaining requisite FDA approval has historically been costly and time-consuming. Current FDA requirements for a new human biological product to be marketed in the United States include: (1) the successful conclusion of preclinical laboratory and animal tests, if appropriate, to gain preliminary

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information on the product's safety; (2) filing with the FDA of an IND to conduct human clinical trials for drugs or biologics; (3) the successful completion of adequate and well-controlled human clinical trials to establish the safety and efficacy of the investigational new drug for its recommended use; and (4) filing by a company and acceptance and approval by the FDA of a Biologic License Application, or BLA, for a biological investigational new drug, to allow commercial distribution of a biologic product. The FDA also requires that any drug or formulation to be tested in humans be manufactured in accordance with its Good Manufacturing Practices, or GMP, regulations. This has been extended to include any drug that will be tested for safety in animals in support of human testing. The GMPs set certain minimum requirements for procedures, record-keeping and the physical characteristics of the laboratories used in the production of these drugs. A delay in one or more of the procedural steps outlined above could be harmful to us in terms of getting our immunotherapies through clinical testing and to market.

### **We can provide no assurance that our clinical product candidates will obtain regulatory approval or that the results of clinical studies will be favorable.**

We are currently evaluating the safety and efficacy of ADXS-HPV in a number of ongoing clinical trials. However, even though the initiation and conduct of these trials is in accordance with the governing regulatory authorities in each country, as with any investigational new drug (under an IND in the United States, or the equivalent in countries outside of the United States), we are at risk of a clinical hold at any time based on the evaluation of the data and information submitted to the governing regulatory authorities.

There can be delays in obtaining FDA (U.S.) and/or other necessary regulatory approvals in the United States and in countries outside the United States for any investigational new drug and failure to receive such approvals would have an adverse effect on the investigational new drug's potential commercial success and on our business, prospects, financial condition and results of operations. The time required to obtain approval by the FDA and non-U.S. regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. For example, the FDA or non-U.S. regulatory authorities may disagree with the design or implementation of our clinical trials or study endpoints; or we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks. In addition, the FDA or non-U.S. regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials or the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere. The FDA or non-U.S. regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and the approval policies or regulations of the FDA or non-U.S. regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

In addition to the foregoing, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not submitted for nor obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

### **We may not obtain or maintain the benefits associated with orphan drug designation, including market exclusivity.**

Although we have submitted a new request for orphan drug designation for ADXS-HPV for use in the treatment of invasive cervical cancer our original request was denied and there can be no assurance that our new request will be

We can provide no assurance that our clinical product candidates will obtain regulatory approval or that the results of

granted. Although, we have been granted orphan drug designation for ADXS-HPV for use in the treatment of HPV-associated anal cancer and for HPV-associated head and neck cancer in the United States, and intend to request a similar designation for these uses in the European Union, we may not be granted orphan drug designation, or even if granted, we may not receive the benefits associated with orphan drug designation. This may result from a failure to maintain orphan drug status, or result from a competing product reaching the market that has an orphan designation for the same disease indication. Under U.S. rules for orphan drugs, if such a competing product reaches the market before ours does, the competing product could potentially obtain a scope of market exclusivity that limits or precludes our product from being sold in

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the United States for seven years. Even if we obtain exclusivity, the FDA could subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. A competitor also may receive approval of different products for the same indication for which our orphan product has exclusivity, or obtain approval for the same product but for a different indication for which the orphan product has exclusivity.

In addition, if and when we request orphan drug designation in Europe, the European exclusivity period is ten years but can be reduced to six years if the drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMEA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

### **We may not obtain or maintain the benefits associated with breakthrough therapy designation.**

On October 7, 2013, we submitted a request for breakthrough therapy designation (BTD) to the IND for ADXS-HPV in the treatment of invasive cervical cancer in the United States. The FDA denied the request in December 2013, but stated that a new request may be submitted if we obtain new clinical evidence that supports BTD.

If we resubmit, we may not be granted breakthrough therapy designation, or even if granted, we may not receive the benefits associated with breakthrough therapy designation. This may result from a failure to maintain breakthrough therapy status if ADXS11-001 is no longer considered to be a breakthrough therapy. For example, a drug's development program may be granted breakthrough therapy designation using early clinical testing that shows a much higher response rate than available therapies. However, subsequent interim data derived from a larger study may show a response that is substantially smaller than the response seen in early clinical testing. Another example is where breakthrough therapy designation is granted to two drugs that are being developed for the same use. If one of the two drugs gains traditional approval, the other would not retain its designation unless its sponsor provided evidence that the drug may demonstrate substantial improvement over the recently approved drug. When breakthrough therapy designation is no longer supported by emerging data or the designated drug development program is no longer being pursued, the FDA may choose to send a letter notifying the sponsor that the program is no longer designated as a breakthrough therapy development program.

### **We rely upon patents to protect our technology. We may be unable to protect our intellectual property rights and we may be liable for infringing the intellectual property rights of others.**

Our ability to compete effectively will depend on our ability to maintain the proprietary nature of our technologies, including the *Lm*-LLO based immunotherapy platform technology, and the proprietary technology of others with whom we have entered into collaboration and licensing agreements.

We own or have an exclusive license from Penn to 43 patents that have been granted in the United States and foreign jurisdictions, and 52 patent applications that are pending in the United States and foreign jurisdictions. We have obtained the rights to all future patent applications in this field originating in the laboratories of Dr. Yvonne Paterson and Dr. Fred Frankel.

We own or hold licenses to a number of issued patents and U.S. pending patent applications, as well as foreign patents

and foreign counterparts. Our success depends in part on our ability to obtain patent protection both in the United States and in other countries for our product candidates, as well as the methods for treating patients in the product indications using these product candidates. Such patent protection is costly to obtain and maintain, and we cannot guarantee that sufficient funds will be available. Our ability to protect our product candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Even if our product candidates, as well as methods for treating patients for prescribed indications using these product candidates are covered by valid and enforceable patents and have claims with sufficient scope, disclosure and support in the specification, the patents will provide

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protection only for a limited amount of time. Accordingly, rights under any issued patents may not provide us with sufficient protection for our product candidates or provide sufficient protection to afford us a commercial advantage against competitive products or processes.

In addition, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents have issued or will issue, we cannot guarantee that the claims of these patents are or will be valid or enforceable or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. Furthermore, different countries have different procedures for obtaining patents, and patents issued in different countries offer different degrees of protection against use of the patented invention by others. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

The patent positions of biotechnology and pharmaceutical companies, including our patent position, involve complex legal and factual questions, and, therefore, validity and enforceability cannot be predicted with certainty. Patents may be challenged, deemed unenforceable, invalidated, or circumvented. Our patents can be challenged by our competitors who can argue that our patents are invalid, unenforceable, lack sufficient written description or enablement, or that the claims of the issued patents should be limited or narrowly construed. Patents also will not protect our product candidates if competitors devise ways of making or using these product candidates without infringing our patents.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our technologies, methods of treatment, product candidates, and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets and we have the funds to enforce our rights, if necessary.

The expiration of our owned or licensed patents before completing the research and development of our product candidates and receiving all required approvals in order to sell and distribute the products on a commercial scale can adversely affect our business and results of operations.

### **Litigation regarding patents, patent applications and other proprietary rights may be expensive and time consuming. If we are involved in such litigation, it could cause delays in bringing product candidates to market and harm our ability to operate.**

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents in the future and allege that the products or use of our technologies infringe these patent claims or that we are employing their proprietary technology without authorization.

In addition, third parties may challenge or infringe upon our existing or future patents. Proceedings involving our patents or patent applications or those of others could result in adverse decisions regarding:

the patentability of our inventions relating to our product candidates; and/or

the enforceability, validity or scope of protection offered by our patents relating to our product candidates.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid

Litigation regarding patents, patent applications and other proprietary rights may be expensive and time consuming

infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may:

incur substantial monetary damages;

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encounter significant delays in bringing our product candidates to market; and/or be precluded from participating in the manufacture, use or sale of our product candidates or methods of treatment requiring licenses.

**We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.**

We also rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

**We are dependent upon our license agreement with Penn; if we breach the license agreement and/or fail to make payments due and owing to Penn under our license agreement, our business will be materially and adversely affected.**

Pursuant to the terms of our Second and Third Amendment Agreements with Penn, as amended, we have acquired exclusive worldwide licenses for patents and patent applications related to our proprietary *Listeria* vaccine technology. The license provides us with the exclusive commercial rights to the patent portfolio developed at Penn as of the effective date of the license, in connection with Dr. Paterson and requires us to pay various milestone, legal, filing and licensing payments to commercialize the technology. As of January 31, 2014, we owed Penn approximately \$127,000 under all licensing agreements. As of January 31, 2014, Penn owned 28,468 shares of the Company's common stock. We can provide no assurance that we will be able to make all payments due and owing thereunder, that such licenses will not be terminated or expire during critical periods, that we will be able to obtain licenses from Penn for other rights that may be important to us, or, if obtained, that such licenses will be obtained on commercially reasonable terms. The loss of any current or future licenses from Penn or the exclusivity rights provided therein could materially harm our financial condition and operating results.

**If we are unable to obtain licenses needed for the development of our product candidates, or if we breach any of the agreements under which we license rights to patents or other intellectual property from third parties, we could lose license rights that are important to our business.**

If we are unable to maintain and/or obtain licenses needed for the development of our product candidates in the future, we may have to develop alternatives to avoid infringing on the patents of others, potentially causing increased costs and delays in drug development and introduction or precluding the development, manufacture, or sale of planned products. Some of our licenses provide for limited periods of exclusivity that require minimum license fees and payments and/or may be extended only with the consent of the licensor. We can provide no assurance that we will be able to meet these minimum license fees in the future or that these third parties will grant extensions on any or all such licenses. This same restriction may be contained in licenses obtained in the future.

Additionally, we can provide no assurance that the patents underlying any licenses will be valid and enforceable. To the extent any products developed by us are based on licensed technology, royalty payments on the licenses will reduce our gross profit from such product sales and may render the sales of such products uneconomical. In addition, the loss of any current or future licenses or the exclusivity rights provided therein could materially harm our business financial condition and our operations.

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**We have no manufacturing, sales, marketing or distribution capability and we must rely upon third parties for such.**

We do not intend to create facilities to manufacture our products and therefore are dependent upon third parties to do so. We currently have agreements with Recipharm Cobra Biologics Limited, Vibalogics GmbH and SynCo Bio Partners B.V. for production of our immunotherapies for research and development and testing purposes; and for the development of scale-up and commercial manufacturing processes. We depend on our manufacturers to meet our deadlines, quality standards and specifications. Our reliance on third parties for the manufacture of our drug substance, investigational new drugs and, in the future, any approved products, creates a dependency that could severely disrupt our research and development, our clinical testing, and ultimately our sales and marketing efforts if the source of such supply proves to be unreliable or unavailable. If the contracted manufacturing source is unreliable or unavailable, we may not be able to manufacture clinical drug supplies of our immunotherapies, and our preclinical and clinical testing programs may not be able to move forward and our entire business plan could fail. If we are able to commercialize our products in the future, there is no assurance that our manufacturers will be able to meet commercialized scale production requirements in a timely manner or in accordance with applicable standards or current GMP.

**If we are unable to establish or manage strategic collaborations in the future, our revenue and drug development may be limited.**

Our strategy includes eventual substantial reliance upon strategic collaborations for marketing and commercialization of ADXS-HPV, and we may rely even more on strategic collaborations for research, development, marketing and commercialization of our other immunotherapies. To date, we have not entered into any strategic collaborations with third parties capable of providing these services although we have been heavily reliant upon third party outsourcing for our clinical trials execution and production of drug supplies for use in clinical trials. In addition, we have not yet licensed, marketed or sold any of our immunotherapies or entered into successful collaborations for these services in order to ultimately commercialize our immunotherapies. Establishing strategic collaborations is difficult and time-consuming. Our discussions with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. For example, potential collaborators may reject collaborations based upon their assessment of our financial, clinical, regulatory or intellectual property position. If we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of our immunotherapies or the generation of sales revenue. To the extent that we enter into co-promotion or other collaborative arrangements, our product revenues are likely to be lower than if we directly marketed and sold any products that we may develop.

Management of our relationships with our collaborators will require:

significant time and effort from our management team;  
coordination of our research and development programs with the research and development priorities of our collaborators; and

effective allocation of our resources to multiple projects.

If we continue to enter into research and development collaborations at the early phases of drug development, our success will in part depend on the performance of our corporate collaborators. We will not directly control the amount or timing of resources devoted by our corporate collaborators to activities related to our immunotherapies. Our corporate collaborators may not commit sufficient resources to our research and development programs or the commercialization, marketing or distribution of our immunotherapies. If any corporate collaborator fails to commit sufficient resources, our preclinical or clinical development programs related to this collaboration could be delayed or terminated. Also, our collaborators may pursue existing or other development-stage products or alternative

We have no manufacturing, sales, marketing or distribution capability and we must rely upon third parties ~~for~~ such.

technologies in preference to those being developed in collaboration with us. Finally, if we fail to make required milestone or royalty payments to our collaborators or to observe other obligations in our agreements with them, our collaborators may have the right to terminate those agreements.

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**We may incur substantial liabilities from any product liability claims if our insurance coverage for those claims is inadequate.**

We face an inherent risk of product liability exposure related to the testing of our immunotherapies in human clinical trials, and will face an even greater risk if the approved products are sold commercially. An individual may bring a liability claim against us if one of the immunotherapies causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our immunotherapies;
- damage to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues;
- the inability to commercialize immunotherapies; and
- increased difficulty in raising required additional funds in the private and public capital markets.

We have insurance coverage on our clinical trials for each clinical trial site. We do not have product liability insurance because we do not have products on the market. We currently are in the process of obtaining insurance coverage and to expand such coverage to include the sale of commercial products if marketing approval is obtained for any of our immunotherapies. However, insurance coverage is increasingly expensive and we may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

**We may incur significant costs complying with environmental laws and regulations.**

We and our contracted third parties use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. As appropriate, we store these materials and wastes resulting from their use at our or our outsourced laboratory facility pending their ultimate use or disposal. We contract with a third party to properly dispose of these materials and wastes. We are subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with such laws and regulations may be costly.

**If we use biological materials in a manner that causes injury, we may be liable for damages.**

Our research and development activities involve the use of biological and hazardous materials. Although we believe our safety procedures for handling and disposing of these materials complies with federal, state and local laws and regulations, we cannot entirely eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of these materials. We do not carry specific biological waste insurance coverage, workers compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended or terminated.

We may incur substantial liabilities from any product liability claims if our insurance coverage for those claims is inadequate.

**We need to attract and retain highly skilled personnel; we may be unable to effectively manage growth with our limited resources.**

As of March 25, 2014, we had 18 employees, all of which were full time employees. Our ability to attract and retain highly skilled personnel is critical to our operations and expansion. We face competition for these types of personnel from other technology companies and more established organizations, many of which have significantly larger operations and greater financial, technical, human and other resources than we have. We may not be successful in attracting and retaining qualified personnel on a timely basis, on competitive terms, or at all. If we are not successful in attracting and retaining these personnel, or integrating them into

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our operations, our business, prospects, financial condition and results of operations will be materially adversely affected. In such circumstances we may be unable to conduct certain research and development programs, unable to adequately manage our clinical trials and other products, and unable to adequately address our management needs.

### **We depend upon our senior management and key consultants and their loss or unavailability could put us at a competitive disadvantage.**

We depend upon the efforts and abilities of our senior executives, as well as the services of several key consultants, including Yvonne Paterson, Ph.D. The loss or unavailability of the services of any of these individuals for any significant period of time could have a material adverse effect on our business, prospects, financial condition and results of operations. We have not obtained, do not own, nor are we the beneficiary of, key-person life insurance.

### **The biotechnology and immunotherapy industries are characterized by rapid technological developments and a high degree of competition. We may be unable to compete with more substantial enterprises.**

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, our actual or proposed immunotherapies could become obsolete before we recoup any portion of our related research and development and commercialization expenses. Competition in the biopharmaceutical industry is based significantly on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain governmental approval for testing, manufacturing and marketing. We compete with specialized biopharmaceutical firms in the United States, Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many biopharmaceutical companies have focused their development efforts in the human therapeutics area, including cancer. Many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies. These companies, as well as academic institutions and governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants. Our ability to compete successfully with other companies in the pharmaceutical field will also depend to a considerable degree on the continuing availability of capital to us.

We are aware of certain investigational new drugs under development or approved products by competitors that are used for the prevention, diagnosis, or treatment of certain diseases we have targeted for drug development. Various companies are developing biopharmaceutical products that have the potential to directly compete with our immunotherapies even though their approach to may be different. The biotechnology and biopharmaceutical industries are highly competitive, and this competition comes from both biotechnology firms and from major pharmaceutical companies, including companies like: Aduro Biotech, Agenus Inc., Bionovo Inc., Bristol-Myers Squibb, Celgene Corporation, Celldex Therapeutics, Cerus Corporation, Dendreon Corporation, Inovio Pharmaceutical Inc., Oncolytics Biotech Inc., Oncothyreon Inc., each of which is pursuing cancer vaccines and/or immunotherapies. Many of these companies have substantially greater financial, marketing, and human resources than we do (including, in some cases, substantially greater experience in clinical testing, manufacturing, and marketing of pharmaceutical products). We also experience competition in the development of our immunotherapies from universities and other research institutions and compete with others in acquiring technology from such universities and institutions.

In addition, certain of our immunotherapies may be subject to competition from investigational new drugs and/or products developed using other technologies, some of which have completed numerous clinical trials.

We depend upon our senior management and key consultants and their loss or unavailability could put us at a competitive disadvantage.

We believe that our immunotherapies under development and in clinical trials will address unmet medical needs in the treatment of cancer. Our competition will be determined in part by the potential indications for which drugs are developed and ultimately approved by regulatory authorities. Additionally, the timing of market introduction of some of our potential products or of competitors' products may be an important competitive factor. Accordingly, the relative speed with which we can develop immunotherapies, complete preclinical testing, clinical trials and approval processes and supply commercial quantities to market is expected to be important competitive factors. We expect that competition among products approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price and patent position.

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## **Risks Related to our Securities and this Offering**

### **The price of our common stock may be volatile.**

The trading price of our common stock may fluctuate substantially. The price of our common stock that will prevail in the market may be higher or lower than the price you have paid, depending on many factors, some of which are beyond our control and may not be related to our operating performance. These fluctuations could cause you to lose part or all of your investment in our common stock. Those factors that could cause fluctuations include, but are not limited to, the following:

- price and volume fluctuations in the overall stock market from time to time;
- fluctuations in stock market prices and trading volumes of similar companies;
- actual or anticipated changes in our net loss or fluctuations in our operating results or in the expectations of securities analysts;
- the issuance of new equity securities pursuant to a future offering, including issuances of preferred stock;
- general economic conditions and trends;
- positive and negative events relating to healthcare and the overall pharmaceutical and biotech sector;
- major catastrophic events;
- sales of large blocks of our stock;
- significant dilution caused by the anti-dilutive clauses in our financial agreements;
- departures of key personnel;
- changes in the regulatory status of our immunotherapies, including results of our clinical trials;
- events affecting Penn or any future collaborators;
- announcements of new products or technologies, commercial relationships or other events by us or our competitors;
- regulatory developments in the United States and other countries;
- failure of our common stock to be listed or quoted on the NASDAQ Capital Market or other national market system;
- changes in accounting principles; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Due to the potential volatility of our stock price, we may therefore be the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

**If our stockholders do not approve an amendment to our Amended and Restated Certificate of Incorporation to increase the number of authorized shares of our common stock, and an amendment to our 2011 Omnibus Incentive Plan to increase the number of shares issuable thereunder, our ability to raise additional capital, competitively pursue future partnering and other business opportunities and provide adequate incentives to our employees could be materially adversely effected.**

To maximize the benefit of this current financing for us, we expect to deplete almost all remaining authorized shares of our common stock available for issuance under our Amended and Restated Certificate of Incorporation. To maximize the number of authorized shares available for issuance in this offering, we opted to un-reserve certain shares of our common stock that had been previously reserved for conditional restricted stock and restricted stock unit grants

to our senior executive officers and directors under our 2011 Omnibus Incentive Plan. Furthermore, we have depleted significantly all of the shares of our common stock reserved for issuance under our 2011 Omnibus Incentive Plan. As a result, we are currently unable to offer equity incentives under our 2011 Omnibus Incentive Plan to new or existing employees. The unavailability of authorized shares of common stock places us in a competitive disadvantage since our ability to (i) raise

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additional capital through the sale of our common stock or securities exercisable or convertible into shares of our common stock, (ii) utilize our common stock for potential future partnering opportunities and other legitimate corporate business purposes, and (iii) attract and retain key personnel, is compromised. Our board of directors has approved both an amendment to our Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock and an amendment to our 2011 Omnibus Incentive Plan to increase the number of shares of common stock issuable thereunder. We submitted such amendments to our stockholders for approval at our 2014 Annual Meeting of Stockholders. If stockholder approval is not received for these amendments, we believe it will compromise our ability to competitively pursue future business and financial endeavors with common stock or securities exercisable or convertible into or exchangeable for shares of our common stock as consideration and to provide incentives to our employees, which could have an adverse effect on our business, financial position and results of operations.

### **A DTC Chill on the electronic clearing of trades in our securities in the future may affect the liquidity of our stock and our ability to raise capital.**

Because our common stock may, from time to time, be considered a penny stock, there is a risk that the Depository Trust Company (DTC) may place a chill on the electronic clearing of trades in our securities. This may lead some brokerage firms to be unwilling to accept certificates and/or electronic deposits of our stock and other securities and also some may not accept trades in our securities altogether. In the past, DTC has placed a deposit chill on our shares, and although the chill is currently removed, no assurance can be given that a chill will not be reinstated in the future. A future DTC chill would affect the liquidity of our securities and make it difficult to purchase or sell our securities in the open market. It may also have an adverse effect on our ability to raise capital because investors may be unable to easily resell our securities into the market. Our inability to raise capital on terms acceptable to us, if at all, could have a material and adverse effect on our business and operations.

### **You may have difficulty selling our shares because they may be deemed penny stocks.**

Our common stock may be deemed to be penny stock as that term is defined in Rule 3a51-1, promulgated under the Exchange Act. Penny stocks are, generally, stocks:

with a price of less than \$5.00 per share;

that are neither traded on a recognized national exchange nor listed on an automated quotation system sponsored by a registered national securities association meeting certain minimum initial listing standards; and of issuers with net tangible assets less than \$2.0 million (if the issuer has been in continuous operation for at least three years) or \$5.0 million (if in continuous operation for less than three years), or with average revenue of less than \$6.0 million for the last three years.

Section 15(g) of the Exchange Act and Rule 15g-2 promulgated thereunder require broker-dealers dealing in penny stocks to provide potential investors with a document disclosing the risks of penny stocks and to obtain a manually signed and dated written receipt of the document before effecting any transaction in a penny stock for the investor's account. We urge potential investors to obtain and read this disclosure carefully before purchasing any shares that are deemed to be penny stock.

Rule 15g-9 promulgated under the Exchange Act requires broker-dealers in penny stocks to approve the account of any investor for transactions in such stocks before selling any penny stock to that investor. This procedure requires the broker-dealer to:

A DTC Chill on the electronic clearing of trades in our securities in the future may affect the liquidity of our stock

obtain from the investor information about his or her financial situation, investment experience and investment objectives;  
reasonably determine, based on that information, that transactions in penny stocks are suitable for the investor and that the investor has enough knowledge and experience to be able to evaluate the risks of penny stock transactions;  
provide the investor with a written statement setting forth the basis on which the broker-dealer made his or her determination; and

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receive a signed and dated copy of the statement from the investor, confirming that it accurately reflects the investor's financial situation, investment experience and investment objectives.

Compliance with these requirements may make it harder for investors in our common stock to resell their shares to third parties. Accordingly, our common stock should only be purchased by investors, who understand that such investment is a long-term and illiquid investment, and are capable of and prepared to bear the risk of holding our common stock for an indefinite period of time.

Our stock closed at \$4.07 per share on March 26, 2014, and no assurance can be given that the per share price of our common stock will maintain such levels such that our stock will not be subject to these rules in the future.

### **A limited public trading market may cause volatility in the price of our common stock and warrants.**

The listing of our common stock on the NASDAQ Capital Market does not assure that a meaningful, consistent and liquid trading market currently exists, and in recent years such market has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies like us. Our common stock is thus subject to this volatility. Sales of substantial amounts of common stock, or the perception that such sales might occur, could adversely affect prevailing market prices of our common stock and our stock price may decline substantially in a short time and our shareholders could suffer losses or be unable to liquidate their holdings. Also there are large blocks of restricted stock that have met the holding requirements under Rule 144 that may be sold without restriction. Our stock is thinly traded due to the limited number of shares available for trading on the market thus causing large swings in price.

### **The market prices for our common stock may be adversely impacted by future events.**

Our common stock began trading on the over-the-counter-markets on July 28, 2005 and is currently listed on the NASDAQ Capital Market under the symbol ADXS. Market prices for our common stock will be influenced by a number of factors, including:

- the issuance of new equity securities pursuant to a future offering, including issuances of preferred stock;
- changes in interest rates;
- significant dilution caused by the anti-dilutive clauses in our financial agreements;
- competitive developments, including announcements by competitors of new products or services or significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- variations in quarterly operating results;
- change in financial estimates by securities analysts;
- the depth and liquidity of the market for our common stock;
- investor perceptions of our company and the pharmaceutical and biotech industries generally; and
- general economic and other national conditions.

**If we fail to remain current with our listing requirements, we could be removed from the NASDAQ Capital Market, which would limit the ability of broker-dealers to sell our securities and the ability of shareholders to sell their securities in the secondary market.**

We must be a reporting issuer under Section 12 of the Securities Exchange Act of 1934, as amended, and must meet the listing requirements in order to maintain the listing of our common stock on the NASDAQ Capital Market. If we do not meet these requirements, the market liquidity for our securities could be severely adversely affected by limiting the ability of broker-dealers to sell our securities and the ability of shareholders to sell their securities in the secondary market.

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**Our internal control over financial reporting and our disclosure controls and procedures have been ineffective in the past, and may be ineffective again in the future, and failure to improve them at such time could lead to errors in our financial statements that could require a restatement or untimely filings, which could cause investors to lose confidence in our reported financial information, and a decline in our stock price.**

Our internal control over financial reporting and our disclosure controls and procedures have been ineffective in the past. We have taken steps to improve our disclosure controls and procedures and our internal control over financial reporting, and as of October 31, 2013, our chief executive officer and chief financial officer concluded that internal control over financial reporting was effective, and as of January 31, 2014, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective. On February 26, 2014, we entered into an engagement letter to initiate SOX assessment services, including the development of control design documents and control test plans. However, there is no assurance that our disclosure controls and procedures will remain effective or that there will be no material weaknesses in our internal control over financial reporting in the future. Additionally, as a result of the historical material weaknesses in our internal control over financial reporting and the historical ineffectiveness of our disclosure controls and procedures, current and potential stockholders could lose confidence in our financial reporting, which would harm our business and the trading price of our stock.

**Sales of additional equity securities may adversely affect the market price of our common stock and your rights may be reduced.**

We expect to continue to incur drug development and selling, general and administrative costs, and to satisfy our funding requirements, we will need to sell additional equity securities, which may be subject to registration rights and warrants with anti-dilutive protective provisions. The sale or the proposed sale of substantial amounts of our common stock or other equity securities in the public markets may adversely affect the market price of our common stock and our stock price may decline substantially. Our shareholders may experience substantial dilution and a reduction in the price that they are able to obtain upon sale of their shares. Also, new equity securities issued may have greater rights, preferences or privileges than our existing common stock.

**Additional authorized shares of common stock available for issuance may adversely affect the market price of our securities.**

We are currently authorized to issue 25,000,000 shares of our common stock. As of March 25, 2014, we had 14,322,466 shares of our common stock issued and outstanding, excluding shares issuable upon exercise of our outstanding warrants, options, convertible promissory notes, and shares of common stock earned but not yet issued under our 2011 Omnibus Incentive Plan. Under our 2011 Employee Stock Purchase Plan, or ESPP, our employees can buy our common stock at a discounted price. To the extent the shares of common stock are issued, options and warrants are exercised or convertible promissory notes are converted, holders of our common stock will experience dilution. In addition, in the event of any future financing of equity securities or securities convertible into or exchangeable for, common stock, holders of our common stock may experience dilution. As of March 25, 2014, warrants to purchase 204,207 shares of our common stock were exercisable at approximately \$9.16 per share and were subject to weighted-average anti-dilution protection upon certain equity issuances below \$9.16 per share (as may be further adjusted as defined in the warrant). In addition, as of March 25, 2014, we had outstanding options to purchase 473,923 shares of our common stock at a weighted average exercise price of approximately \$15.71 per share and

Our internal control over financial reporting and our disclosure controls and procedures have been ineffective in the

outstanding warrants to purchase 4,513,502 shares of our common stock (including the above warrants subject to weighted-average anti-dilution protection); and approximately 30,230 shares of our common stock were available for grant under the ESPP. Although we entered into agreements providing for the repayment or conversion of certain of our outstanding indebtedness, not all the holders of our outstanding convertible promissory notes have agreed to exchange their securities at this time.

**The accounting treatment for certain of our warrants is complex and subject to judgments concerning the valuation of embedded derivative rights within the applicable securities. Fluctuations in the valuation of these rights could cause us to take charges to our earnings and make our financial results unpredictable.**

Certain of our outstanding warrants contain, or may be deemed to contain from time to time, embedded derivative rights in accordance with U.S. generally accepted accounting principles, or GAAP. These derivative

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rights, or similar rights in securities we may issue in the future, need to be, or may need to be, separately valued as of the end of each accounting period in accordance with GAAP. We record these embedded derivatives as liabilities at issuance, valued using the Black-Scholes Model and are subject to revaluation at each reporting date. Any change in fair value between reporting periods is reported on our statement of operations. At January 31, 2014 and October 31, 2013, the fair value of the embedded derivative liability was \$0 as the related securities were paid off, converted or reached maturity. For the three months ended January 31, 2014 and January 31, 2013, we reported income of \$0, due to changes in fair value of the embedded derivative liability. Changes in the valuations of these rights, the valuation methodology or the assumptions on which the valuations are based could cause us to take charges to our earnings, which would adversely impact our results of operations. Moreover, the methodologies, assumptions and related interpretations of accounting or regulatory authorities associated with these embedded derivatives are complex and in some cases uncertain, which could cause our accounting for these derivatives, and as a result, our financial results, to fluctuate. There is a risk that questions could arise from investors or regulatory authorities concerning the appropriate accounting treatment of these instruments, which could require us to restate previous financial statements, which in turn could adversely affect our reputation, as well as our results of operations.

### **We do not intend to pay cash dividends.**

We have not declared or paid any cash dividends on our common stock, and we do not anticipate declaring or paying cash dividends for the foreseeable future. Any future determination as to the payment of cash dividends on our common stock will be at our board of directors' discretion and will depend on our financial condition, operating results, capital requirements and other factors that our board of directors considers to be relevant.

### **Our certificate of incorporation, Bylaws and Delaware law have anti-takeover provisions that could discourage, delay or prevent a change in control, which may cause our stock price to decline.**

Our certificate of incorporation, Bylaws and Delaware law contain provisions which could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our shareholders. We are authorized to issue up to 5,000,000 shares of preferred stock. This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our Board of Directors without further action by shareholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third party and thereby preserve control by the present management.

Provisions of our certificate of incorporation, Bylaws and Delaware law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a shareholder might consider favorable. Such provisions may also prevent or frustrate attempts by our shareholders to replace or remove our management. In particular, the certificate of incorporation, Bylaws and Delaware law, as applicable, among other things, provide the Board of Directors with the ability to alter the Bylaws without shareholder approval, and provide that vacancies on the Board of Directors may be filled by a majority of directors in office, although less than a quorum.

We are also subject to Section 203 of the Delaware General Corporation Law, which, subject to certain exceptions, prohibits business combinations between a publicly-held Delaware corporation and an interested shareholder, which is

The accounting treatment for certain of our warrants is complex and subject to judgments concerning the valuation of

generally defined as a shareholder who becomes a beneficial owner of 15% or more of a Delaware corporation's voting stock for a three-year period following the date that such shareholder became an interested shareholder.

These provisions are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of our company to first negotiate with its board. These provisions may delay or prevent someone from acquiring or merging with us, which may cause the market price of our common stock to decline.

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**Our management will have broad discretion over the use of the net proceeds from this offering and we may use the net proceeds in ways with which you disagree or which do not produce beneficial results.**

We currently intend to use the net proceeds from this offering to fund our continued research and development initiatives in connection with expanding our product line and for other general corporate purposes (see "Use of Proceeds"). Other than as specified under "Use of Proceeds," we have not allocated specific amounts of the net proceeds from this offering for any of the foregoing purposes. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds of this offering. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for us or our stockholders. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, and results of operation.

**You will experience immediate and substantial dilution as a result of this offering and may experience additional dilution in the future as we do further financings and transactions.**

You will incur immediate and substantial dilution as a result of this offering. After giving effect to the sale by us of shares of common stock offered in this offering at a public offering price of \$ per share, and after deducting the underwriters' discount and commissions and estimated offering expenses payable by us (but excluding exercise of the representative's warrant and the exercise of the underwriter's over-allotment option), investors in this offering can expect an immediate dilution of \$ per share. In addition, in the past, we issued options and warrants to acquire shares of common stock and issued notes convertible into shares of our common stock. To the extent these options or warrants are ultimately exercised or notes converted, you will sustain further future dilution.

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## **USE OF PROCEEDS**

We estimate that our net proceeds from the sale of the common stock offered pursuant to this prospectus supplement and the accompanying prospectus, will be approximately \$    million, or approximately \$    million if the underwriters exercise in full their option to purchase    additional shares, based upon the public offering price of \$    per share and after deducting the underwriting discount and commissions, and the estimated offering expenses that are payable by us.

We currently intend to use the net proceeds from this offering to fund our continued research and development initiatives in connection with expanding our product line and for other general corporate purposes.

We have not yet determined the amount of net proceeds to be used specifically for any of the foregoing purposes. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds from this offering. Pending any use, as described above, we intend to invest the net proceeds in high-quality, short-term, interest-bearing securities.

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## **DIVIDEND POLICY**

We have not declared or paid any cash dividends on our common stock, and we do not anticipate declaring or paying cash dividends for the foreseeable future. We are not subject to any legal restrictions respecting the payment of dividends, except that we may not pay dividends if the payment would render us insolvent. Any future determination as to the payment of cash dividends on our common stock will be at our board of directors' discretion and will depend on our financial condition, operating results, capital requirements and other factors that our board of directors considers to be relevant.

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The following table sets forth our capitalization, as of

on an actual basis as of January 31, 2014;

on a pro forma basis to give effect to (i) the issuance of 306,122 shares of our common stock to an accredited investor at \$4.90 per share resulting in gross proceeds of \$1.5 million, (ii) payoff of the Moore Notes<sup>(1)</sup> in the amount of approximately \$168,280, and (iii) the receipt of \$1.0 million in licensing revenue under a licensing agreement.

on a pro forma as adjusted basis to give effect to the events described above and the issuance and sale of the securities in this offering at the public offering price of \$ per share, assuming no exercise of the underwriters over-allotment option.

You should consider this table in conjunction with our financial statements and the notes to those financial statements in our Quarterly Report on Form 10-Q for the quarter ended January 31, 2014 incorporated by reference into this prospectus supplement. See [Where You Can Find More Information](#).

	As of January 31, 2014		Pro Forma As Adjusted
	Actual	Pro Forma	
Short-term and long-term notes payable <sup>(2)</sup>	\$ 127,808	\$ 62,883	
Shareholders' Equity (deficiency):			
Common Stock \$0.001 par value; authorized 25,000,000 shares, issued and outstanding 14,009,475 at January 31, 2014, 14,315,597 shares pro forma and shares pro forma, as adjusted, respectively	14,009	14,315	
Additional paid-in capital	90,499,008	91,998,702	
Deficit accumulated during the development stage	(75,653,215)	(74,656,414)	
Total shareholders' deficiency	14,859,802	17,356,603	
Total Capitalization	\$ 14,987,610	\$ 17,419,486	

## Notes:

On September 26, 2013, we entered into a debt conversion and repayment agreement with Thomas A. Moore, our director and former Chief Executive Officer, with respect to the repayment and partial conversion of amounts owed (1) to Mr. Moore under outstanding promissory notes issued pursuant to that certain Note Purchase Agreement dated September 22, 2008, as amended from time to time. We paid Mr. Moore \$168,280 on February 4, 2014, fully satisfying its obligations under the Moore Notes, which no longer remain outstanding.

(2) The amount represents the sum of the funded short- and long-term debt (including interest) from the following captions of our balance sheet: short-term convertible notes, note payable-former officer.

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If you invest in our securities, your interest will be immediately and substantially diluted to the extent of the difference between the public offering price per share of our common stock and as adjusted net tangible book value per share of our common stock after giving effect to this offering.

Our net tangible book value per share as of January 31, 2014 was \$12,360,758 or \$0.88 per share of common stock. Our pro forma net tangible book value per share as of January 31, 2014 was \$14,857,558, or \$1.04, per share of common stock after giving effect to: (i) the issuance of 306,122 shares of our common stock to an accredited investor at \$4.90 per share, resulting in gross proceeds of \$1.5 million, (ii) payoff of the Moore Notes in the amount of approximately \$168,280, and (iii) the receipt of \$1.0 million in revenue under a licensing agreement.

Our pro forma as adjusted net tangible book value per share as of January 31, 2014 was \$ , or \$ per share of common stock after giving effect to the sale of the shares in this offering at the public offering price of \$ per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. This represents an immediate increase in pro forma net tangible book value of approximately \$ per share to our existing stockholders, and an immediate dilution of \$ per share to investors purchasing securities in the offering.

The following table illustrates the per share dilution to investors purchasing shares in the offering:

Public offering price per share	\$
Pro Forma Net tangible book value per share as of January 31, 2014	\$ 1.04
Increase in net tangible book value per share attributable to this offering	\$
Pro forma as adjusted net tangible book value per share after this offering	\$
Amount of dilution in net tangible book value per share to new investors in this offering	\$

The information above assumes that the underwriters do not exercise their over-allotment option. If the underwriters exercise their over-allotment option in full, the pro forma as adjusted net tangible book value will increase to \$ per share, representing an immediate increase to existing stockholders of \$ per share and an immediate dilution of \$ per share to new investors. If any shares are issued upon exercise of outstanding options or warrants, new investors will experience further dilution.

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Aegis Capital Corp. is acting as the representative of the underwriters of the offering. We have entered into an underwriting agreement dated March , 2014 with the representative. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to each underwriter named below and each underwriter named below has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Underwriter	Number of Shares
Aegis Capital Corp.	
Total	

The underwriters are committed to purchase all the shares of common stock offered by us other than those covered by the option to purchase additional shares described below, if they purchase any shares. The obligations of the underwriters may be terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, pursuant to the underwriting agreement, the underwriters' obligations are subject to customary conditions, representations and warranties contained in the underwriting agreement, such as receipt by the underwriters of officers' certificates and legal opinions.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act of 1933, as amended, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters propose to offer the shares offered by us to the public at the public offering price set forth on the cover of this prospectus. In addition, the underwriters may offer some of the shares to other securities dealers at such price less a concession of \$ per share. If all of the shares offered by us are not sold at the public offering price, the underwriters may change the offering price and other selling terms by means of a further supplement to this prospectus supplement.

*Discounts and Commissions.* The following table shows the public offering price, underwriting discount and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option:

	Total		
	Per	Without	With
	Share	Over-Allotment	Over-Allotment
Public offering price	\$	\$	\$
Underwriting discount ( %)	\$	\$	\$
Non-accountable expense allowance ( %)	\$	\$	\$
Proceeds, before expense, to us	\$	\$	\$

We have agreed to pay the underwriters' expenses relating to the offering, including (a) all fees, expenses and disbursements relating to background checks of our officers and directors in an amount not to exceed \$5,000 in the aggregate; (b) all fees, expenses and disbursements relating to the registration, qualification or exemption of securities offered under the securities laws of foreign jurisdictions designated by the underwriters; (c) upon successfully completing this offering, \$21,775 for the underwriters' use of Ipreo's book-building, prospectus tracking and



compliance software for this offering; and (d) upon successfully completing this offering, up to \$10,000 of the representative's actual accountable road show expenses for the offering.

We estimate that the total expenses of the offering payable by us, excluding the total underwriting discount, will be approximately \$ .

*Overallotment Option.* We have granted the underwriters an over-allotment option. This option, which is exercisable for up to 30 days after the date of this prospectus supplement, permits the underwriters to purchase a maximum of additional shares (15% of the shares sold in this offering) from us to cover over-allotments, if any. If the underwriters exercise all or part of this option, they will purchase shares covered

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by the option at the public offering price that appears on the cover page of this prospectus, less the underwriting discount. If this option is exercised in full, the total price to the public will be \$      and the total net proceeds, before expenses, to us will be \$      .

*Discretionary Accounts.* The underwriters do not intend to confirm sales of the securities offered hereby to any accounts over which they have discretionary authority.

*Lock-Up Agreements.* We, our directors and executive officers expect to enter into lock up agreements with the representative prior to the commencement of this offering pursuant to which each of these persons or entities, for a period of three months from the date of this prospectus supplement without the prior written consent of the representative, agree not to (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our securities or any securities convertible into or exercisable or exchangeable for shares of our common stock owned or acquired on or prior to the closing date of this offering (including any shares of common stock acquired after the closing date of this offering upon the conversion, exercise or exchange of such securities); (2) file or caused to be filed any registration statement relating to the offering of any shares of our capital stock; or (3) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock, whether any such transaction described in clause (1), (2) or (3) above is to be settled by delivery of common stock or such other securities, in cash or otherwise, except for certain exceptions and limitations.

The lock-up period described in the preceding paragraphs will be automatically extended if: (1) during the last 17 days of the restricted period, we issue an earnings release or announce material news or a material event; or (2) prior to the expiration of the lock-up period, we announce that we will release earnings results during the 16-day period beginning on the last day of the lock-up period, in which case the restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the date of the earnings release.

*Representative's Warrants.* We have agreed to issue to the representative warrants to purchase up to a total of shares of common stock (3% of the shares of common stock sold in this offering, excluding the over-allotment). The warrants will be exercisable at any time, and from time to time, in whole or in part, during the four-year period commencing one year from the date of this prospectus supplement, which period shall not extend further than five years from March 4, 2014, the effective date of our registration statement, in compliance with FINRA Rule 5110(f)(2)(H)(i). The warrants are exercisable at a per share price equal to 125% of the public offering price per share in the offering. The warrants have been deemed compensation by FINRA and are therefore subject to a 180 day lock-up pursuant to Rule 5110(g)(1) of FINRA. Accordingly, the representative (or permitted assignees under Rule 5110(g)(1)) will not sell, transfer, assign, pledge, or hypothecate these warrants or the securities underlying these warrants, for a period of 180 days from the date of this prospectus supplement. In addition, the warrants provide for piggyback registration rights, in certain cases. The piggyback registration right provided will not be greater than seven years from the date of this prospectus supplement in compliance with FINRA Rule 5110(f)(2)(H)(v). We will bear all fees and expenses attendant to registering the securities issuable on exercise of the warrants other than underwriting commissions incurred and payable by the holders. The exercise price and number of shares issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend, extraordinary cash dividend or our recapitalization, reorganization, merger or consolidation.

*Right of First Refusal.* Until fourteen months from the date of this prospectus supplement, the representative, or any subsidiary or successor, shall have a right of first refusal to act as sole book runner for any public or private equity and public debt offerings greater than \$5 million during such period.

*Electronic Offer, Sale and Distribution of Securities.* A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The representative may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same

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basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of, nor incorporated by reference into, this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

*Stabilization.* In connection with this offering, the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate-covering transactions, penalty bids and purchases to cover positions created by short sales.

Stabilizing transactions permit bids to purchase securities so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the securities while the offering is in progress.

Over-allotment transactions involve sales by the underwriters of securities in excess of the number of securities the underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of securities over-allotted by the underwriters is not greater than the number of securities that they may purchase in the over-allotment option. In a naked short position, the number of securities involved is greater than the number of securities in the over-allotment option. The underwriters may close out any short position by exercising their over-allotment option and/or purchasing securities in the open market.

Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of securities to close out the short position, the underwriters will consider, among other things, the price of securities available for purchase in the open market as compared with the price at which they may purchase securities through exercise of the over-allotment option. If the underwriters sell more securities than could be covered by exercise of the over-allotment option and, therefore, have a naked short position, the position can be closed out only by buying securities in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the securities in the open market that could adversely affect investors who purchase in the offering.

Penalty bids permit the representative to reclaim a selling concession from a syndicate member when the securities originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our securities or preventing or retarding a decline in the market price of our securities. As a result, the price of our securities in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our securities. These transactions may be effected on The NASDAQ Capital Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

*Passive market making.* In connection with this offering, underwriters and selling group members may engage in passive market making transactions in our common stock on The NASDAQ Capital Market in accordance with Rule 103 of Regulation M under the Exchange Act, during a period before the commencement of offers or sales of the shares and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, then that bid must then be lowered when specified purchase limits are exceeded.

*Potential Conflicts of Interest.* The underwriters and their affiliates have provided, or may in the future provide, various investment banking, commercial banking, financial advisory, brokerage and other services to us and our affiliates for which services they have received, and may in the future receive, customary fees and expense

reimbursement. Aegis Capital Corp. served as the placement agent in connection with our bridge financing of 5% convertible debentures, which was consummated on June 21, 2013. We received gross

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proceeds of \$250,000 in the bridge financing and paid to Aegis a commission of \$20,000. Aegis Capital Corp. acted as the representatives of the underwriters in connection with our public offering of common stock, which was consummated on October 16, 2013. We received gross proceeds of \$26,453,306 in such public offering and paid to Aegis Capital Corp. a commission of \$1,851,500.

The underwriters and their affiliates may, from time to time, engage in transactions with and perform services for us in the ordinary course of their business for which they may receive customary fees and reimbursement of expenses. In the ordinary course of their various business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own accounts and for the accounts of their customers and such investment and securities activities may involve securities and/or instruments of our company. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

The principal business address of Aegis Capital Corp. is 810 Seventh Avenue, 18<sup>th</sup> Floor, New York, New York 10019.

## **Offer Restrictions Outside the United States**

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

### **Australia**

This prospectus is not a disclosure document under Chapter 6D of the Australian Corporations Act, has not been lodged with the Australian Securities and Investments Commission and does not purport to include the information required of a disclosure document under Chapter 6D of the Australian Corporations Act. Accordingly, (i) the offer of the securities under this prospectus is only made to persons to whom it is lawful to offer the securities without disclosure under Chapter 6D of the Australian Corporations Act under one or more exemptions set out in section 708 of the Australian Corporations Act, (ii) this prospectus is made available in Australia only to those persons as set forth in clause (i) above, and (iii) the offeree must be sent a notice stating in substance that by accepting this offer, the offeree represents that the offeree is such a person as set forth in clause (i) above, and, unless permitted under the Australian Corporations Act, agrees not to sell or offer for sale within Australia any of the securities sold to the offeree within 12 months after its transfer for the offeree under this prospectus.

### **China**

The information in this document does not constitute a public offer of the securities, whether by way of sale or subscription, in the People's Republic of China (excluding, for purposes of this paragraph, Hong Kong Special

Administrative Region, Macau Special Administrative Region and Taiwan). The securities may not be offered or sold directly or indirectly in the PRC to legal or natural persons other than directly to qualified domestic institutional investors.

## **European Economic Area Belgium, Germany, Luxembourg and Netherlands**

The information in this document has been prepared on the basis that all offers of common stock will be made pursuant to an exemption under the Directive 2003/71/EC ( Prospectus Directive ), as implemented in Member States of the European Economic Area (each, a Relevant Member State ), from the requirement to produce a prospectus for offers of securities.

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An offer to the public of common stock has not been made, and may not be made, in a Relevant Member State except pursuant to one of the following exemptions under the Prospectus Directive as implemented in that Relevant Member State:

- (a) to legal entities that are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- (b) to any legal entity that has two or more of (i) an average of at least 250 employees during its last fiscal year; (ii) a total balance sheet of more than €43,000,000 (as shown on its last annual unconsolidated or consolidated financial statements) and (iii) an annual net turnover of more than €50,000,000 (as shown on its last annual unconsolidated or consolidated financial statement);
- (c) to fewer than 100 natural or legal persons (other than qualified investors within the meaning of Article 2(1)I of the Prospectus Directive) subject to obtaining the prior consent of the company or any underwriter for any such offer; or
- (d) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of common stock shall result in a requirement for the publication by the company of a prospectus pursuant to Article 3 of the Prospectus Directive.

### **France**

This document is not being distributed in the context of a public offering of financial securities (*offre au public de titres financiers*) in France within the meaning of Article L.411-1 of the French Monetary and Financial Code (*Code monétaire et financier*) and Articles 211-1 et seq. of the General Regulation of the French *Autorité des marchés financiers* (AMF). The common stock has not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France.

This document and any other offering material relating to the common stock have not been, and will not be, submitted to the AMF for approval in France and, accordingly, may not be distributed or caused to be distributed, directly or indirectly, to the public in France.

Such offers, sales and distributions have been and shall only be made in France to (i) qualified investors (*investisseurs qualifiés*) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-1 to D.411-3, D.744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation and/or (ii) a restricted number of non-qualified investors (*cercle restreint d'investisseurs non-qualifiés*) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-4, D.744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation.

Pursuant to Article 211-3 of the General Regulation of the AMF, investors in France are informed that the common stock cannot be distributed (directly or indirectly) to the public by the investors otherwise than in accordance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 to L.621-8-3 of the French Monetary and Financial Code.

### **Ireland**

The information in this document does not constitute a prospectus under any Irish laws or regulations and this document has not been filed with or approved by any Irish regulatory authority as the information has not been prepared in the context of a public offering of securities in Ireland within the meaning of the Irish Prospectus (Directive 2003/71/EC) Regulations 2005 (the Prospectus Regulations). The common stock has not been offered or sold, and will not be offered, sold or delivered directly or indirectly in Ireland by way of a public offering, except to (i) qualified investors as defined in Regulation 2(1) of the Prospectus Regulations and (ii) fewer than 100 natural or



legal persons who are not qualified investors.

## **Israel**

The common stock offered by this prospectus has not been approved or disapproved by the Israeli Securities Authority (the ISA), or ISA, nor have such common stock been registered for sale in Israel. The shares may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus. The ISA has not issued permits, approvals or licenses in connection with the offering or publishing

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the prospectus; nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the common stock being offered. Any resale in Israel, directly or indirectly, to the public of the common stock offered by this prospectus is subject to restrictions on transferability and must be effected only in compliance with the Israeli securities laws and regulations.

### **Italy**

The offering of the common stock in the Republic of Italy has not been authorized by the Italian Securities and Exchange Commission (*Commissione Nazionale per le Società e la Borsa*, *CONSOB*) pursuant to the Italian securities legislation and, accordingly, no offering material relating to the common stock may be distributed in Italy and such securities may not be offered or sold in Italy in a public offer within the meaning of Article 1.1(t) of Legislative Decree No. 58 of 24 February 1998 ( *Decreto No. 58* ), other than:

to Italian qualified investors, as defined in Article 100 of Decree no. 58 by reference to Article 34-ter of CONSOB Regulation no. 11971 of 14 May 1999 ( *Regulation no. 11971* ) as amended ( *Qualified Investors* ); and in other circumstances that are exempt from the rules on public offer pursuant to Article 100 of Decree No. 58 and Article 34-ter of Regulation No. 11971 as amended.

Any offer, sale or delivery of the common stock or distribution of any offer document relating to the common stock in Italy (excluding placements where a Qualified Investor solicits an offer from the issuer) under the paragraphs above must be:

made by investment firms, banks or financial intermediaries permitted to conduct such activities in Italy in accordance with Legislative Decree No. 385 of 1 September 1993 (as amended), Decree No. 58, CONSOB Regulation No. 16190 of 29 October 2007 and any other applicable laws; and

in compliance with all relevant Italian securities, tax and exchange controls and any other applicable laws. Any subsequent distribution of the common stock in Italy must be made in compliance with the public offer and prospectus requirement rules provided under Decree No. 58 and the Regulation No. 11971 as amended, unless an exception from those rules applies. Failure to comply with such rules may result in the sale of such common stock being declared null and void and in the liability of the entity transferring the common stock for any damages suffered by the investors.

### **Japan**

The common stock has not been and will not be registered under Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948), as amended (the *FIEL*) pursuant to an exemption from the registration requirements applicable to a private placement of securities to Qualified Institutional Investors (as defined in and in accordance with Article 2, paragraph 3 of the *FIEL* and the regulations promulgated thereunder).

Accordingly, the common stock may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan other than Qualified Institutional Investors. Any Qualified Institutional Investor who acquires common stock may not resell them to any person in Japan that is not a Qualified Institutional Investor, and acquisition by any such person of common stock is conditional upon the execution of an agreement to that effect.

### **Portugal**

This document is not being distributed in the context of a public offer of financial securities (*oferta pública de valores mobiliários*) in Portugal, within the meaning of Article 109 of the Portuguese Securities Code (*Código dos Valores Mobiliários*). The common stock have not been offered or sold and will not be offered or sold, directly or indirectly, to

the public in Portugal. This document and any other offering material relating to the common stock have not been, and will not be, submitted to the Portuguese Securities Market Commission (*Comissão do Mercado de Valores Mobiliários*) for approval in Portugal and, accordingly, may not be distributed or caused to be distributed, directly or indirectly, to the public in Portugal, other than under circumstances that are deemed not to qualify as a public offer under the Portuguese Securities Code. Such

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offers, sales and distributions of common stock in Portugal are limited to persons who are qualified investors (as defined in the Portuguese Securities Code). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

### **Sweden**

This document has not been, and will not be, registered with or approved by *Finansinspektionen* (the Swedish Financial Supervisory Authority). Accordingly, this document may not be made available, nor may the common stock be offered for sale in Sweden, other than under circumstances that are deemed not to require a prospectus under the Swedish Financial Instruments Trading Act (1991:980) (*Sw. lag (1991:980) om handel med finansiella instrument*). Any offering of common stock in Sweden is limited to persons who are qualified investors (as defined in the Financial Instruments Trading Act). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

### **Switzerland**

The common stock may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ( SIX ) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering material relating to the common stock may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering material relating to the common stock has been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of common stock will not be supervised by, the Swiss Financial Market Supervisory Authority (FINMA).

This document is personal to the recipient only and not for general circulation in Switzerland.

### **United Arab Emirates**

Neither this document nor the common stock has been approved, disapproved or passed on in any way by the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates, nor have we received authorization or licensing from the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates to market or sell the common stock within the United Arab Emirates. This document does not constitute and may not be used for the purpose of an offer or invitation. No services relating to the common stock, including the receipt of applications and/or the allotment or redemption of such shares, may be rendered within the United Arab Emirates by us.

No offer or invitation to subscribe for common stock is valid or permitted in the Dubai International Financial Centre.

### **United Kingdom**

Neither the information in this document nor any other document relating to the offer has been delivered for approval to the Financial Services Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended ( FSMA )) has been published or is intended to be published in

respect of the common stock. This document is issued on a confidential basis to qualified investors (within the meaning of section 86(7) of FSMA) in the United Kingdom, and the common stock may not be offered or sold in the United Kingdom by means of this document, any accompanying letter or any other document, except in circumstances which do not require the publication of a prospectus pursuant to section 86(1) FSMA. This document should not be distributed, published or reproduced, in whole or in part, nor may its contents be disclosed by recipients to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) received in connection with the issue or sale of the common stock has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of FSMA does not apply to us.

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In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 ( FPO ), (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated (together relevant persons ). The investments to which this document relates are available only to, and any invitation, offer or agreement to purchase will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

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## **LEGAL MATTERS**

The validity of the securities being offered by this prospectus has been passed upon for us by Reed Smith LLP, New York, New York. Certain legal matters in connection with this offering will be passed upon for the underwriters by Blank Rome LLP, New York, New York.

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## **EXPERTS**

The financial statements of Advaxis, Inc. as of October 31, 2013 and 2012, and for the years then ended appearing in its Annual Report filed on Form 10-K for the year ended October 31, 2013, have been audited by Marcum LLP, an independent registered public accounting firm, as set forth in its report thereon, included therein, and incorporated herein by reference. Such financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing. The financial statements for the cumulative period from March 1, 2002 (inception) to October 31, 2011 incorporated in this Prospectus Supplement by reference to the Annual Report on Form 10-K for the year ended October 31, 2013, have been audited by McGladrey LLP, an independent registered public accounting firm, as stated in their report incorporated by reference herein, and have been so incorporated in reliance upon such report and upon the authority of such firm as experts in accounting and auditing.

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## **WHERE YOU CAN FIND MORE INFORMATION**

We are a reporting company and file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy our reports, proxy statements and other information, at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the Public Reference Room. The SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, where our SEC filings are also available. The address of the SEC's web site is <http://www.sec.gov>.

We also maintain a web site at [www.advaxis.com](http://www.advaxis.com), through which you can access our SEC filings. The information set forth on our web site is not part of this prospectus supplement.

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## **INCORPORATION OF DOCUMENTS BY REFERENCE**

We incorporate by reference the filed documents listed below, except as superseded, supplemented or modified by this prospectus, and any future filings we will make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act:

Our Annual Report on Form 10-K for the fiscal year ended October 31, 2013, as filed with the SEC on January 29, 2014, as amended by Form 10-K/A filed with the SEC on February 6, 2014;

Our Quarterly Report on Form 10-Q for the fiscal quarter ended January 31, 2014, as filed with the SEC on March 17, 2014;

Our Current Reports on Form 8-K filed with the SEC on December 13, 2013\*, December 19, 2013, January 22, 2014\*, February 11, 2014, March 24, 2014 (re: Items 1.01 and 3.02), and March 24, 2014 (re: Item 5.02)\*

(\*excluding items 2.02 and 7.01 and exhibits to such items);

Our definitive Proxy Statement on Schedule 14A filed with the SEC on February 28, 2014; and a description of our common stock, par value \$0.001 per share, contained in our Registration Statement on Form 8-A, filed with the Commission on October 15, 2013 and under the caption "Description of Securities" in the Registrant's prospectus, dated as of October 11, 2013, forming a part of the Registration Statement on Form S-1 (Registration No. 333-188637) filed with the Commission, including any amendments or reports filed for the purpose of updating such description.

In addition, all documents that we file pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus supplement and prior to the termination of this offering shall be deemed to be incorporated by reference into this prospectus supplement and to be a part hereof from the date of filing of such documents.

We will provide to each person, including any beneficial owner, to whom a copy of this prospectus is delivered, a copy of any or all of the information that we have incorporated by reference into this prospectus. We will provide this information upon written or oral request at no cost to the requester. You may request this information by contacting our corporate headquarters at the following address: Advaxis, Inc., 305 College Road East, Princeton, New Jersey 08540, Attn: Lisa Caperelli, Senior Director, Investor Relations and Corporate Communications, or by calling 609-452-9813, Ext. 120.

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## PROSPECTUS

**\$50,000,000**

### Common Stock

We may offer and sell an indeterminate number of shares of our common stock from time to time under this prospectus. You should read this prospectus and any prospectus supplement carefully before you invest.

This prospectus provides a general description of the securities we may offer. Each time we sell securities, we will provide specific terms of the securities offered in a supplement to this prospectus. The prospectus supplement may also add, update or change information contained in this prospectus. You should carefully read this prospectus and the applicable prospectus supplement carefully before you invest in any securities. This prospectus may not be used to consummate a sale of securities unless accompanied by the applicable prospectus supplement.

Our common stock is traded on the NASDAQ Capital Market, under the symbol ADXS. On February 13, 2014, the last reported sale price for our common stock on the NASDAQ Capital Market was \$5.29 per share.

As of February 13, 2014, the aggregate market value of the voting and non-voting common equity held by non-affiliates, computed by reference to the price at which the common equity was last sold or the average bid and asked price of such common equity on that date, was approximately \$70,386,676, based on 13,903,885 shares of outstanding common stock, of which 13,305,610 were held by non-affiliates. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell securities in a public primary offering with a value exceeding more than one-third of our public float in any 12-month period so long as our public float remains below \$75.0 million. We have not offered any securities pursuant to General Instruction I.B.6 of Form S-3 during the 12 calendar months prior to and including the date of this prospectus.

**INVESTING IN OUR SECURITIES INVOLVES RISKS. YOU SHOULD REVIEW CAREFULLY THE RISKS AND UNCERTAINTIES DESCRIBED UNDER THE HEADING RISK FACTORS ON PAGE 5 AND CONTAINED IN THE APPLICABLE PROSPECTUS SUPPLEMENT AND UNDER SIMILAR HEADINGS IN THE OTHER DOCUMENTS THAT ARE INCORPORATED BY REFERENCE INTO THIS PROSPECTUS.**

We may offer our common stock in one or more offerings in amounts, at prices, and on terms determined at the time of the offering. We may sell our common stock through agents we select or through underwriters and dealers we select. If we use agents, underwriters or dealers, we will name them and describe their compensation in a prospectus supplement.

**NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF**

**THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.**

The date of this prospectus is March 4, 2014.

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## **ABOUT THIS PROSPECTUS**

This prospectus is a part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, utilizing a shelf registration process. Under this shelf process, we may sell the securities described in this prospectus in one or more offerings. This prospectus provides you with a general description of the securities we may offer. Each time we sell securities under this shelf registration, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus or in any documents that we have incorporated by reference into this prospectus. You should read this prospectus and any applicable prospectus supplement, together with the information incorporated herein by reference as described under the heading **Where You Can Find More Information**.

You should rely only on the information that we have provided or incorporated by reference in this prospectus and any applicable prospectus supplement. We have not authorized any dealer, salesman or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus or any applicable prospectus supplement. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus or the accompanying prospectus supplement. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you.

This prospectus and the accompanying supplement to this prospectus do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor do this prospectus and the accompanying supplement to this prospectus constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus or any applicable prospectus supplement is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus or any applicable prospectus supplement is delivered or securities sold on a later date.

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## SUMMARY

### Prospectus Summary

This summary highlights selected information from this prospectus and does not contain all of the information that you need to consider in making your investment decision. You should carefully read the entire prospectus, including the risks of investing discussed under **Risk Factors** on page 5, the information incorporated by reference, including our financial statements, and the exhibits to the registration statement of which this prospectus is a part. Unless otherwise stated or the context requires otherwise, references in this prospectus to Advaxis, we, us, or our refer to Advaxis, I

## Our Company

### Business Overview

We are a clinical development stage biotechnology company focused on the discovery, development and commercialization of our proprietary Lm-LLO immunotherapy product candidates to treat cancers and infectious diseases. These immunotherapies are based on a platform technology that utilizes live attenuated *Listeria monocytogenes*, which we refer to as *Listeria* or Lm, that have been bioengineered to secrete antigen/adjuvant fusion proteins. We believe that these Lm-LLO strains are a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy because they access and direct antigen presenting cells, or APC, to stimulate anti-tumor T-cell immunity, stimulate and activate the immune system with the equivalent of multiple adjuvants, and simultaneously reduce tumor protection in the tumor microenvironment to enable the T-cells to eliminate tumors. Other immunotherapies may employ individual elements of our comprehensive approach, but, to our knowledge, none combine all of these elements together in a single, easily administered, well-tolerated yet comprehensive immunotherapy.

The effectiveness of our approach has been validated by numerous publications in multiple models of human disease.

In the clinic, ADXS-HPV, our lead Lm-LLO immunotherapy for the treatment of HPV-associated cancers, is well-tolerated and has been administered to both young patients with pre-malignant dysplasia, as well as patients with advanced disease. Clinical efficacy has been demonstrated by apparent prolonged survival, complete and partial tumor responses, and the prolonged stabilization of advanced cancer. The preliminary data from our completed Phase 2 clinical trial of ADXS-HPV in patients with recurrent cervical cancer demonstrate that ADXS-HPV is an active agent in this disease setting with a manageable safety profile. We achieved proof of concept with this Phase 2 study, and over the next two to five years, we plan to advance ADXS-HPV through registrational Phase 3 trials and regulatory approval(s) in the United States and relevant markets for the treatment of women with cervical cancer. We are currently evaluating this same Lm-LLO immunotherapy in Phase 1/2 clinical trials for two other HPV-associated cancers: head and neck cancer and anal cancer. In addition, we plan to advance ADXS-PSA, our second Lm-LLO immunotherapy, into a Phase 1 dose escalation trial to determine the maximum tolerated dose for the treatment of prostate cancer in the first half of 2014. A third Lm-LLO immunotherapy, ADXS-CHER2, is being evaluated for safety and efficacy in the treatment of companion dogs with HER2 over-expressing osteosarcoma. We plan to advance ADXS-CHER2 into a Phase 1 dose escalation trial to determine the maximum tolerated dose for the treatment of breast cancer.

We have a robust and extensive patent portfolio relating to our core Lm-LLO immunotherapy technology. Our current patent portfolio includes 42 issued patents and 38 pending patent applications. To develop our technology, we may enter into commercial partnerships, joint ventures, or other arrangements with competitive or complementary companies, including pharmaceutical or biotechnology companies or universities during the preclinical or clinical stages. Our current collaborations include the preclinical development of Lm-LLO immunotherapies for a number of indications. We currently have over 15 distinct immunotherapies in various stages of development, developed directly by us and through strategic collaborations with recognized centers of excellence. These include but are not limited to the following Advaxis immunotherapy and corresponding tumor antigen: ADXS11-001/HPV16-E7, ADXS31-142/Prostate Specific Antigen, ADXS31-164/HER2/neu Chimera, Lm-LLO-HMW-MAA/HMW-MAA, C-terminus fragment, Lm-LLO-ISG15/ISG15, Lm-LLO CD105/Endoglin, Lm-LLO-flk/VEGF and Bivalent Therapy, HER-2-Chimera/HMW-MAA-C. We will continue to conduct preclinical research to develop additional Lm-LLO

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constructs to expand our platform technology and may develop additional distinct immunotherapies in the future. We are exploring potential development and commercialization collaborations for certain product candidates in our development pipeline.

We have sustained losses from operations in each fiscal year since our inception, and we expect these losses to continue for the indefinite future, due to the substantial investment in research and development. As of October 31, 2013, we had an accumulated deficit of \$70,465,823, and stockholders' equity of \$18,002,142.

## **Our *Lm*-LLO Immunotherapy Platform Technology**

Our *Lm*-LLO immunotherapies are based on a platform technology under exclusive license from the Trustees of the University of Pennsylvania, or Penn, that utilizes live attenuated *Lm* bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm* strains use a fragment of the protein listeriolysin, or LLO, fused to a tumor associated antigen, or TAA, or other antigen of interest and we refer to these as *Lm*-LLO immunotherapies. Regardless of which antigen(s) is fused to LLO, the proposed mechanism of action is basically the same. We believe these *Lm*-LLO immunotherapies redirect the potent immune response to *Lm* that is inherent in humans, to the TAA or other antigen of interest.

*Lm*-LLO immunotherapies stimulate the immune system to induce antigen-specific anti-tumor immune responses involving both innate and adaptive arms of the immune system. In addition, our technology facilitates the immune response by altering the tumor microenvironment to reduce immunologic tolerance in the tumors but leaves normal tissues unchanged. This makes the tumor more susceptible to immune attack by inhibiting the T-cells, or Tregs, and myeloid-derived suppressor cells, or MDSC, that we believe promote immunologic tolerance of cancer cells in the tumor.

The field of immunotherapy is a relatively new area of cancer treatment development that holds tremendous promise to generate more effective and better tolerated treatments for cancer than the more traditional, high dose chemotherapy and radiation therapies that have been the mainstay of cancer treatment thus far. There are many approaches toward immunotherapy that have been recently approved or are in development. We believe *Lm*-LLO immunotherapies will offer a more comprehensive immunotherapy in a single, well-tolerated, easy to administer treatment than other alternative immunotherapy treatments.

## **Our Preclinical and Clinical Development Pipeline**

Our most advanced product candidates in clinical development are ADXS-HPV, ADXS-PSA and ADXS-CHER2:

**ADXS-HPV.** ADXS-HPV is an *Lm*-LLO immunotherapy directed against HPV. ADXS-HPV is designed to target cells expressing the HPV gene E7. Expression of the E7 gene from high-risk HPV strains is responsible for the transformation of infected cells into dysplastic and malignant tissues and in the laboratory, was more effective than ADXS vectors targeting HPV E6. Eliminating these cells can eliminate the dysplasia or malignancy. ADXS-HPV is designed to direct antigen-presenting cells to generate powerful innate and cellular immune responses to HPV transformed cells resulting in the infiltration of cytotoxic T cells and attack on tumors. At the same time, we believe ADXS-HPV treatment may cause a reduction in the number and function of immunosuppressive regulatory Tregs and MDSC in the tumors that are protecting tumors from immune attack. ADXS-HPV is being evaluated in four ongoing clinical trials for HPV-associated diseases: locally advanced cervical cancer (with the GOG, largely underwritten by the NCI, U.S.); head and neck cancer (underwritten by the CRUK, U.K.); head and neck cancer (ISMMS, U.S.) and anal cancer (BrUOG, U.S.). Our next goal is to conduct Phase 1/2 trials to optimize the dose and schedule of

ADXS-HPV, which we believe may further increase efficacy with respect to both clinical response and survival. Additional studies will investigate how best to combine ADXS-HPV with existing cytotoxic treatments. We plan to advance ADXS-HPV through registrational Phase 3 trials and regulatory approval in the United States and relevant markets for the treatment of cervical cancer. We also plan to evaluate ADXS-HPV in Phase 1/2 clinical trials for the treatment of patients with HPV-positive head and neck cancer and HPV-positive anal cancer. Future plans for the ADXS-HPV franchise are contingent upon a number of variables including available resources, types and number of studies, study initiation, patient enrollment, clinical and safety data generated, regulatory interactions and changing competitive landscape.

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**ADXS-PSA.** ADXS-PSA is an *Lm*-LLO immunotherapy directed against PSA. ADXS-PSA is designed to target cells expressing PSA. ADXS-PSA secretes the PSA antigen, fused to LLO, directly inside the APC, that are cable of driving a cellular immune response to PSA expressing cells. In preclinical analysis, the localized effect is the inhibition of the Treg and MDSC cells that we believe may promote immunologic tolerance of the PSA cancer cells of the tumor. We have conducted a pre-Investigational New Drug application, or IND, meeting with the FDA to discuss the chemistry, manufacturing and controls, pharmacology, toxicity and clinical plans for ADXS-PSA. We will finalize the toxicology and good manufacturing practice, or GMP, documentation required for the IND we plan to submit to the FDA and advance ADXS-PSA into a Phase 1 dose escalation trial to determine the maximum tolerated dose for the treatment of prostate cancer. Future plans for the ADXS-PSA clinical program are contingent upon a number of variables including available resources, types and number of studies, study initiation, patient enrollment, clinical and safety data generated, regulatory interactions and changing competitive landscape.

**ADXS-cHER2.** ADXS-cHER2 is an *Lm*-LLO immunotherapy for HER2 overexpressing cancers (such as breast, gastric and other cancers in humans and for osteosarcoma in canines). ADXS-cHER2 secretes the cHER2 antigen, fused to LLO, directly inside APC that are capable of driving a cellular immune response to cHER2 overexpressing cells. In preclinical analysis, localized effect is the inhibition of the Treg and MDSC cells that we believe may promote immunologic tolerance of the HER2 overexpressing cancer cells of the tumor. We currently are conducting a Phase 1 study in companion dogs evaluating the safety and efficacy of ADXS-cHER2 in the treatment of canine osteosarcoma. Preliminary data has shown encouraging survival in 9 dogs treated with ADXS-cHER2, as compared to 11 untreated dogs, appearing to validate the activity of the platform. We plan to meet with the U.S. Department of Agriculture, to discuss the requirements to proceed forward with our first immunotherapy in the veterinary market. Future plans for the ADXS-cHER2 program are contingent upon a number of variables including available resources, types and number of studies, study initiation, patient enrollment, clinical and safety data generated, regulatory interactions and changing competitive landscape.

## **Corporate Information**

We were originally incorporated in the State of Colorado on June 5, 1987 under the name Great Expectations, Inc. We were a publicly-traded shell company without any business until November 12, 2004 when we acquired Advaxis, Inc., a Delaware corporation, through a Share Exchange and Reorganization Agreement, dated as of August 25, 2004, which we refer to as the Share Exchange, by and among Advaxis, the stockholders of Advaxis and us. As a result of the Share Exchange, Advaxis became our wholly-owned subsidiary and our sole operating company. On December 23, 2004, we amended and restated our articles of incorporation and changed our name to Advaxis, Inc. On June 6, 2006, our stockholders approved the reincorporation of our company from Colorado to Delaware by merging the Colorado entity into our wholly-owned Delaware subsidiary. Our date of inception, for financial statement purposes, is March 1, 2002.

Our principal executive offices are located at 305 College Road East, Princeton, New Jersey 08540 and our telephone number is (609) 452-9813. We maintain a website at [www.advaxis.com](http://www.advaxis.com) which contains descriptions of our technology, our drugs and the trial status of each drug. The information on our website is not incorporated into this prospectus.

## **The Securities We May Offer**

We may offer shares of our common stock, from time to time under this prospectus, together with any applicable prospectus supplement, at prices and on terms to be determined by market conditions at the time of offering. This prospectus provides you with a general description of the securities we may offer. Holders of our common stock are

entitled to one vote for each share held of record on each matter submitted to a vote of stockholders. Each time we offer our common stock, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities. A prospectus supplement to be provided to you may also add, update or change information contained in this prospectus or in documents

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we have incorporated by reference. However, no prospectus supplement will offer a security that is not registered and described in this prospectus at the time of the effectiveness of the registration statement of which this prospectus is a part.

We may sell the securities directly to or through underwriters, dealers or agents. We, and our underwriters or agents, reserve the right to accept or reject all or part of any proposed purchase of securities. If we do offer securities through underwriters or agents, we will include in the applicable prospectus supplement:

the names of those underwriters or agents;  
applicable fees, discounts and commissions to be paid to them;  
details regarding over-allotment options, if any; and  
the net proceeds to us.

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## **RISK FACTORS**

Investing in our securities involves a high degree of risk. You should carefully consider and evaluate all of the information included and incorporated by reference or deemed to be incorporated by reference in this prospectus or the applicable prospectus supplement, including the risk factors contained herein and those incorporated by reference herein from our Annual Report on Form 10-K for the fiscal year ended October 31, 2013, as updated by annual, quarterly and other reports and documents we file with the SEC after the date of this prospectus and that are incorporated by reference herein or contained in the applicable prospectus supplement. Our business, results of operations or financial condition could be adversely affected by any of these risks or by additional risks and uncertainties not currently known to us or that we currently consider immaterial.

### **Risks Related to our Business and Industry**

#### **We are a development stage company.**

We are an early development stage biotechnology company with a history of losses and can provide no assurance as to future operating results. As a result of losses that will continue throughout our development stage, we may exhaust our financial resources and be unable to complete the development of our products. We anticipate that our ongoing operational costs will increase significantly as we continue conducting our clinical development program. Our deficit will continue to grow during our drug development period. Since our inception, we have had no revenue, and do not expect to have any revenue for another three to five years, depending on when we can commercialize our immunotherapies, if at all.

We have sustained losses from operations in each fiscal year since our inception, and we expect losses to continue for the indefinite future due to the substantial investment in research and development. As of October 31, 2013, we had an accumulated deficit of \$70,465,823 and shareholders' equity of \$18,002,142. We expect to spend substantial additional sums on the continued administration and research and development of proprietary products and technologies with no certainty that our immunotherapies will become commercially viable or profitable as a result of these expenditures. If we fail to raise a significant amount of capital, we may need to significantly curtail operations or cease operations in the near future. If any of our product candidates fails in clinical trials or does not gain regulatory approval, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

#### **Our limited operating history does not afford investors a sufficient history on which to base an investment decision.**

We commenced our *Lm-LLO* based immunotherapy development business in February 2002 and have existed as a development stage company since such time. Prior thereto we conducted no business. Accordingly, we have a limited operating history. We have no approved products or products pending approval and therefore have not derived any revenue from the sales of products and have not yet demonstrated ability to obtain regulatory approval, formulate and manufacture commercial scale products, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, there is limited information for investors to use as a basis for assessing our future viability. Investors must consider the risks and difficulties we have encountered in the rapidly evolving vaccine and immunotherapy industry. Such risks include the following:

difficulties, complications, delays and other unanticipated factors in connection with the development of new drugs;

competition from companies that have substantially greater assets and financial resources than we have;  
need for acceptance of our immunotherapies;  
ability to anticipate and adapt to a competitive market and rapid technological developments;  
need to rely on multiple levels of complex financing agreements with outside funding due to the length of drug  
development cycles and governmental approved protocols associated with the pharmaceutical industry; and  
dependence upon key personnel including key independent consultants and advisors.

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We cannot be certain that our strategy will be successful or that we will successfully address these risks. In the event that we do not successfully address these risks, our business, prospects, financial condition and results of operations could be materially and adversely affected. We may be required to reduce our staff, discontinue certain research or development programs of our future products and cease to operate.

### **We may face legal claims; Litigation is expensive and we may not be able to afford the costs.**

We may face legal claims involving stockholders, consumers, competitors, and other issues. As described in *Legal Proceedings* in Part I Item 3 of this prospectus, we are engaged in a number of legal proceedings. Litigation and other legal proceedings are inherently uncertain, and adverse rulings could occur, including monetary damages, or an injunction stopping us from engaging in business practices, or requiring other remedies, such as compulsory licensing of patents.

The costs of litigation or any proceeding relating to our intellectual property or contractual rights could be substantial even if resolved in our favor. Some of our competitors or financial funding sources have far greater resources than we do and may be better able to afford the costs of complex litigation. Also, in a law suit for infringement or contractual breaches, even if frivolous, will require considerable time commitments on the part of management, its attorneys and consultants. Defending these types of proceedings or legal actions involve considerable expense and could negatively affect our financial results.

### **We can provide no assurance of the successful and timely development of new products.**

Our immunotherapies are at various stages of research and development. Further development and extensive testing will be required to determine their technical feasibility and commercial viability. We will need to complete significant additional clinical trials demonstrating that our product candidates are safe and effective to the satisfaction of the FDA and other non-U.S. regulatory authorities. The drug approval process is time-consuming, involves substantial expenditures of resources, and depends upon a number of factors, including the severity of the illness in question, the availability of alternative treatments, and the risks and benefits demonstrated in the clinical trials. Our success will depend on our ability to achieve scientific and technological advances and to translate such advances into licensable, FDA-approvable, commercially competitive products on a timely basis. Failure can occur at any stage of the process. If such programs are not successful, we may invest substantial amounts of time and money without developing revenue-producing products. As we enter a more extensive clinical program for our product candidates, the data generated in these studies may not be as compelling as the earlier results.

Immunotherapies and vaccines that we may develop are not likely to be commercially available until five to ten or more years. The proposed development schedules for our immunotherapies may be affected by a variety of factors, including technological difficulties, clinical trial failures, regulatory hurdles, competitive products, intellectual property challenges and/or changes in governmental regulation, many of which will not be within our control. Any delay in the development, introduction or marketing of our products could result either in such products being marketed at a time when their cost and performance characteristics would not be competitive in the marketplace or in the shortening of their commercial lives. In light of the long-term nature of our projects, the unproven technology involved and the other factors described elsewhere in this section, there can be no assurance that we will be able to successfully complete the development or marketing of any new products.



## **Our research and development expenses are subject to uncertainty.**

Factors affecting our research and development expenses include, but are not limited to:

- competition from companies that have substantially greater assets and financial resources than we have;
- need for acceptance of our immunotherapies;
- ability to anticipate and adapt to a competitive market and rapid technological developments;
- amount and timing of operating costs and capital expenditures relating to expansion of our business, operations and infrastructure;

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need to rely on multiple levels of outside funding due to the length of drug development cycles and governmental approved protocols associated with the pharmaceutical industry; and

dependence upon key personnel including key independent consultants and advisors.

There can be no guarantee that our research and development expenses will be consistent from period to period. We may be required to accelerate or delay incurring certain expenses depending on the results of our studies and the availability of adequate funding.

### **We are subject to numerous risks inherent in conducting clinical trials.**

We outsource the management of our clinical trials to third parties. Agreements with clinical investigators and medical institutions for clinical testing and with other third parties for data management services, place substantial responsibilities on these parties that, if unmet, could result in delays in, or termination of, our clinical trials. For example, if any of our clinical trial sites fail to comply with FDA-approved good clinical practices, we may be unable to use the data gathered at those sites. If these clinical investigators, medical institutions or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for, or successfully commercialize, agents such as ADXS-HPV. We are not certain that we will successfully recruit enough patients to complete our clinical trials nor that we will reach our primary endpoints. Delays in recruitment, lack of clinical benefit or unacceptable side effects would delay or prevent the initiation of the Phase 3 trials of ADXS-HPV.

We or our regulators may suspend or terminate our clinical trials for a number of reasons. We may voluntarily suspend or terminate our clinical trials if at any time we believe they present an unacceptable risk to the patients enrolled in our clinical trials or do not demonstrate clinical benefit. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the patients enrolled in our clinical trials.

Our clinical trial operations are subject to regulatory inspections at any time. If regulatory inspectors conclude that we or our clinical trial sites are not in compliance with applicable regulatory requirements for conducting clinical trials, we may receive reports of observations or warning letters detailing deficiencies, and we will be required to implement corrective actions. If regulatory agencies deem our responses to be inadequate, or are dissatisfied with the corrective actions we or our clinical trial sites have implemented, our clinical trials may be temporarily or permanently discontinued, we may be fined, we or our investigators may be precluded from conducting any ongoing or any future clinical trials, the government may refuse to approve our marketing applications or allow us to manufacture or market our products, and we may be criminally prosecuted.

The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval for ADXS-HPV or our other product candidates, which would materially harm our business, results of operations and prospects.

### **The successful development of immunotherapies is highly uncertain.**

Successful development of biopharmaceuticals is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Immunotherapies that appear promising in the early phases of development may fail to reach the market for several reasons including:

preclinical study results that may show the immunotherapy to be less effective than desired (e.g., the study failed to meet its primary objectives) or to have harmful or problematic side effects;

clinical study results that may show the immunotherapy to be less effective than expected (e.g., the study failed to meet its primary endpoint) or to have unacceptable side effects;

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failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis, or Biologics License Application preparation, discussions with the FDA, an FDA request for additional preclinical or clinical data, or unexpected safety or manufacturing issues; manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make the immunotherapy uneconomical; and the proprietary rights of others and their competing products and technologies that may prevent the immunotherapy from being commercialized.

Success in preclinical and early clinical studies does not ensure that large-scale clinical studies will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical studies and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one immunotherapy to the next, and may be difficult to predict.

Even if we are successful in getting market approval, commercial success of any of our product candidates will also depend in large part on the availability of coverage and adequate reimbursement from third-party payers, including government payers such as the Medicare and Medicaid programs and managed care organizations, which may be affected by existing and future health care reform measures designed to reduce the cost of health care. Third-party payers could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other health care payers were not to provide adequate coverage and reimbursement levels for one any of our products once approved, market acceptance and commercial success would be reduced.

In addition, if one of our products is approved for marketing, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply (or ensure that our third party providers) comply with cGMPs, and GCPs, for any clinical trials that we conduct post-approval. In addition, there is always the risk that we or a regulatory authority might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our product candidates post-market approval could have a material adverse effect on our business, financial condition and results of operations.

### **We must comply with significant government regulations.**

The research and development, manufacture and marketing of human therapeutic and diagnostic products are subject to regulation, primarily by the FDA in the United States and by comparable authorities in other countries. These national agencies and other federal, state, local and foreign entities regulate, among other things, research and development activities (including testing in animals and in humans) and the testing, manufacturing, handling, labeling, storage, record keeping, approval, advertising and promotion of the products that we are developing. If we obtain approval for any of our product candidates, our operations will be directly or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statue and the federal False Claims Act, and privacy laws. Noncompliance with applicable laws and requirements can result in various adverse consequences, including delay in approving or refusal to approve product licenses or other applications, suspension or termination of clinical investigations, revocation of approvals previously granted, fines, criminal prosecution, civil and criminal penalties, recall or seizure of products, exclusion from having our products reimbursed by federal health care programs, the curtailment or restructuring of our operations, injunctions against shipping products and total or partial suspension of production and/or refusal to allow a company to enter into

governmental supply contracts.

The process of obtaining requisite FDA approval has historically been costly and time-consuming. Current FDA requirements for a new human biological product to be marketed in the United States include: (1) the successful conclusion of preclinical laboratory and animal tests, if appropriate, to gain preliminary

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information on the product's safety; (2) filing with the FDA of an IND to conduct human clinical trials for drugs or biologics; (3) the successful completion of adequate and well-controlled human clinical trials to establish the safety and efficacy of the investigational new drug for its recommended use; and (4) filing by a company and acceptance and approval by the FDA of a Biologic License Application, or BLA, for a biological investigational new drug, to allow commercial distribution of a biologic product. The FDA also requires that any drug or formulation to be tested in humans be manufactured in accordance with its Good Manufacturing Practices, or GMP, regulations. This has been extended to include any drug that will be tested for safety in animals in support of human testing. The GMPs set certain minimum requirements for procedures, record-keeping and the physical characteristics of the laboratories used in the production of these drugs. A delay in one or more of the procedural steps outlined above could be harmful to us in terms of getting our immunotherapies through clinical testing and to market.

### **We can provide no assurance that our clinical product candidates will obtain regulatory approval or that the results of clinical studies will be favorable.**

We are currently evaluating the safety and efficacy of ADXS-HPV in a number of ongoing clinical trials. However, even though the initiation and conduct of these trials is in accordance with the governing regulatory authorities in each country, as with any investigational new drug (under an IND in the United States, or the equivalent in countries outside of the United States), we are at risk of a clinical hold at any time based on the evaluation of the data and information submitted to the governing regulatory authorities.

There can be delays in obtaining FDA (U.S.) and/or other necessary regulatory approvals in the United States and in countries outside the United States for any investigational new drug and failure to receive such approvals would have an adverse effect on the investigational new drug's potential commercial success and on our business, prospects, financial condition and results of operations. The time required to obtain approval by the FDA and non-U.S. regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. For example, the FDA or non-U.S. regulatory authorities may disagree with the design or implementation of our clinical trials or study endpoints; or we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks. In addition, the FDA or non-U.S. regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials or the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere. The FDA or non-U.S. regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and the approval policies or regulations of the FDA or non-U.S. regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

In addition to the foregoing, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not submitted for nor obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

### **We may not obtain or maintain the benefits associated with orphan drug designation, including market exclusivity.**

Although we have submitted a new request for orphan drug designation for ADXS-HPV for use in the treatment of invasive cervical cancer our original request was denied and there can be no assurance that our new request will be

We can provide no assurance that our clinical product candidates will obtain regulatory approval or that the results of

granted. Although, we have been granted orphan drug designation for ADXS-HPV for use in the treatment of HPV-associated anal cancer and for HPV-associated head and neck cancer in the United States, and intend to request a similar designation for these uses in the European Union, we may not be granted orphan drug designation, or even if granted, we may not receive the benefits associated with orphan drug designation. This may result from a failure to maintain orphan drug status, or result from a competing product reaching the market that has an orphan designation for the same disease indication. Under U.S. rules for orphan drugs, if such a competing product reaches the market before ours does, the competing product could potentially obtain a scope of market exclusivity that limits or precludes our product from being

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sold in the United States for seven years. Even if we obtain exclusivity, the FDA could subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. A competitor also may receive approval of different products for the same indication for which our orphan product has exclusivity, or obtain approval for the same product but for a different indication for which the orphan product has exclusivity.

In addition, if and when we request orphan drug designation in Europe, the European exclusivity period is ten years but can be reduced to six years if the drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMEA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

### **We may not obtain or maintain the benefits associated with breakthrough therapy designation.**

On October 7, 2013, we submitted a request for breakthrough therapy designation (BTD) to the IND for ADXS-HPV in the treatment of invasive cervical cancer in the United States. The FDA denied the request in December 2013, but stated that a new request may be submitted if we obtain new clinical evidence that supports BTD.

If we resubmit, we may not be granted breakthrough therapy designation, or even if granted, we may not receive the benefits associated with breakthrough therapy designation. This may result from a failure to maintain breakthrough therapy status if ADXS11-001 is no longer considered to be a breakthrough therapy. For example, a drug's development program may be granted breakthrough therapy designation using early clinical testing that shows a much higher response rate than available therapies. However, subsequent interim data derived from a larger study may show a response that is substantially smaller than the response seen in early clinical testing. Another example is where breakthrough therapy designation is granted to two drugs that are being developed for the same use. If one of the two drugs gains traditional approval, the other would not retain its designation unless its sponsor provided evidence that the drug may demonstrate substantial improvement over the recently approved drug. When breakthrough therapy designation is no longer supported by emerging data or the designated drug development program is no longer being pursued, the FDA may choose to send a letter notifying the sponsor that the program is no longer designated as a breakthrough therapy development program.

### **We rely upon patents to protect our technology. We may be unable to protect our intellectual property rights and we may be liable for infringing the intellectual property rights of others.**

Our ability to compete effectively will depend on our ability to maintain the proprietary nature of our technologies, including the *Lm*-LLO based immunotherapy platform technology, and the proprietary technology of others with whom we have entered into collaboration and licensing agreements.

We have 42 patents that have been issued and 38 patent applications that are pending. We have licensed all of these patents and 25 of the pending patent applications from Penn. We have obtained the rights to all future patent applications in this field originating in the laboratories of Dr. Yvonne Paterson and Dr. Fred Frankel.

We own or hold licenses to a number of issued patents and U.S. pending patent applications, as well as foreign patents and foreign counterparts. Our success depends in part on our ability to obtain patent protection both in the United



States and in other countries for our product candidates, as well as the methods for treating patients in the product indications using these product candidates. Such patent protection is costly to obtain and maintain, and we cannot guarantee that sufficient funds will be available. Our ability to protect our product candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Even if our product candidates, as well as methods for treating patients for prescribed indications using these product candidates are covered by valid and enforceable patents and have claims with sufficient scope, disclosure and support in the specification, the patents will provide

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protection only for a limited amount of time. Accordingly, rights under any issued patents may not provide us with sufficient protection for our product candidates or provide sufficient protection to afford us a commercial advantage against competitive products or processes.

In addition, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents have issued or will issue, we cannot guarantee that the claims of these patents are or will be valid or enforceable or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. Furthermore, different countries have different procedures for obtaining patents, and patents issued in different countries offer different degrees of protection against use of the patented invention by others. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

The patent positions of biotechnology and pharmaceutical companies, including our patent position, involve complex legal and factual questions, and, therefore, validity and enforceability cannot be predicted with certainty. Patents may be challenged, deemed unenforceable, invalidated, or circumvented. Our patents can be challenged by our competitors who can argue that our patents are invalid, unenforceable, lack sufficient written description or enablement, or that the claims of the issued patents should be limited or narrowly construed. Patents also will not protect our product candidates if competitors devise ways of making or using these product candidates without infringing our patents.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our technologies, methods of treatment, product candidates, and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets and we have the funds to enforce our rights, if necessary.

The expiration of our owned or licensed patents before completing the research and development of our product candidates and receiving all required approvals in order to sell and distribute the products on a commercial scale can adversely affect our business and results of operations.

### **Litigation regarding patents, patent applications and other proprietary rights may be expensive and time consuming. If we are involved in such litigation, it could cause delays in bringing product candidates to market and harm our ability to operate.**

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents in the future and allege that the products or use of our technologies infringe these patent claims or that we are employing their proprietary technology without authorization.

In addition, third parties may challenge or infringe upon our existing or future patents. Proceedings involving our patents or patent applications or those of others could result in adverse decisions regarding:

the patentability of our inventions relating to our product candidates; and/or

the enforceability, validity or scope of protection offered by our patents relating to our product candidates.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid

Litigation regarding patents, patent applications and other proprietary rights may be expensive and time consuming

infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may:

incur substantial monetary damages;

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encounter significant delays in bringing our product candidates to market; and/or be precluded from participating in the manufacture, use or sale of our product candidates or methods of treatment requiring licenses.

**We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.**

We also rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

**We are dependent upon our license agreement with Penn; if we breach the license agreement and/or fail to make payments due and owing to Penn under our license agreement, our business will be materially and adversely affected.**

Pursuant to the terms of our Second and Third Amendment Agreements with Penn, as amended, we have acquired exclusive worldwide licenses for patents and patent applications related to our proprietary *Listeria* vaccine technology. The license provides us with the exclusive commercial rights to the patent portfolio developed at Penn as of the effective date of the license, in connection with Dr. Paterson and requires us to pay various milestone, legal, filing and licensing payments to commercialize the technology. As of October 31, 2013, we owed Penn approximately \$325,000 in patent expenses (including licensing fees). We can provide no assurance that we will be able to make all payments due and owing thereunder, that such licenses will not be terminated or expire during critical periods, that we will be able to obtain licenses from Penn for other rights that may be important to us, or, if obtained, that such licenses will be obtained on commercially reasonable terms. The loss of any current or future licenses from Penn or the exclusivity rights provided therein could materially harm our financial condition and operating results.

**If we are unable to obtain licenses needed for the development of our product candidates, or if we breach any of the agreements under which we license rights to patents or other intellectual property from third parties, we could lose license rights that are important to our business.**

If we are unable to maintain and/or obtain licenses needed for the development of our product candidates in the future, we may have to develop alternatives to avoid infringing on the patents of others, potentially causing increased costs and delays in drug development and introduction or precluding the development, manufacture, or sale of planned products. Some of our licenses provide for limited periods of exclusivity that require minimum license fees and payments and/or may be extended only with the consent of the licensor. We can provide no assurance that we will be able to meet these minimum license fees in the future or that these third parties will grant extensions on any or all such licenses. This same restriction may be contained in licenses obtained in the future.

Additionally, we can provide no assurance that the patents underlying any licenses will be valid and enforceable. To the extent any products developed by us are based on licensed technology, royalty payments on the licenses will reduce our gross profit from such product sales and may render the sales of such products uneconomical. In addition, the loss of any current or future licenses or the exclusivity rights provided therein could materially harm our business financial condition and our operations.

**We have no manufacturing, sales, marketing or distribution capability and we must rely upon third parties for such.**

We do not intend to create facilities to manufacture our products and therefore are dependent upon third parties to do so. We currently have agreements with Recipharm Cobra Biologics Limited and Vibalogics GmbH for production of our immunotherapies for research and development and testing purposes. We depend on our manufacturers to meet our deadlines, quality standards and specifications. Our reliance on third parties

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for the manufacture of our drug substance, investigational new drugs and, in the future, any approved products, creates a dependency that could severely disrupt our research and development, our clinical testing, and ultimately our sales and marketing efforts if the source of such supply proves to be unreliable or unavailable. If the contracted manufacturing source is unreliable or unavailable, we may not be able to manufacture clinical drug supplies of our immunotherapies, and our preclinical and clinical testing programs may not be able to move forward and our entire business plan could fail. If we are able to commercialize our products in the future, there is no assurance that our manufacturers will be able to meet commercialized scale production requirements in a timely manner or in accordance with applicable standards or current GMP.

### **If we are unable to establish or manage strategic collaborations in the future, our revenue and drug development may be limited.**

Our strategy includes eventual substantial reliance upon strategic collaborations for marketing and commercialization of ADXS-HPV, and we may rely even more on strategic collaborations for research, development, marketing and commercialization of our other immunotherapies. To date, we have not entered into any strategic collaborations with third parties capable of providing these services although we have been heavily reliant upon third party outsourcing for our clinical trials execution and production of drug supplies for use in clinical trials. In addition, we have not yet licensed, marketed or sold any of our immunotherapies or entered into successful collaborations for these services in order to ultimately commercialize our immunotherapies. Establishing strategic collaborations is difficult and time-consuming. Our discussions with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. For example, potential collaborators may reject collaborations based upon their assessment of our financial, clinical, regulatory or intellectual property position. If we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of our immunotherapies or the generation of sales revenue. To the extent that we enter into co-promotion or other collaborative arrangements, our product revenues are likely to be lower than if we directly marketed and sold any products that we may develop.

Management of our relationships with our collaborators will require:

significant time and effort from our management team;  
coordination of our research and development programs with the research and development priorities of our collaborators; and

effective allocation of our resources to multiple projects.

If we continue to enter into research and development collaborations at the early phases of drug development, our success will in part depend on the performance of our corporate collaborators. We will not directly control the amount or timing of resources devoted by our corporate collaborators to activities related to our immunotherapies. Our corporate collaborators may not commit sufficient resources to our research and development programs or the commercialization, marketing or distribution of our immunotherapies. If any corporate collaborator fails to commit sufficient resources, our preclinical or clinical development programs related to this collaboration could be delayed or terminated. Also, our collaborators may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with us. Finally, if we fail to make required milestone or royalty payments to our collaborators or to observe other obligations in our agreements with them, our collaborators may have the right to terminate those agreements.

### **We may incur substantial liabilities from any product liability claims if our insurance coverage for those claims is inadequate.**

We have no manufacturing, sales, marketing or distribution capability and we must rely upon third parties for such.

We face an inherent risk of product liability exposure related to the testing of our immunotherapies in human clinical trials, and will face an even greater risk if the approved products are sold commercially. An individual may bring a liability claim against us if one of the immunotherapies causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for our immunotherapies;

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damage to our reputation;  
withdrawal of clinical trial participants;  
costs of related litigation;  
substantial monetary awards to patients or other claimants;  
loss of revenues;  
the inability to commercialize immunotherapies; and

increased difficulty in raising required additional funds in the private and public capital markets.

We have insurance coverage on our clinical trials for each clinical trial site. We do not have product liability insurance because we do not have products on the market. We currently are in the process of obtaining insurance coverage and to expand such coverage to include the sale of commercial products if marketing approval is obtained for any of our immunotherapies. However, insurance coverage is increasingly expensive and we may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

**We may incur significant costs complying with environmental laws and regulations.**

We and our contracted third parties use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. As appropriate, we store these materials and wastes resulting from their use at our or our outsourced laboratory facility pending their ultimate use or disposal. We contract with a third party to properly dispose of these materials and wastes. We are subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with such laws and regulations may be costly.

**If we use biological materials in a manner that causes injury, we may be liable for damages.**

Our research and development activities involve the use of biological and hazardous materials. Although we believe our safety procedures for handling and disposing of these materials complies with federal, state and local laws and regulations, we cannot entirely eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of these materials. We do not carry specific biological waste insurance coverage, workers compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended or terminated.

**We need to attract and retain highly skilled personnel; we may be unable to effectively manage growth with our limited resources.**

As of February 13, 2014, we had 17 employees, all of which were full time employees. Our ability to attract and retain highly skilled personnel is critical to our operations and expansion. We face competition for these types of personnel from other technology companies and more established organizations, many of which have significantly larger operations and greater financial, technical, human and other resources than we have. We may not be successful in attracting and retaining qualified personnel on a timely basis, on competitive terms, or at all. If we are not successful in attracting and retaining these personnel, or integrating them into our operations, our business, prospects, financial condition and results of operations will be materially adversely affected. In such circumstances we may be unable to



conduct certain research and development programs, unable to adequately manage our clinical trials and other products, and unable to adequately address our management needs.

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**We depend upon our senior management and key consultants and their loss or unavailability could put us at a competitive disadvantage.**

We depend upon the efforts and abilities of our senior executives, as well as the services of several key consultants, including Yvonne Paterson, Ph.D. The loss or unavailability of the services of any of these individuals for any significant period of time could have a material adverse effect on our business, prospects, financial condition and results of operations. We have not obtained, do not own, nor are we the beneficiary of, key-person life insurance.

**The biotechnology and immunotherapy industries are characterized by rapid technological developments and a high degree of competition. We may be unable to compete with more substantial enterprises.**

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, our actual or proposed immunotherapies could become obsolete before we recoup any portion of our related research and development and commercialization expenses. Competition in the biopharmaceutical industry is based significantly on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain governmental approval for testing, manufacturing and marketing. We compete with specialized biopharmaceutical firms in the United States, Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many biopharmaceutical companies have focused their development efforts in the human therapeutics area, including cancer. Many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies. These companies, as well as academic institutions and governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants. Our ability to compete successfully with other companies in the pharmaceutical field will also depend to a considerable degree on the continuing availability of capital to us.

We are aware of certain investigational new drugs under development or approved products by competitors that are used for the prevention, diagnosis, or treatment of certain diseases we have targeted for drug development. Various companies are developing biopharmaceutical products that have the potential to directly compete with our immunotherapies even though their approach to may be different. The biotechnology and biopharmaceutical industries are highly competitive, and this competition comes from both biotechnology firms and from major pharmaceutical companies, including companies like: Aduro Biotech, Agenus Inc., Bionovo Inc., Bristol-Myers Squibb, Celgene Corporation, Celldex Therapeutics, Cerus Corporation, Dendreon Corporation, Inovio Pharmaceutical Inc., Oncolytics Biotech Inc., Oncothyreon Inc., each of which is pursuing cancer vaccines and/or immunotherapies. Many of these companies have substantially greater financial, marketing, and human resources than we do (including, in some cases, substantially greater experience in clinical testing, manufacturing, and marketing of pharmaceutical products). We also experience competition in the development of our immunotherapies from universities and other research institutions and compete with others in acquiring technology from such universities and institutions.

In addition, certain of our immunotherapies may be subject to competition from investigational new drugs and/or products developed using other technologies, some of which have completed numerous clinical trials.

We believe that our immunotherapies under development and in clinical trials will address unmet medical needs in the treatment of cancer. Our competition will be determined in part by the potential indications for which drugs are developed and ultimately approved by regulatory authorities. Additionally, the timing of market introduction of some

We depend upon our senior management and key consultants and their loss or unavailability could put us at a competitive disadvantage.

of our potential products or of competitors' products may be an important competitive factor. Accordingly, the relative speed with which we can develop immunotherapies, complete preclinical testing, clinical trials and approval processes and supply commercial quantities to market is expected to be important competitive factors. We expect that competition among products approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price and patent position.

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## **Risks Related to our Securities**

### **The price of our common stock and warrants may be volatile.**

The trading price of our common stock and warrants may fluctuate substantially. The price of our common stock and warrants that will prevail in the market may be higher or lower than the price you have paid, depending on many factors, some of which are beyond our control and may not be related to our operating performance. These fluctuations could cause you to lose part or all of your investment in our common stock and warrants. Those factors that could cause fluctuations include, but are not limited to, the following:

- price and volume fluctuations in the overall stock market from time to time;
- fluctuations in stock market prices and trading volumes of similar companies;
- actual or anticipated changes in our net loss or fluctuations in our operating results or in the expectations of securities analysts;
- the issuance of new equity securities pursuant to a future offering, including issuances of preferred stock;
- general economic conditions and trends;
- positive and negative events relating to healthcare and the overall pharmaceutical and biotech sector;
- major catastrophic events;
- sales of large blocks of our stock;
- significant dilution caused by the anti-dilutive clauses in our financial agreements;
- departures of key personnel;
- changes in the regulatory status of our immunotherapies, including results of our clinical trials;
- events affecting Penn or any future collaborators;
- announcements of new products or technologies, commercial relationships or other events by us or our competitors;
- regulatory developments in the United States and other countries;
- failure of our common stock or warrants to be listed or quoted on The NASDAQ Capital Market, NYSE Amex Equities or other national market system;
- changes in accounting principles; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Due to the potential volatility of our stock price, we may therefore be the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

### **A DTC Chill on the electronic clearing of trades in our securities in the future may affect the liquidity of our stock and our ability to raise capital.**

Because our common stock may, from time to time, be considered a penny stock, there is a risk that the Depository Trust Company (DTC) may place a chill on the electronic clearing of trades in our securities. This may lead some brokerage firms to be unwilling to accept certificates and/or electronic deposits of our stock and other securities and also some may not accept trades in our securities altogether. In the past, DTC has placed a deposit chill on our shares, and although the chill is currently removed, no assurance can be given that a chill will not be reinstated in the future. A future DTC chill would affect the liquidity of our securities and make it difficult to purchase or sell our securities in the open market. It may also have an



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adverse effect on our ability to raise capital because investors may be unable to easily resell our securities into the market. Our inability to raise capital on terms acceptable to us, if at all, could have a material and adverse effect on our business and operations.

### **You may have difficulty selling our shares because they may be deemed penny stocks.**

If our common stock price falls, our common stock may be deemed to be penny stock as that term is defined in Rule 3a51-1, promulgated under the Exchange Act. Penny stocks are, generally, stocks:

with a price of less than \$5.00 per share;

that are neither traded on a recognized national exchange nor listed on an automated quotation system sponsored by a registered national securities association meeting certain minimum initial listing standards; and of issuers with net tangible assets less than \$2.0 million (if the issuer has been in continuous operation for at least three years) or \$5.0 million (if in continuous operation for less than three years), or with average revenue of less than \$6.0 million for the last three years.

Section 15(g) of the Exchange Act and Rule 15g-2 promulgated thereunder require broker-dealers dealing in penny stocks to provide potential investors with a document disclosing the risks of penny stocks and to obtain a manually signed and dated written receipt of the document before effecting any transaction in a penny stock for the investor's account. We urge potential investors to obtain and read this disclosure carefully before purchasing any shares that are deemed to be penny stock.

Rule 15g-9 promulgated under the Exchange Act requires broker-dealers in penny stocks to approve the account of any investor for transactions in such stocks before selling any penny stock to that investor. This procedure requires the broker-dealer to:

obtain from the investor information about his or her financial situation, investment experience and investment objectives;

reasonably determine, based on that information, that transactions in penny stocks are suitable for the investor and that the investor has enough knowledge and experience to be able to evaluate the risks of penny stock transactions; provide the investor with a written statement setting forth the basis on which the broker-dealer made his or her determination; and

receive a signed and dated copy of the statement from the investor, confirming that it accurately reflects the investor's financial situation, investment experience and investment objectives.

Compliance with these requirements may make it harder for investors in our common stock to resell their shares to third parties. Accordingly, our common stock should only be purchased by investors, who understand that such investment is a long-term and illiquid investment, and are capable of and prepared to bear the risk of holding our common stock for an indefinite period of time.

Although one reason we asked our shareholders to approve a reverse stock split was to increase the price per share of our common stock such that it would not be subject to the penny stock rules. Our stock closed at \$5.29 per share on February 13, 2014, and no assurance can be given that the per share price of our common stock will maintain such levels such that our stock will not be subject to these rules in the future.

**A limited public trading market may cause volatility in the price of our common stock and warrants.**

The quotation of our common stock on the NASDAQ does not assure that a meaningful, consistent and liquid trading market currently exists, and in recent years such market has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies like us. Our common stock is thus subject to this volatility. Sales of substantial amounts of common stock, or the perception that such sales might occur, could adversely affect prevailing market prices of our common stock and our stock price may decline substantially in a short time and our shareholders could suffer losses or be unable to liquidate their holdings. Also there are large blocks of restricted stock that have met the holding

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requirements under Rule 144 that may be sold without restriction. Our stock is thinly traded due to the limited number of shares available for trading on the market thus causing large swings in price. In addition, there is no established trading market for our warrants.

### **The market prices for our common stock may be adversely impacted by future events.**

Our common stock began trading on the over-the-counter-markets on July 28, 2005 and is currently quoted on the NASDAQ Capital Market under the symbol ADXS. Market prices for our common stock and warrants will be influenced by a number of factors, including:

- the issuance of new equity securities pursuant to a future offering, including issuances of preferred stock;
- changes in interest rates;
- significant dilution caused by the anti-dilutive clauses in our financial agreements;
- competitive developments, including announcements by competitors of new products or services or significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- variations in quarterly operating results;
- change in financial estimates by securities analysts;
- the depth and liquidity of the market for our common stock and warrants;
- investor perceptions of our company and the pharmaceutical and biotech industries generally; and
- general economic and other national conditions.

### **Speculative nature of warrants.**

The five-year warrants we issued in October 2013 do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Holders of the warrants may exercise their right to acquire the common stock and pay an exercise price, prior to their specified expiry date, after which date any unexercised warrants will expire and have no further value. Moreover, the market value of the warrants is uncertain and there can be no assurance that the market value of the warrants will equal or exceed their exercise price. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the warrants, and consequently, whether it will ever be profitable for holders of the warrants to exercise the warrants.

### **If we fail to remain current with our listing requirements, we could be removed from the NASDAQ Capital Market, which would limit the ability of broker-dealers to sell our securities and the ability of shareholders to sell their securities in the secondary market.**

Companies trading on the NASDAQ Capital Market, such as our company, must be reporting issuers under Section 12 of the Exchange Act, as amended, and must meet the listing requirements in order to maintain the listing of our common stock on the NASDAQ Capital Market. If we do not meet these requirements, the market liquidity for our securities could be severely adversely affected by limiting the ability of broker-dealers to sell our securities and the ability of shareholders to sell their securities in the secondary market.



**Our internal control over financial reporting and our disclosure controls and procedures have been ineffective in the past, and may be ineffective again in the future, and failure to improve them at such time could lead to errors in our financial statements that could require a restatement or untimely filings, which could cause investors to lose confidence in our reported financial information, and a decline in our stock price.**

Our internal control over financial reporting and our disclosure controls and procedures have been ineffective in the past. We have taken steps to improve our disclosure controls and procedures and our internal control over financial reporting, and as of October 31, 2013, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures and internal control over financial reporting were

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effective. However, there is no assurance that our disclosure controls and procedures will remain effective or that there will be no material weaknesses in our internal control over financial reporting in the future. Additionally, as a result of the historical material weaknesses in our internal control over financial reporting and the historical ineffectiveness of our disclosure controls and procedures, current and potential stockholders could lose confidence in our financial reporting, which would harm our business and the trading price of our stock.

### **Sales of additional equity securities may adversely affect the market price of our common stock and your rights may be reduced.**

We expect to continue to incur drug development and selling, general and administrative costs, and to satisfy our funding requirements, we will need to sell additional equity securities, which may be subject to registration rights and warrants with anti-dilutive protective provisions. The sale or the proposed sale of substantial amounts of our common stock or other equity securities in the public markets may adversely affect the market price of our common stock and our stock price may decline substantially. Our shareholders may experience substantial dilution and a reduction in the price that they are able to obtain upon sale of their shares. Also, new equity securities issued may have greater rights, preferences or privileges than our existing common stock.

### **Additional authorized shares of common stock available for issuance may adversely affect the market price of our securities.**

We are currently authorized to issue 25,000,000 shares of our common stock. As of February 13, 2014, we had 13,903,855 shares of our common stock issued and outstanding, excluding shares issuable upon exercise of our outstanding warrants, options, convertible promissory notes and shares of common stock earned but not yet issued under our director compensation program. Under our 2011 Employee Stock Purchase Plan, or ESPP, our employees can buy our common stock at a discounted price. To the extent the shares of common stock are issued, options and warrants are exercised or convertible promissory notes are converted, holders of our common stock will experience dilution. In addition, in the event of any future financing of equity securities or securities convertible into or exchangeable for, common stock, holders of our common stock may experience dilution. As of February 13, 2014, warrants to purchase 202,503 shares of our common stock were exercisable at approximately \$9.24 per share and were subject to weighted-average anti-dilution protection upon certain equity issuances below \$9.24 per share (as may be further adjusted as defined in the warrant). In addition, as of February 13, 2014, we had outstanding options to purchase 467,923 shares of our common stock at a weighted average exercise price of approximately \$15.86 per share and outstanding warrants to purchase 4,265,262 shares of our common stock (including the above warrants subject to weighted-average anti-dilution protection); and approximately 28,449 shares of our common stock were available for grant under the ESPP. Although we entered into agreements providing for the repayment or conversion of certain of our outstanding indebtedness, not all the holders of our outstanding convertible promissory notes have agreed to exchange their securities at this time.

### **The accounting treatment for certain of our warrants is complex and subject to judgments concerning the valuation of embedded derivative rights within the applicable securities. Fluctuations in the valuation of these rights could cause us to take charges to our earnings and make our financial results unpredictable.**

Sales of additional equity securities may adversely affect the market price of our common stock and your rights may

Certain of our outstanding warrants contain, or may be deemed to contain from time to time, embedded derivative rights in accordance with U.S. generally accepted accounting principles, or GAAP. These derivative rights, or similar rights in securities we may issue in the future, need to be, or may need to be, separately valued as of the end of each accounting period in accordance with GAAP. We record these embedded derivatives as liabilities at issuance, valued using the Black-Scholes Model and are subject to revaluation at each reporting date. Any change in fair value between reporting periods is reported on our statement of operations. At October 31, 2013, and October 31, 2012, the fair value of the embedded derivative liability was \$0 as the related securities were paid off, converted or reached maturity. For the twelve months ended October 31, 2013 and October 31, 2012, we reported income of \$0 and approximately \$400,000, respectively, due to changes in the fair value of the embedded derivative liability partially resulting from debt to equity exchanges during the period. Changes in the valuations of these rights, the valuation methodology or the assumptions on which the valuations are based could cause us to take charges to our earnings, which would

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adversely impact our results of operations. Moreover, the methodologies, assumptions and related interpretations of accounting or regulatory authorities associated with these embedded derivatives are complex and in some cases uncertain, which could cause our accounting for these derivatives, and as a result, our financial results, to fluctuate. There is a risk that questions could arise from investors or regulatory authorities concerning the appropriate accounting treatment of these instruments, which could require us to restate previous financial statements, which in turn could adversely affect our reputation, as well as our results of operations.

### **We do not intend to pay cash dividends.**

We have not declared or paid any cash dividends on our common stock, and we do not anticipate declaring or paying cash dividends for the foreseeable future. Any future determination as to the payment of cash dividends on our common stock will be at our board of directors' discretion and will depend on our financial condition, operating results, capital requirements and other factors that our board of directors considers to be relevant.

### **Our certificate of incorporation, Bylaws and Delaware law have anti-takeover provisions that could discourage, delay or prevent a change in control, which may cause our stock price to decline.**

Our certificate of incorporation, Bylaws and Delaware law contain provisions which could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our shareholders. We are authorized to issue up to 5,000,000 shares of preferred stock. This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our Board of Directors without further action by shareholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third party and thereby preserve control by the present management.

Provisions of our certificate of incorporation, Bylaws and Delaware law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a shareholder might consider favorable. Such provisions may also prevent or frustrate attempts by our shareholders to replace or remove our management. In particular, the certificate of incorporation, Bylaws and Delaware law, as applicable, among other things; provide the Board of Directors with the ability to alter the Bylaws without shareholder approval, and provide that vacancies on the Board of Directors may be filled by a majority of directors in office, although less than a quorum.

We are also subject to Section 203 of the Delaware General Corporation Law, which, subject to certain exceptions, prohibits business combinations between a publicly-held Delaware corporation and an interested shareholder, which is generally defined as a shareholder who becomes a beneficial owner of 15% or more of a Delaware corporation's voting stock for a three-year period following the date that such shareholder became an interested shareholder.

These provisions are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of our company to first negotiate with its board. These provisions may delay or prevent someone from acquiring or merging with us, which may cause the market price of our common stock to decline.

We do not intend to pay cash dividends.



TABLE OF CONTENTS**Item 2. Properties.**

Our corporate offices are currently located at 305 College Road East, Princeton, New Jersey 08540. On April 1, 2011, we entered into a Sublease Agreement for such office, which is an approximately 10,000 square foot leased facility in Princeton, NJ approximately 12 miles south of our prior location. The agreement has a termination date of November 29, 2015.

On March 13, 2013, we entered into a modification of the Sublease Agreement whereby all unpaid accrued lease amounts and future lease amounts through June 30, 2013, which we estimated to be approximately \$450,000, would be satisfied by a payment in total of \$200,000, with \$100,000 paid on March 13, 2013 and \$100,000 paid upon the close of our public offering in October 2013. These amounts were paid as scheduled. In addition, lease payments for the period July 1, 2013 through November 30, 2015 was reduced to a total of \$20,000 per month.

**Item 3. Legal Proceedings.**

On March 22, 2013, the Company was notified that Brio Capital L.P., which we refer to as Brio, had filed a lawsuit against Advaxis, in the Supreme Court of the State of New York, County of New York, titled Brio Capital L.P. v. Advaxis Inc., Case No. 651029/2013, which we refer to as the Action. The complaint in the Action alleges, among other things, that Advaxis breached the terms of certain warrants to purchase shares of our common stock that we originally issued to Brio on October 17, 2007 and on June 18, 2009, and that Brio has suffered damages as a result thereof. Brio's complaint seeks (i) a preliminary and permanent injunction directing us to issue to Brio 21,742 shares of our common stock, along with the necessary corporate resolutions and legal opinions to enable Brio to sell such common stock publicly without restriction; and (ii) damages of at least \$500,000 (in an amount to be determined at trial), along with interest, costs and attorneys' fees related to the Action. On April 15, 2013, in partial resolution of the Brio lawsuit, we issued 21,742 shares of common stock and provided certain corporate resolutions and legal opinions necessary to enable Brio to sell such common stock publicly without restriction. On October 29, 2013, we entered into a settlement agreement with Brio to settle the remaining claims under the Action, which agreement was to become binding only when approved by the court at a fairness hearing. The parties later agreed to amend the settlement by the Company paying Brio \$205,000 in full settlement of all claims related to this lawsuit in exchange for a release of claims and cancellation of the warrants. The matter is now finally settled and the Action dismissed with prejudice.

On August 19, 2013, we entered into an agreement with Maxim Group LLC, or Maxim, to terminate a July 2012 engagement agreement between the parties, pursuant to which Maxim asserted claims for unpaid fees related to the introduction of investors to us and services provided. As consideration for terminating the agreement, we agreed to pay Maxim approximately \$589,000 in monthly installment payments in either cash or shares of our common stock, and a warrant to purchase 30,154 shares of our common stock at an exercise price of \$4.90 per share. Additionally, in order to move the settlement forward, we reluctantly agreed to pay Maxim an additional \$150,000 upon the completion of a contemplated public offering of securities. On September 17, 2013, we issued 25,582 shares of our common stock as an installment payment under this agreement and also issued the warrant to acquire 30,154 shares of our common stock at \$4.90 per share, and on September 27, 2013, we issued 158,385 shares of our common stock to satisfy the remaining amount owed under this agreement. Maxim rejected the delivery of these 158,385 shares and claimed that we may not prepay our obligations under the agreement notwithstanding any language to the contrary in the agreement. Upon receipt of the rejected shares, Advaxis cancelled the issuance of such shares. Upon the completion of our public offering in October 2013, we paid the aforementioned \$150,000 and commenced final settlement of the disputed amounts owed. On or about November 14, 2013, Maxim initiated a proceeding by confession of judgment in New York State Court to recover monies it believes Advaxis owes it under the Termination Agreement in the amount of \$484,709.50. On November 15, 2013, the New York County Clerk's office entered a

judgment in favor of Maxim. On or about November 22, 2013, Maxim mailed a Notice of Entry to Advaxis and the parties decided to settle the dispute without any admission of liability or wrongdoing and on December 23, 2013, the parties executed a Settlement Agreement and Releases. On December 27, 2013, we paid Maxim \$285,000 in final settlement of all matters related to their claim.

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In addition to the foregoing, we are from time to time involved in legal proceedings in the ordinary course of our business. We do not believe that any of these claims and proceedings against us is likely to have, individually or in the aggregate, a material adverse effect on our financial condition or results of operations.

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## **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus and the documents incorporated by reference contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on our management's current beliefs, expectations and assumptions about future events, conditions and results and on information currently available to us. Discussions containing these forward-looking statements may be found, among other places, in the Sections entitled Business, Risk Factors and Management's Discussion and Analysis of Financial Condition and Results of Operations incorporated by reference from our most recent Annual Report on Form 10-K and in our Quarterly Reports on Form 10-Q, as well as any amendments thereto, filed with the SEC.

Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but not always, made through the use of words or phrases such as anticipate, estimate, plan, project, continuing, believe, expect, future and int expressions to identify forward-looking statements, but are not the exclusive means of identifying forward-looking statements in this prospectus. Additionally, statements concerning future matters such as our interpretation of the trials for our product candidates, the ability to successfully complete additional clinical trials on a timely basis and obtain regulatory approvals for one or more of our product candidates, the potential biological effects and indications for our product candidates, the market opportunity for our product candidates, our ability to complete additional discovery and development activities for drug candidates, our ability to timely raise additional funds to support our operations and the period of time for which our existing cash will enable us to fund our operations and other statements regarding matters that are not historical in nature are forward-looking statements.

Such statements are based on currently available operating, financial and competitive information and are subject to various risks, uncertainties and assumptions that could cause actual results to differ materially from those anticipated or implied in our forward-looking statements due to a number of factors including, but not limited to, those set forth below under the section entitled Risk Factors in our most recent Annual Report on Form 10-K, as well as any amendments thereto filed with the SEC. Given these risks, uncertainties and other factors, many of which are beyond our control, you should not place undue reliance on these forward-looking statements.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to revise any forward-looking statements to reflect events or developments occurring after the date of this prospectus, even if new information becomes available in the future.

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## **USE OF PROCEEDS**

Unless the applicable prospectus supplement states otherwise, we expect to use the net proceeds of the sale of these securities for general corporate purposes, which may include repayment of existing indebtedness, working capital, capital expenditures, acquisitions, joint ventures and stock repurchase programs. As of the date of this prospectus, we have not identified as probable any specific material proposed uses of these proceeds. If, as of the date of any prospectus supplement, we have identified any such uses, we will describe them in the prospectus supplement. The amount of securities offered from time to time pursuant to this prospectus and any prospectus supplement, and the precise amounts and timing of the application of net proceeds from the sale of those securities, will depend upon our funding requirements. Pending these uses, we intend to invest the net proceeds in investment-grade, interest-bearing securities.

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## PLAN OF DISTRIBUTION

We may sell securities to one or more underwriters or dealers for public offering and sale by them, or we may sell the securities to investors directly or through agents. The applicable prospectus supplement will set forth the terms of the offering and the method of distribution and will identify any firms acting as underwriters, dealers or agents in connection with the offering, including:

- the name or names of any underwriters;
- the purchase price of the securities;
- any underwriting discounts and other items constituting underwriters' compensation;
- any initial public offering price and the net proceeds we will receive from such sale;
- any discounts or concessions allowed or reallocated or paid to dealers; and

any securities exchange or market on which the securities offered in the prospectus supplement may be listed.

We may distribute our securities from time to time in one or more transactions at a fixed price or prices, which may be changed, or at prices determined as the prospectus supplement specifies, including in at-the-market offerings. We may sell our securities through a rights offering, forward contracts, or similar arrangements.

We may authorize underwriters, dealers, or agents to solicit offers by certain purchasers to purchase the securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. The contracts will be subject only to those conditions set forth in the applicable prospectus supplement, and the prospectus supplement will set forth any commissions we pay for solicitation of these contracts.

Any underwriting discounts or other compensation which we pay to underwriters or agents in connection with the offering of our securities, and any discounts, concessions or commissions which underwriters allow to dealers, will be set forth in the prospectus supplement. Underwriters may sell our securities to or through dealers, and such dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and commissions from the purchasers for whom they may act as agents. Underwriters, dealers and agents that participate in the distribution of our securities may be deemed to be underwriters under the Securities Act and any discounts or commissions they receive from us and any profit on the resale of our securities they realize may be deemed to be underwriting discounts and commissions under the Securities Act. Any such underwriter or agent will be identified, and any such compensation received from us, will be described in the applicable supplement to this prospectus. Unless otherwise set forth in the supplement to this prospectus relating thereto, the obligations of the underwriters or agents to purchase our securities will be subject to conditions precedent and the underwriters will be obligated to purchase all our offered securities if any are purchased. The public offering price and any discounts or concessions allowed or reallocated or paid to dealers may be changed from time to time.

Any common stock sold pursuant to this prospectus and applicable prospectus supplement, will be approved for trading, upon notice of issuance, on the NASDAQ Capital Market or such other stock exchange that our securities are trading upon.

Agents and underwriters may be entitled to indemnification by us against certain civil liabilities, including liabilities under the Securities Act of 1933, as amended, or to contribution with respect to payments which the agents or underwriters may be required to make in respect thereof.

An underwriter may engage in over-allotment, stabilizing transactions, short covering transactions and penalty bids in accordance with securities laws. Over-allotment involves sales in excess of the offering size, which creates a short

position. Stabilizing transactions permit bidders to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Short covering transactions involve purchases of the securities in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a covering transaction to cover short positions. Those activities may cause the price of

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the securities to be higher than it would otherwise be. The underwriters may engage in these activities on any exchange or other market in which the securities may be traded. If commenced, the underwriters may discontinue these activities at any time.

Certain of the underwriters and their affiliates may be customers of, engage in transactions with, and perform services for, us and our subsidiaries in the ordinary course of business at any time. We may sell the securities covered in this prospectus in any of these ways (or in any combination).

In compliance with the guidelines of the Financial Services Regulatory Authority, Inc., or FINRA, the maximum compensation to be received by a FINRA member or independent broker-dealer may not exceed 8% of the offering proceeds. It is anticipated that the maximum compensation to be received in any particular offering of securities will be less than this amount.

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## DESCRIPTION OF COMMON STOCK

### General

At the date hereof, we are authorized by our certificate of incorporation to issue an aggregate of 25,000,000 shares of common stock, par value \$0.001 per share. On July 12, 2013, we effected a reverse stock split at a ratio of 1-for-125 of all the issued and outstanding shares of our common stock. We also reduced our authorized shares of common stock from 1,000,000,000 to 25,000,000. As of February 13, 2014, there were 13,903,885 shares of common stock outstanding.

We may sell from time to time, in one or more offerings, common stock in a dollar amount that does not exceed, in the aggregate, \$50,000,000. This prospectus contains only a summary of the common stock we may offer. The specific terms of any securities actually offered for sale, together with the terms of that offering, the initial price and the net proceeds to us from the sale of these securities, will be set forth in an accompanying prospectus supplement. That prospectus supplement also will contain information, where applicable, about material United States federal income tax considerations relating to the securities, and the securities exchange, if any, on which the securities will be listed. This prospectus may not be used to consummate a sale of securities unless it is accompanied by a prospectus supplement.

The following summary of the terms of our common stock may not be complete and is subject to, and qualified in its entirety by reference to, the terms and provisions of our amended and restated certificate of incorporation and our amended and restated bylaws. You should refer to, and read this summary together with, our amended and restated certificate of incorporation and amended and restated bylaws to review all of the terms of our common stock that may be important to you.

### Common Stock

Holders of our common stock are entitled to one vote for each share held of record on each matter submitted to a vote of stockholders. Holders of our common stock do not have a cumulative voting right, which means that the holders of more than one-half of the outstanding shares of common stock, subject to the rights of the holders of the preferred stock, if any, can elect all of our directors, if they choose to do so. In this event, the holders of the remaining shares of common stock would not be able to elect any directors. Except as otherwise required by Delaware law, and subject to the rights of the holders of preferred stock, if any, all stockholder action is taken by the vote of a majority of the outstanding shares of common stock voting as a single class present at a meeting of stockholders at which a quorum consisting of one-third of the outstanding shares of common stock is present in person or proxy.

Subject to the prior rights of any class or series of preferred stock which may from time to time be outstanding, if any, holders of our common stock are entitled to receive ratably, dividends when, as, and if declared by our board of directors out of funds legally available for that purpose and, upon our liquidation, dissolution, or winding up, are entitled to share ratably in all assets remaining after payment of liabilities and payment of accrued dividends and liquidation preferences on the preferred stock, if any. Holders of our common stock have no preemptive rights and have no rights to convert their common stock into any other securities. The outstanding common stock is validly authorized and issued, fully-paid and nonassessable.

## Registration Rights

Certain of our outstanding shares of common stock, shares of common stock issuable upon conversion of our convertible notes and shares of common stock issuable upon exercise of outstanding warrants are subject to demand or piggyback registration rights.

## Anti-Takeover Provisions

### Delaware Law

We are subject to Section 203 of the Delaware General Corporation Law. This provision generally prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date the stockholder became an interested stockholder, unless:

prior to such date, the board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

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upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned by persons who are directors and also officers and by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

on or subsequent to such date, the business combination is approved by the board of directors and authorized at an annual meeting or special meeting of stockholders and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines a business combination to include:

any merger or consolidation involving the corporation and the interested stockholder;  
any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;  
subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;  
any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or  
the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of a corporation, or an affiliate or associate of the corporation and was the owner of 15% or more of the outstanding voting stock of a corporation at any time within three years prior to the time of determination of interested stockholder status; and any entity or person affiliated with or controlling or controlled by such entity or person.

These statutory provisions could delay or frustrate the removal of incumbent directors or a change in control of our company. They could also discourage, impede, or prevent a merger, tender offer, or proxy contest, even if such event would be favorable to the interests of stockholders.

### **Amended and Restated Certificate of Incorporation and Bylaw Provisions**

Our amended and restated certificate of incorporation and bylaws contain provisions that could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. In particular, the certificate of incorporation and bylaws, as applicable, among other things:

provide our board of directors with the ability to alter its bylaws without stockholder approval; and  
provide that vacancies on our board of directors may be filled by a majority of directors in office, although less than a quorum.

Such provisions may have the effect of discouraging a third-party from acquiring us, even if doing so would be beneficial to our stockholders. These provisions are intended to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by them, and to discourage some types of transactions that may involve an actual or threatened change in control of our company. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage some tactics that may be used in proxy fights. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company outweigh the disadvantages of discouraging such proposals because, among other things, negotiation of such proposals could result in an



improvement of their terms. However,

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these provisions could have the effect of discouraging others from making tender offers for our shares that could result from actual or rumored takeover attempts. These provisions also may have the effect of preventing changes in our management.

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Securities Transfer Corporation, 2591 Dallas Parkway, Suite 102, Frisco, TX 75034.

**Listing**

The shares of our common stock are quoted on the NASDAQ Capital Market under the symbol ADXS. On February 13, 2014, the last reported sale price per share for our common stock as reported by the NASDAQ Capital Market was \$5.29.

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## **LEGAL MATTERS**

The legality and validity of the securities offered from time to time under this prospectus will be passed upon by Reed Smith LLP.

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## **EXPERTS**

The financial statements of Advaxis, Inc. appearing in its Annual Report filed on Form 10-K as of October 31, 2013 and 2012, and for the years then ended, have been audited by Marcum LLP, an independent registered public accounting firm, as set forth in its report thereon, included therein, and incorporated herein by reference. Such financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing. The financial statements for the cumulative period from March 1, 2002 (inception) to October 31, 2011 incorporated in this Prospectus by reference to the Annual Report on Form 10-K for the year ended October 31, 2013, have been audited by McGladrey LLP, an independent registered public accounting firm, as stated in their report incorporated by reference herein, and have been so incorporated in reliance upon such report and upon the authority of such firm as experts in accounting and auditing.

### Change in Our Public Accounting Firm

On December 19, 2012, which we refer to as the Dismissal Date, we advised McGladrey LLP, that it was dismissed as our independent registered public accounting firm. Effective December 14, 2012, we engaged Marcum LLP, as our independent registered public accounting firm to audit our financial statements for the year ended October 31, 2012. The decision to dismiss McGladrey as our independent registered public accounting firm was approved by the Audit Committee of our Board of Directors.

The reports of McGladrey on our financial statements for the fiscal years of 2011 and 2010 contained no adverse opinion or disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principle. In connection with its audits for the fiscal years of 2011 and 2010, there have been no disagreements with McGladrey on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction McGladrey, would have caused them to make reference thereto in their reports on the financial statements for such years.

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## **WHERE YOU CAN FIND MORE INFORMATION**

We are a reporting company and file annual, quarterly and current reports, proxy statements and other information with the SEC. We have filed with the SEC a registration statement on Form S-3 under the Securities Act with respect to the securities we are offering under this prospectus. This prospectus does not contain all of the information set forth in the registration statement and the exhibits to the registration statement. For further information with respect to us and the securities we are offering under this prospectus, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement. You may read and copy the registration statement, as well as our reports, proxy statements and other information, at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the Public Reference Room. The SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, where our SEC filings are also available. The address of the SEC's web site is <http://www.sec.gov>.

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## INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to incorporate by reference into this prospectus the information we file with the SEC. This means that we can disclose important information to you by referring you to those documents without restating that information in this document. The information incorporated by reference into this prospectus is considered to be part of this prospectus, and information we file with the SEC pursuant to Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, after the date of this prospectus and prior to the termination of this offering, will automatically update and supersede the information contained in this prospectus and documents listed below. We incorporate by reference into this prospectus the documents listed below, except to the extent information in those documents differs from information contained in this prospectus, and any future filings made by us with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, including exhibits (other than in each case, documents or information deemed to be furnished and not filed in accordance with SEC rules):

- (a) Our Annual Report on Form 10-K for the fiscal year ended October 31, 2013, as filed with the SEC on January 29, 2014, as amended by Form 10-K/A filed with the SEC on February 6, 2014;
- (b) Our Current Reports on Form 8-K filed with the SEC on December 13, 2013\*, December 19, 2013, January 22, 2014\* and February 11, 2014 (\* excluding items 7.01 and 9.01, and Exhibit 99.1); and
- (c) The description of our common stock, par value \$0.001 per share, contained in our Registration Statement on Form 8-A, filed with the Commission on October 15, 2013 and under the caption "Description of Securities" in the Registrant's prospectus, dated as of October 11, 2013, forming a part of the Registration Statement on Form S-1 (Registration No. 333-188637) filed with the Commission, including any amendments or reports filed for the purpose of updating such description.

In addition, all documents that we file pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this Registration Statement and prior to the filing of a post-effective amendment which indicates that all securities offered hereby have been sold or which deregisters all securities then remaining unsold shall be deemed to be incorporated by reference into this Registration Statement and to be a part hereof from the date of filing of such documents. Any statement contained herein or in a document incorporated or deemed to be incorporated by reference or deemed to be a part of this Registration Statement shall be deemed to be modified or superseded for purposes of this Registration Statement to the extent that a statement contained in this Registration Statement or in any other subsequently filed document that also is or is deemed to be incorporated by reference or deemed to be a part of this Registration Statement modifies or supersedes such statement. Any statement contained in a document that is deemed to be incorporated by reference or deemed to be a part of this Registration Statement after the most recent effective date may modify or replace existing statements contained in this Registration Statement. In either case, any statement so modified or superseded shall not be deemed to constitute a part of this Registration Statement, except as so modified or superseded.

We will provide to each person, including any beneficial owner, to whom a copy of this prospectus is delivered, a copy of any or all of the information that we have incorporated by reference into this prospectus. We will provide this information upon written or oral request at no cost to the requester. You may request this information by contacting our corporate headquarters at the following address: Advaxis, Inc., 305 College Road East, Princeton, New Jersey 08540, Attn: Lisa Caperelli, Senior Director, Investor Relations and Corporate Communications, or by calling 609-452-9813, Ext. 120.



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**Shares**  
**Common Stock**

**PROSPECTUS SUPPLEMENT**

**Aegis Capital Corp**

April , 2014