

Advaxis, Inc.  
Form S-1/A  
September 27, 2013

As filed with the Securities and Exchange Commission on September 27, 2013

**Registration No. 333-188637**

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**AMENDMENT NO. 1  
TO  
FORM S-1  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

**ADVAXIS, INC.**

*(Exact name of registrant as specified in its charter)*

Delaware  
(State or other jurisdiction  
of incorporation or organization)

2836  
(Primary Standard Industrial  
Classification Code Number)

02-0563870  
(I.R.S. Employer  
Identification No.)

**305 College Road East  
Princeton, New Jersey 08540  
(609) 452-9813**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive office)

**Mr. Daniel J. O Connor  
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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after this Registration Statement is declared effective.

If any of the Securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act Registration Statement number of the earlier effective Registration Statement for the same offering:

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, please check the following box and list the Securities Act Registration Statement number of the earlier effective Registration Statement for the same offering:

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act Registration Statement number of the earlier effective Registration Statement for the same offering:

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Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Non-accelerated filer

(Do not check if smaller reporting company)

Accelerated filer

Smaller reporting company

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Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price <sup>(1)</sup>	Amount of Registration Fee <sup>(2)</sup>
Common Stock, \$0.001 par value per share <sup>(2)(3)</sup>	\$ 23,000,000	\$ 3137.20
Common Stock Purchase Warrants	\$ 23,000	\$ 3.14 (4)
Shares of Common Stock, \$0.001 par value per share, underlying Common Stock Purchase Warrants <sup>(2)(7)</sup>	\$ 14,375,000	\$ 1960.75
Representative's Common Stock Purchase Warrant		(5)
Shares of Common Stock underlying Representative's Common Stock Purchase Warrant <sup>(2)(6)</sup>	\$ 750,000	\$ 102.30
Total Registration Fee <sup>(8)</sup>	\$ 38,148,000	\$ 5,203.39

(1) Estimated solely for the purpose of calculating the amount of registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended (the Securities Act).

(2) Pursuant to Rule 416, under the Securities Act the securities being registered hereunder include such indeterminate number of additional shares of common stock as may be issued after the date hereof as a result of stock splits, stock dividends or similar transactions.

(3) Includes shares the underwriters have the option to purchase to cover over-allotments, if any.

(4) Estimated solely for purpose of calculating the registration fee pursuant to Rule 457(i) under the Securities Act.

(5) No registration fee required pursuant to Rule 457(g) under the Securities Act.

(6) Estimated solely for purpose of calculating the registration fee pursuant to Rule 457(g) under the Securities Act, based on an estimated proposed maximum aggregate offering price of \$750,000 or 125% of \$600,000 (3% of \$20,000,000).

(7) There will be issued a warrant to purchase one share of common stock for every two shares offered. The warrants are exercisable at a per share price equal to [125%] of the common stock public offering price.

(8) Filing fee of \$5,201.82 previously paid.

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to Section 8(a), may determine.**

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

**PRELIMINARY PROSPECTUS                      SUBJECT TO COMPLETION                      DATED SEPTEMBER 27, 2013**

**Shares of Common Stock**

**Warrants to Purchase                      Shares of Common Stock**

We are offering      shares of our common stock and warrants to purchase up to an aggregate of      shares of our common stock. The warrants will have a per share exercise price of \$      [[125%] of public offering price of the common stock]. The warrants are exercisable immediately and will expire [five] years from the date of issuance. On July 12, 2013, we effected a 1-for-125 reverse stock split of our issued and outstanding common stock.

Our common stock is traded on the OTCQB Marketplace, operated by the OTC Markets Group, under the symbol ADXS. We have applied to list our common stock and warrants on The NASDAQ Capital Market under the symbols ADXS and ADXSW, respectively. No assurance can be given that our application will be approved. On September 25, 2013, the last reported sale price for our common stock on the OTCQB Marketplace was \$6.60 per share.

**Our business and an investment in our securities involves a high degree of risk. See Risk Factors beginning on page 19 of this prospectus for a discussion of information that you should consider before investing in our securities.**

**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.**

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

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 107 of this prospectus for a description of compensation payable to the underwriters.

The underwriters may also purchase up to an additional      shares of common stock and      warrants from us at the public offering price, less the underwriting discount, within 45 days from the date of this prospectus to cover over-allotments, if any.

The underwriters expect to deliver the shares and warrants against payment therefor on or about , 2013.

## **Aegis Capital Corp**

, 2013

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You should rely only on the information contained in this prospectus or in any free writing prospectus that we may specifically authorize to be delivered or made available to you. We have not, and the underwriters have not, authorized anyone to provide you with any information other than that contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. 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 may only be used where it is legal to offer and sell our securities. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date. We are not, and the underwriters are not, making an offer of these securities in any jurisdiction where the offer is not permitted.

For investors outside the United States: We have not and the underwriters have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside the United States.

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## PROSPECTUS SUMMARY

*This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our securities, you should carefully read this entire prospectus, including our financial statements and the related notes and the information set forth under the headings Risk Factors and Management's Discussion and Analysis of Financial Condition and Results of Operations in each case included elsewhere in this prospectus. Unless otherwise stated or the context requires otherwise, references in this prospectus to Advaxis, we, us, or our refer to Advaxis, Inc.*

### Advaxis, Inc.

#### Business Overview

We are a clinical development stage biotechnology company focused on the discovery, development and commercialization of our proprietary *Lm*-LLO immunotherapies 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 Human Papilloma Virus-, or HPV-, associated diseases, 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 ongoing 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 June 2013, we submitted three requests for orphan drug designation to the U.S. Food and Drug Administration, or FDA, Office of Orphan Products Development, or OOPD, for ADXS-HPV in the treatment of invasive cervical cancer, head and neck cancer and anal cancer, and in August 2013 received notification that our anal cancer orphan drug designation request was granted. In addition, we plan to advance ADXS-PSA, which is an *Lm*-LLO immunotherapy directed against prostate-specific antigen, or PSA, our second *Lm*-LLO immunotherapy, into a Phase 1 trial to determine the maximum tolerated dose for the treatment of prostate cancer in the first half of 2014. We plan for this to be a dose escalation trial to evaluate safety and determine the maximum tolerated dose for the treatment of prostate cancer. A third *Lm*-LLO immunotherapy, ADXS-cHER2, is being evaluated for safety and efficacy in the treatment of companion dogs with human epidermal growth factor receptor-2, or HER2, over-expressing osteosarcoma.

We have a robust and extensive patent portfolio that protects our core technology, new constructs, inventions, and improvements. Our current patent portfolio includes 41 issued patents and 35 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

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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. We are exploring potential development and commercialization collaborations for certain drug 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 July 31, 2013 and October 31, 2012, we had an accumulated deficit of \$60,181,464 and \$47,601,427, respectively, and stockholders deficiency of \$6,726,819 and \$5,962,724, respectively.

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

Our immunotherapies are based on a platform technology under exclusive license from the University of Pennsylvania, or Penn, that utilizes live attenuated *Lm* bioengineered to secrete antigen/adjuvant fusion proteins within APC, to generate a strong T-cell immunity. 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. We refer to these as *Lm*-LLO immunotherapies. We believe these *Lm*-LLO immunotherapies redirect the potent immune response to *Lm* that is inherent in humans to the TAA or antigen of interest. In addition, our technology facilitates the immune response by altering the tumor microenvironment to reduce immunologic tolerance in the tumors but leave normal tissues unchanged. This makes the tumor more susceptible to immune attack.

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.

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.

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**Our Preclinical and Clinical Development Pipeline**

Our most advanced drug candidates in clinical development are ADXS-HPV, ADXS-PSA and ADXS-cHER2:

**ADXS-HPV.** ADXS-HPV is an *Lm*-LLO immunotherapy directed against HPV-associated cancers. ADXS-HPV directs the patient's own APC to generate a comprehensive immune response focused around creating cytotoxic T-cells that we believe may be capable of infiltrating the tumors and directly killing HPV-transformed cancer cells. At the same time, ADXS-HPV also causes a reduction in the number and function of immunosuppressive regulatory Tregs and myeloid-derived suppressor cells, or MDSC, that protect tumors by deactivating T-cells, thereby potentially enabling the cytotoxic T-cells to be effective at killing tumor cells within the tumor microenvironment. 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 also in early stage clinical trials for head and neck cancer and for 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.

**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, 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 and providing the rationale to advance into human clinical trials. We plan to meet with the U.S. Department of Agriculture, or USDA, 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.

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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***

We have completed dosing in *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 American Society of Clinical Oncology, or ASCO, annual meeting in June 2013, the trial completed enrollment and 110 patients received 264 doses of ADXS11-001. As of June 2013, the percentage of patients at 12 months was 36% (39/110) and at 18 months was 22% (16/73), which compares favorably with published reports cited by the National Comprehensive Cancer Network Guidelines and/or the Gynecological Oncology Group, or GOG, of historical 12 month survival of 0-22% with single agent therapies considered active in recurrent cervical cancer and suggests that ADXS-HPV is an active treatment in this disease. The study is expected to be completed in August 2013.

Survival results were not significantly different between treatment groups. Survival outcomes and tumor responses were not affected by Eastern Cooperative Oncology Group (or ECOG) performance status (0-2); type of prior therapy (radiation alone, chemotherapy alone, or a combination of both); or aggressiveness of disease (defined as recurrence  $\leq 2$  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 (33/65) had durable stable disease for at least 3 months as indicated by the orange dashed lines in the following waterfall plot. 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 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.

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***Lm-LLO-E7-15 Best Response Data***

**(as of May 17, 2013)**

ADXS-HPV continues to demonstrate a well-tolerated and manageable safety profile with 41% (45/110) of patients reporting predominately cytokine-release syndrome 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. Serious adverse events are defined as resulting in death, are life-threatening, cause significant disability or require inpatient hospitalization.

## **Business Strategy**

Our strategy is to maintain and fortify a leadership position in the discovery, acquisition and development of *Lm-LLO* immunotherapies that target for cancer and infectious disease. 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 registrational Phase 3 trials and regulatory approval in the United States and relevant markets for the treatment of cervical cancer. If successful, we plan to submit a Biologics 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 European Medicines Agency, or 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 for ADXS-HPV with the FDA and in August 2013 received notification that our anal cancer orphan drug designation request was granted. Orphan status is granted by the FDA to promote the development of products that demonstrate promise for the treatment of rare diseases affecting fewer

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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 for ADXS-HPV if it is approved by the FDA for the treatment of invasive cervical, head and neck and or anal cancer, 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 to determine the maximum tolerated dose for the treatment of patients with prostate cancer.

***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 drug 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 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.

***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

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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:

Complete our Phase 2 clinical study in India of ADXS-HPV in the treatment of recurrent cervical cancer, report final Phase 2 data at the Society for Immunotherapy of Cancer, or SITC, Annual Meeting, optimize the dose and schedule through additional Phase 1/2 trials and finalize the registration strategy;

Conduct an end of Phase 2 meeting with the FDA, draft Phase 3 protocols and submit a Special Protocols Assessment for ADXS-HPV;

Continue to support the Phase 2 clinical trial of ADXS-HPV in the treatment of advanced cervical cancer with the GOG, largely underwritten by the National Cancer Institute, or NCI;

Continue our collaboration with the Cancer Research, United Kingdom, or CRUK, to support the Phase 1/2 clinical trial of ADXS-HPV in the treatment of head and neck cancer, entirely underwritten by the CRUK;

Initiate an additional Phase 1/2 study in head and neck cancer for ADXS-HPV; seek to conduct Advisory Board with key opinion leaders;

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

Discuss development plan for ADXS-HPV in anal cancer with the FDA in light of Orphan Drug Designation; Obtain Orphan Drug Designation for two separate indications: the treatment of invasive cervical cancer and the treatment of HPV-positive head and neck cancer;

Continue our collaboration with the School of Veterinary Medicine at Penn to support the Phase 1/2 clinical trial of ADXS-cHER2 in canine osteosarcoma;

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

Continue the preclinical analyses and manufacturing activities required to support the IND submission for ADXS-PSA for the treatment of prostate cancer in preparation for a Phase 1 study;

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

Continue to actively pursue licensing discussions with multiple partners for our immunotherapies, execute definitive license agreement in strategic markets with high HPV prevalence consistent with already established commercial terms.

## **Risks**

We are a development stage company and have generated minimal revenues to date. Since our inception, we have incurred substantial losses. Our business and our ability to execute our business strategy are subject

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to a number of risks of which you should be aware before you decide to buy our securities. In particular, you should carefully consider the following risks, which are discussed more fully in Risk Factors beginning on page 19 of this prospectus.

We are a development stage company.

As a result of our current lack of financial liquidity and negative stockholders' equity, our auditors have expressed substantial concern about our ability to continue as a going concern.

We have significant indebtedness, which may restrict our business and operations, adversely affect our cash flow and restrict our future access to sufficient funding to finance desired growth.

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

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

Our research and development expenses are subject to uncertainty.

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

The successful development of immunotherapies is highly uncertain.

We must comply with significant government regulations.

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

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.

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

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.

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

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

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

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

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

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

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

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 price of our common stock and warrants may be volatile.

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

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

There is no assurance of an established public trading market.

We may not be able to achieve secondary trading of our stock in certain states because our common stock is not nationally traded.

Speculative nature of warrants.

If we fail to remain current on our reporting requirements, we could be removed from the OTCQB Marketplace, which would limit the ability of broker-dealers to sell our securities and the ability of stockholders 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.

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

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

The accounting treatment for our convertible securities and 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.

We do not intend to pay cash dividends.

If we sell shares of our common stock under our committed equity line financing facility, our existing stockholders will experience immediate dilution and, as a result, our stock price may go down.

If we are not able to satisfy the conditions to each draw down under the committed equity line financing facility, we will not be able to sell our common stock pursuant to the committed equity line financing facility.

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 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.

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.

On July 12, 2013, we effected a 1-for-125 reverse stock split of our outstanding common stock. However, the reverse stock split may not increase our stock price sufficiently and we may not be able to list our common stock and warrants on The NASDAQ Capital Market, in which case this offering may not be completed.

Even if the reverse stock split achieves the requisite increase in the market price of our common stock, we cannot assure you that we will be able to continue to comply with the minimum bid price requirement of The NASDAQ Capital Market.

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Even if the reverse stock split increases the market price of our common stock, there can be no assurance that we will be able to comply with other continued listing standards of The NASDAQ Capital Market.

The reverse stock split may decrease the liquidity of the shares of our common stock.

Following the reverse stock split, the resulting market price of our common stock may not attract new investors, including institutional investors, and may not satisfy the investing requirements of those investors. Consequently, the trading liquidity of our common stock may not improve.

## **Recent Developments**

### **Debt Conversion Agreements**

In September 2013, we entered into agreements with certain holders of our outstanding indebtedness to amend the terms of their existing arrangements and provide for repayment thereof or conversion into our securities, as follows:

*Moore Notes.* On September 26, 2013, we entered into a debt conversion and repayment agreement with Thomas A Moore, a Director of our company and our former Chief Executive Officer, with respect to the repayment and partial conversion of amounts owed 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 refer to these outstanding notes as the Moore Notes. As provided in the agreement, following the closing of this offering: (a) we will pay Mr. Moore \$100,000 in cash as partial repayment of the Moore Notes, (b) one-half of the remaining balance (approximately \$162,659) will automatically convert at the closing of this offering into restricted shares of our common stock and warrants at a conversion price equal to the public offer price in this offering, and (c) within three months of the closing of this offering, we will pay Mr. Moore in cash the then remaining outstanding balance under the Moore Notes (after taking into account the \$100,000 payment and automatic conversion in our securities). Following the cash payments and partial conversion into our securities, there will no longer be any outstanding balances under the Moore Notes and we will no longer have any obligations under the Moore Notes. Securities received by Mr. Moore upon conversion will be restricted securities and subject to customary lock-up restrictions.

*Redwood Bridge Notes.* On September 27, 2013, we entered into an exchange agreement with Redwood Management, LLC, with respect to the conversion of amounts owed to Redwood under that certain convertible promissory note with an aggregate principal amount of \$277,778 issued to Redwood in June 2013 in a bridge financing. We agreed to issue 125,000 restricted shares of our common stock to Redwood, in exchange for the convertible promissory note. Accordingly, we no longer have any outstanding obligations to Redwood under these bridge financing notes.

We are currently negotiating with the holders of approximately \$1,628,000 outstanding principal amount of convertible promissory notes to exchange those outstanding securities for shares of our common stock or new convertible promissory notes that have fixed (rather than variable) conversion prices. There can be no guarantee that we will be successful in agreeing to terms with such holders, and there is a risk that such indebtedness may continue to be outstanding following this offering.

### **Series B Preferred Redemption**

On September 26, 2013, we entered into a Notice of Redemption and Settlement Agreement with Optimus Capital Partners, LLC, a Delaware limited liability company, dba Optimus Life Sciences Capital Partners, LLC, Optimus CG II, Ltd., a Cayman Islands exempted Company and Socius CG II, Ltd., a Bermuda exempted Company, pursuant to which we agreed to redeem our outstanding shares of Series B Preferred Stock. Pursuant to the agreement, we agreed to cancel an outstanding receivable in the amount of \$10,633,584 as of the date of the agreement as payment in full of the redemption payment due under the terms of the Series B Preferred Stock and agreed to issue 33,750 shares of our

common stock to settle a disagreement regarding the calculation of the settlement amount under a July 2012 Order and Stipulation. In

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connection with the redemption, we agreed to cancel the outstanding warrant held by Optimus. Accordingly, following such redemption, there are no longer any shares of our Series B Preferred Stock issued and outstanding.

**JMJ Financial September 2013**

On September 4, 2013, in a private placement, we issued MJM Financial a convertible promissory note. The face amount of the note reflects an aggregate principal amount of \$800,000 for total consideration of \$720,000 (or a 10% original issue discount). However, we have currently only borrowed \$575,000 from MJM Financial under this convertible promissory note. MJM Financial paid us \$500,000 in cash as consideration for the note. We also issued MJM Financial 19,231 restricted shares of our common stock as a \$50,000 origination fee for this convertible promissory note. MJM Financial has no obligation to lend us the remaining \$220,000 of available principal amount under the note and may never do so. The convertible promissory note matures September 4, 2014 and, in addition to the 10% original issue discount, provides for payment of a one time interest charge of 5% on funded amounts. The convertible promissory note is convertible at any time, in whole or in part, at MJM Financial's option into shares of our common stock at the lesser of \$2.65 or 70% of the average of the lowest two closing prices in the 20-day pricing period preceding a conversion. However, at no time will MJM Financial be entitled to convert any portion of the note to the extent that after such conversion, MJM Financial (together with its affiliates) would beneficially own more than 4.99% of our outstanding shares common stock as of such date. We agreed to reserve at least 2,000,000 shares of our common stock for conversion of the note.

If we complete a public offering of \$5,000,000 or more, MJM Financial has the right, at its election, to require us to repay the note, in whole or in part, in amount equal to 125% of the sum of the funded principal amount being repaid plus all accrued and unpaid interest liquidated damages, fees, and other amounts due on such principal amount. Accordingly, MJM had the right to require repayment from the proceeds from this offering. In connection with the sale of this convertible promissory note to MJM Financial, MJM Financial agreed to amend the terms of its April 2013 note to eliminate its right to participate in our next public offering of securities, and we agreed that MJM Financial may require us to repay its April 2013 note, in whole or in part, if we complete a public offering of \$5,000,000 or more (down from \$10,000,000). Accordingly, MJM had the right to require repayment of the April 2013 note from the proceeds from this offering. Although we are currently negotiating with MJM Financial to exchange these April 2013 and September 2013 notes for shares of our common stock or new notes without variable conversion rate terms and waive any right to repayment out of the proceeds of this offering, there is no guarantee that MJM Financial will agree to any such exchange or waiver.

**Sale of Notes Collateralized by NOLs and R&D Tax Credits**

On August 20, 2013, in a private placement pursuant to a note purchase agreement, we issued an accredited investor a secured convertible promissory note in the aggregate principal amount of \$108,000, for a purchase price of \$100,000. On September 18, 2013, we borrowed an additional \$150,000 from this accredited investor and amended and restated the terms of the August note and issued this investor 12,000 shares of our common stock. As amended and restated, this note has an aggregate principal amount of \$258,000, bears interest at a rate of 20% per annum and is due February 21, 2014, nine months after its original issuance date. To secure prompt payment under the note, we granted the holder a continuing security interest in all net proceeds we receive up to the aggregate amount of \$258,000 plus accrued interest from the sale of our net operating loss and or research and development tax credits through the New Jersey Economic Development Program. We may prepay the note at any time, however, if we pay the note prior to receiving the proceeds from such sales through the New Jersey Economic Development Program, we agreed to pay the sum of \$295,200.

### **Termination of Engagement Agreement**

On August 19, 2013, we entered into an agreement with a financial advisor to terminate a July 2012 engagement agreement between the parties, pursuant to which the advisor 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 the advisor 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

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exercise price of \$4.90 per share. Additionally, we agreed to pay the advisor 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.

### **New Chief Executive Officer and New Chairman of the Board**

At a meeting of the Board held on August 14, 2013, Thomas A. Moore indicated his intent to resign as our Chairman of the Board and President and Chief Executive Officer, or CEO, effective August 19, 2013 in line with the previously contemplated succession plan. Mr. Moore will continue to serve on the Board and will act as a consultant to us. In light of Mr. Moore's notification to the Board of his intent to resign as President and CEO and the Board's succession plan, the Board appointed Daniel J. O'Connor (formerly Executive Vice President), to the position of President and CEO, effective August 19, 2013. Mr. O'Connor's appointment as President and CEO is the outcome of the succession planning initiatives over the past year by Mr. Moore and the Board. The Board also fixed the number of Board members at seven and appointed Mr. O'Connor as a Director to fill the newly created vacancy in accordance with our bylaws, all effective August 19, 2013. Mr. O'Connor will hold office as a Director until our next annual meeting of stockholders, subject to his earlier resignation or removal. Mr. O'Connor has not currently been appointed to any standing committee of the Board. Dr. James Patton, Chairman of the Audit Committee, was elected to serve as Non-Executive Chairman of the Board effective August 19, 2013. We have entered into an employment agreement with Mr. O'Connor and a consulting agreement with Mr. Moore, which both took effect on August 19, 2013. For a description of the agreements, see Management Summary Compensation Table Discussion of Summary Compensation Table.

### **Orphan Drug Designation**

In August 2013, the FDA granted our orphan drug designation request for ADXS-HPV for anal cancer.

### **Reverse Stock Split and Share Capital Decrease**

In July 2013, we amended our Amended and Restated Certificate of Incorporation by the filing of two Certificates of Amendment with the Delaware Secretary of State as follows: (a) on July 11, 2013, to effect a 1-for-125 reverse stock split of our common stock, par value \$0.001 per share, to take effect on July 12, 2013 at 4:30 p.m. EDT, and (b) on July 12, 2013, to decrease the total number of authorized shares of our common stock on a post-reverse stock split basis, so that the total number of shares that we have the authority to issue is 30,000,000 shares, of which 25,000,000 shares are common stock and 5,000,000 shares are blank check preferred stock. The reverse stock split was effective at approximately 4:30 p.m. EDT on July 12, 2013, and the share capital decrease took effect thereafter upon filing with the Delaware Secretary of State.

### **Yenson Company, Ltd. MOU**

In April 2013, we signed a memorandum of understanding with FusionVax, which was subsequently re-executed between us and Yenson Company, Ltd., or Yenson. The memorandum of understanding sets out the framework for entry into a definitive agreement to license ADXS-HPV for commercialization in Asia (except India). Under the terms of the memorandum of understanding, we agreed to work towards drafting a definitive agreement that exclusively licenses the rights to ADXS-HPV to Yenson (or NewCo) for the Asia territory, exclusive of India, for all indications. Subject to the entry into a definitive agreement, Yenson will pay us an up-front payment, certain event-based financial milestones, an annual exclusive licensing fee, and an annual net sales royalty in countries with issued patents. In

exchange for the up-front payment, we will provide Yenson an equal amount worth of our common stock. Yenson will be responsible for conducting clinical trials and pursuing commercialization of ADXS-HPV in Asia and, in exchange, we will pay Yenson net sales annual royalty on ADXS-HPV in the United States of less than 1%. Yenson, accompanied with Taiwan Biotech Co., Ltd. and several Taiwanese venture capital funds plan to form a new company (NewCo) and transfer all rights to the NewCo to execute the obligations and commitments described in the memorandum of understanding. On August 28, 2013, we entered into a Securities Purchase Agreement with Yenson, pursuant to which we issued Yenson 45,353 shares of our common stock and a 3-year warrant to acquire 22,161 shares of our common stock at an exercise price of \$2.76 per share for \$100,000 in cash.

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## **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

### Securities offered by us

shares of common stock and warrants to purchase up to an aggregate of shares of common stock.

### Common stock to be outstanding immediately after this offering

shares of common stock ( if the warrants are exercised in full). If the underwriter's over-allotment option is exercised in full, the total number of shares of common stock outstanding immediately after this offering would be ( if the warrants are exercised in full).

### Description of Warrants

The warrants will have a per share exercise price equal to \$ [[125%] of public offering price of the common stock]. The warrants are exercisable immediately and expire five years from the date of issuance.

### Use of proceeds

We intend to use the net proceeds received from this offering to fund our research and development activities and for working capital and general corporate purposes. We also intend to use \$100,000 of the proceeds to make a required payment under the terms of our sublease as modified (see Business Description of Property ), further use approximately \$185,000 for payment under the terms of a settlement agreement with Vibalogics GmbH for overdue balances (see Business Collaborations, Partnerships and Agreements Vibalogics GmbH ), use \$150,000 for payments due under an engagement agreement termination agreement, use \$100,000 as partial payment of our outstanding obligations to our Director, Mr. Moore, under the Moore Notes (as defined elsewhere in this prospectus) and use approximately \$495,000 to repay outstanding indebtedness. See Use of Proceeds on page 38.

### Risk factors

See Risk Factors beginning on page 19 and the other information included in this prospectus for a discussion of factors you should carefully consider before investing in our securities.

### OTCQB Marketplace trading symbol

ADXS

### Proposed Symbol and Listing

We have applied to list our common stock and warrants on The NASDAQ Capital Market under the symbols ADXS and ADXSW, respectively.

Unless we indicate otherwise, all information in this prospectus:

reflects a 1-for-125 reverse stock split of our issued and outstanding shares of common stock, options and warrants effected on July 12, 2013 and the corresponding adjustment of all common stock prices per share and stock option and warrant exercise prices per share;

is based on 5,534,596 shares of common stock issued and outstanding as of September 27, 2013; excludes 125,000 shares of common stock issuable upon conversion of \$277,778 in outstanding principal amount of convertible promissory notes and accrued interest thereon, which the holders have agreed to convert to common stock.

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excludes 24,645 shares of common stock issuable upon conversion of approximately \$162,659 in outstanding debt and accrued interest thereon (assuming an offer price of \$6.60 per share, the closing price on September 25, 2013) which the holder has agreed to convert to common stock and warrants at a conversion price equal to the offering price upon the closing of this offering but does not include 12,333 shares of common stock underlying these warrants. assumes no exercise by the underwriters of their option to purchase up to an additional    shares of common stock and warrants to cover over-allotments, if any.

excludes 123,804 shares of common stock issuable upon conversion of outstanding warrants to purchase shares of our common stock exercisable at approximately \$15.11 per share and are subject to weighted-average anti-dilution protection upon certain equity issuances below \$15.11 per share (as may be further adjusted as defined in the warrant) as of September 27, 2013;

excludes 624,025 shares of our common stock issuable upon exercise of outstanding warrants at a weighted average exercise price of \$14.78 per share as of September 27, 2013;

excludes 467,923 shares of our common stock issuable upon exercise of outstanding stock options under our stock incentive plans at a weighted average exercise price of \$20.00 per share as of September 27, 2013;

excludes 737,422 shares of common stock issuable upon conversion of outstanding convertible promissory notes in the aggregate principal amount of approximately \$1,628,000 at their current conversion prices as of September 27, 2013;

excludes 32,425 shares of common stock earned but not yet issued to our Chief Executive Officer; and excludes shares of common stock underlying the warrants to be issued to the underwriters in connection with this offering.

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TABLE OF CONTENTS**SUMMARY FINANCIAL DATA**

The following table sets forth our summary statement of operations data for the fiscal years ended October 31, 2012 and 2011 derived from our audited financial statements and related notes included elsewhere in this prospectus. The summary financial data for the nine months ended July 31, 2013 and 2012, and as of July 31, 2013, are derived from our unaudited financial statements appearing elsewhere in this prospectus and are not indicative of results to be expected for the full year. Our financial statements are prepared and presented in accordance with generally accepted accounting principles in the United States. The results indicated below are not necessarily indicative of our future performance. You should read this information together with the sections entitled Capitalization, Management Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes included elsewhere in this prospectus.

	Nine Months Ended July 31,		Year Ended October 31,	
	2013	2012	2012	2011
	\$	\$	\$	\$
Revenue				
<u>Operating Expenses</u>				
Research and Development Expenses	4,411,793	5,760,158	6,646,094	8,078,901
General and Administrative Expenses	6,299,670	4,297,110	5,688,677	4,939,935
Total Operating expenses	10,711,463	10,057,268	12,334,771	13,018,836
Loss from Operations	(10,711,463)	(10,057,268)	(12,334,771)	(13,018,836)
Other Income (expense):				
Interest expense	(600,004 )	(4,241,805 )	(4,536,528 )	(4,698,983 )
Other Income (expense)	(15,926 )	25,715	12,002	(78,911 )
(Loss) Gain on note retirement	349,009	(2,173,491 )	(2,187,787 )	(461,595 )
Net changes in fair value of common stock warrant liability and embedded derivative liability	(2,326,843 )	6,020,434	6,630,610	9,763,113
Net Loss before benefit for income taxes	(13,305,227)	(10,426,415)	(12,416,474)	(8,495,212 )
Income tax benefit	725,190	346,787	346,787	379,472
Net Loss	(12,580,037)	(10,079,628)	(12,069,687)	(8,115,740 )
Dividends attributable to preferred shares	555,000	555,000	740,000	1,538,686
Net Loss applicable to Common Stock	\$(13,135,037)	\$(10,634,628)	\$(12,809,687)	\$(9,654,426 )
Net Loss per share, basic and diluted	\$(3.13 )	\$(4.45 )	\$(4.99 )	\$(5.41 )
Weighted average number of shares outstanding, basic and diluted	4,190,062	2,387,443	2,564,819	1,783,348

As of July 31, 2013

	Actual	Pro Forma, As Adjusted <sup>(1)</sup>
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## Balance Sheet Data:

Cash and cash equivalents	\$40	\$17,177,288
Total assets	4,363,383	21,543,613
Total liabilities	11,090,202	10,196,488
Total shareholders (deficiency)	(6,726,819)	11,632,907

Pro forma, as adjusted amounts give effect to (i) the issuance of common stock, warrants and convertible notes from August 1, 2013 through and immediately prior to the date of this offering, (ii) the conversion of approximately \$899,722 in aggregate principal amount of promissory notes, together with all interest accrued and unpaid thereon through the date of conversion into 407,478 shares of our common stock, (iii) the conversion of (1) \$162,659 in aggregate principal amount of convertible promissory notes, together with all interest accrued and unpaid thereon through the date of conversion into 24,645 shares of our common stock and warrants to purchase 12,323 shares of our common stock with the same terms as the warrants offered in this offering upon completion of this offering at the assumed public offering price of \$6.60 per share (the closing price on September 25, 2013) and \$0.01 per warrant, (iv) the redemption of our outstanding shares of Series B Preferred Stock and cancellation of an underlying receivable; (v) a

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one-time charge to earnings of approximately \$247,250 that will occur immediately upon the completion of this offering for employee bonuses that are payable upon the closing of this offering, 50% of which will be paid in restricted stock units and the resulting reduction in cash on our pro forma balance sheet of approximately \$124,000, (vi) the sale of 3,030,303 shares and warrants to acquire 1,515,152 shares in this offering at the assumed public offering price of \$6.60 per share (the closing price on September 25, 2013) and \$.01 per warrant, (vii) the repayment of approximately \$596,000 in other convertible notes payable and accrued interest from the net proceeds received in this offering and repayment of contractual obligations of approximately \$435,000 (viii) after deducting underwriting discounts and commissions and other estimated offering expenses payable by us.

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## **RISK FACTORS**

*Any investment in our securities involves a high degree of risk. Investors should carefully consider the risks described below and all of the information contained in this prospectus before deciding whether to purchase our common stock and warrants. Our business, financial condition or results of operations could be materially adversely affected by these risks if any of them actually occur. This prospectus also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks we face as described below and elsewhere in this prospectus.*

### **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 July 31, 2013 we had an accumulated deficit of \$60,181,464 and stockholders' deficiency of \$6,726,819. 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.

#### **As a result of our current lack of financial liquidity and negative stockholders equity, our auditors have expressed substantial concern about our ability to continue as a going concern.**

Our limited capital resources and operations to date have been funded primarily with the proceeds from public and private equity and debt financings, as well as state net operating losses, or NOLs, and research tax credits and income earned on investments and grants. Based on our currently available cash, we do not have adequate cash on hand to cover our anticipated expenses for the next 12 months. If we fail to raise a significant amount of capital, we may need to significantly curtail operations, cease operations or seek federal bankruptcy protection in the near future. In addition, from time to time, we may be unable to make payroll due to our lack of cash. These conditions have caused our auditors to raise substantial doubt about our ability to continue as a going concern. Consequently, the audit report prepared by our independent public accounting firm relating to our financial statements for the year ended October 31, 2012 included a going concern explanatory paragraph.

**We have significant indebtedness, which may restrict our business and operations, adversely affect our cash flow and restrict our future access to sufficient funding to finance desired growth.**

As of July 31, 2013, the total outstanding principal and interest of our indebtedness was approximately \$2.4 million, including notes outstanding to our former Chief Executive Officer in the amount of approximately \$0.4 million. Certain of our indebtedness contain restrictive covenants that limit our ability to issue certain types of indebtedness, which may prevent us from obtaining additional indebtedness on commercially reasonable terms, or at all. If we are not able to service our debt, we will need to refinance all or part of that debt, sell assets, borrow more money or sell securities, which we may not be able to do on commercially reasonable terms, or at all. The terms of our notes include customary events of default and covenants that restrict our ability to incur additional indebtedness. These restrictions and covenants may prevent us from engaging in transactions that might otherwise be considered beneficial to us. A breach of the provisions of our indebtedness could result in an event of default under our outstanding notes. If an event of

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default occurs under our notes (after any applicable notice and cure periods), the holders will be entitled to accelerate the repayment of amounts outstanding, plus accrued and unpaid interest. In the event of a default under our senior indebtedness, the holders could also foreclose against the assets securing such obligations. In the event of a foreclosure on all or substantially all of our assets, we may not be able to continue to operate as a going concern.

**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 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.

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 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

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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;
- 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.

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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;  
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

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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 Statute 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 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

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

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.

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

Although we requested orphan drug designation for ADXS-HPV for use in the treatment of invasive cervical cancer and head and neck cancer in the United States, have been granted orphan drug designation for ADXS-HPV for use in anal 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 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 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 41 patents that have been issued and 35 patent applications that are pending. We have licensed all of these patents and 24 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. Further, we rely on a combination of trade secrets and nondisclosure, and other contractual agreements and technical measures to protect our rights in the technology. We depend upon confidentiality agreements with our officers, employees, consultants, and subcontractors to maintain the proprietary nature of the technology. These measures may not afford us sufficient or complete protection, and others may independently develop technology similar to ours, otherwise avoid the confidentiality agreements, or produce patents that would materially and adversely affect our business, prospects, financial condition, and results of operations. Such competitive events, technologies and patents may limit our ability to raise funds, prevent other companies from collaborating with us, and in certain cases prevent us from further developing our technology due to third party patent blocking rights.

Although we have successfully defended our intellectual property concerning our *Listeria*-based technology in challenges to our patents, there can be no guarantees that we will be successful in the future in similar challenges or that other patents or intellectual property in our portfolio will not be challenged. If we are not successful in defending

our intellectual property, it would have a material adverse effect on our business, financial condition and results of operations.

**We are dependent upon our license agreement with Penn; if we 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

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pay various milestone, legal, filing and licensing payments to commercialize the technology. As of July 31, 2013, we owed Penn approximately \$460,000 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 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. As of September 27, 2013, we have overdue balances with Vibalogics GmbH in the amount of approximately \$185,000.

**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

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

**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

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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 September 27, 2013, we had 14 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. Even if we have the financial resources to expand our operations and staff following completion of this offering, 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.

**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. For a more detailed description of our consulting agreements, see Business Collaborations, Partnerships and Agreements beginning on page 70 of this prospectus.

**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

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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 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.

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

### **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 after this offering 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;

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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 Stock 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.

**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.



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Although one reason we asked our stockholders 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, and our stock closed at \$6.60 per share on September 25, 2013, 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 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.

**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 OTCQB 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 stockholders 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. In addition, there is no established trading market for the warrants being offered in this offering. Although, we applied for listing of our common stock and warrants on The NASDAQ Stock Market, no assurance can be given that our application will be approved, or that, if the application is approved, the price of our common stock will be less volatile, or that the price of the warrants will not be volatile.

**There is no assurance of an established public trading market.**

Our common stock began trading on the over-the-counter-markets on July 28, 2005 and is quoted under the symbol ADXS. The OTCQB Marketplace, where our common stock currently is quoted, is an inter-dealer, over-the-counter market that provides significantly less liquidity than The NASDAQ Stock Market. Quotes for stocks included on the OTCQB Marketplace are not listed in the financial sections of newspapers. As such, investors and potential investors may find it difficult to obtain accurate stock price quotations, and holders of our common stock and warrants may be unable to resell their securities at or near their original offering price or at any price. 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;

A DTC Chill on the electronic clearing of trades in our securities in the future may affect the liquidity of 55r stock

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;

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investor perceptions of our company and the technologies industries generally; and  
general economic and other national conditions.

Although, we have applied for listing of our common stock and warrants on The NASDAQ Stock Market, no assurance can be given that our application will be approved.

**We may not be able to achieve secondary trading of our stock in certain states because our common stock is not nationally traded.**

Because our common stock is not listed for trading on a national securities exchange, our common stock is subject to the securities laws of the various states and jurisdictions of the United States in addition to federal securities law. This regulation covers any primary offering we might attempt and all secondary trading by our stockholders. If we fail to take appropriate steps to register our common stock or qualify for exemptions for our common stock in certain states or jurisdictions of the United States, the investors in those jurisdictions where we have not taken such steps may not be allowed to purchase our stock or those who presently hold our stock may not be able to resell their shares without substantial effort and expense. These restrictions and potential costs could be significant burdens on our stockholders.

Although, we intend to apply for listing of our common stock and warrants on The NASDAQ Stock Market, no assurance can be given that our application will be approved.

**Speculative nature of warrants.**

The warrants 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. Specifically, commencing on the date of issuance, holders of the warrants may exercise their right to acquire the common stock and pay an exercise price of \$      per share [125%] of public offering price of the common stock], prior to five years from the date of issuance, after which date any unexercised warrants will expire and have no further value. Moreover, following this offering, 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 public offering 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 reporting requirements, we could be removed from the over-the-counter markets, which would limit the ability of broker-dealers to sell our securities and the ability of stockholders to sell their securities in the secondary market. In addition, it would be an event of default under certain of our outstanding notes.**

Companies trading on the OTCQB Marketplace, such as our company, must be reporting issuers under Section 12 of the Exchange Act, as amended, and must be current in their reports under Section 13, in order to maintain price quotation privileges. For our third quarter 2012, we were unable to file our respective quarterly report on Form 10-Q in a timely manner, but we were able to make the filings and cure our compliance deficiencies within the grace period allowed by the OTCQB Marketplace. If we fail to remain current on our reporting requirements, we could be removed from the over-the-counter markets. As a result, 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 stockholders to sell their securities in the secondary market. In addition, the terms of certain of our outstanding debt instruments require that we remain current in our reporting obligations. If we were to fail to remain current, it could be an event of default under certain of our outstanding notes, which could have a material adverse effect on our company.

We may not be able to achieve secondary trading of our stock in certain states because our common stock is not na

**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, 2012, our chief executive officer and chief financial

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officer concluded that our disclosure controls and procedures and internal control over financial reporting were 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 stockholders 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 September 27, 2013, we had 5,534,596 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 September 27, 2013, warrants to purchase 123,804 shares of our common stock are exercisable at approximately \$15.11 per share and are subject to weighted-average anti-dilution protection upon certain equity issuances below \$15.11 per share (as may be further adjusted as defined in the warrant). In addition, as of September 27, 2013, we had outstanding options to purchase 467,923 shares of our common stock at a weighted average exercise price of approximately \$17.50 per share and outstanding warrants to purchase 747,829 shares of our common stock (including the above warrants subject to weighted-average anti-dilution protection); and approximately 35,632 shares of our common stock are 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. As of the date hereof, after taking into account such agreements and the planned use of proceeds, we will have approximately \$1,628,000 outstanding aggregate principal amount of convertible promissory notes with variable conversion prices, which would be convertible into approximately 737,422 shares of our common stock based on the current conversion price under such notes. However, because such notes have variable conversion rates, the amount of shares issuable could increase or decrease.

**The accounting treatment for our convertible securities and certain of our warrants is complex and subject to judgments concerning the valuation of embedded derivative rights within the applicable securities. Fluctuations in**

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

**the valuation of these rights could cause us to take charges to our earnings and make our financial results unpredictable.**

Our outstanding convertible promissory notes and 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

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Model and a subject to revaluation at each reporting date. Any change in fair value between reporting periods is reported on our statement of operations. At July 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 nine months ended July 31, 2013 and 2012, we reported loss of approximately \$0 in each period due to changes in the fair value of the embedded derivative liability partially resulting from debt to equity exchanges during the period. For the twelve months ended October 31, 2012 and October 31, 2011, we reported income of approximately \$400,000 and approximately \$1.9 million, 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 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. In addition, the terms of our Series B Preferred Stock prohibit the payment of dividends on our common stock for so long as any shares of our Series B Preferred Stock are outstanding.

**If we sell shares of our common stock under our committed equity line financing facility, our existing stockholders will experience immediate dilution and, as a result, our stock price may go down.**

On October 19, 2012, we entered into a committed equity line financing facility, or financing arrangement, under which we may sell up to \$10.0 million of our common stock to Hanover over a 24-month period subject to a maximum of 920,000 shares of our common stock. In connection with such financing arrangement, we issued 28,000 shares of common stock to Hanover upon receipt of their commitment to purchase our common stock in the financing arrangement and we agreed to pay up to 14,400 additional shares of our common stock to Hanover to maintain such financing arrangement for the 24-month term, which together with the other 877,600 shares of our common stock, represents approximately 18% of our outstanding shares of our common stock as of September 27, 2013. The issuance of such shares of our common stock to Hanover will have an immediately dilutive impact on our existing stockholders.

Hanover may resell some or all of the shares we issue to them pursuant to the financing arrangement and such sales could cause the market price of our common stock to decline significantly with advances under the financing arrangement. To the extent of any such decline, any subsequent advances would require us to issue a greater number of shares of common stock to Hanover in exchange for each dollar of the advance. Under these circumstances, our existing stockholders would experience greater dilution and the total amount of financing that we will be able to raise pursuant to the financing arrangement could be significantly lower than \$10.0 million. Although Hanover is precluded from short sales of shares acquired pursuant to advances under the financing arrangement, the sale of our common stock under the financing arrangement could encourage short sales by third parties, which could contribute to the

further decline of our stock price.

**If we are not able to satisfy the conditions to each draw down under the committed equity line financing facility, we will not be able to sell our common stock pursuant to the committed equity line financing facility.**

Our ability to sell securities pursuant to the committed equity line financing facility is subject to conditions to each draw down notice that we present to Hanover requiring Hanover to purchase a specified number of shares of our common stock, which we refer to in this prospectus as a draw down, that must be satisfied prior to the closing of any sale of our common stock pursuant to such draw down. These include, among others:

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accuracy in all material respects of our representations and warranties (except for such representations and warranties qualified by materiality, which shall be accurate in all respects) and our compliance with covenants in all material respects (including, without limitation, our prior delivery to Hanover of any commitment fee shares or maintenance fee shares to be issued to Hanover pursuant to the Purchase Agreement);

a resale registration statement with respect to shares of our common stock to be purchased by Hanover in such draw down must have been declared effective by the SEC and must be available for resale of such shares of our common stock by Hanover;

no material adverse effect on us shall have occurred or be continuing;

all the material filings by us required under the Securities Exchange Act of 1934, as amended, or the Exchange Act, shall have been filed with the SEC; and

the number of shares of our common stock in such draw down shall not exceed:

• 300% of the average trading volume of our common stock during the 10 trading day period prior to such draw down date;

• together with the shares of our common stock in all prior draw downs, \$10 million of the shares of our common stock; or

• such number of shares of our common stock that would result in Hanover beneficially owning more than 9.99% of our common stock after giving effect to such draw down.

We may not be able to satisfy these conditions and/or the other conditions to a draw down under the committed equity line financing facility. If we are unable to satisfy such conditions, we will not be able to sell any of our common stock pursuant to the committed equity line financing facility.

**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 stockholders. 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 stockholders.

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. Our Board of Directors has designated 1,000 shares as Series A, none of which are outstanding, and 2,500 shares as Series B, 740 shares of which are currently outstanding. 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 stockholder might consider favorable. Such provisions may also prevent or frustrate attempts by our stockholders 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 stockholder 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 stockholder, which is

If we are not able to satisfy the conditions to each draw down under the committed equity line financing facility, we w

generally defined as a stockholder 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 stockholder became an interested stockholder.

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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.

**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 research and development activities and for working capital and general corporate purposes and repayment of certain debt (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 up to shares of common stock and warrants to purchase up to an aggregate of shares of common stock offered in this offering at a public offering price of \$ per share and \$ per warrant, and after deducting the underwriter's discount and estimated offering expenses payable by us, 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.

**Risks Related to Our Reverse Stock Split**

**On July 12, 2013, we effected a 1-for-125 reverse stock split of our outstanding common stock prior to this offering. However, the reverse stock split may not increase our stock price sufficiently and we may not be able to list our common stock and warrants on The NASDAQ Capital Market, in which case this offering may not be completed.**

We expect that the reverse stock split of our outstanding common stock will increase the market price of our common stock so that we will be able to meet the minimum bid price requirement of the Listing Rules of The NASDAQ Capital Market. However, the effect of a reverse stock split upon the market price of our common stock cannot be predicted with certainty, and the results of reverse stock splits by companies in similar circumstances have been varied. It is possible that the market price of our common stock following the reverse stock split will not increase

Our management will have broad discretion over the use of the net proceeds from this offering and we may use the

sufficiently for us to be in compliance with the minimum bid price requirement, or if it does, that such price will be sustained. If we are unable meet the minimum bid price requirement, we may be unable to list our shares and warrants on The NASDAQ Capital Market, in which case this offering may not be completed.

**Even if the reverse stock split achieves the requisite increase in the market price of our common stock, we cannot assure you that we will be able to continue to comply with the minimum bid price requirement of The NASDAQ Capital Market.**

Even if the reverse stock split achieves the requisite increase in the market price of our common stock to be in compliance with the minimum bid price of The NASDAQ Capital Market, there can be no assurance that the market price of our common stock following the reverse stock split will remain at the level required for continuing compliance with that requirement. It is not uncommon for the market price of a company's common stock to decline in the period following a reverse stock split. If the market price of our common stock declines following the effectuation of a reverse stock split, the percentage decline may be greater than

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would occur in the absence of a reverse stock split. In any event, other factors unrelated to the number of shares of our common stock outstanding, such as negative financial or operational results, could adversely affect the market price of our common stock and jeopardize our ability to meet or maintain The NASDAQ Capital Market's minimum bid price requirement. In addition to specific listing and maintenance standards, The NASDAQ Capital Market has broad discretionary authority over the initial and continued listing of securities, which it could exercise with respect to the listing of our common stock.

**Even if the reverse stock split increases the market price of our common stock, there can be no assurance that we will be able to comply with other continued listing standards of The NASDAQ Capital Market.**

Even if the market price of our common stock increases sufficiently so that we comply with the minimum bid price requirement, we cannot assure you that we will be able to comply with the other standards that we are required to meet in order to maintain a listing of our common stock on The NASDAQ Capital Market. Our failure to meet these requirements may result in our common stock being delisted from The NASDAQ Capital Market, irrespective of our compliance with the minimum bid price requirement.

**The reverse stock split may decrease the liquidity of the shares of our common stock.**

The liquidity of the shares of our common stock may be affected adversely by the reverse stock split given the reduced number of shares that will be outstanding following the reverse stock split, especially if the market price of our common stock does not increase as a result of the reverse stock split. In addition, the reverse stock split may increase the number of stockholders who own odd lots (less than 100 shares) of our common stock, creating the potential for such stockholders to experience an increase in the cost of selling their shares and greater difficulty effecting such sales.

**Following the reverse stock split, the resulting market price of our common stock may not attract new investors, including institutional investors, and may not satisfy the investing requirements of those investors. Consequently, the trading liquidity of our common stock may not improve.**

Although we believe that a higher market price of our common stock may help generate greater or broader investor interest, there can be no assurance that the reverse stock split will result in a share price that will attract new investors, including institutional investors. In addition, there can be no assurance that the market price of our common stock will satisfy the investing requirements of those investors. As a result, the trading liquidity of our common stock may not necessarily improve.

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## **CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA**

This prospectus contains forward-looking statements. Such forward-looking statements include those that express plans, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. These forward-looking statements are based on our current expectations and projections about future events and they are subject to risks and uncertainties known and unknown that could cause actual results and developments to differ materially from those expressed or implied in such statements.

In some cases, you can identify forward-looking statements by terminology, such as expects, anticipates, intends, estimates, plans, believes, seeks, may, should, could, continue, project or the negative of such terms and other expressions. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this prospectus.

You should read this prospectus and the documents that we reference herein and therein and have filed as exhibits to the registration statement, of which this prospectus is part, completely and with the understanding that our actual future results may be materially different from what we expect. You should assume that the information appearing in this prospectus is accurate as of the date on the front cover of this prospectus only. Because the risk factors referred to above could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statements.

These risks and uncertainties, along with others, are described above under the heading Risk Factors. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We qualify all of the information presented in this prospectus, and particularly our forward-looking statements, by these cautionary statements.

This prospectus also includes industry data that we obtained from industry publications and surveys and internal company sources. The industry publications and industry data contained in this prospectus have been obtained from sources believed to be reliable.

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## **USE OF PROCEEDS**

We estimate that our net proceeds from the sale of the common stock and warrants offered pursuant to this prospectus will be approximately \$18.0 million, or approximately \$20.8 million if the underwriters exercise in full their option to purchase additional shares of common stock and additional warrants, assuming a public offering price of \$6.60 per share of common stock, which is based on the closing price of the our common stock on September 25, 2013, and an assumed public offering price of \$0.01 per warrant, and after deducting the underwriting discount and the estimated offering expenses that are payable by us.

We currently intend use the net proceeds from this offering to fund our research and development activities and for working capital and general corporate purposes. We also intend to use \$100,000 of the proceeds to make a required payment under the terms of our sublease as modified (see Business Description of Property ), use approximately \$185,000 for payment under the terms of a settlement agreement with Vibalogics GmbH for overdue balances (see Business Collaborations, Partnerships and Agreements Vibalogics GmbH ), use \$150,000 for payments due under the terms of a settlement agreement with a former advisor, and use \$100,000 as partial payment of our outstanding obligations to our Director, Mr. Moore, under the Moore Notes (as defined elsewhere in this prospectus).

In addition, we intend to use approximately \$62,000 of the proceeds from this offering to pay overdue debt that matured in 2011 and includes an original issue discount of 10%, and approximately \$433,000 to repay convertible promissory notes issued in May and July 2013, which each bear interest at a rate of 8% per annum and mature February and April 2014, respectively. We used the proceeds from these notes for working capital.

Other than described above, we have not yet determined the amount of the remaining net proceeds to be used specifically for any purposes. Accordingly, our management will have significant discretion and flexibility in applying the majority of 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.

TABLE OF CONTENTS**PRICE RANGE OF COMMON STOCK**

Our common stock has been quoted on the OTC Bulletin Board under the symbol ADXS.OB since July 28, 2005. Currently, our common stock is also traded on the OTCQB Market place, a new market for OTC-traded companies that are registered and current in their reporting obligations to the SEC or a U.S. banking or insurance regulator. The following table shows the reported high and low closing bid quotations per share for our common stock based on information provided by the OTCQB Marketplace. Such over-the-counter market quotations reflect inter-dealer prices, without markup, markdown or commissions and, particularly because our common stock is traded infrequently, may not necessarily represent actual transactions or a liquid trading market. These prices reflect the 1-for-125 reverse stock split effected on July 12, 2013 as well as rounding. Prior to this offering, there was no trading market for the warrants.

Fiscal 2013	High	Low
Fourth Quarter (August 1, 2013 through September 25, 2013)	\$ 7.96	\$ 2.70
Third Quarter (May 1, 2013 July 31, 2013)	\$ 7.50	\$ 3.18
Second Quarter (February 1, 2013 April 30, 2013)	\$ 17.50	\$ 8.75
First Quarter (November 1, 2012 January 31, 2013)	\$ 8.75	\$ 3.75

Fiscal 2012	High	Low
Fourth Quarter (August 1, 2012 October 31, 2012)	\$ 10.00	\$ 5.00
Third Quarter (May 1, 2012 July 31, 2012)	\$ 17.50	\$ 8.75
Second Quarter (February 7, 2012 April 30, 2012)	\$ 18.75	\$ 13.75
First Quarter (November 1, 2011 January 31, 2012)	\$ 22.50	\$ 18.75

Fiscal 2011	High	Low
Fourth Quarter (August 1, 2011 October 31, 2011)	\$ 20.00	\$ 16.25
Third Quarter (May 1, 2011 July 31, 2011)	\$ 30.00	\$ 17.50
Second Quarter (February 7, 2011 April 30, 2011)	\$ 26.25	\$ 15.00
First Quarter (November 1, 2010 January 31, 2011)	\$ 20.00	\$ 15.00

The closing price of our common stock on the OTCQB Marketplace on September 25, 2013 was \$6.60 per share. As of September 25, 2013, we had 95 stockholders of record of our common stock. An application has been made to list the common stock and the warrants on The NASDAQ Capital Market under the symbols ADXS and ADXSW, respectively.

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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. In addition, the terms of certain of our outstanding convertible notes restrict our ability to pay dividends. 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.

The terms of our Series B Preferred Stock prohibit the payment of dividends on our common stock for so long as any shares of our Series B Preferred Stock are outstanding. On September 26, 2013, we redeemed all the outstanding shares of our Series B Preferred Stock.

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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 the pro forma 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 July 31, 2013 was \$(9,266,609) or \$(1.88) per share of common stock. Our pro forma net tangible book value per share as of July 31, 2013 was \$(10,637,143), or \$(1.93) per share of common stock after giving effect to: (i) the issuance of common stock, convertible notes and warrants from August 1, 2013 through and immediately prior to the date of this offering, (ii) the conversion of \$899,722 in aggregate principal amount of convertible promissory notes, together with all interest accrued and unpaid thereon through the date of conversion into 407,478 shares of our common stock, (iii) the redemption of our outstanding shares of Series B Preferred Stock and cancellation of an underlying receivable; and (iv) a one-time charge to earnings of \$247,250 ] that will occur immediately upon the completion of this offering for employee bonuses that are payable upon the closing of this offering, 50% of which will be paid in restricted stock units.

After giving effect to (i) the sale of the 3,030,303 shares and warrants to acquire 1,515,152 shares in this offering at the assumed public offering price of \$6.60 per share (the closing price on September 25, 2013) and \$.01 per warrant, (ii) the conversion of approximately \$162,659 in aggregate principal amount of promissory notes, together with all interest accrued and unpaid thereon through the date of conversion into 24,645 shares of our common stock and warrants to acquire 12,323 shares of our common stock with the same terms as the warrants offered in this offering upon completion of this offering at the assumed public offering price of \$6.60 per share (the closing price on September 25, 2013) and \$0.01 per warrant, (iii) the repayment of approximately \$596,000 in other notes payable and accrued interest from the net proceeds received in this offering and repayment of contractual obligations of approximately \$435,000 and (iv) after deducting underwriting discounts and commissions and other estimated offering expenses payable by us, our pro forma as adjusted net tangible book value at July 31, 2013 would have been approximately \$10,012,917, or \$1.04 per share. This represents an immediate increase in pro forma net tangible book value of approximately \$2.92 per share to our existing stockholders, and an immediate dilution of \$6 per share to investors purchasing securities in the offering.

Dilution in pro forma net tangible book value per share represents the difference between the amount per share paid by purchasers of our common stock in this offering and the pro forma net tangible book value per share of our common stock immediately after this offering.

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

Assumed public offering price per share	\$6.60
Net tangible book value per share as of July 31, 2013	\$(1.88)
Increase in net tangible book value per share attributable to this offering	\$2.92
Pro forma as adjusted net tangible book value per share after this offering	\$1.04
Amount of dilution in net tangible book value per share to new investors in this offering	\$5.56

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 \$1.32 per share, representing an immediate increase to existing stockholders of \$3.20 per share and an immediate dilution of \$5.28 per share to new investors. If any shares are issued upon exercise of outstanding options, warrants, or

convertible notes, new investors will experience further dilution.

TABLE OF CONTENTS**CAPITALIZATION**

The following table sets forth our capitalization, as of July 31, 2013:

on an actual basis;

on a pro forma basis to give effect to (i) the issuance of common stock, convertible notes and warrants from August 1, 2013 through and immediately prior to the date of this offering, (ii) the conversion of \$899,722 in aggregate principal amount of convertible promissory notes, together with all interest accrued and unpaid thereon through the date of conversion, into 407,478 shares of our common stock, (iii) the redemption of our outstanding shares of Series B Preferred Stock and cancellation of an underlying receivable; and (iv) a one-time charge to earnings of \$247,250 that will occur immediately upon the completion of this offering for employee bonuses that are payable upon the closing of this offering, 50% of which will be paid in restricted stock units; and

on a pro forma as adjusted basis to give effect to the events described above and (i) the sale of the securities in this offering at the assumed public offering price of \$6.60 per share (the closing price on September 25, 2013) and \$.01 per warrant, (ii) the conversion of approximately \$162,659 in aggregate principal amount of promissory notes, together with all interest accrued and unpaid thereon through the date of conversion into 12,323 shares of our common stock and warrants to acquire 24,645 shares of our common stock with the same terms as the warrants offered in this offering upon completion of this offering at the assumed public offering price of \$6.60 per share (the closing price on September 25, 2013) and \$0.01 per warrant, (iii) the repayment of approximately \$596,000 in other notes payable and accrued interest from the net proceeds received in this offering and repayment of contractual obligations of approximately \$435,000 and after deducting underwriting discounts and commissions and other estimated offering expenses payable by us, and the use of the net proceeds therefrom.

You should consider this table in conjunction with our financial statements and the notes to those financial statements included elsewhere in this prospectus.

	As of July 31, 2013		Pro Forma As Adjusted
	Actual	Pro Forma	
Short-term and long-term notes payable <sup>(1)</sup>	\$2,602,272	\$2,692,542	\$2,048,993
Shareholders' Equity (deficiency):			
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; Series B Preferred Stock; issued and outstanding 740 at July 31, 2013. Liquidation preference of \$10,277,570, actual, pro forma and pro forma, as adjusted, respectively			
Common Stock \$0.001 par value; authorized 25,000,000 shares, issued and outstanding 4,898,248 at July 31, 2013, \$0 pro forma and \$0 pro forma, as adjusted, respectively	4,898	5,704	8,759
Additional paid-in capital	64,083,331	55,737,725	73,897,328
Promissory Note Receivable	(10,633,584)		
Deficit accumulated during the development stage	(60,181,464)	(61,911,198)	(62,273,181)
Total shareholders' deficiency	(6,726,819)	16,167,769	11,632,907
Total Capitalization	\$(9,329,091)	\$(18,860,311)	\$13,681,899

Notes:

(1)

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, notes payable-other and the long-term convertible note exclusive of fair value adjustment.

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# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis should be read together with our financial statements and the related notes appearing elsewhere in this prospectus. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. See *Forward-Looking Statements* for a discussion of the uncertainties, risks and assumptions associated with these statements. Actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth under *Risk Factors* and elsewhere in this prospectus.*

## Overview

We are a clinical development stage biotechnology company with the intent to develop safe and effective immunotherapies for cancer and infectious diseases. These immunotherapies are based on a platform technology under exclusive license from 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 which we refer to these as *Lm*-LLO immunotherapies. We believe these *Lm*-LLO agents redirect the potent immune response to *Lm* which is inherent in humans, to the TAA or antigen of interest.

*Lm*-LLO based 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, this technology facilitates the immune response by altering the microenvironment of tumors to make them more susceptible to immune attack.

Our lead construct, ADXS-HPV, is being evaluated in four ongoing clinical trials for HPV-associated diseases as follows: recurrent cervical cancer (India), locally advanced cervical cancer (with the GOG, largely underwritten by the NCI, U.S.); head and neck cancer (with the CRUK, U.K.) and anal cancer (BrUOG, U.S.). In addition, we have developed immunotherapies for prostate cancer and HER2 overexpressing cancers (such as breast, gastric and other cancers in humans and osteosarcoma in canines). Over fifteen distinct constructs are in various stages of development, developed directly by us and through strategic collaborations with recognized centers of excellence.

We have no customers. Since our inception in 2002, we have focused our development efforts on understanding our technology and establishing a drug development pipeline that incorporates this technology into therapeutic immunotherapies, currently those targeting HPV-associated diseases (cervical cancer, head and neck cancer and anal cancer), prostate cancer, and HER2 overexpressing cancers. Although no immunotherapies have been commercialized to date, research and development and investment continues to be placed behind the pipeline and the advancement of this technology. Pipeline development and the further exploration of the technology for advancement entail risk and expense. We anticipate that our ongoing operational costs will increase significantly as we continue conducting our clinical development program.

If we fail to raise a significant amount of capital, we may need to significantly curtail operations or cease operations in the near future. Any sale of our common stock or issuance of rights to acquire our common stock below \$3.16 per share (as may be further adjusted) with respect to certain of our outstanding debt instruments or \$15.11 per share (as may be further adjusted) with respect to certain of our outstanding warrants will trigger a significant dilution due to the anti-dilution protection provisions contained therein.

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 July 31, 2013 and October 31, 2012, we had an accumulated deficit of \$60,181,464 and \$47,601,427, respectively and shareholders deficiency of \$6,726,819 and \$5,962,724, respectively. Our research and development costs decreased from approximately \$8.1 million for the year ended October 31, 2011 to approximately \$6.6 million for the year ended October 31, 2012. Research and development expenses decreased by approximately \$1,348,000 to approximately \$4,412,000 for the nine months ended July 31, 2013 as compared with approximately \$5,760,000 for the nine months ended July 31, 2012. Our projected annual staff, overhead, laboratory and nonclinical expenses are estimated to be approximately \$4.1 million for the current fiscal year ended October 31, 2013. We expect to incur significant additional costs. The timing and estimated costs of these projects are difficult to predict. We may attempt to accelerate the timing of the required financing and, conversely, if the trial or trials are not successful we may slow our spending and defer

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the timing of additional financing. While we will attempt to attract a corporate partnership and grants, we have not assumed the receipt of any additional financial resources in our cash planning.

To date, we have outsourced many functions of drug development including manufacturing and clinical trial management. Accordingly, the expenses of these outsourced services account for a significant amount of our accumulated loss. We cannot predict when, if ever, any of our immunotherapies will become commercially viable or approved by the U.S. Food and Drug Administration, or FDA. We expect to spend substantial additional sums on the continued research and development of proprietary products and technologies, including conducting clinical trials for our immunotherapies, with no certainty that our immunotherapies will become commercially viable or profitable as a result of these expenditures.

## **Results of Operations**

### **Nine Months Ended July 31, 2013 Compared to Nine Months Ended July 31, 2012**

#### **Revenue**

We did not record any revenue for the nine months ended July 31, 2013 and 2012.

#### **Research and Development Expenses**

Research and development expenses decreased by approximately \$1,348,000 to approximately \$4,412,000 for the nine months ended July 31, 2013 as compared with approximately \$5,760,000 for the same period a year ago. This is primarily attributable to decreased clinical trial expenses due to the near completion of dosing patients in our India trial and less clinical trial activity as compared with the same period a year ago. This was slightly offset by an increase in overall compensation in the current period primarily resulting from higher stock-based compensation for options granted to employees as compared with the same period a year ago.

We anticipate a significant increase in research and development expenses as a result of our intended expanded development and commercialization efforts primarily related to clinical trials and product development. In addition, we expect to incur expenses in the development of strategic and other relationships required to license manufacture and distribute our product candidates when they are approved.

#### **General and Administrative Expenses**

General and administrative expenses increased by approximately \$2,003,000 to approximately \$6,300,000 for the nine months ended July 31, 2013 as compared with approximately \$4,297,000 for the same period a year ago. This was primarily due to higher stock-based compensation expense for options and shares granted to employees and directors as compared to the same year period a year ago as well as severance costs related to a former employee. In addition, a portion of the increase is attributable to increased legal and consulting fees in the current period as compared to the prior year period.

### **Interest Expense**

For the nine months ended July 31, 2013, interest expense decreased significantly to approximately \$600,000 from \$4,242,000 in the same period a year ago, which decrease is largely a result of the significant reduction in overall debt. These reductions included the May 2012 exchange of approximately \$4.5 million aggregate principal value of convertible promissory notes for shares of our common stock and warrants and the conversion of approximately \$1.8 million aggregate principal value of various convertible promissory notes into shares of our common stock during 2012 and 2013. In addition, in the period a year ago, we recorded interest expense of approximately \$500,000 related to the issuance of shares to JMJ Financial under a previously disclosed Settlement Agreement, resulting in non-cash expense from the recognition of a beneficial conversion feature. This decrease was slightly offset by approximately \$157,000 in non-cash interest expense recorded in the current period related to the issuance of 28,000 shares of our common stock (Commitment Fee Shares) under the Hanover Purchase Agreement.

### **Other Income/(Expense)**

Other expense was approximately \$15,926 for the nine months ended July 31, 2013 as a result of approximately \$5,100 in interest income from payments made to us under the terms of a convertible promissory note, more than offset by expense of approximately \$21,077 related to unfavorable changes in foreign exchange rates relating to transactions with certain vendors.

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Other income was approximately \$26,000 for the nine months ended July 31, 2012 as compared with other expense of approximately \$49,000 in the same period a year ago as a result of favorable changes in foreign exchange rates relating to transactions with certain vendors.

**(Loss) Gain on Note Retirement and Accounts Payable**

For the nine months ended July 31, 2013, we recorded non-cash income of approximately \$349,000 primarily resulting from the settlement of outstanding payables with shares of our common stock or at a discount. This income was partially offset by charges incurred related to the conversion of notes into shares of our common stock by investors.

For the nine months ended July 31, 2012, we recorded a charge to income of approximately \$2,173,000 primarily resulting from entering into exchange agreements with May, October and December 2011 investors in which these investors exchanged convertible promissory notes in the aggregate principal amount of approximately \$4.5 million for (i) an aggregate of approximately 418,000 shares of our common stock and (ii) warrants to purchase up to approximately 46,000 shares of common stock at an exercise price of \$18.75 per share. In addition, the Company recognized noncash expense resulting from the conversion of promissory notes, by investors, during the nine months ended July 31, 2012. These expenses were partially offset by noncash income resulting from the issuance of shares to Numoda under a stock purchase agreement and the July 2012 warrant exchanges.

**Changes in Fair Values**

For the nine months ended July 31, 2013, we recorded non-cash expense of approximately \$2.3 million. This was primarily the result of non-cash expense of approximately \$1.2 million from the mark-to-market of our convertible promissory notes, accounted for under fair value accounting. In addition, we recorded non-cash expense of approximately \$1.1 million from changes in the fair value of the warrant liability resulting from an increase in the fair value of each liability warrant due to an increase in our share price from \$5.63 at October 31, 2012 to \$9.00 at January 31, 2013 in addition to a larger range of share prices used in the calculation of the BSM Model volatility input and the number of outstanding liability warrants increasing during the current period compared to the same period a year ago.

For the nine months ended July 31, 2012, we recorded income from changes in the fair value of the warrant liability and embedded derivative liability of approximately \$6.0 million primarily resulting from a decrease in the fair value of each liability warrant due primarily to a decrease in our share price from \$18.75 at October 31, 2010 to \$8.75 at July 31, 2012. In addition, there was a decrease in the fair value of each liability warrant due to a smaller range of share prices used in the calculation of the BSM Model volatility input.

Potential future increases or decreases in our stock price will result in increased or decreased warrant and embedded derivative liabilities, respectively, on our balance sheet and therefore increased or decreased expenses being recognized in our statement of operations in future periods.

**Income Tax Benefit**

We may be eligible, from time to time, to receive cash from the sale of our NOLs under the State of New Jersey NOL Transfer Program. In the nine months ended July 31, 2013, we received a net cash amount of approximately \$725,000 from the sale of our state NOLs and research & development tax credits for the periods ended October 31, 2010 and 2011.

In the nine months ended July 31, 2012, we received a net cash amount of \$346,787 from the sale of our state NOLs for the periods through October 31, 2010.

## **Fiscal Year 2012 Compared to Fiscal Year 2011**

### **Revenue**

We recorded no revenue for the years ended October 31, 2012 and October 31, 2011.

### **Research and Development Expenses**

Research and development expenses decreased by approximately \$1,433,000 to approximately \$6,646,000 for the fiscal year ended October 31, 2012 as compared with approximately \$8,079,000 for the same period a

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year ago. This is primarily attributable to clinical trial expenses, which decreased in the current year resulting from lower manufacturing costs due to the near completion of dosing patients in our India trial and less clinical trial activity. These decreases were slightly offset by an increase in expenses related to the initiation of preclinical trial studies in other cancer indications.

We anticipate a significant increase in research and development expenses as a result of expanded development and commercialization efforts primarily related to clinical trials and product development. In addition, expenses will be incurred in the development of strategic and other relationships required to license manufacture and distribute our product candidates.

### **General and Administrative Expenses**

General and administrative expenses increased by approximately \$749,000 or 15%, to approximately \$5,689,000 for the fiscal year ended October 31, 2012 as compared with approximately \$4,940,000 for the same period a year ago. This was primarily the result of noncash expenses related to the issuance of shares of our common stock under various agreements entered into in the current period as well as an increase in stock-based compensation related to the issuance of additional options to employees, consultants and directors. In addition, we incurred penalties and fees resulting from the late filing of certain registration statements related to our various capital raises. These increases were slightly offset by lower in legal and consulting costs in the current period when compared with the same period a year ago.

### **Interest Expense**

In the fiscal year ended October 31, 2012, interest expense decreased by approximately \$162,000 to approximately \$4,537,000 from approximately \$4,699,000 for the fiscal year ended October 31, 2011. We recorded less interest expense in the current period primarily resulting from the significant reduction in overall debt including the \$4.5 million aggregate principal value of convertible promissory notes exchanged for shares of our common stock and warrants in May, 2012 and approximately \$4.3 million aggregate principal value of various convertible promissory notes converted during 2012. These decreases were somewhat offset by additional interest expense related to the issuance of convertible promissory notes in the aggregate principal amount of approximately \$3.2 million during the current period. Additionally, certain common shares issued to an investor, were recognized as a beneficial conversion feature resulting in noncash interest expense in the current period.

### **Other Expense/Income**

Other income was approximately \$12,000 for the fiscal year ended October 31, 2012 as a result of favorable changes in foreign exchange rates relating to transactions with certain vendors. Other expenses were approximately \$79,000 in the fiscal year ended October 31, 2011 resulting from a write-off of intangible assets and unfavorable changes in foreign exchange rates relating to transactions with certain vendors.

### **Gain (Loss) on Note Retirement, Warrant Exchanges and Accounts Payable**

For the fiscal year ended October 31, 2012, we recorded a charge to income of approximately \$2,188,000, primarily resulting from the extinguishment of debt instruments in the aggregate amount of \$8.8 million in exchange for shares of our common stock and warrants. These losses were partially offset by noncash gains resulting from the issuance of shares to Numoda in payment of a trade payable under a stock purchase agreement.

For the fiscal year ended October 31, 2011, we recorded income of approximately \$462,000, primarily due to the exchange by an investor of 2007 warrants that contained anti-dilution provisions, for a larger number of warrants with no anti-dilution provisions.

### **Changes in Fair Values**

The change in fair value of the common stock warrant liability and embedded derivative liability increased income by approximately \$6.0 million for the fiscal year ended October 31, 2012 compared to income of approximately \$9.8 million for the fiscal year ended October 31, 2011. In the current fiscal year, essentially all of the \$6.6 million resulted from a decrease in the Black-Scholes value of each liability warrant due primarily to a decrease in our share price from \$17.50 at October 31, 2011 to \$5.63, at October 31, 2012. In addition, there was a decrease in the Black-Scholes value of each liability warrant due to a smaller range of share prices used in the calculation of the Black-Scholes-Merton Model volatility input.

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For the fiscal year ended October 31, 2011, we recorded income as the fair value of its warrant and embedded derivative liability decreased primarily due to declines in the underlying stock price (and therefore decreases in the corresponding warrant liability and embedded derivative liability) from share prices as high as \$26.25, at April 30, 2011, to share prices as low as \$17.50 at October 31, 2011. In addition, the number of warrants increased in the current fiscal year, increasing the income recorded due to changes in fair value from decreases in the underlying stock price.

Potential future increases or decreases in our stock price will result in increased or decreased warrant and embedded derivative liabilities, respectively, on our balance sheet and therefore increased expenses being recognized in our statement of operations in future periods.

### **Income Tax Benefit**

In the fiscal year ended October 31, 2012, we recorded an income tax benefit of approximately \$347,000 in income, due to the receipt of a net operating losses tax credit from the State of New Jersey tax program compared to approximately \$379,000 in net operating losses tax credits received from the State of New Jersey tax program in the year ended October 31, 2011. In December 2012, we received notification that we will receive a net cash amount of approximately \$725,000 from the sale of our net operating losses and research and development tax credits for the years ended October 31, 2010 and 2011. We received this amount in January 2013.

## **Liquidity and Capital Resources**

Since our inception through July 31, 2013, we have reported accumulated net losses of approximately \$60.1 million and recurring negative cash flows from operations. We anticipate that we will continue to generate significant losses from operations for the foreseeable future.

Our limited capital resources and operations to date have been funded primarily with the proceeds from public, private equity and debt financings, NOL tax sales and income earned on investments and grants. 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 July 31, 2013 and October 31, 2012, we had an accumulated deficit of \$60,181,464 and \$47,601,427, respectively and stockholders' deficiency of \$6,726,819 and \$5,962,724, respectively.

We do not have adequate cash on hand to cover our anticipated expenses for the next 12 months. If we fail to raise a significant amount of capital, we may need to significantly curtail or cease operations in the near future. These conditions have raised substantial doubt about our ability to continue as a going concern. Although we are working diligently to raise funds, including through this offering, no assurances can be provided that we will have sufficient cash and credit to sustain operations or that we will be successful in obtaining additional funding.

### **Discussion of Cash Flows**

Cash used in operating activities, for the nine months ended July 31, 2013, was approximately \$4.9 million resulting primarily from spending associated with our clinical trial programs and general & administrative spending. For the year ended October 31, 2012, cash used in operating activities was approximately \$4.6 million, resulting from research and development spending of approximately \$3.2 million. General and administrative spending on day-to-day operations was approximately \$1.4 million.

Cash used in investing activities, for the nine months ended July 31, 2013, was approximately \$201,000 resulting primarily from legal spending in support of our patents. For the year ended October 31, 2012, cash used in investing activities was approximately \$397,000 resulting from legal cost spending in support of our intangible assets (patents) and costs paid to Penn for patents.

Cash provided by financing activities, for the nine months ended July 31, 2013, was approximately \$5.1 million, primarily consisting of net proceeds received from the sale of convertible promissory notes (\$2.0 million), the sale of our common stock primarily from the use of the Hanover Equity Enhancement Program (\$3.0 million) and the exercise of warrants resulting in proceeds of approximately \$94,000. For the

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year ended October 31, 2012, cash provided by financing activities was approximately \$3.9 million, primarily consisting of net proceeds received from the sale of convertible promissory notes (\$3.5 million) and the exercise of warrants (\$0.4 million).

For the nine months ended July 31, 2013, we issued to certain accredited investors (including JMJ Financial, as described above) convertible promissory notes in the aggregate principal amount of approximately \$2,138,277 for an aggregate net purchase price of approximately \$2,110,500. These convertible promissory notes were issued with either original issue discounts ranging from 15% to 25% or are interest-bearing and are convertible into shares of our common stock. Some of these convertible promissory notes were issued along with warrants. These convertible promissory notes mature between January and December of 2014. In addition, during the nine months ended July 31, 2013, Mr. Moore loaned us \$11,200 under the Moore Notes.

For the year ended October 31, 2012, we issued to certain accredited investors convertible promissory notes in the aggregate principal amount of approximately \$3,670,000 for an aggregate net purchase price of approximately \$3.1 million. These convertible promissory notes were issued with either original issue discounts ranging from 15% to 25% or are interest-bearing and are convertible into shares of our common stock. Some of these convertible promissory notes were issued along with warrants. These convertible promissory notes mature between January and June of 2013.

During the nine months ended July 31, 2013, we issued 17,657 shares of our common stock, to accredited investors, at a price per share of \$4.375, resulting in total net proceeds of \$77,250.

On October 26, 2012, we entered into a Common Stock Purchase Agreement with Hanover Holdings that is sometimes referred to as a committed equity line financing facility, which requires Hanover to purchase up to \$10.0 million of shares of our common stock over the 24-month term following the date of effectiveness of the resale registration statement which was December 12, 2012. During the nine months ended July 31, 2013, we issued 348,724 shares of our common stock to Hanover in connection with the settlement of drawdowns pursuant to the Hanover Purchase Agreement, at prices ranging from approximately \$3.32 to \$7.48 per share. The per share price for such shares was established under the terms of the Hanover Purchase Agreement. We received total net proceeds of approximately \$2,934,624 in connection with these drawdowns.

For the year ended October 31, 2012, we received proceeds of approximately \$412,000 resulting from the exercise of approximately 21,960 warrants at an exercise price of \$18.75.

For the year ended October 31, 2012, we repaid a total of approximately \$88,000 in principal value of convertible promissory notes.

## **Off-Balance Sheet Arrangements**

As of July 31, 2013 and October 31, 2012, respectively, we had no off-balance sheet arrangements.

## **Recent Financing Activities**

### **Debt Conversion Agreements**

In September 2013, we entered into agreements with certain holders of our outstanding indebtedness to amend the terms of their existing arrangements and provide for repayment thereof or conversion into our securities as follows:

*Moore Notes.* On September 26, 2013, we entered into a debt conversion agreement with Thomas A Moore, a Director of our company and our former Chief Executive Officer, with respect to the repayment and partial conversion of amounts owed 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 refer to these outstanding notes as the Moore Notes. As provided in the agreement, following the closing of this offering: (a) we will pay Mr. Moore \$100,000 in cash as partial repayment of the Moore Notes, (b) one-half of the remaining balance (approximately \$162,659) will automatically convert at the closing of the this offering into the securities being offered and sold in this offering at a conversion price equal to the public offer price, and (c) within three months of the closing of any such financing, we will pay Mr. Moore in cash the then remaining outstanding balance under the Moore Notes (after taking into account the \$100,000

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payment and automatic conversion in our securities). Following the cash payments and partial conversion into our securities, there will no longer be any outstanding balances under the Moore Notes and we will no longer have any obligations under the Moore Notes. Securities received by Mr. Moore upon conversion will be restricted securities and subject to customary lock-up restrictions.

*Redwood Bridge Notes.* On September 27, 2013, we entered into an exchange agreement with Redwood Management, LLC, with respect to the conversion of amounts owed to Redwood under that certain convertible promissory note with an aggregate principal amount of \$277,778 issued to Redwood in June 2013 in a bridge financing. We agreed to issue 125,000 restricted shares of our common stock to Redwood, in exchange for the convertible promissory note. Accordingly, we no longer have any outstanding obligations to Redwood under these bridge financing notes.

We are currently negotiating with the holders of approximately \$1,628,000 outstanding principal amount of convertible promissory notes to exchange those outstanding securities for shares of our common stock or new convertible promissory notes that have fixed (rather than variable) conversion prices. There can be no guarantee that we will be successful in agreeing to terms with such holders, and there is a risk that such indebtedness may continue to be outstanding following this offering.

### **Series B Preferred Redemption**

On September 26, 2013, we entered into a Notice of Redemption and Settlement Agreement with Optimus Capital Partners, LLC, a Delaware limited liability company, dba Optimus Life Sciences Capital Partners, LLC, Optimus CG II, Ltd., a Cayman Islands exempted Company and Socius CG II, Ltd., a Bermuda exempted Company, pursuant to which we agreed to redeem our outstanding shares of Series B Preferred Stock. Pursuant to the agreement, we agreed to cancel an outstanding receivable in the amount of \$10,633,584 as of the date of the agreement as payment in full of the redemption payment due under the terms of the Series B Preferred Stock and agreed to issue 33,750 shares of our common stock to settle a disagreement regarding the calculation of the settlement amount under a July 2012 Order and Stipulation. In connection with the redemption, we agreed to cancel the outstanding warrant held by Optimus. Accordingly, following such redemption, there are no longer any shares of our Series B Preferred Stock issued and outstanding.

### **JMJ September 2013 Note**

On September 4, 2013, we entered into a securities purchase agreement with JMJ Financial pursuant to which we issued JMJ Financial, in a private placement, an \$800,000 convertible promissory note and 19,231 restricted shares of our common stock as a \$50,000 origination fee for the note. The securities agreement provides that we will true up JMJ Financial by issuing additional shares of our common stock if JMJ Financial does not receive at least \$50,000 of net proceeds from the sale of such shares of common stock when, and if, it disposes of such shares.

The face amount of the note reflects an aggregate principal amount of \$800,000 for total consideration of \$720,000 (or a 10% original issue discount). However, we only borrowed \$575,000 from JMJ Financial under this convertible promissory note, for which JMJ Financial paid us \$500,000 in cash. JMJ Financial has no obligation to lend us the remaining \$220,000 of available principal amount under the note and may never do so. We have no obligation to pay JMJ Financial any amounts on the unfunded portion of the note. We may not prepay any portion of the note without JMJ Financial's consent.

The convertible promissory note matures September 4, 2014 and, in addition to the 10% original issue discount, provides for payment of a one time interest charge of 5% on funded amounts. The convertible promissory note is convertible at any time, in whole or in part, at JMJ Financial's option into shares of our common stock at the lesser of \$2.65 or 70% of the average of the lowest two closing prices in the 20-day pricing period preceding a conversion.

However, at no time will JMJ Financial be entitled to convert any portion of the note to the extent that after such conversion, JMJ Financial (together with its affiliates) would beneficially own more than 4.99% of our outstanding shares common stock as of such date. We agreed to reserve at least 2,000,000 shares of our common stock for conversion of the note. The note also provides for penalties and rescission rights if we do not deliver shares of our common stock upon conversion within the required timeframes.

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The convertible promissory note includes customary event of default provisions, and provides for a default rate of the lesser of 18% or the maximum permitted by law. Upon the occurrence of an event of default, the lender may require us to pay in cash the Mandatory Default Amount, which is defined in the note to mean the greater of (i) the outstanding principal amount of the note plus all interest, liquidated damages and other amounts owing under the note, divided by the conversion price on the date payment of such amount is demanded or paid in full, whichever is lower, multiplied by the volume-weighted-average price, or VWAP, on the date payment of such amount is demanded or paid in full, whichever has a higher VWAP, or (ii) 150% of the outstanding principal amount of the note plus 100% of all interest, liquidated damages and other amounts owing under the note.

If we complete a public offering of \$5,000,000 or more, JMJ Financial has the right, at its election, to require us to repay the note, in whole or in part, an amount equal to 125% of the sum of the funded principal amount being repaid plus all accrued and unpaid interest liquidated damages, fees, and other amounts due on such principal amount. Accordingly, JMJ Financial has the right to require repayment from the proceeds from this offering. Although we are currently negotiating with JMJ Financial to exchange this note for shares of our common stock or new notes without variable conversion rate terms and waive any right to repayment out of the proceeds of this offering, there is no guarantee that JMJ Financial will agree to any such exchange or waiver.

### **Yenson Investment**

On August 28, 2013, we entered into a Securities Purchase Agreement with Yenson, pursuant to which we issued Yenson 45,353 shares of our common stock and a 3-year warrant to acquire 22,161 shares of our common stock at an exercise price of \$2.76 per share for \$100,000 in cash.

### **Sale of Notes Collateralized by Sale of NOLs and R&D Tax Credits**

On August 20, 2013, in a private placement pursuant to a note purchase agreement, we issued an accredited investor a secured convertible promissory note in the aggregate principal amount of \$108,000, for a purchase price of \$100,000. On September 18, 2013, we borrowed an additional \$150,000 from this accredited investor and amended and restated the terms of the August note and issued this investor 12,000 shares of our common stock. As amended and restated, this note has an aggregate principal amount of \$258,000, bears interest at a rate of 20% per annum and is due February 21, 2014, nine months after its original issuance date. To secure prompt payment under the note, we granted the holder a continuing security interest in all net proceeds we receive up to the aggregate amount of \$258,000 plus accrued interest from the sale of our net operating loss and or research and development tax credits through the New Jersey Economic Development Program (described below). We may prepay the note at any time, however, if we pay the note prior to receiving the proceeds from such sales through the New Jersey Economic Development Program, we agreed to pay the sum of \$295,200.

### **Fourth Asher Financing**

On July 12, 2013, in a private placement pursuant to a note purchase agreement, we issued Asher Enterprises, Inc., or Asher, a convertible promissory note in the aggregate principal amount of \$103,500, for a purchase price of \$100,000.

This note bears interest at a rate of 8%, which interest accrues, but does not become payable until maturity or acceleration of the principal of the note. This note is convertible into shares of our common stock at a conversion price equal to 65% of the arithmetic average of the five lowest closing trading prices for shares of our common stock during the 10 trading day period ending on the latest complete trading day prior to the applicable conversion date. This note matures on April 16, 2014, nine months from its issuance date. We intend to exercise our right to repay this note and expect to use a portion of the proceeds from this offering to pay this outstanding note in full. See Use of Proceeds.

**Redwood Bridge**

On June 21, 2013, we entered into a bridge financing arrangement with Redwood Management, LLC, or Redwood. Accordingly, on June 21, 2013, we entered into a Securities Purchase Agreement with Redwood providing for the issuance and sale of up to \$555,556 of aggregate principal amount of 5% convertible debentures, or the Bridge Notes, to Redwood, and we issued Redwood Bridge Notes with a stated principal amount of \$277,778 for total consideration of \$250,000 in cash (representing a 10% original issue discount). On September 27, 2013, Redwood agreed to exchange the Bridge Notes for 125,000 restricted shares of our

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common stock as described above under Debt Conversion Agreements. Accordingly, these notes are no longer outstanding. For additional information regarding the terms of these Bridge Notes, see note 5 to our interim unaudited financial statements included elsewhere in this prospectus.

**JMJ April 2013 Note**

On April 26, 2013, in a private placement, we issued MJM Financial a convertible promissory note. The face amount of the note reflects an aggregate principal amount of \$800,000 for total consideration of \$720,000 (or a 10% original issue discount). As of April 26, 2013, we had only borrowed \$425,000 from MJM Financial under this convertible promissory note. MJM Financial paid us \$300,000 in cash and exchanged a promissory note with an aggregate principal amount of \$125,000 that we issued to MJM Financial on December 26, 2012 as consideration for the note. On June 27, 2013, we borrowed an additional \$100,000 under this convertible promissory note for which MJM Financial paid us in cash. MJM Financial has no obligation to lend us the remaining \$195,000 of available principal amount under the note and may never do so. We have no obligation to pay MJM Financial any amounts on the unfunded portion of the note. We may not prepay any portion of the note without MJM Financial's consent.

The convertible promissory note matures April 26, 2014 and, in addition to the 10% original issue discount, provides for payment of a one time interest charge of 5% on funded amounts. The convertible promissory note is convertible at any time, in whole or in part, at MJM Financial's option into shares of our common stock at the lesser of \$8.75 or 70% of the average of the lowest two closing prices in the 20-day pricing period preceding a conversion. However, at no time will MJM Financial be entitled to convert any portion of the note to the extent that after such conversion, MJM Financial (together with its affiliates) would beneficially own more than 4.99% of our outstanding shares common stock as of such date. We agreed to reserve at least 160,000 shares of our common stock for conversion of the note.

The note also provides for penalties and rescission rights if we do not deliver shares of our common stock upon conversion with the require timeframes.

The convertible promissory note includes customary event of default provisions, and provides for a default rate of the lesser of 18% or the maximum permitted by law. Upon the occurrence of an event of default, the lender may require us to pay in cash an amount equal to the Mandatory Default Amount which is defined in the note to mean the greater of (i) the outstanding principal amount of the note plus all interest, liquidated damages and other amounts owing under the note, divided by the conversion price on the date payment of such amount is demanded or paid in full, whichever is lower, multiplied by the volume-weighted-average price, or VWAP, on the date payment of such amount is demanded or paid in full, whichever has a higher VWAP, or (ii) 150% of the outstanding principal amount of the note plus 100% of all interest, liquidated damages and other amounts owing under the note.

We also granted MJM Financial the right, at its election, to participate in the next public offering of our securities by exchanging, in whole or in part, the funded portion of this note for a subscription to such public offering in an amount equal to 125% of the sum of the funded portion of the principal amount of being exchanged plus all accrued and unpaid interest, liquidated damages, fees, and other amounts due on such exchanged principal amount. However, in September 2013, MJM Financial agreed to amend the April 2013 note to remove this right. If we complete a public offering of \$10,000,000 or more, MJM Financial has the right, at its election, to require us to repay the note, in whole or in part, in an amount equal to 125% of the sum of the funded principal amount being repaid plus all accrued and unpaid interest liquidated damages, fees, and other amounts due on such principal amount. In September 2013, we agreed to lower this threshold to \$5,000,000 in connection with sale of the new convertible promissory note to MJM Financial. Accordingly, MJM Financial has the right to require repayment from the proceeds from this offering. Although we are currently negotiating with MJM Financial to exchange this note for shares of our common stock or new notes without variable conversion rate terms and waive any right to repayment out of the proceeds of this offering, there is no guarantee that MJM Financial will agree to any such exchange or waiver.

**New Jersey Economic Development Authority**

On December 13, 2012 we announced that we had received preliminary approval for \$796,913 from the sale of certain net operating loss carryovers from prior years through the Technology Business Tax Certificate

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Transfer Program sponsored by the New Jersey Economic Development Authority (NJEDA). On January 24, 2013, we received approximately \$725,192 after sales commission and other expenses in this non-dilutive funding.

**Tonaquint Note**

On December 13, 2012, we entered into a securities purchase agreement with Tonaquint, Inc. pursuant to which we issued Tonaquint a convertible promissory note for the initial principal amount of \$890,000 (which we refer to as the Tonaquint Note) in exchange for (i) \$400,000 in cash and (ii) two \$200,000 secured mortgage notes from Tonaquint. We also entered into a security agreement with Tonaquint dated the same date that gave Tonaquint a security interest in the two mortgage notes and issued Tonaquint a 5-year warrant to purchase that number of shares equal to \$667,500 (75% of the principal amount under the note) divided by market price (as defined in the warrant agreement) as described below. The mortgage notes issued to us by Tonaquint bore interest at a rate of 5% per annum and were originally due in August 2013 and October 2013, respectively, unless the Tonaquint Note matured prior to such time or if certain payment conditions had not been met as of such dates. However, in March 2013, Tonaquint made accelerated payments (including interest income) of \$202,493 and \$202,657 to us under the mortgage notes and these mortgage notes are no longer outstanding. Accordingly, the security agreement was also terminated at such time.

The Tonaquint Note reflects an original issue discount of \$80,000 plus \$10,000 of carried transaction expense that, bears interest at a rate of 8% per annum and matures 26 months after its issue date. The Tonaquint Note can currently be converted at any time, from time to time, at the option of the holder, in whole or in part. The original conversion price was \$20.00 per share, however, this was adjusted down due to the issuance of shares of our common stock or other securities convertible into or exchangeable for shares of our common stock below that price.

As contemplated by the terms of the note, we began making installment payments on the Tonaquint Note beginning in June 2013 (180 days after issuance). The monthly installment payments equal \$49,444 (\$890,000 divided by 18) and are to be made until the Tonaquint Note is paid in full. We have the option to make such payments in cash or stock, or a combination thereof, although we are required to make the payment in cash if certain conditions are not met. If we pay in stock, then we issue stock at a price per share equal to 80% of the average of the 5 lowest daily closing bid prices for our common stock during the 20 trading days prior to the installment date (or 70% if the average of the 3 lowest volume weighted average prices during such 20-day period is less than \$1.25 per share). The note also requires us to true-up Tonaquint by issuing additional shares of our common stock if the market price (determined per the terms of the note) is lower than the price per share of our common stock on the installment date.

We agreed to reserve that number of shares equal to: (i) two times the higher of (A) the outstanding balance of the note divided by the then applicable conversion price, and (B) the outstanding balance of the note divided by the market price (as defined in the note), plus (ii) two times the number of shares that would be required to be delivered upon complete exercise of the warrant pursuant to the terms thereof. We also granted Tonaquint a 2-year right of participation in any transaction or arrangement structured, in whole or in part, in accordance with Section 3(a)(9) or Section 3(a)(10) of the Securities Act and granted Tonaquint piggyback registration rights in connection with any public offering of securities.

We also issued Tonaquint a warrant to purchase that number of shares equal to \$667,500 (75% of the principal amount under the note) divided by market price (as defined in the warrant agreement) on the December 13, 2013 issue date, which expires December 31, 2018 (the last calendar day of the month that is 5-years from the issue date) and provides for a variable exercise price per share. On March 14, 2013, we issued 170,623 shares of our common stock resulting from the partial cashless exercise of the warrant issued to Tonaquint during the three months ended January 31, 2013. Warrants to purchase up to 86,282 shares of our common stock issued to Tonaquint remain outstanding.

Although we are currently negotiating with Tonaquint to exchange its notes for shares of our common stock and

exchange its warrant for a warrant with a fixed exercise price and waive its registration rights, there is no guarantee that Tonaquint will agree to any such exchange or waiver.

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**Private Placements of Convertible Notes to Hanover**

On December 6, 2012, in a private placement pursuant to a note purchase agreement, we issued Hanover Holdings I, LLC, or Hanover, a convertible promissory note in the aggregate principal amount of \$100,000 for a purchase price of \$100,000, which we refer to as the Hanover December 2012 Note. The Hanover December 2012 Note bears interest at a rate of 12% per annum, which interest accrues, but does not become payable until maturity or acceleration of the principal of such Hanover December 2012 Note. The Hanover December 2012 Note is convertible into shares of our common stock at a conversion price of \$3.75 per share. On June 11, 2013, the Hanover December 2012 Note was converted into 26,667 shares of our common stock at a conversion price of \$3.75. This note no longer remains outstanding. On December 5, 2012, Hanover exchanged certain other notes that had been issued to Hanover in September and October 2012 for convertible notes in the form of the Hanover December 2012 Note in all material respects (other than date of issuance, exchange date, the maturity date of May 19, 2012 solely with respect to the exchanged note issued in exchange for the prior note from September 2012 and the maturity date of June 19, 2013 solely with respect to the exchange note issued in exchange for the prior note from October 2012) that also are convertible into shares of our common stock at a conversion price of \$3.75 per share, which we refer to as the Exchanged Hanover PIPE Notes. Each of the Hanover December 2012 Notes and the Exchanged Hanover PIPE Notes are subject to limitations on conversion if after giving effect to such conversion Hanover would beneficially own more than 4.99% of our common stock.

**Equity Enhancement Program**

On October 26, 2012, we entered into a Common Stock Purchase Agreement with Hanover. Under the agreement, we may, subject to certain customary conditions require Hanover to purchase up to \$10.0 million of shares of our common stock over the 24-month term following the effectiveness of the resale registration statement described below. We refer to this financing arrangement (often called a committed equity line) as the Equity Enhancement Program. Over the 24-month term following the effectiveness of the resale registration statement, we generally have the right, but not the obligation, to direct Hanover to periodically purchase shares of our common stock in specific amounts under certain conditions at our sole discretion. The purchase price for such shares of common stock will be the higher of (i) the minimum price, which we refer to as the Floor Price, set forth in our notice electing to effect such issuance, which we refer to as the Draw Down Notice, and (ii) 90% of the arithmetic average of the five lowest closing sale prices of the common stock during the applicable ten trading day pricing period (or, if less, the arithmetic average of all trading days with closing sale prices in excess of the Floor Price), subject to adjustment upon an alternative transaction. Each trading day with a closing sale price less than the Floor Price is excluded from the calculation of the purchase price and automatically reduces the number of trading days in the applicable pricing period.

In consideration for Hanover's execution and delivery of the purchase agreement, we issued Hanover 28,000 shares of our common stock, which we refer to as the Commitment Fee Shares. We have also agreed to issue Hanover up to 14,400 additional shares of our common stock, which we refer to as the Maintenance Fee Shares, during any full calendar quarter during the term of the purchase agreement, if no shares of our common stock have been purchased or sold because we did not deliver a draw down notice to Hanover. The number of Maintenance Fee Shares to be delivered to Hanover, from time to time, with respect to any calendar quarter, will be equal to approximately \$15,000 worth of shares of our common stock at a 10% discount to market.

As of September 27, 2013 we have received \$2,964,137 and have issued 359,224 shares of our common stock pursuant to this arrangement.

On September 24, 2013, we notified Hanover that we irrevocably commit to suspend any draw downs under the Purchase Agreement without the prior written consent of Aegis Capital Corp. for a six month period from the closing of this offering.

## **Critical Accounting Estimates**

The preparation of financial statements in accordance with GAAP accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts and related disclosures in the financial statements.

Management considers an accounting estimate to be critical if:

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it requires assumptions to be made that were uncertain at the time the estimate was made, and changes in the estimate of difference estimates that could have been selected could have material impact in our results of operations or financial condition.

While we base our estimates and judgments on our experience and on various other factors that we believe to be reasonable under the circumstances, actual results could differ from those estimates and the differences could be material. The most significant estimates impact the following transactions or account balances: stock compensation, warrant valuation, impairment of intangibles, dilution caused by anti-dilution provisions in the warrants and other agreements.

### **Stock Based Compensation**

We account for stock-based compensation using fair value recognition and record stock-based compensation as a charge to earnings net of the estimated impact of forfeited awards. As such, we recognize stock-based compensation cost only for those stock-based awards that are estimated to ultimately vest over their requisite service period, based on the vesting provisions of the individual grants.

The process of estimating the fair value of stock-based compensation awards and recognizing stock-based compensation cost over their requisite service period involves significant assumptions and judgments. We estimate the fair value of stock option awards on the date of grant using the Black-Scholes option-valuation model for the remaining awards, which requires that we make certain assumptions regarding: (i) the expected volatility in the market price of our common stock; (ii) dividend yield; (iii) risk-free interest rates; and (iv) the period of time employees are expected to hold the award prior to exercise (referred to as the expected holding period). As a result, if we revise our assumptions and estimates, our stock-based compensation expense could change materially for future grants.

Stock-based compensation for directors is reflected in general and administrative expenses in the statements of operations. Stock-based compensation for employees and consultants could be reflected in research and development expenses or general and administrative expenses in the consolidated statements of operations.

### **Fair Value of Financial Instruments**

The carrying amounts of financial instruments, including cash, receivables, accounts payable and accrued expenses approximated fair value, as of the balance sheet date presented, because of the relatively short maturity dates on these instruments. The carrying amounts of the financing arrangements issued approximate fair value, as of the balance sheet date presented, because interest rates on these instruments approximate market interest rates after consideration of stated interest rates, anti-dilution protection and associated warrants. The estimate of fair value of such financial instruments involves the exercise of significant judgment and the use of estimates by management

### **Derivative Financial instruments**

We do not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. We evaluate all of our financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the statements of operations. The determination of fair value requires the use of judgment and estimates by management. For stock-based derivative financial instruments, we used the Black-Scholes valuation model which approximated the binomial lattice options pricing model to value the derivative instruments at inception and on subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative liabilities are

classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the instrument could be required within 12 months of the balance sheet date. The variables used in the model are projected based on our historical data, experience, and other factors. Changes in any of these variables could result in material adjustments to the expense recognized for changes in the valuation of the warrant derivative liability.

### **Hybrid Financial Instruments**

For certain hybrid financial instruments, we elected to apply the fair value option to account for certain instruments. We made an irrevocable election to measure such hybrid financial instruments at fair value in

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their entirety, with changes in fair value recognized in earnings at each balance sheet date. The election may be made on an instrument by instrument basis. The determination of fair value requires the use of judgment and estimates by management.

### **Debt Discount and Amortization of Debt Discount**

Debt discount represents the fair value of embedded conversion options of various convertible debt instruments and attached convertible equity instruments issued in connection with debt instruments. The determination of fair value requires the use of judgment and estimates by management. The debt discount is amortized over the earlier of (i) the term of the debt or (ii) conversion of the debt, using the straight-line method, which approximates the interest method. The amortization of debt discount is included as a component of other expenses in the accompanying statements of operations.

## **New Accounting Pronouncements**

In February 2013, the FASB issued ASU No. 2013-02, Reporting of Amounts Reclassified Out of Other Comprehensive Income. ASU 2013-02 finalized the reporting for reclassifications out of accumulated other comprehensive income, which was previously deferred, as discussed below. The amendments do not change the current requirements for reporting net income or other comprehensive income in financial statements. However, they do require an entity to provide information about the amounts reclassified out of accumulated other comprehensive income by component. An entity is also required to present on the face of the financials where net income is reported or in the footnotes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income, but only if the amount reclassified is required under U.S. GAAP to be reclassified to net income in its entirety in the same reporting period. Other amounts need only be cross-referenced to other disclosures required that provide additional detail of these amounts. The amendments in this update are effective for reporting periods beginning after December 15, 2012. Early adoption is permitted.

In March 2013, the FASB issued ASU 2013-07, Presentation of Financial Statements (Topic 205): Liquidation Basis of Accounting. The amendments require an entity to prepare its financial statements using the liquidation basis of accounting when liquidation is imminent. Liquidation is imminent when the likelihood is remote that the entity will return from liquidation and either (a) a plan for liquidation is approved by the person or persons with the authority to make such a plan effective and the likelihood is remote that the execution of the plan will be blocked by other parties or (b) a plan for liquidation is being imposed by other forces (for example, involuntary bankruptcy). If a plan for liquidation was specified in the entity's governing documents from the entity's inception (for example, limited-life entities), the entity should apply the liquidation basis of accounting only if the approved plan for liquidation differs from the plan for liquidation that was specified at the entity's inception. The amendments require financial statements prepared using the liquidation basis of accounting to present relevant information about an entity's expected resources in liquidation by measuring and presenting assets at the amount of the expected cash proceeds from liquidation. The entity should include in its presentation of assets any items it had not previously recognized under U.S. GAAP but that it expects to either sell in liquidation or use in settling liabilities (for example, trademarks). The amendments are effective for entities that determine liquidation is imminent during annual reporting periods beginning after December 15, 2013, and interim reporting periods therein. Entities should apply the requirements prospectively from the day that liquidation becomes imminent. Early adoption is permitted. Management does not expect the pronouncement to have a material effect on our financial position, results of operations or cash flows.

In July 2013, the FASB issued ASU 2013-11, Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists. Under

this new guidance, companies must present this unrecognized tax benefit in the financial statements as a reduction to deferred tax assets created by net operating losses or other tax credits from prior periods that occur in the same taxing jurisdiction. If the unrecognized tax benefit exceeds such credits it should be presented in the financial statements as a liability. This update is effective for annual and interim reporting periods for fiscal years beginning after December 15, 2013. Management does not expect the pronouncement to have a material effect on our financial position, results of operations or cash flows.

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## **BUSINESS**

### **General**

We are a clinical development stage biotechnology company focused on the discovery, development and commercialization of our proprietary *Lm*-LLO immunotherapies 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*, 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 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 ongoing 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.

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

Our immunotherapies are based on a platform technology under exclusive license from 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 leave 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 and 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:

Approach 1: Collect the patient's antigen presenting cells and treat them in a laboratory, and then give them back to the patient so that they might stimulate the generation of T-cells that can attack the tumors. *Lm-LLO* immunotherapies access those cells directly, right inside the patient, and eliminate the need to collecting the cells and processing them in a laboratory.

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Approach 2: Stimulate the activity of the immune system by adding adjuvants to increase the activity. However, individual adjuvants can activate the immune system in an imbalanced and sometimes counterproductive way that may increase the levels of cells that block cancer killing cells from doing their job. *Lm*-LLO immunotherapies by themselves act as multiple adjuvants and stimulate a comprehensive immune response. *Lm*-LLO immunotherapies stimulate the specific type of immunologic environment to generate the type of immunity that is required to kill the targeted cancerous cells.

Approach 3: Block one of the many mechanisms of immunologic tolerance. Tumors can sometimes escape the immune system by hiding behind immunologic tolerance usually reserved to protect normal tissues. However the non-tumor specific blocking of immune tolerance can give rise to serious and sometimes fatal auto-immune side effects. *Lm*-LLO immunotherapies have the unique ability to over-ride several mechanisms of immune tolerance that may be protecting tumors but do not change the immune tolerance of normal tissues, thereby avoiding auto-immune side effects.

As is described further below, we believe our *Lm*-LLO immunotherapies will offer a more comprehensive immunotherapy in a single, well-tolerated, easy to administer treatment.

### **Mechanism of Action**

Our platform technology is based on the use of live attenuated *Lm* bioengineered with multiple copies of a plasmid that encode a fusion protein sequence that includes a fragment of LLO joined to the tumor associated antigen, or TAA, of interest. Due to the attenuation of the *Lm* strains, these bacteria are nonpathogenic and are therefore no longer able to cause an infection. *Lm* stimulate a profound innate immune response and are phagocytized by antigen presenting cells, or APC. APC are phagocytic sentinel cells that circulate throughout the body taking up and breaking down foreign and dying cells.

The specific details of the intracellular life cycle of *Lm* are important for the understanding of our platform technology. The following diagram illustrates how the live attenuated bioengineered *Lm* in our *Lm*-LLO immunotherapies are phagocytized and processed by an APC:

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*Lm*-LLO immunotherapies are bioengineered with multiple copies of a plasmid that encode a fusion protein sequence that includes a fragment of LLO joined to the TAA of interest. Some *Lm* escape from the phagolysosome via LLO, which forms pores in the membrane of the phagolysosome and allows the *Lm* to escape into the cytosol and secrete antigen-LLO fusion proteins. These fusion protein antigens are presented via the MHC class I pathway to generate activated CD8+ T cells, or killer T cells. The majority of *Lm* are broken down in the phagolysosome and the *Lm* fragments are processed via the MHC class II pathway generating antigen-specific CD4+ T cells, or helper T cells.

We believe the activated T cells will then find and infiltrate tumors and destroy the tumor cells. Immunologic tolerance in the tumor microenvironment is mediated by Tregs and MDSC is reduced. Thus we believe *Lm*-LLO immunotherapies may simultaneously stimulate innate and adaptive tumor-specific immunity while simultaneously reducing immune tolerance to tumors. 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.

## **Research and Development Program**

### **Our Development Pipeline**

The following table summarizes the stage of development of our three most advanced clinical drug candidates:

Our first *Lm*-LLO based immunotherapy, ADXS-HPV, uses HPV-E7, an antigen that is present in Human Papilloma Virus (HPV). HPV-associated cancers account for approximately 6-8% of all cancers worldwide, including cervical cancer, head and neck cancers, anal cancer and others. ADXS-PSA is directed against prostate cancer. ADXS-CHER2 is directed against HER2, an antigen found in HER2 overexpressing cancers such as breast, gastric and other cancers, as well as canine osteosarcoma. By varying the antigen, we believe we will be able to create different immunotherapies that may be useful across multiple therapeutic areas and tumor types such as ADXS-PSA for the treatment of prostate cancer and ADXS-CHER2, for the treatment of HER2 over-expressing cancers such as breast, gastric and other human cancers as well as canine osteosarcoma.

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Our most advanced drug candidates in clinical development are ADXS-HPV, ADXS-PSA and ADXS-cHER2:

Immunotherapy Indication	Stage of Clinical Development
ADXS-HPV <b>Cervical Cancer</b>	<b>Phase 1</b> We sponsored and completed in 2007 with 15 patients.
<b>Cervical Cancer</b>	<b>Phase 2</b> We sponsored study, initiated in November 2010 in India in 110 patients with recurrent cervical cancer. We completed enrollment in May 2012 and the last patient visit was in September 2013.
<b>Cervical Cancer</b>	<b>Phase 2</b> The GOG of the NCI is conducting a study in 67 patients with recurrent/refractory cervical cancer. As of September 2013, 13 patients have been enrolled in the safety run-in portion of the study. The study is open group wide to the GOG.
<b>Head &amp; Neck Cancer</b>	<b>Phase 1/2</b> The CRUK is funding a study of 27 patients with head and neck cancer at 3 U.K. sites, and 16 patients have been enrolled in the study as of September 2013.
ADXS-HPV <b>Anal Cancer</b>	<b>Phase 1/2</b> The BrUOG is funding and conducting a study in 25 patients with anal cancer at Brown University, M.D. Anderson Cancer Center, Montefiore Medical Center and Boston Medical Center. The study opened for enrollment in December 2012 and 4 patients have been enrolled in the study as of September 2013.
ADXS-PSA <b>Prostate Cancer</b>	<b>Phase 1</b> We plan to initiate a Phase 1 study in the first half of 2014.
ADXS-cHER2 <b>Canine Osteosarcoma</b>	<b>Phase 1</b> We are sponsoring a study of 15 dogs with osteosarcoma. Dosing commenced in July 2012, and 13 dogs have been enrolled in the study as of September 2013.

## Overview of Drug Candidates

### ADXS-HPV Franchise

Published studies have shown that of the more than 100 strains of HPV, 15 are known to be sexually transmitted high-risk oncogenic types of HPV that are responsible for 5% of all cancers worldwide and 10% of cancers in women. HPV infection can cause cells to become cancerous through the expression of the E6 and E7 genes. According to data extrapolated from the incidence rates reported in the WHO Human Papillomavirus and Related Cancers in the World Summary Report 2010, the worldwide annual incidence of HPV-associated cancers is approximately 527,000 cervical cancer; 99,000 anal cancer, 86,000 penile cancer, 80,000 head and neck cancer, 27,000 vulvar cancer and 13,000 vaginal cancer. Current preventative vaccines cannot protect the 20 million women who are already infected with HPV; and of the high risk oncogenic strains, only HPV 16 and 18 are present in these vaccines. According to a study published by Trimble, et. al. in Lancet Oncology, 80% of sexually active Americans will have contracted at least one strain of HPV by age 50. Challenges with acceptance, accessibility and compliance have resulted in only a third of young women being vaccinated in the United States and even less in other countries around the world. HPV is associated with 99% of cervical cancer, which in late stage is a highly aggressive malignancy with poor prognosis, no standard of care, and for which traditional cancer therapy is ineffective. HPV-associated head and neck cancer is growing at an epidemic rate in western countries; and occurs more frequently (3:1) in men than women due to changes

in sexual practices. HPV is associated with over 25% of head and neck cancers in the United States, the number of HPV-positive head and neck cancer cases has already equaled the number of cases of cervical cancer and continues to increase in frequency and current therapies lead to poor quality of life. HPV

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is associated with over 80% of anal cancers and is also increasing in frequency. Current therapies are toxic and have long-term side effects with no approved therapy for recurrent disease.

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: recurrent cervical cancer (India), locally advanced cervical cancer (with the GOG, largely underwritten by the NCI, U.S.); head and neck cancer (with the CRUK, U.K.) 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.

### **ADXS-PSA**

ADXS-PSA is an *Lm*-LLO immunotherapy directed against prostate-specific antigen, or 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-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 reports and 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 dose for the treatment of prostate cancer in early 2014. 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 antigen presenting cells that we believe are capable of driving a cellular immune response to cHER2 overexpressing cells. In preclinical analysis, the localized effect is the inhibition of the Treg and MDSC cells, an effect that we believe will 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 and providing the rationale to advance into human clinical trials. We plan to meet with the U.S. Department of Agriculture, or USDA, to

discuss the requirements to proceed forward 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.

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## **Recent Clinical Research Developments**

We have completed dosing in *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.

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As reported at the ASCO Annual Meeting in June 2013, the trial completed enrollment and 110 patients received 264 doses of ADXS11-001. The percentage of patients at 12 months was 36% (39/110) and at 18 months was 22% (16/73). The National Comprehensive Cancer Network Guidelines and/or GOG published studies cite historical 12 month survival data of 0-22% with single agent therapy in recurrent cervical cancer. This study shows 12 month survival of 36% (39/110) and is consistent with an active agent in recurrent cervical cancer:

**Landmark Survival**

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.*

In June 2013, a data update was presented at the 2013 ASCO Annual Meeting. Abstract # 5529, titled *ADXS11-001 immunotherapy targeting HPV-E7: Preliminary survival data from a P2 study in Indian women with recurrent/refractory cervical cancer*. The presentation described 12 month survival and preliminary 18 month survival and updated safety, tumor response, and survival data as well as histological data for the first time. The data continue to be encouraging and are consistent with the data presented in February 2013. Survival results were not significantly different between treatment groups. Survival outcomes and tumor responses were not affected by ECOG performance status (0-2); type of prior therapy (radiation alone, chemotherapy alone, or a combination of both); or aggressiveness of disease (defined as recurrence  $\leq 2$  years from initial diagnosis) versus non-aggressive disease (defined as recurrence  $> 2$  years from initial diagnosis).

The most important prognostic factors for overall survival and response rate in cervical cancer have been identified in published reports as: ECOG performance status, number of prior therapies, interval from initial therapy to time of recurrence, and local recurrence compared to distant metastases.

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**Prognostic Factors for Overall Survival in Cervical Cancer**

Most important prognostic factors for overall survival and response rate are:

ECOG performance status,  
Number of prior therapies,  
Interval from initial therapy to time of recurrence, and  
Local recurrence vs. distant metastases\*

\* *Monk 2009, JCO*

Tumor responses have been observed in 11% of the patient with both treatment arms with six complete responses, or CR: four in the ADXS alone group; two in the ADXS+ cisplatin treatment arm and six partial responses, or PR; three in the ADXS alone treatment arm; three in the ADXS+ cisplatin treatment arm. 41% (45/110) of patients (33/65) had durable stable disease for at least 3 months as indicated by the orange dashed lines in the waterfall plot below. Activity against different high risk HPV strains beyond HPV 16 and HPV 18 have been observed, including HPV 16, 18, 31, 33 and 45.

***Lm-LLO-E7-15 Best Response Data***

**(as of May 17, 2013)**

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ADXS-HPV has been shown to eliminate major tumors as observed in Patient 110-002 below:

**Patient 110-002: Major Tumors Eliminated**

Patient 110-002 enrolled with 284mm (sum of linear measures) of disease at 10 sites, including liver, lung, and peri-aortic nodes. The patient was previously treated with surgery and radiation (EBRTx25), and recurred within 1 year with metastatic disease. She was randomized to receive ADXS/Cis. At 3 months, she had 84mm of tumor at 5 sites, at 6 months 56mm at 3 sites, at 9 months 34mm at 2 sites, and at 12 months 20mm in a single peri-aortic node not amenable to biopsy.

ADXS-HPV continues to demonstrate a well-tolerated and manageable safety profile with 41% (45/110) of patients reporting predominately cytokine-release syndrome 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. Serious adverse events result in death, are life-threatening, cause significant disability or require inpatient hospitalization.

In April 2013, we announced that we had discontinued our Phase 2 dose escalation study that was being conducted in the United States in 120 patients with cervical intraepithelial neoplasia (CIN) 2/3. The goal of this study was to provide a non-surgical treatment that could replace the current surgical treatment (LEEP) for CIN 2/3. This study commenced in March 2010 to assess the safety and efficacy of ADXS-HPV in women with this pre-cancerous condition. Given that we had no prior experience with ADXS-HPV in otherwise healthy subjects, our strategy was to start with a much lower dose than that used in patients with late-stage cervical cancer.

Cohort 1 received  $5 \times 10^7$  cfu, a dose that was 1/20th of the dose that has demonstrated clinical activity in our Phase 2 study in patients with recurrent cervical cancer ( $1 \times 10^9$  cfu). Enrollment was completed in this

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Cohort (41 patients) in September 2011 and although statistical significance was not reached, clinical benefit was observed that warranted further investigation. We completed enrollment of the mid-dose Cohort (40 patients) in June 2012 with a dose that was six times higher than Cohort 1 but 1/3 of the  $1 \times 10^9$  cfu dose. The data from this Cohort were significantly delayed due to study challenges, one of which was a high rate of discontinuation with 6 patients failing to complete the study. While incomplete, the second Cohort did not demonstrate significant clinical efficacy. In discussions with the investigators and sites, we learned that patients were not compliant with the current route of administration and regimen which consisted of an IV infusion every month for 3 months, as opposed to the standard of care, which is a single surgical office procedure (LEEP) that removes the malignant tissue. This was evident in the high rate of discontinuations in the trial (4 patients in Cohort 1 and 6 patients in Cohort 2). In addition, CIN 2/3 is a localized disease as opposed to a advanced metastatic cancer, and it is not necessary to give a systemic treatment nor is there a tolerance for an IV infusion in this clinical setting.

Based on the findings of Cohorts 1 and 2 and knowledge gained, we elected not to pursue Cohort 3 of the study and to instead evaluate our options for this patient population and indication that may include alternative dosage forms and routes of administration.

In June 2013, we submitted three applications for Orphan Drug Designation with the FDA for ADXS-HPV for use in the treatment of invasive cervical cancer, head and neck cancer and anal cancer, and in August 2013, we received notification that our anal cancer request was granted.

## **Business Strategy**

Our strategy is to maintain and fortify a leadership position in the discovery, acquisition and development of *Lm*-LLO immunotherapies that target for cancer and infectious disease. 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 registrational Phase 3 trials and regulatory approval in the United States and relevant markets for the treatment of cervical cancer. If successful, we plan to submit a Biologics 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 for ADXS-HPV with the FDA and one of these applications, for anal cancer, was granted in August 2013. 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 for ADXS-HPV if it is approved by the FDA for the treatment of cervical, head and neck and or anal cancer, 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.

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

***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 drug discovery platform to identify new therapeutic immunotherapies.*** We intend to utilize our proprietary discovery platform to identify new antigen-associated drug candidates. We may conduct some of these efforts internally and/or leverage our platform to forge strategic collaborations. We have utilized our proprietary drug discovery platform to identify a number of preclinical drug candidates and may initiate studies to support IND submissions either alone or in collaboration with strategic partners. Specifically, 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 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.

***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.

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*Continue to both leverage and strengthen our intellectual property portfolio.* We believe we have a strong intellectual property position relating to the development and commercialization of *Lm-LLO* immunotherapies. We plan to continue to leverage this portfolio to create value. In addition to strengthening our existing intellectual property position, 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:

Complete our Phase 2 clinical study in India of ADXS-HPV in the treatment of recurrent cervical cancer, report final Phase 2 data at the SITC Annual Meeting, optimize the dose and schedule through additional Phase 1/2 trials and finalize the registration strategy;

Conduct an end of Phase 2 meeting with the FDA, draft Phase 3 protocols and submit a Special Protocols Assessment for ADXS-HPV;

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

Continue our collaboration with the CRUK to support the Phase 1/2 clinical trial of ADXS-HPV in the treatment of head and neck cancer, entirely underwritten by the CRUK;

Initiate an additional Phase 1/2 study in head and neck cancer for ADXS-HPV; seek to conduct Advisory Board with key opinion leaders;

Continue our collaboration with the BrUOG to support the Phase 1/2 clinical trial of ADXS-HPV in the treatment of anal cancer, entirely underwritten by the BrUOG;

Discuss development plan for ADXS-HPV in anal cancer with the FDA in light of Orphan Drug Designation;

Obtain Orphan Drug Designation for two separate indications: the treatment of invasive cervical cancer and the treatment of HPV-positive head and neck cancer;

Continue our collaboration with the School of Veterinary Medicine at Penn to support the Phase 1/2 clinical trial of ADXS-cHER2 in canine osteosarcoma;

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

Continue the preclinical analyses and manufacturing activities required to support the IND submission for ADXS-PSA for the treatment of prostate cancer in preparation for a Phase 1 study;

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

Continue to actively pursue licensing discussions with multiple partners for our immunotherapies, execute definitive license agreement in strategic markets with high HPV prevalence consistent with already established commercial terms.

### **Recent Developments**

#### **Debt Conversion Agreements**

In September 2013, we entered into agreements with certain holders of our outstanding indebtedness to amend the terms of their existing arrangements and provide for repayment thereof or conversion into our securities, as follows:

*Moore Notes.* On September 26, 2013, we entered into a debt conversion and repayment agreement with Thomas A Moore, a Director of our company and our former Chief Executive Officer, with respect to the repayment and partial conversion of amounts owed to Mr. Moore under outstanding promissory notes issued pursuant to that certain Note Purchase Agreement dated September 22,



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2008, as amended from time to time. We refer to these outstanding notes as the Moore Notes. As provided in the agreement, following the closing of a major financing and uplisting to a major stock exchange, such as this offering: (a) we will pay Mr. Moore \$100,000 in cash as partial repayment of the Moore Notes, (b) one-half of the remaining balance (approximately \$162,659) will automatically convert at the closing of this offering into the securities being offered and sold in this offering at a conversion price equal to the public offer price, and (c) within three months of the closing of this offering, we will pay Mr. Moore in cash the then remaining outstanding balance under the Moore Notes (after taking into account the \$100,000 payment and automatic conversion in our securities). Following the cash payments and partial conversion into our securities, there will no longer be any outstanding balances under the Moore Notes and we will no longer have any obligations under the Moore Notes. Securities received by Mr. Moore upon conversion will be restricted securities and subject to customary lock-up restrictions.

*Redwood Bridge Notes.* On September 27, 2013, we entered into an exchange agreement with Redwood Management, LLC, with respect to the conversion of amounts owed to Redwood under that certain convertible promissory note with an aggregate principal amount of \$277,778 issued to Redwood in June 2013 in a bridge financing. We agreed to issue 125,000 restricted shares of our common stock to Redwood, in exchange for the convertible promissory note. Accordingly, we no longer have any outstanding obligations to Redwood under these bridge financing notes.

We are currently negotiating with the holders of approximately \$1,628,000 outstanding principal amount of convertible promissory notes to exchange those outstanding securities for shares of our common stock or new convertible promissory notes that have fixed (rather than variable) conversion prices. There can be no guarantee that we will be successful in agreeing to terms with such holders, and there is a risk that such indebtedness may continue to be outstanding following this offering.

### **Series B Preferred Redemption**

On September 26, 2013, we entered into a Notice of Redemption and Settlement Agreement with Optimus Capital Partners, LLC, a Delaware limited liability company, dba Optimus Life Sciences Capital Partners, LLC, Optimus CG II, Ltd., a Cayman Islands exempted Company and Socius CG II, Ltd., a Bermuda exempted Company, pursuant to which we agreed to redeem our outstanding shares of Series B Preferred Stock. Pursuant to the agreement, we agreed to cancel an outstanding receivable in the amount of \$10,633,584 as of the date of the agreement as payment in full of the redemption payment due under the terms of the Series B Preferred Stock and agreed to issue 33,750 shares of our common stock to settle a disagreement regarding the calculation of the settlement amount under a July 2012 Order and Stipulation. In connection with the redemption, we agreed to cancel the outstanding warrant held by Optimus. Accordingly, following such redemption, there are no longer any shares of our Series B Preferred Stock issued and outstanding.

### **Brio Settlement**

On September 18, 2013, we entered into a non-binding settlement agreement with Brio Capital L.P. to settle the remaining claims under our dispute with Brio Capital, L.P. See [Business Legal Proceedings](#) for more information.

### **Termination of Engagement Agreement**

On August 19, 2013, we entered into an agreement with a financial advisor to terminate a July 2012 engagement agreement between the parties, pursuant to which the advisor 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 the advisor approximately \$589,000 in monthly installment payments in either cash or shares of our common stock, and a 3-year warrant to purchase 30,154 shares of our common stock at an exercise price of \$4.90 per share. Additionally, we agreed to pay the advisor \$150,000 upon the completion of a contemplated public offering of securities.

**New Chief Executive Officer and New Chairman of the Board**

At a meeting of the Board held on August 14, 2013, Thomas A. Moore indicated his intent to resign as our Chairman of the Board and President and Chief Executive Officer, or CEO, effective August 19, 2013 in

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line with the previously contemplated succession plan. Mr. Moore will continue to serve on the Board and will act as a consultant to us. In light of Mr. Moore's notification to the Board of his intent to resign as President and CEO and the Board's succession plan, the Board appointed Daniel J. O'Connor (formerly Executive Vice President), to the position of President and CEO, effective August 19, 2013. Mr. O'Connor's appointment as President and CEO is the outcome of the succession planning initiatives over the past year by Mr. Moore and the Board. The Board also fixed the number of Board members at seven and appointed Mr. O'Connor as a Director to fill the newly created vacancy in accordance with our bylaws, all effective August 19, 2013. Mr. O'Connor will hold office as a Director until our next annual meeting of stockholders, subject to his earlier resignation or removal. Mr. O'Connor has not currently been appointed to any standing committee of the Board. Dr. James Patton, Chairman of the Audit Committee, was elected to serve as Non-Executive Chairman of the Board effective August 19, 2013. We have entered into an employment agreement with Mr. O'Connor and a consulting agreement with Mr. Moore, which both took effect on August 19, 2013. For a description of these agreements, see Summary Compensation Table Discussion on Summary Compensation Table.

### **Orphan Drug Designation**

In August 2013, the FDA granted our orphan drug designation request for ADXS-HPV for anal cancer.

### **Reverse Stock Split and Share Capital Decrease**

In July 2013, we amended our Amended and Restated Certificate of Incorporation by the filing of two Certificates of Amendment with the Delaware Secretary of State as follows: (a) on July 11, 2013, to effect a 1-for-125 reverse stock split of our common stock, par value \$0.001 per share, to take effect on July 12, 2013 at 4:30 p.m. EDT, and (b) on July 12, 2013, to decrease the total number of authorized shares of our common stock on a post-reverse stock split basis, so that the total number of shares that we have the authority to issue is 30,000,000 shares, of which 25,000,000 shares are common stock and 5,000,000 shares are blank check preferred stock. The reverse stock split was effective at approximately 4:30 p.m. EDT on July 12, 2013, and the share capital decrease took effect thereafter upon filing with the Delaware Secretary of State.

### **Yenson Company, Ltd. MOU**

In April 2013, we signed a memorandum of understanding with FusionVax, which was subsequently re-executed between us and Yenson Company, Ltd., or Yenson. The memorandum of understanding sets out the framework for entry into a definitive agreement to license ADXS-HPV for commercialization in Asia (except India). Under the terms of the memorandum of understanding, we agreed to work towards drafting a definitive agreement that exclusively licenses the rights to ADXS-HPV to Yenson (or NewCo) for the Asia territory, exclusive of India, for all indications. Subject to the entry into a definitive agreement, Yenson will pay us an up-front payment, certain event-based financial milestones, an annual exclusive licensing fee, and an annual net sales royalty in countries with issued patents. In exchange for the up-front payment, we will provide Yenson an equal amount worth of our common stock. Yenson will be responsible for conducting clinical trials and pursuing commercialization of ADXS-HPV in Asia and, in exchange, we will pay Yenson net sales annual royalty on ADXS-HPV in the United States of less than 1%. Yenson, accompanied with Taiwan Biotech Co., Ltd. and several Taiwanese venture capital funds plan to form a new company (NewCo) and transfer all rights to NewCo to execute the obligations and commitments described in the memorandum of understanding. On August 28, 2013, we entered into a Securities Purchase Agreement with Yenson, pursuant to which we issued Yenson 45,353 shares of our common stock and a 3-year warrant to acquire 22,161 shares of our common stock at an exercise price of \$2.76 per share for \$100,000 in cash.

## Our History

We were originally incorporated in the State of Colorado on June 5, 1987 under the name Great Expectations, Inc. In 1999, we became a reporting company under the Exchange Act. We were a publicly-traded shell company without any business until November 12, 2004 when we acquired Advaxis, Inc., a Delaware corporation, through Share Exchange. As a result of such acquisition, Advaxis become 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 the company from the state of Colorado to the state of Delaware by merging us into its wholly-owned subsidiary. Our date of inception, for financial statement purposes, is March 1, 2002.

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Our statements of income and cash flows disclose our accumulated losses and net cash increases (decreases), respectively since inception. Our principal executive offices are located at 305 College Road East, Princeton, NJ 08540 and our telephone number is (609) 452-9813.

We maintain a website at [www.advaxis.com](http://www.advaxis.com) that contains descriptions of our technology, our drugs and the trial status of each drug. The information on, or that can be accessed through, our website is not part of this prospectus.

On July 28, 2005 we began trading on the Over-The-Counter Bulletin Board (OTC:BB) under the ticker symbol ADXS.

## **Collaborations, Partnerships and Agreements**

### **University of Pennsylvania**

On July 1, 2002 we entered into an exclusive worldwide license agreement with Penn with respect to the innovative work of Yvonne Paterson, Ph.D., Associate Dean for Research and Professor in the School of Nursing at Penn, and former Professor of Microbiology at Penn, in the area of innate immunity, or the immune response attributed to immune cells, including dendritic cells, macrophages and natural killer cells, that respond to pathogens non-specifically (subject to certain U.S. government rights). This agreement has been amended from time to time and was amended and restated as of February 13, 2007.

This license, unless sooner terminated in accordance with its terms, terminates upon the later of (a) the expiration of the last to expire of the Penn patent rights; or (b) twenty years after the effective date of the license. Penn may terminate the license agreement early upon the occurrence of certain defaults by us, including, but not limited to, a material breach by us of the Penn license agreement that is not cured within 60 days after notice of the breach is provided to us.

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. In exchange for the license, Penn received shares of our common stock, which currently represent approximately 0.2% of our common stock outstanding on a fully-diluted basis. As of the date of this prospectus, Penn owns 28,468 shares of our common stock. In addition, Penn is entitled to receive a non-refundable initial license fee, license fees, royalty payments and milestone payments based on net sales and percentages of sublicense fees and certain commercial milestones. Under the licensing agreement, Penn is entitled to receive 1.5% royalties on net sales in all countries. Notwithstanding these royalty rates, we have agreed to pay Penn a total of \$525,000 over a three-year period as an advance minimum royalty after the first commercial sale of a product under each license (which we are not expecting to begin paying within the next five years). In addition, under the license, we are obligated to pay an annual maintenance fee of \$100,000 commencing on December 31, 2010, and each December 31<sup>st</sup> thereafter for the remainder of the term of the agreement until the first commercial sale of a Penn licensed product. Overall, the amended and restated agreement payment terms reflect lower near term requirements but the savings are offset by higher long term milestone payments for the initiation of a Phase 3 clinical trial and the regulatory approval for the first Penn licensed product. We are responsible for filing new patents and maintaining and defending the existing patents licensed to use and we are obligated to reimburse Penn for all attorneys fees, expenses, official fees and other charges incurred in the preparation, prosecution and maintenance of the patents licensed from Penn.

Furthermore, upon the achievement of the first sale of a product in certain fields, Penn will be entitled to certain milestone payments, as follows: \$2.5 million will be due upon the first commercial sale of the first product in the cancer field and \$1.0 million will be due upon the date of first commercial sale of a product in each of the secondary strategic fields sold.

As a result of our payment obligations under the license, assuming we have net sales in the aggregate amount of \$100.0 million from our cancer products, our total payments to Penn over the next ten years could reach an aggregate of \$5.4 million. If over the next 10 years our net sales total an aggregate amount of only \$10.0 million from our cancer products, total payments to Penn could be \$4.4 million.

As part of the Second Amendment, dated May 10, 2010, we exercised our option for the rights to seven additional patent dockets, including 23 additional patent applications, for (i) an option exercise fee payable in

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the form of \$35,000 in cash and \$70,000 in our common stock (approximately 3,111 shares of our common stock based on a price of \$22.50 per share) and (ii) the assumption of certain historical costs of approximately \$462,000 associated with the 23 additional patent applications acquired under the second amendment. As of July 31, 2013, approximately \$138,000 of these historical costs remained outstanding.

Strategically, we intend to maintain our relationship with Dr. Paterson and Penn to generate new intellectual property and to exploit all existing intellectual property covered by the license.

Penn is not involved in the management of our company or in our decisions with respect to exploitation of the patent portfolio.

**Dr. Yvonne Paterson**

Dr. Paterson is the Associate Dean for Research and Professor in the School of Nursing at Penn, and former Professor of Microbiology at Penn, and the inventor of our licensed technology. Dr. Paterson is a fellow of the American Academy for the Advancement of Science, and has been an invited speaker at national and international health field conferences and leading academic institutions. Dr. Paterson has served on many federal advisory boards, such as the NIH expert panel to review primate centers, the Office of AIDS Research Planning Fiscal Workshop and the Allergy and Immunology NIH Study Section. She has written over one hundred publications in the areas of HIV, AIDS and cancer research. Dr. Paterson has trained over forty post-doctoral and doctoral students in the fields of Biochemistry and Immunology.

In the past we have entered into consulting agreements with Dr. Paterson, providing for compensation through cash payments and equity awards. Currently, we do not have a written agreement in place, but Dr. Paterson continues to consult with us on a regular basis, and we intend to continue to compensate Dr. Paterson in cash, equity awards, or a combination thereof as we deem appropriate from time to time.

**Recipharm Cobra Biologics Limited (formerly Cobra Biomanufacturing PLC)**

We outsource the manufacture and supply of our cervical cancer immunotherapy ADXS-HPV to Recipharm Cobra Biologics Limited, or Cobra. We began this partnership in July 2003. Cobra has extensive experience in manufacturing gene therapy and manufactures and supplies biologic therapeutics for the pharmaceutical and biotech industry. We currently have two agreements with Cobra; one to conduct ongoing stability testing of the ADXS-HPV immunotherapy that they have manufactured, and another to provide analytic services and certification necessary to import ADXS-HPV for use in the United Kingdom head and neck cancer study mentioned below.

**Vibalogics GmbH**

In April 2008, we entered into a series of agreements with Vibalogics GmbH in Cuxhaven Germany to provide fill and finish services for our final clinical materials that were made for our scheduled clinical trials described above. These agreements cover the fill and finish operations as well as specific tests required in order to release the clinical drug supplies for human use. We have entered into agreements with Vibalogics to produce two *Lm-LLO* immunotherapies, ADXS-PSA and ADXS-cHER2 for research and/or clinical development. As of July 31, 2013, approximately \$263,000 in invoices from Vibalogics GmbH remained outstanding. In April 2013, we entered into a settlement agreement with Vibalogics for payment of past-due amounts and intend to use a portion of the proceeds from this offering to pay down amounts owing to Vibalogics. See Use of Proceeds.

**Numoda Corporation**

On June 19, 2009, we entered into a Master Agreement and on July 8, 2009 we entered into a Project Agreement with Numoda Corporation, which we refer to as Numoda, a leading clinical trial and logistics management company, to oversee Phase 2 clinical activity with ADXS-HPV for the multicenter Phase 2 U.S. trial of ADXS-HPV in CIN 2/3 and to act as our U.S. CRO for the multicenter Phase 2 study of ADXS-HPV in recurrent cervical cancer being conducted in India. The scope of the Project Agreement covers over three years, with an estimated cost of approximately \$12.2 million for both trials. In May 2010, we issued 28,000 shares of common stock to Numoda Capital at a price per share of \$21.25 in satisfaction of \$595,000 of services rendered to us by Numoda. As of July 31, 2013, we have paid Numoda approximately \$7.6 million for clinical trial activities. The Master Agreement with Numoda terminated on June 12, 2012.

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The Project Agreement with Numoda continues until the project that is the subject of such agreement is completed, unless earlier terminated in accordance with the Master Agreement with Numoda.

On June 13, 2012, we entered into a stock purchase agreement with Numoda, pursuant to which we issued to Numoda 120,000 shares of our common stock at a purchase price per share of \$18.75, in exchange for the immediate cancellation of \$2,250,000 of accounts receivables owed by us to Numoda pursuant to the Master Agreement.

**National Cancer Institute Gynecologic Oncology Group**

On December 13, 2009, we entered into an agreement for GOG to conduct a multicenter, Phase 2 clinical trial of ADXS-HPV, our *Lm*-LLO based immunotherapy targeted to HPV, in 67 patients with recurrent or refractory cervical cancer who have failed prior cytotoxic therapy. This Phase 2 trial is being underwritten by GOG and will be conducted by GOG investigators. This patient population is similar to the patient population in the cervical cancer study being conducted in India as well as the patients in the Phase 1 trial of ADXS-HPV. Under this Clinical Trial Services Agreement, we are responsible for covering the costs of translational research and agreed to pay a total of \$8,003 per patient, with the majority of the costs of this study underwritten by GOG. This agreement shall continue in force until we receive completed case histories for all participants in the clinical trial and questions about data submitted have been resolved, unless terminated earlier upon the occurrence of certain events, including, but not limited to, the FDA imposing a permanent hold on the drug which is subject to the clinical trial, a material breach by us of the agreement that is not cured within a reasonable time period after notice of the breach is provided to us, or sixty days prior written notice by either party for any reason. As of September 2013, 13 patients are enrolled in the study.

**Cancer Research U.K.**

On February 9, 2010, Cancer Research U.K. (CRUK), the U.K. organization dedicated to cancer research, agreed to fund the cost of a clinical trial to investigate the use of ADXS-HPV, our *Lm*-LLO based immunotherapy targeted to HPV, for the treatment of head and neck cancer. This Phase 1/2 clinical trial will investigate the safety and efficacy of ADXS-HPV 6 weeks post-treatment with surgery, radiotherapy and chemotherapy alone or in combination in head and neck cancer patients. We will provide the study drug, with all other associated costs to be funded by CRUK. The study is to be conducted at 3 sites in the United Kingdom (Aintree Hospital at the University of Liverpool, The Royal Marsden Hospital in London and Cardiff Hospital at the University of Wales). As of September 2013, Aintree Hospital has enrolled 16 patients into the study.

**School of Veterinary Medicine at Penn**

On August 17, 2010, we entered into a clinical trial agreement with the School of Veterinary Medicine at Penn to investigate the use of ADXS-CHER2 for the treatment of canine osteosarcoma in 15 dogs. This study commenced dosing in July of 2012 and 13 dogs have been enrolled and dosed as of August 2013.

**Georgia Health Sciences University Cancer Center**

On March 20, 2012, we announced the continuation of our collaboration with Dr. Samir N. Khleif, the former Chief of the Vaccines Section at the National Cancer Institute, at his new position as Director of the Georgia Health Sciences University Cancer Center in Augusta, Georgia. Dr. Khleif and his laboratory will continue to elaborate the molecular immunologic mechanisms by which live, attenuated strains of *Lm* can effect therapeutic changes in cancer and other diseases.

**Brown University Oncology Group**

In January 2013, we entered into an agreement with The Miriam Hospital, an affiliate of Brown University Oncology Group (BrUOG), to evaluate the safety and effectiveness of ADXS-HPV when combined with standard chemotherapy and radiation treatment for anal cancer. BrUOG will fund and conduct a Phase 1/2 study of ADXS-HPV in 25 patients with anal cancer at Brown University, M.D. Anderson Cancer Center, Montefiore Medical Center, Boston Medical Center, and other sites. Four patients have been enrolled in the study as of September 2013.

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TABLE OF CONTENTS**Intellectual Property**

Protection of our intellectual property is important to our business. We have a robust and extensive patent portfolio that protects our core technology, new constructs, inventions, and improvements. Currently, our patent portfolio includes 41 issued patents and 35 pending patent applications. All of these patents and patent applications are assigned from Penn with the exception of 11 pending patent applications, which are owned by our company. We continuously add to this portfolio by filing applications to protect our ongoing research and development efforts. We aggressively prosecute and defend our patents and proprietary technology and have successfully defended critical patents in the European Patent Court. Our material patents that cover the use, methods, and compositions of our *Lm*-LLO immunotherapies for certain constructs including, but not limited to, ADXS-HPV, ADXS-PSA, and ADXS-cHER2, expire at various dates between 2013 and 2024, prior to available patent extensions.

Some of the key patents acquired from Penn are for the development of preclinical constructs. In 2011, we licensed a patent pertaining to antigen ISG-15 from Penn, which has been investigated as an effective immunological target for the treatment of a number of different cancers in animal models, including ovarian, colon, breast and other cancers. Other licensed patents include *Lm*-LLO immunotherapies that were found in a number of animal models to have the ability to induce therapeutic Th-1 immune responses, a response that can enhance effectiveness of immunotherapies. We have also been issued patents that protect a new strain of *Listeria* as an improvement over the strain currently in clinical testing that is more attenuated, more immunogenic and does not contain an antibiotic resistance gene.

Our approach to the intellectual property portfolio is to create significant offensive and defensive patent protection for every immunotherapy and technology platform that we develop. We endeavor to maintain a coherent and aggressive strategic approach to building our patent portfolio with an emphasis in the field of cancer vaccines.

We successfully defended our intellectual property concerning our *Lm*-based technology by contesting a challenge made by Anza Therapeutics, Inc., which we refer to as Anza, to our patent position in Europe on a claim not available in the United States. The European Patent Office, which we refer to as the EPO, Board of Appeals in Munich, Germany ruled in favor of the Trustees of Penn and us, Penn's exclusive licensee, and reversed a patent ruling that revoked a technology patent that had resulted from an opposition filed by Anza. The ruling of the EPO Board of Appeals is final and cannot be appealed. The granted claims, the subject matter of which was discovered by Dr. Yvonne Paterson, are directed to the method of preparation and composition of matter of recombinant bacteria expressing tumor antigens for the treatment of patients with cancer.

The successful development of our immunotherapies will include our ability to create and maintain intellectual property related to our drug candidates.

Material patents currently underlying the license agreement with Penn are shown in the following table.

Title	Expiration	Product Candidate	Jurisdiction
Specific Immunotherapy of Cancer Using a Live Recombinant Bacterial Vaccine Vector	18-Apr-2017  03-Nov-2015	All ADXS product candidates, including ADXS-HPV, ADXS-HER2, ADXS-PSA	United States, Germany, Switzerland, France, Ireland, UK, Belgium, Japan, Canada United States

Live, Recombinant Listeria  
*Monocytogenes* and Production of  
Cytotoxic T-Cell Response

Methods and Compositions for  
Immunotherapy of Cancer

08-Nov-2014

All ADXS product candidates,  
including ADXS-HPV,  
ADXS-HER2, ADXS-PSA  
All ADXS product candidates,  
including ADXS-HPV,  
ADXS-HER2, ADXS-PSA

United States

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Title	Expiration	Product Candidate	Jurisdiction
Fusion of Non-Hemolytic, Truncated Form of Listeriolysin O to Antigens to Enhance Immunogenicity	2-Aug-2020	All ADXS product candidates, including ADXS-HPV, ADXS-HER2, ADXS-PSA	United States, Germany, France, Great Britain Israel, European Union
Compositions and Methods for Enhancing Immunogenicity of Antigens	2-Aug-2020	All ADXS product candidates, including ADXS-HPV, ADXS-HER2, ADXS-PSA	United States, Germany, France European Union, Israel
Compositions and Methods for Enhancing Immunogenicity of Antigens	15-Nov-2023	All ADXS product candidates, including ADXS-HPV, ADXS-HER2, ADXS-PSA	United States
Methods and Compositions for Immunotherapy of Cancer	08-Nov-2014	All ADXS product candidates, including ADXS-HPV, ADXS-HER2, ADXS-PSA	United States
Compositions and Methods for Enhancing Immunogenicity of Antigens	29-Mar-2020	All ADXS product candidates, including ADXS-HPV, ADXS-HER2, ADXS-PSA	United States
Immunogenic Compositions Comprising DAL/DAT Double-Mutant, Auxotrophic, Attenuated Strains of <i>Listeria</i> and their Methods of Use	18-Nov-2017	ADXS-PSA and ADXS-HER	United States
Isolated Nucleic Acids Comprising <i>Listeria</i> DAL and DAT Genes	18-Nov-2017	ADXS-PSA and ADXS-HER	United States
Isolated Nucleic Acids Comprising <i>Listeria</i> DAL and DAT Genes	18-Nov-2017	ADXS-PSA and ADXS-HER	United States
Immunogenic Compositions Comprising DAL/DAT Double Mutant, Auxotrophic Attenuated Strains of <i>Listeria</i> and their Methods of Use	31-Jan-2020	ADXS-PSA and ADXS-HER	United States
Methods and Compositions for Immunotherapy of Cancer	13-Jul-2016	ADXS-HER2	United States
<i>Listeria</i> -based and LLO-based Vaccines	24-Sep-2024	ADXS-HER2	United States

**Governmental Regulation****The Drug Development Process**

The FDA requires that pharmaceutical and certain other therapeutic products undergo significant clinical experimentation and clinical testing prior to their marketing or introduction to the general public. Clinical testing, known as clinical trials or clinical studies, is either conducted internally by pharmaceutical or biotechnology companies or is conducted on behalf of these companies by Clinical Research Organizations, which we refer to as

CROs.

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The process of conducting clinical studies is highly regulated by the FDA, as well as by other governmental and professional bodies. Below, we describe the principal framework in which clinical studies are conducted, as well as describe a number of the parties involved in these studies.

*Protocols.* Before commencing clinical studies, the sponsor of an investigational new drug must typically receive governmental and institutional approval. In the United States, Federal approval is obtained by submitting an IND to the FDA and amending it for each new proposed study. The clinical research plan is known in the industry as a *protocol*. A protocol is the blueprint for each drug study. The protocol sets forth, among other things, the following:

Criteria for subject or patient inclusion/exclusion;  
Dosing requirements and timing;  
Tests to be performed; and  
Evaluations and data assessment.

*Institutional Review Board (Ethics Committee).* An institutional review board is an independent committee of professionals and lay persons which reviews clinical research studies involving human beings and is required to adhere to guidelines issued by the FDA. The institutional review board does not report to the FDA and its members are not appointed by the FDA, but its records are audited by the FDA. All clinical studies must be approved by an institutional review board. The institutional review board is convened by the site or institution where the protocol will be conducted and its role is to protect the rights of the subjects and patients in the clinical studies. It must approve the protocols to be used and then oversee the conduct of the study, including oversight of the communications which we or the CRO conducting the study at that specific site proposes to use to recruit subjects or patients, and the informed consent form which the subjects or patients will be required to sign prior to their enrollment in the clinical studies.

*Clinical Trials.* Human clinical studies or testing of an investigational new drug prior to FDA approval are generally done in three stages known as Phase 1, Phase 2, and Phase 3 testing. The names of the phases are derived from the CFR 21 that regulates the FDA. Generally, there are multiple studies conducted in each phase.

*Phase 1.* Phase 1 studies involve testing an investigational new drug on a limited number of patients. Phase 1 studies determine a drug's basic safety, maximum tolerated dose and how the drug is absorbed by, and eliminated from, the body. This phase lasts an average of six months to a year. Typically, cancer therapies are initially tested on late stage cancer patients.

*Phase 2.* Phase 2 trials involve larger numbers of patients that have been diagnosed with the targeted disease or condition. Phase 2 testing typically lasts an average of one to three years. In Phase 2, the drug is tested to determine its safety and effectiveness for treating a specific disease or condition. Phase 2 testing also involves determining acceptable dosage levels of the drug. If Phase 2 studies show that an investigational new drug has an acceptable range of safety risks and probable effectiveness, a company will continue to evaluate the investigational new drug in Phase 3 studies.

*Phase 3.* Phase 3 studies involve testing even larger numbers of patients, typically several hundred to several thousand patients. The purpose is to confirm effectiveness and long-term safety on a large scale. These studies generally last two to six years. Given the larger number of patients required to conduct Phase 3 studies, they are generally conducted at multiple sites and often times in multiple countries.

*Biologic License Application.* The results of the clinical trials using biologics are submitted to the FDA as part of Biologic License Application, which we refer to as BLA. Following the completion of Phase 3 studies, if the Sponsor of a potential product in the United States believes it has sufficient information to support the safety and effectiveness of the investigational new drug, the Sponsor submits a BLA to the FDA requesting that the investigational new drug

be approved for sale. The application is a comprehensive, multi-volume filing that includes the results of all preclinical and clinical studies, information about the drug's composition, and the Sponsor's plans for manufacturing, packaging, labeling and testing the investigational new drug. The FDA's review of an application is designated either as a standard review with a target review

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time of 10 months or a priority review with a target of 6 months. Depending upon the completeness of the application and the number and complexity of requests and responses between the FDA and the Sponsor, the review time can take months to many years, with the mean review lasting 13.1 months. Once approved, drugs and other products may be marketed in the United States, subject to any conditions imposed by the FDA.

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.

### **Orphan Drug Designation**

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, 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. If a sponsor demonstrates that a drug is intended to treat a rare disease or condition, the FDA grants orphan drug designation to the product for that use. The benefits of orphan drug designation can obtain substantial incentives, including research and development tax credits and exemption from user fees, enhanced access to advice from the FDA while the drug is being developed, and market exclusivity once the product reaches approval and begins sales, provided that the new product is first to market. In order to qualify for these incentives, a company must apply for designation of its product as an Orphan Drug and obtain approval from the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. A drug that is approved for the orphan drug designated indication is granted seven years of orphan drug exclusivity. During that period, the FDA generally may not approve any other application for the same product for the same indication, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity.

In June 2013, we submitted three applications for Orphan Drug Designation with the FDA for ADXS-HPV for use in the treatment of invasive cervical cancer, head and neck cancer and anal cancer and in August 2013, our request for anal cancer to be designated an orphan drug was granted.

Orphan drug status in the European Union has similar but not identical benefits in that jurisdiction. The applicable exclusivity period, for example, is ten years in Europe, and 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.

### **Non-U.S. Regulation**

Before our products can be marketed outside the United States, they are subject to regulatory approval of the respective authorities in the country in which the product should be marketed. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices might not be approved for such product.

In Europe, marketing authorizations may be submitted at a centralized, a decentralized or national level. The centralized procedure is mandatory for the approval of biotechnology products and provides for the grant of a single marketing authorization that is valid in all European Union member states. As of January 1995, a mutual recognition procedure is available at the request of the applicant for all medicinal products that are not subject to the centralized procedure. There can be no assurance that the chosen regulatory strategy will secure regulatory approvals on a timely basis or at all.

While we intend to market our products outside the United States in compliance with our respective license agreements, we have not made any applications with non-U.S. authorities. Our current business strategy, however,

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includes filing three applications to request Orphan Drug Designation with the EMEA for ADX-HPV for use in the treatment of invasive cervical cancer, head and neck cancer and anal cancer.

## **Manufacturing**

The FDA requires that any drug or formulation to be tested in humans be manufactured in accordance with its 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.

We have entered into agreements with Cobra and Vibalogics for the manufacture of a portion of our immunotherapies. Both companies have extensive experience in manufacturing gene therapy products for investigational studies. Both companies are full service manufacturing organizations that manufacture and supply biologic based therapeutics for the pharmaceutical and biotech industry. These services include cell banking, GMP manufacturing and stability testing.

Our agreements with Vibalogics cover the manufacture of GMP material for two immunotherapies ADXS-PSA, an *Lm*-LLO immunotherapy for the treatment of prostate cancer, and ADXS-cHER2, an *Lm*-LLO immunotherapy for the treatment of HER2 overexpressing cancers (such as breast, gastric and other cancers and for canine osteosarcoma).

Our agreement with Cobra covers GMP manufacturing in several stages, including process development, manufacturing of non-GMP material for toxicology studies and manufacturing of GMP material for the Phase 1 and Phase 2 trials.

## **Competition**

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. The biotechnology and biopharmaceutical industries are highly competitive, and this competition comes from both biotechnology firms and from major pharmaceutical companies, including: Aduro Biotech, Agenus Inc., Bristol-Myers Squibb, Celgene Corporation, Celldex Therapeutics, Dendreon Corporation, Inovio Pharmaceutical Inc., Oncolytics Biotech Inc., Oncothyreon Inc., et al., 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.

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 immunotherapies or of competitors' products may be an important competitive factor. Accordingly, the speed with which we can develop immunotherapies, complete preclinical testing, clinical trials and approval processes and supply commercial quantities to market are 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.

## **Employees**

As of September 27, 2013, we had 14 employees, all of which were full time employees. None of our employees is represented by a labor union, and we consider our relationship with our employees to be good.

Because we intend to continue to outsource many functions, we do not anticipate any significant increase in the number of employees in the clinical area and the research and development area to support clinical requirements, and in the general and administrative and business development areas over the next two years, even as we expand our research and development activities.

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## Description of Property

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 payable upon the consummation of a future capital raising transactions. Accordingly, we intend to use proceeds from this offering to pay this obligation. See Use of Proceeds. In addition, lease payments for the period July 1, 2013 through November 30, 2015 was reduced to a total of \$20,000 per month.

## Legal Proceedings

On March 22, 2013, we were notified that a lawsuit against Advaxis had been filed by Brio Capital L.P., which we refer to as Brio, 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, each at an initial exercise price of \$25.00 per share, 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 settlement of the Brio lawsuit, we issued 21,742 shares of common stock and provided certain corporate resolutions and legal opinions necessary to enable Brio Capital L.P. to sell such common stock publicly without restriction. On September 18, 2013, we entered into a non-binding settlement agreement with Brio Capital L.P. to settle the remaining claims under the Action, which agreement will become binding only when approved by the court at a fairness hearing. Under the non-binding agreement, we agreed to issue Brio Capital L.P. \$250,000 in shares of our common stock based on a volume weighted average price and Brio Capital L.P. agreed to trading restrictions in respect of such shares of our common stock. Prior to the fairness hearing, we may pay Brio Capital L.P. in cash. The non-binding agreement is null and void if the application for the fairness hearing is not made prior to November 11, 2013 and if the hearing does not occur on or before November 30, 2013, among other items.

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.

TABLE OF CONTENTS**MANAGEMENT**

The following are our current executive officers and directors and their respective ages and positions as of September 27, 2013:

Name	Age	Position
Executive Officers		
Daniel J. O Connor	48	Chief Executive Officer, President and Director
Mark J. Rosenblum	60	Chief Financial Officer, Senior Vice President and Secretary
Robert G. Petit	53	Chief Scientific Officer, Executive Vice President
Chris L. French	55	Executive Director of Medical Affairs, Vice President
Non-Employee Directors		
Dr. James Patton	55	Chairman of the Board
Roni Appel	46	Director
Richard Berman	70	Director
Dr. Thomas McKearn	64	Director
Thomas A. Moore	62	Director
Dr. David Sidransky	53	Director

**Executive Officers**

**Daniel J. O Connor.** Mr. O Connor joined our company on January 1, 2013, as our Senior Vice President, Corporate Development and Chief Legal Officer and was appointed our Executive Vice President effective May 3, 2013 and our Chief Executive Officer and President effective August 19, 2013. Mr. O Connor also joined the Board of Directors on August 19, 2013. Mr. O Connor has 15 years of executive, legal, and regulatory experience in the biopharmaceutical industry with ImClone Systems, PharmaNet (now Inventive Health Clinical) and Bracco Diagnostics. Joining ImClone in 2003, Mr. O Connor supported the clinical development, launch, and commercialization of ERBITUX(R). As ImClone's senior vice president, general counsel, and secretary, he played a key role in resolving numerous issues facing ImClone, including extensive licensing negotiations, in advance of the company being sold to Eli Lilly and Company in 2008. Prior to joining ImClone, Mr. O Connor was PharmaNet's general counsel and instrumental in building the company from a start-up contract research organization to an established world leader in clinical research. Mr. O Connor was also a criminal prosecutor in New Jersey and gained leadership experience as a Captain in the U.S. Marines, serving in the Persian Gulf in 1990. Most recently, from 2009 to 2013, Mr. O Connor was the vice president and general counsel of Bracco Diagnostics, a large private pharmaceutical and medical device company. Mr. O Connor's extensive background in the biopharmaceutical industry, as well as legal, executive and regulatory experience make him particularly qualified to serve as our director.

**Mark J. Rosenblum.** Effective as of January 5, 2010, Mr. Rosenblum joined our company as our Chief Financial Officer, Senior Vice President and Secretary. From August 1985 through June 2003, Mr. Rosenblum was employed by Wellman, Inc., a public chemical manufacturing company. Between 1996 and 2003, Mr. Rosenblum was the Chief Accounting Officer, Vice President and Controller at Wellman, Inc. Mr. Rosenblum was the Chief Financial Officer of HemobioTech, Inc., a public company primarily engaged in the commercialization of human blood substitute technology licensed from Texas Tech University, from April 1, 2005 until December 31, 2009. Mr. Rosenblum holds both a Masters in Accountancy and a B.S. degree from the University of South Carolina. Mr. Rosenblum is a certified public accountant.

**Robert G. Petit, Ph.D.** Dr. Petit joined our company in October 2010 and was appointed Chief Scientific Officer effective May 3, 2013 and named an Executive Vice President on August 19, 2013. Dr. Petit has 25 years of experience in all medical and scientific aspects of pharmaceutical development with a particular focus on immunotherapy for cancer. His diverse professional experience includes discovery, translational development, selection of candidate drugs, licensing due diligence, design and conduct of complete U.S. and international clinical development programs from preclinical through Phase 4. He has designed, planned, and executed U.S. and global clinical development programs for 13 drugs, three immunotherapies, two cellular immunotherapies, and five therapeutic vaccine programs. He has experience with five New Drug Application/Biologic License Application filings and significant regulatory interactions

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with FDA/Health Ministries. He has held several INDs and has been awarded several U.S. and international patents. His industry experience has been gained within large pharma, mid-sized specialty pharma, and small biopharma. Dr. Petit joined Advaxis from Bristol-Myers Squibb, where he served from December 2005 to October 2010 as the U.S. Medical Lead for Yervoy (Ipilimumab), Director of Medical Strategy for New Oncology Products, and Director of Global Clinical Research. Before Bristol Myers-Squibb, Robert was the Vice President of Clinical Development at both MGI Pharma and Aesgen Inc., following several years within the Pharmacia organization. Dr. Petit co-founded the Cancer Immunotherapy Program at St. Luke's Hospital in Milwaukee and was Assistant Professor of Pathology and Laboratory Medicine at the University of Wisconsin Medical School. Dr. Petit received his doctorate from the Ohio State University College of Medicine in Immunology and Medical Microbiology with a focus on Viral Oncology.

**Chris L. French, MBA.** Ms. French joined our company in June 2011 and is our Executive Director of Medical Affairs and was named Vice President in August 2013. Ms. French joined us from Bristol Myers-Squibb where she was U.S. Director of Oncology Scientific Communications and medical strategy lead in U.S. Oncology Medical Affairs New Products from November 2007 to April 2011. Ms. French has over 20 years of basic science research and pharmaceutical experience in drug development in start-up, midsize and large pharmaceutical companies. She has held management positions in medical affairs, regulatory affairs, scientific communications, drug development, and business development. Prior to BMS, Ms. French was the Senior Director of Program Management at MGI Pharma; Vice President of Regulatory and Scientific Affairs at Aesgen and the Director of the Dermatology Business Unit at Atrix, Inc.

## **Non-Employee Directors**

**Dr. James P. Patton.** Dr. Patton has served as a member of our Board of Directors since our business combination with Great Expectations and Associates, Inc. in November 2004 and as Chairman of our Board of Directors from November 2004 until December 31, 2005 and again since August 19, 2013. Dr. Patton was the Chief Executive Officer of Great Expectations and Associates, Inc. from February 2002 to November 2002. Since February 1999, Dr. Patton has been the Vice President of Millennium Oncology Management, Inc., which provides management services for radiation oncology care to four sites. Dr. Patton has been a trustee of Dundee Wealth US, a mutual fund family, since October 2006. He is a founder and has been chairman of VAL Health, LLC, a health care consultancy, from 2011 to the present. In addition, he was President of Comprehensive Oncology Care, LLC since 1999, a company that owned and operated a cancer treatment facility in Exton, Pennsylvania until its sale in 2008. From February 1999 to September 2003, Dr. Patton also served as a consultant to LibertyView Equity Partners SBIC, LP, a venture capital fund based in Jersey City, New Jersey. From July 2000 to December 2002, Dr. Patton served as a director of Pinpoint Data Corp. From February 2000 to November 2000, Dr. Patton served as a director of Healthcare Solutions. From June 2000 to June 2003, Dr. Patton served as a director of LifeStar Response. He earned his B.S. from the University of Michigan, his Medical Doctorate from Medical College of Pennsylvania, and his M.B.A. from Penn's Wharton School. Dr. Patton was also a Robert Wood Johnson Foundation Clinical Scholar. He has published papers regarding scientific research in human genetics, diagnostic test performance and medical economic analysis. Dr. Patton's experience as a trustee and consultant to funds that invest in life science companies provide him with the perspective from which we benefit. Additionally, Dr. Patton's medical experience and service as a principal and director of other life science companies make Dr. Patton particularly qualified to serve as our director.

**Roni A. Appel.** Mr. Appel has served as a member of our Board of Directors since November 2004. He was our President and Chief Executive Officer from January 1, 2006 and Secretary and Chief Financial Officer from November 2004, until he resigned as our Chief Financial Officer on September 7, 2006 and as our President, Chief Executive Officer and Secretary on December 15, 2006. From December 15, 2006 to December 2007, Mr. Appel

served as a consultant to us. Mr. Appel currently is a self-employed consultant. Previously, he served as Chief Executive Officer of Anima Cell Metrology Ltd., from 2008 through January 31, 2013. From 1999 to 2004, he was a partner and managing director of LV Equity Partners (f/k/a LibertyView Equity Partners). From 1998 until 1999, he was a director of business development at Americana Financial Services, Inc. From 1994 to 1998, he was an attorney and completed his MBA at Columbia University. Mr. Appel's longstanding service with us and his entrepreneurial investment career in early stage biotech businesses qualify him to serve as our director.

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**Richard J. Berman.** Mr. Berman has served as a member of our Board of Directors since September 1, 2005. Richard

Berman's business career spans over 35 years of venture capital, senior management and merger & acquisitions experience. In the past 5 years, Mr. Berman has served as a director and/or officer of over a dozen public and private companies. From 2006 to 2011, he was Chairman of National Investment Managers, a company with \$12 billion in pension administration assets. In 2012, he became vice chairman of Energy Smart Resources, Inc. From 1998 to 2012,

Mr. Berman served as a Director of Easy Link International. Mr. Berman is currently a director of three public companies: Advaxis, Inc., Neostem, Inc. (since 2005), and Lustros, Inc. (since 2012). From 1998 to 2000, he was employed by Internet Commerce Corporation (now Easylink Services) as Chairman and CEO. Previously, Mr. Berman worked at Goldman Sachs; was Senior Vice President of Bankers Trust Company, where he started the M&A and Leveraged Buyout Departments; created the largest battery company in the world in the 1980s by merging Prestolite, General Battery and Exide to form Exide Technologies (XIDE); helped to create what is now Soho (NYC) by developing five buildings; and advised on over \$4 billion of M&A transactions (completed over 300 deals). He is a past Director of the Stern School of Business of NYU where he obtained his B.S. and M.B.A. He also has US and foreign law degrees from Boston College and The Hague Academy of International Law, respectively. Mr. Berman's extensive knowledge of our industry, his role in the governance of publicly held companies and his directorships in other life science companies qualify him to serve as our director.

**Dr. Thomas J. McKearn.** Dr. McKearn has served as a member of our Board of Directors since our business combination with Great Expectations and Associates, Inc. in November 2004. Dr. McKearn served as a director of Great Expectations and Associates, Inc. between July 2002 and November 2004. He brings more than 30 years of experience in the translation of biotechnology science into oncology products. As one of the founders of Cytogen Corporation in 1981 and later its Chief Executive Officer, an Executive Director of Strategic Science and Medicine at Bristol-Myers Squibb, then for ten years, from April 2002 to August 2012, at Agennix, Inc. (formerly GPC-Biotech) as VP of Medical Affairs and later as the VP of Strategic Clinical Affairs, and now as the President, Research & Development at Onconova since September 2012, he has worked to bring the most innovative laboratory findings into the clinic and through the FDA regulatory process for the benefit of cancer patients who need better ways to cope with their afflictions. Prior to entering the biotechnology industry in 1981, Dr. McKearn received his medical, graduate and post-graduate training at the University of Chicago and served on the faculty of the Medical School at the University of Pennsylvania. Dr. McKearn's experience in managing life science companies, his knowledge of medicine and his commercialization of biotech products qualify him to serve as our director.

**Thomas A. Moore.** Mr. Moore was appointed to our Board of Directors as an independent director in September 2006 served as our Chief Executive Officer and Chairman of the Board from December 2006 through August 19, 2013. Previously, from June 2002 to June 2004, Mr. Moore was President and Chief Executive Officer of Biopure Corporation, a developer of oxygen therapeutics that are intravenously administered to deliver oxygen to the body's tissues. From 1996 to November 2000, he was President and Chief Executive Officer of Nelson Communications. Previously, Mr. Moore had a 23-year career with the Procter & Gamble Company in multiple managerial positions, including President of Health Care Products where he was responsible for prescription and over-the-counter medications worldwide, and group vice president of the Procter & Gamble Company. Mr. Moore's extensive business, managerial, executive and leadership experience in the healthcare industry make him particularly qualified to serve as our director.

On September 14, 2005, a civil action captioned Securities & Exchange Commission v. Biopure Corp. et al., No. 05-11853-PBS (D. Mass.) was filed alleging that Mr. Moore made and approved misleading public statements about the status of FDA regulatory proceedings concerning a product manufactured by his former employer, Biopure Corp.

Mr. Moore vigorously defended the action. On December 11, 2006, the SEC and Mr. Moore jointly sought a continuance of all proceedings based upon a tentative agreement in principle to settle the SEC action. The SEC's Commissioners approved the terms of the settlement, and the court formally adopted the settlement. Under the terms

of settlement, Mr. Moore paid a \$120,000 fine to the SEC.

***Dr. David Sidransky.*** Dr. David Sidransky has served as a member of our Board of Directors since July 2013. Dr. Sidransky is also the Director of the Head and Neck Cancer Research Division at Johns Hopkins University School of Medicine and is a Professor of Oncology, Otolaryngology Head and Neck Surgery, Cellular & Molecular Medicine, Urology, Genetics, and Pathology at Johns Hopkins University and Hospital.

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In the field of oncology, Dr. Sidransky is one of the most highly-cited researchers in clinical and medical journals in the world, with over 400 peer-reviewed publications in the past decade. He has also contributed to more than 60 cancer reviews and chapters. Dr. Sidransky is a founder of a number of biotechnology companies and holds numerous biotechnology patents. He has served as Vice Chairman of the Board of Directors of ImClone Systems, Inc., a global biopharmaceutical company committed to advancing oncology care, and was a director, until its merger with Eli Lilly. Dr. Sidransky remains Chairman of Tamir Biotechnology, and Chairman of Champions Oncology, Inc., and serves on the Boards of Directors of KV Pharmaceutical Company and Rosetta Genomics. Dr. Sidransky is serving and has served on scientific advisory boards of MedImmune, Roche, Amgen and Veridex, LLC (a Johnson & Johnson diagnostic company), among others. From 2005 to 2008, Dr. Sidransky served as Director of the American Association for Cancer Research (AACR) and was the Chairperson of the first and second (September 2006 and 2007) AACR International Conferences on Molecular Diagnostics in Cancer Therapeutic Development: Maximizing Opportunities for Individualized Treatment. Dr. Sidransky is the recipient of many awards and honors, including the 1997 Sarstedt International Prize from the German Society of Clinical Chemistry, the 1998 Alton Ochsner Award Relating Smoking and Health by the American College of Chest Physicians, and the 2004 Hinda and Richard Rosenthal Award from the AACR. Dr. Sidransky is certified in Internal Medicine and Medical Oncology by the American Board of Medicine. Dr. Sidransky received his bachelor's degree from Brandeis University and his medical degree from the Baylor College of Medicine. Dr. Sidransky's extensive medical background and biotechnology experience, combined with his leadership role at a prominent academic institution and role as a director at other public companies make Dr. Sidransky particularly qualified to serve as our director.

## **Director Independence**

In accordance with the disclosure requirements of the SEC, and because the OTCQB Marketplace, does not have its own rules for director independence, we have adopted The NASDAQ Stock Market listing standards for independence effective April 2010. Although we are not presently listed on any national securities exchange, each of our directors, other than Messrs. O'Connor and Moore, is independent in accordance with the definition set forth in the rules of The NASDAQ Stock Market. Each current member of each of our Board committees (other than our Research and Development Committee) is an independent director under The NASDAQ Stock Market standards applicable to such committees. The Board considered the information included in transactions with related parties as outlined below along with other information the Board considered relevant, when considering the independence of each director.

## **Audit Committee**

The Audit Committee of our Board of Directors is currently composed of three directors, all of whom satisfy the independence and other standards for Audit Committee members under the rules of The NASDAQ Stock Market (although our securities are not listed on The NASDAQ Stock Market but are quoted on the OTCQB Marketplace). For fiscal 2012, the Audit Committee was composed of Mr. Berman and Dr. Patton, with Mr. Berman serving as the Audit Committee's financial expert as defined under Item 407 of Regulation S-K of the Securities Act of 1933, as amended, which we refer to as the Securities Act. Mr. Appel was appointed to the Audit Committee in August 2013.

The Audit Committee operates under a written Audit Committee Charter, which is available to stockholders on our website at <http://www.advaxis.com/investors/corporate-governance/>.

## **Compensation Committee**

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The Compensation Committee of our Board of Directors currently consists of Messrs. Appel and Berman and Dr. Sidransky. For fiscal 2012, the Compensation Committee was composed of Mr. Berman and Dr. McKearn. In August 2013, our Board appointed the current members.

The Compensation Committee operates under a written Compensation Committee Charter, which is available to stockholders on our website at <http://www.advaxis.com/investors/corporate-governance/>.

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## **Nominating and Corporate Governance Committee**

The Nominating and Corporate Governance Committee of our Board of Directors currently consists of Mr. Berman and Dr. Patton. For fiscal 2012, the Nominating and Corporate Governance Committee was composed of Mr. Berman and Mr. Moore. Dr. Patton was appointed to replace Mr. Moore on this Committee in April 2013.

The Nominating and Corporate Governance Committee operates under a written Nominating and Corporate Governance Committee Charter, which is available to stockholders on our website at <http://www.advaxis.com/investors/corporate-governance/>.

## **Research and Development Committee**

The Research and Development Committee was established in August 2013 with the purpose of providing advice and guidance to the Board on scientific and medical matters and development. The Research and Development Committee currently consists of Dr. Sidransky (Chairman), Dr. McKearn and Mr. Moore. The Research and Development Committee operates under a written charter, which is available on our web-site at <http://www.advaxis.com/investor/corporate-governance/>.

TABLE OF CONTENTS**EXECUTIVE AND DIRECTOR COMPENSATION****Summary Compensation Table**

The following table sets forth the information as to compensation paid to or earned by our then Chief Executive Officer and our two other most highly compensated executive officers during the fiscal years ended October 31, 2012 and 2011. These individuals are referred to in this proxy statement as our named executive officers. As none of our named executive officers received non-equity incentive plan compensation or nonqualified deferred compensation earnings during the fiscal years ended October 31, 2012 and 2011, we have omitted those columns from the table.

Name and Principal Position	Fiscal Year	Salary	Bonus	Stock Award(s)	Option Award(s) <sup>(1)</sup>	All Other Compensation	Total
Thomas A. Moore, Former CEO and Chairman <sup>(a)</sup>	2012	\$350,000			\$592,000 <sup>(6)</sup>	\$43,985 <sup>(2)</sup>	\$985,985
	2011	\$350,000				\$21,294 <sup>(2)</sup>	\$371,294
Dr. John Rothman, Former Executive VP of Science & Operations <sup>(b)</sup>	2012	\$275,000		\$30,000 <sup>(3)</sup>	\$444,000 <sup>(7)</sup>	\$33,516 <sup>(4)</sup>	\$782,516
	2011	\$275,000	\$83,000	\$30,000 <sup>(3)</sup>	\$	\$34,665 <sup>(4)</sup>	\$422,665
Mark J. Rosenblum Chief Financial Officer	2012	\$250,000		\$	\$310,800 <sup>(8)</sup>	\$21,335 <sup>(5)</sup>	\$582,135
	2011	\$250,000	\$72,000	\$		\$19,211 <sup>(5)</sup>	\$341,211

(a) Mr. Moore resigned as CEO and Chairman (but remains a Director) effective August 19, 2013. We have also entered into a consulting agreement with Mr. Moore effective August 19, 2013.

(b) On March 6, 2013, we announced the departure of Dr. John Rothman effective March 1, 2013. Dr. Rothman will continue to assist us as a consultant for a period of one year.

The amounts shown in this column represent the fair value on grant date determined by multiplying the number of options granted by the closing price of our common stock on the date of grant in accordance with ASC 718. The (1) grant date values have been determined based on the assumptions and methodologies set forth in the consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended October 31, 2012 (Note 11, Stock Options).

(2) Based on our cost of Mr. Moore's coverage for health care and interest received by Mr. Moore for the Moore Notes.

(3) Represents \$30,000 of base salary paid in shares of our common stock in lieu of cash, based on the average monthly stock price.

(4) Based on our cost of Dr. Rothman's coverage for health care and the 401K company match he received.

(5) Based on our cost of Mr. Rosenblum's coverage for health care.

In the fiscal year ended October 31, 2012, we granted stock options to purchase 32,000 shares of our common (6) stock to Mr. Moore in connection with services he performed. The material terms of this grant are described below under the heading Discussion of Summary Compensation Table.

In the fiscal year ended October 31, 2012, we granted stock options to purchase 24,000 shares of our common (7) stock to Dr. Rothman in connection with services he performed. The material terms of this grant are described below under the heading Discussion of Summary Compensation Table.

In the fiscal year ended October 31, 2012, we granted stock options to purchase 16,800 shares of our common (8) stock to Mr. Rosenblum in connection with services he performed. The material terms of this grant are described below under the heading Discussion of Summary Compensation Table.

## Discussion of Summary Compensation Table

*O Connor Employment Agreement.* On August 19, 2013, we entered into an employment agreement with Daniel J. O Connor in connection with his appointment as our President and Chief Executive Officer, which took effect as of such date. The employment agreement provides for an initial term of three years, after which it will be automatically renewed for one year periods unless otherwise terminated by us or Mr. O Connor upon 90 days written notice. Pursuant to the terms of the employment agreement, Mr. O Connor is entitled to a base salary of \$295,000 per year (plus annual cost-of-living adjustments), which salary will be reviewed on an annual basis. As provided in the agreement, the Compensation Committee

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elected to pay 75% of this salary in restricted stock units under the Plan so long as there is capacity under the Plan (prior to this appointment, Mr. O Connor received approximately 75% of his compensation in the form of stock awards). Mr. O Connor is also eligible to receive an annual bonus of 10-50% of his base salary, which amount, if any, will be determined by the Compensation Committee of the Board of Directors based on achievement of certain goals to be established by such committee and Mr. O Connor at the beginning of each fiscal year. The employment agreement also contemplates payment of a one-time bonus in an amount to be determined by the Compensation Committee prior to September 30, 2013, if we close a financing greater than \$15,000,000 during the initial three-year term of the agreement (such as the offering contemplated hereby). We may elect to pay 50% of this one-time bonus in shares of its common stock. Mr. O Connor remains eligible to participate in our benefit plans and receive grants of stock options and other awards under our 2011 Omnibus Incentive Plan, is entitled to 4 weeks of vacation and sick leave, as well as reimbursement of reasonable expenses incurred in fulfilling his duties under the agreement. The employment agreement grants Mr. O Connor the right to participate in future capital raises at a 15% discount to the applicable offering price (or conversion price) of shares offered to investors during such capital raise or offering.

In the event Mr. O Connor's employment is terminated without Just Cause, or if he voluntarily resigns with Good Reason, or if his employment is terminated due to disability (all as defined in the employment agreement), and so long as Mr. O Connor executes a confidential separation and release agreement, in addition to the applicable base salary, plus any accrued but unused vacation time and unpaid expenses that have been earned as of the date of such termination, Mr. O Connor is entitled to the following: 12-months of base salary and continued health and welfare benefits, full vesting of all stock options and extension of the exercise period for such stock options by two years, the issuance of all earned but unissued shares of common stock, and removal of all restrictive legends on shares that qualify for such treatment under Rule 144 of the Securities and Exchange Act of 1934 within 10 business days of the presentation of such shares to the transfer agent.

Mr. O Connor's employment agreement also contains customary covenants regarding non-solicitation, non-compete, confidentiality and works for hire.

In September 2013, the Compensation Committee fixed the amount of Mr. O Connor's one-time transaction bonus at \$88,500 and elected to pay 50% of this bonus in restricted stock units. Additionally, the Compensation Committee determined not to pay any portion of Mr. O Connor's salary in restricted stock units at this time.

*Moore Employment Agreement and Option Agreements.* We were party to an employment agreement with Mr. Moore, dated as of August 21, 2007 (memorializing an oral agreement dated December 15, 2006) through August 19, 2013, that provided that he would serve as our Chairman of the Board and Chief Executive Officer for an initial term of two years.

Under the terms of his former employment agreement, Mr. Moore was entitled to receive a base salary of \$350,000 per year, subject to annual review for increases by our Board of Directors in its sole discretion. The agreement also provided that Mr. Moore was entitled to receive family health insurance at no cost to him. Mr. Moore's former employment agreement did not provide for the payment of a bonus.

During fiscal 2012, on November 8, 2011, we granted Mr. Moore options to purchase 32,000 shares of our common stock. Each option is exercisable at \$18.50 per share. These options vest over a three year period beginning one year from the grant date.

*Moore Consulting Agreement.* In connection with Mr. Moore's resignation as Chairman of the Board and as CEO and President, we entered into a consulting agreement with Mr. Moore, which took effect as of August 19, 2013. Under the consulting agreement, Mr. Moore will assist the development of our veterinary program and perform the duties

assigned by the CEO, the Chairman of the Board and/or Board of Directors related to strategic planning and business development, or any other matter so delegated. Mr. Moore is required to be able to commit at least 20 hours per week to his consulting duties under the agreement. The consulting agreement provides for an initial term of one year, after which it terminate unless we notify Mr. Moore of our intent to renew prior to the expiration of the initial

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term, following which it will be renewed upon such terms and conditions as we may mutually agree. If we elect to continue beyond the initial term, either we or Mr. Moore may terminate at any time for any reason with or without cause upon 90 days written notice.

Pursuant to the terms of the consulting agreement, Mr. Moore is entitled to: (i) annualized compensation of \$350,000 (payable monthly, with the first payment due September 20, 2013), with 12% per annum interest accruing on payments not made in accordance with the agreed terms; (ii) reimbursement for any COBRA costs, (iii) a one-time \$100,000 payment if we close a financing greater than \$5,000,000 during the initial term of the agreement (which one-time payment may be increased to \$429,076.59 at our discretion if the financing exceeds \$15,000,000), which amounts are to be in repayment of the Moore Notes, (iv) be treated as non-employee Director for purposes of attendance fees under our Director compensation program (but not for purposes of the annual retainer), (v) receive a one-time grant of 30,000 options under the our 2011 Omnibus Incentive Plan (the Plan) on or around November 1, 2013, and be considered in Continuous Service for purposes of his outstanding option awards under the Plan (as such term is defined in the Plan) and (v) reimbursement of reasonable documented travel expenses as contemplated by the consulting agreement.

The consulting agreement also provides that if we close any financing equal to or greater than \$15,000,000 but do not fully satisfy our cumulative outstanding financial obligations, if any, to Mr. Moore as described above, then we must pay the remaining balance of any such outstanding financial obligations on the earlier of: (i) six months from the date of closing; or (ii) upon the completion of an underwritten financing (not currently contemplated). However, in September 2013, Mr. Moore entered into a debt conversion and repayment agreement with our company whereby we agreed to a different repayment schedule. See Certain Relationships and Related Transactions Thomas Moore.

Following Mr. Moore's termination of his engagement as a consultant as provided in the agreement, Mr. Moore is entitled to payment of any earned or accrued but unpaid compensation and, provided that Mr. Moore executes a separation agreement and general release, a one-time lump sum \$350,000 disengagement payment, subject to all applicable withholdings and deductions.

The consulting agreement provides for the termination of Mr. Moore's employment agreement described above, and provides that upon termination of that employment agreement, Mr. Moore shall receive (i) accrued but unused vacation time, (ii) reimbursement of reasonable documented expenses incurred and (iii) accrued salary prior, all of which are payable in accordance with the schedule provided in the agreement.

Mr. Moore's consulting agreement also contains customary covenants regarding non-solicitation, non-compete, confidentiality, works for hire, non-disparagement, as well as a general release of liability of our company for claims, including any claims for a default on Mr. Moore's outstanding notes, that accrued prior to the date of execution of the consulting agreement.

*Rothman Employment Agreement and Option Agreements.* On March 6, 2013, we announced the departure of Dr. John Rothman effective March 1, 2013. Dr. Rothman will continue to assist us as a consultant for a period of one year. Dr. Rothman's 2011 and 2012 salary was \$305,000, consisting of \$275,000 in cash and \$30,000 in stock, payable in our common stock, based on the average closing stock price. We also granted Dr. Rothman options to purchase shares of our common stock pursuant to our equity compensation programs. During fiscal 2012, on November 8, 2011, we granted Dr. Rothman options to purchase 24,000 shares of our common stock. Each option is exercisable at \$18.50 per share. These options vest over a three year period beginning one year from the grant date. In connection with Mr. Rothman's departure, we agreed to vest all 62,480 options outstanding and that all such options would expire February 28, 2016.

*Rothman Separation Agreement.* On March 20, 2013, we entered into a Separation Agreement and General Release with Dr. Rothman, pursuant to which Dr. Rothman released us from all claims and agreed to continue to assist us as a consultant until February 28, 2014 in exchange for (i) being compensated on an hourly basis for certain project assignments as requested by us, (ii) receiving an aggregate of approximately \$275,000, paid in installments over the course of the one year consulting period, and (iii) all of the options to purchase shares of our common stock held by Dr. Rothman being fully vested with the exercise period of such options being extended until March 1, 2015.

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*Rosenblum Compensation.* Mr. Rosenblum serves as our Chief Financial Officer, Senior Vice President and Secretary. In fiscal 2012, his salary was \$250,000 per annum, with a discretionary bonus of up to 30% of his base compensation awarded annually in March beginning in 2011. We also granted Mr. Rosenblum options to purchase shares of our common stock pursuant to our equity compensation programs. During fiscal 2012, on November 8, 2011, we granted Mr. Rosenblum options to purchase 16,800 shares of our common stock. Each option is exercisable at \$18.50 per share. These options vest over a three year period beginning one year from the grant date.

On September 4, 2013, we entered into an employment agreement with Mr. Rosenblum, which took effect as of such date. The employment agreement provides for an initial term of one year, after which it will be automatically renewed for one year periods unless otherwise terminated by us or Mr. Rosenblum upon 90 days written notice. Pursuant to the terms of the employment agreement, Mr. Rosenblum is entitled to a base salary of \$275,000 per year (plus annual cost-of-living adjustments), which salary will be reviewed on an annual basis. The Compensation Committee and Mr.

Rosenblum agreed to have 7.5% of this salary paid in restricted stock units under the Plan for so long as there is capacity under the Plan. Mr. Rosenblum is also eligible to receive an annual bonus of 10-50% of his base salary, which amount, if any, will be determined by the Compensation Committee based on achievement of certain goals to be established by such committee and Mr. Rosenblum at the beginning of each fiscal year. The employment agreement also contemplates payment of a one-time bonus in an amount to be determined by September 30, 2013, in the sole discretion of the Compensation Committee if we close a financing greater than \$15,000,000 during the initial one-year term of the agreement. We may elect to pay 50% of this one-time bonus in shares of our common stock. Mr. Rosenblum remains eligible to participate in our benefit plans and receive grants of stock options and other awards under our 2011 Omnibus Incentive Plan, is entitled to four weeks of vacation and sick leave, as well as reimbursement of reasonable expenses incurred in fulfilling his duties under the agreement. The employment agreement grants Mr.

Rosenblum the right to participate in future capital raises at a 15% discount to the applicable offering price (or conversion price) of shares offered to investors during such capital raise or offering.

In the event Mr. Rosenblum's employment is terminated without Just Cause, or if he voluntarily resigns with Good Reason, or if his employment is terminated due to disability (all as defined in the employment agreement), and so long as Mr. Rosenblum executes a confidential separation and release agreement, in addition to the applicable base salary, plus any accrued but unused vacation time and unpaid expenses that have been earned as of the date of such termination, Mr. Rosenblum is entitled to the following: 12-months of base salary and continued health and welfare benefits, full vesting of all stock options and extension of the exercise period for such stock options by two years, the issuance of all earned but unissued shares of common stock, and removal of all restrictive legends on shares that qualify for such treatment under Rule 144 of the Securities and Exchange Act of 1934 within 10 business days of the presentation of such shares to the transfer agent.

In September 2013, the Compensation Committee fixed the amount of Mr. Rosenblum's one-time transaction bonus at \$96,250 and elected to pay 50% of this bonus in restricted stock units. Additionally, the Compensation Committee determined not to pay any portion of Mr. Rosenblum's salary in restricted stock units at this time.

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The following table provides information about the number of outstanding equity awards held by our named executive officers at October 31, 2012. There are no outstanding stock awards, only outstanding option awards.

Name	Option Awards		Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price (\$)	Option Expiration Date
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable			
Thomas A. Moore	20,000 <sup>(1)</sup>			12.50	7/21/19
	19,200			17.875	12/15/16
	10,666	5,333 <sup>(2)</sup>		18.75	10/14/20
	10,666	21,333 <sup>(3)</sup>		18.50	11/08/21
Dr. John Rothman <sup>(4)</sup>	14,000			12.50	7/21/19
	2,880			35.875	3/1/15
	1,200			32.50	3/29/16
	2,400 <sup>(5)</sup>			20.625	2/15/17
	12,000	6,000 <sup>(6)</sup>		18.75	10/14/20
Mark J. Rosenblum	8,000	16,000 <sup>(7)</sup>		18.50	11/08/21
	8,000			16.1375	1/05/20
	6,400	3,200 <sup>(8)</sup>		18.75	10/14/20
	5,600	11,200		18.50	11/8/21

(1) Of these options, approximately 6,666 became exercisable on July 21, 2009, approximately 6,666 became exercisable on July 21, 2010 and approximately 6,666 became exercisable on July 21, 2011.

(2) Of these options, approximately 5,333 became exercisable on October 14, 2011, approximately 5,333 became exercisable on October 14, 2012 and approximately 5,333 will become exercisable on October 14, 2013.

(3) Of these options, approximately 10,666 became exercisable on November 8, 2012, approximately 10,666 will become exercisable on November 8, 2013 and approximately 10,666 will become exercisable on November 8, 2014.

(4) Information for Dr. Rothman is at fiscal year-end. Subsequent to fiscal year end, in connection with Dr. Rothman's departure, we agreed to immediately vest all 62,480 outstanding options and agreed to a February 28, 2015 expiration date for all such options.

(5) Of these options, 600 became exercisable on February 15, 2008, 150 became exercisable in each quarter from the quarter ended April 30, 2008 through the quarter ended October 31, 2010, and 150 became exercisable February 15, 2011. See Note (4) above.

(6) Of these options, 6,000 became exercisable on October 14, 2011, 6,000 became exercisable on October 14, 2012 and 6,000 will become exercisable on October 14, 2013. See Note (4) above.

(7) Of these options, 8,000 became exercisable on November 8, 2012, 8,000 will become exercisable on November 8, 2013 and 8,000 will become exercisable on November 8, 2014. See Note (4) above.

(8) Of these options, 3,200 became exercisable on October 14, 2011, 3,200 became exercisable on October 14, 2012 and 3,200 will become exercisable on October 14, 2013.

(9) Of these options, 5,600 became exercisable on November 8, 2012, 5,600 will become exercisable on November 8, 2013 and 5,600 will become exercisable on November 8, 2014.

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All of our non-employee directors earn a combination of cash compensation and awards of shares of our common stock. For fiscal 2012, each non-employee director (other than Mr. Berman) earned 6,000 shares of our common stock per quarter. Mr. Berman, earned \$2,000 a month in shares of our common stock based on the average closing price of our common stock for the preceding month. Additionally, each non-employee director earned \$2,000 for each Board meeting attended in person and \$750 for each telephonic Board meeting. In addition, each member of a committee of the Board earned \$2,000 per meeting attended in person held on days other than Board meeting days and \$750 for each telephonic committee meeting.

On February 15, 2013 the Board of Directors elected to change its compensation policy. Beginning in fiscal 2013, non-employee directors will receive \$100,000 in compensation, of which at least 50% must be in shares of our common stock. Under his consulting agreement, Mr. Moore has agreed not to receive this retainer while his consulting agreement is in effect. Each director will elect the dollar value of stock based compensation at the beginning of each fiscal year. For each year beginning in fiscal 2014 the share price used in determining the number of shares to be issued will be the average of the 30 preceding trading days prior to November 1 of each fiscal year beginning November 1, 2013. For the fiscal year ended October 31, 2013 all non-employee directors chose to receive all \$100,000 in the form of our common stock priced at \$9.375 (the average closing price of our common stock in the 30 days prior to the February 15, 2013 decision date). Accordingly, each non-employee director will earn 10,666 shares of common stock during 2013. Additionally, for both fiscal 2012 and 2013, each non-employee director will receive 800 non-qualified stock options under our 2011 Omnibus Incentive Plan for Board or committee meetings attended in person and 400 non-qualified stock options under our 2011 Omnibus Incentive Plan for meetings attended by telephone. Stock options awarded for attendance.

The non-employee director cash compensation that was earned for the twelve months ended October 31, 2011 and 2012 was not paid. In March 2012, we issued to our non-employee directors, all earned but unissued shares earned through December 31, 2011. Non-employee director share compensation that was earned for the period from January 1, 2012 through October 31, 2012 remains unissued and unpaid.

Our employee director does not receive any compensation for his services as a director. Our consultant director receives only the attendance fees (paid in stock options) described above.

The table below summarizes the compensation that was earned by our non-employee directors for fiscal 2012. As none of our non-employee directors received option awards, non-equity incentive plan compensation, nonqualified deferred compensation earnings or other compensation during fiscal 2012, we have omitted those columns from the table.

Name	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)	Total (\$)
Roni A. Appel	\$ 29,750	\$ 2,412 <sup>(1)</sup>	\$ 32,162
Dr. James Patton	34,000	2,412 <sup>(1)</sup>	36,412
Dr. Thomas McKearn	30,250	2,412 <sup>(1)</sup>	32,662
Richard Berman	8,750	24,000 <sup>(2)</sup>	32,750

- Represents the grant date fair value of 48 shares of our common stock per quarter earned (but not paid or issued)
- (1) multiplied by the closing price of our common stock on the last day of each quarter if the member attends at least 75% of the meetings annually.
  - (2) Based on \$24,000 of compensation in the form of shares of our common stock earned but not issued to date.

## **Employee Benefit Plans**

We believe that our ability to grant equity-based awards is a valuable and necessary compensation tool that aligns the long-term financial interests of our employees, consultants and directors with the financial interests of our stockholders. In addition, we believe that our ability to grant options and other equity-based

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awards helps us to attract, retain and motivate qualified personnel and service providers, and encourages them to devote their best efforts to our business and financial success. The material terms of our equity incentive plans are described below.

## **2004 Stock Option Plan**

In November 2004, our Board of Directors adopted and our stockholders approved the 2004 Stock Option Plan, which we refer to as the 2004 plan. The 2004 plan provides for the grant of options to purchase up to 19,052 shares of our common stock to employees, officers, directors and consultants. Options may be either incentive stock options or non-qualified options under the Federal tax laws. Incentive stock options may be granted only to our employees, while non-qualified options may be issued, in addition to employees, to non-employee directors and consultants. As of February 25, 2013, all options to purchase shares of our common stock have been granted under the 2004 plan.

The 2004 plan is administered by disinterested members of our Board of Directors or the Compensation Committee, who determine, among other things, the individuals who will receive options, the time period during which the options may be partially or fully exercised, the number of shares of common stock issuable upon the exercise of each option and the option exercise price.

Subject to a number of exceptions, the exercise price per share of common stock subject to an incentive option may not be less than the fair market value per share of common stock on the date the option is granted. The per share exercise price of our common stock subject to a non-qualified option may be established by our Board of Directors, but will not, however, be less than 85% of the fair market value per share of common stock on the date the option is granted. The aggregate fair market value of common stock for which any person may be granted incentive stock options which first become exercisable in any calendar year may not exceed \$100,000 on the date of grant.

No stock option may be transferred by an optionee other than by will or the laws of descent and distribution, and, during the lifetime of an optionee, the option will be exercisable only by the optionee. In the event of termination of employment or engagement other than by death or disability, the optionee will have no more than three months after such termination during which the optionee will be entitled to exercise the option to the extent vested at termination, unless otherwise determined by our Board of Directors. Upon termination of employment or engagement of an optionee by reason of death or permanent and total disability, the optionee's options remain exercisable for one year to the extent the options were exercisable on the date of such termination. No similar limitation applies to non-qualified options.

All options under the 2004 plan were required to be granted within ten years from the effective date of the 2004 plan. The effective date of the 2004 plan was November 12, 2004. Subject to a number of exceptions, holders of incentive stock options granted under the 2004 plan cannot exercise these options more than ten years from the date of grant. Options granted under the 2004 plan generally provide for the payment of the exercise price in cash and may provide for the payment of the exercise price by delivery to us of shares of common stock already owned by the optionee having a fair market value equal to the exercise price of the options being exercised, or by a combination of these methods. Therefore, if it is provided in an optionee's options, the optionee may be able to tender shares of common stock to purchase additional shares of common stock and may theoretically exercise all of his stock options with no additional investment other than the purchase of his original shares. Any unexercised options that expire or that terminate upon an employee's ceasing to be employed by us become available again for issuance under the 2004 plan.

As of September 27, 2011, the date on which the Advaxis, Inc. 2011 Omnibus Incentive Plan was approved by our stockholders, no further awards may be made under the 2004 plan.

## **2005 Stock Option Plan**

In June 2006 our Board of Directors adopted, and on June 6, 2006, our stockholders approved, the 2005 Stock Option Plan, which we refer to as the 2005 plan.

The 2005 plan provides for the grant of options to purchase up to 44,800 shares of our common stock to employees, officers, directors and consultants. Options may be either incentive stock options or non-qualified options under the Federal tax laws. Incentive stock options may be granted only to our

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employees, while non-qualified options may be issued to non-employee directors, consultants and others, as well as to our employees. As of February 25, 2013, all options to purchase shares of our common stock have been granted under the 2005 plan.

The 2005 plan is administered by disinterested members of our Board of Directors or the Compensation Committee, who determine, among other things, the individuals who will receive options, the time period during which the options may be partially or fully exercised, the number of shares of common stock issuable upon the exercise of each option and the option exercise price.

Subject to a number of exceptions, the exercise price per share of common stock subject to an incentive option may not be less than the fair market value per share of common stock on the date the option is granted. The per share exercise price of our common stock subject to a non-qualified option may be established by our Board of Directors, but will not, however, be less than 85% of the fair market value per share of common stock on the date the option is granted. The aggregate fair market value of common stock for which any person may be granted incentive stock options which first become exercisable in any calendar year may not exceed \$100,000 on the date of grant.

Except when agreed to by our Board of Directors or the administrator of the 2005 plan, no stock option may be transferred by an optionee other than by will or the laws of descent and distribution, and, during the lifetime of an optionee, the option will be exercisable only by the optionee. In the event of termination of employment or engagement other than by death or disability, the optionee will have no more than three months after such termination during which the optionee will be entitled to exercise the option, unless otherwise determined by our Board of Directors. Upon termination of employment or engagement of an optionee by reason of death or permanent and total disability, the optionee's options remain exercisable for one year to the extent the options were exercisable on the date of such termination. No similar limitation applies to non-qualified options.

All options under the 2005 plan were required to be granted within ten years from the effective date of the 2005 plan. The effective date of the 2005 plan was January 1, 2005. Subject to a number of exceptions, holders of incentive stock options granted under the 2005 plan cannot exercise these options more than ten years from the date of grant. Options granted under the 2005 plan generally provide for the payment of the exercise price in cash and may provide for the payment of the exercise price by delivery to us of shares of common stock already owned by the optionee having a fair market value equal to the exercise price of the options being exercised, or by a combination of these methods.

Therefore, if it is provided in an optionee's options, the optionee may be able to tender shares of common stock to purchase additional shares of common stock and may theoretically exercise all of his stock options with no additional investment other than the purchase of his original shares.

Any unexercised options that expire or that terminate upon an employee's ceasing to be employed by us become available again for issuance under the 2005 plan.

As of September 27, 2011, the date on which the Advaxis, Inc. 2011 Omnibus Incentive Plan was approved by our stockholders, no further awards may be made under the 2005 plan.

## **2009 Stock Option Plan**

Our Board of Directors adopted the 2009 Stock Option Plan effective July 21, 2009, and recommended that it be submitted to our stockholders for their approval at the next annual meeting. On April 23, 2010, our Board of Directors approved and adopted, and on June 1, 2010 our stockholders approved, the amended and restated 2009 Stock Option Plan, which we refer to as the 2009 plan. An aggregate of 160,000 shares of our common stock (subject to adjustment

by the Compensation Committee) are reserved for issuance upon the exercise of options granted under the 2009 plan. As of February 25, 2013, options to purchase 4,064 shares of our common stock are available for grant under the 2009 plan. However, due to the approval of the Advaxis, Inc. 2011 Omnibus Incentive Plan by our stockholders, on September 27, 2011, no further awards may be made under the 2009 plan (see below for details on the Advaxis Inc. 2011 Omnibus Incentive Plan).

The 2009 plan is to be administered by the Compensation Committee of our Board of Directors; provided, however, that except as otherwise expressly provided in the 2009 plan, our Board of Directors may exercise any power or authority granted to the Compensation Committee under the 2009 plan. Subject to the

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terms of the 2009 plan, the Compensation Committee is authorized to select eligible persons to receive options, determine the type, number and other terms and conditions of, and all other matters relating to, options, prescribe option agreements (which need not be identical for each participant), and the rules and regulations for the administration of the 2009 plan, construe and interpret the 2009 plan and option agreements, correct defects, supply omissions or reconcile inconsistencies therein, and make all other decisions and determinations as the Compensation Committee may deem necessary or advisable for the administration of the 2009 plan.

The maximum number of shares of common stock to which options may be granted to any one individual under the 2009 plan is 48,000 (subject to adjustment by the Compensation Committee). The shares acquired upon exercise of options granted under the 2009 plan will be authorized and issued shares of our common stock. Our stockholders will not have any preemptive rights to purchase or subscribe for any common stock by reason of the reservation and issuance of common stock under the 2009 plan. If any option granted under the 2009 plan should expire or terminate for any reason other than having been exercised in full, the unpurchased shares subject to that option will again be available for purposes of the 2009 plan.

The persons eligible to receive awards under the 2009 plan are the officers, directors, employees, consultants and other persons who provide services to us or any related entity. An employee on leave of absence may be considered as still in our or a related entity's employ for purposes of eligibility for participation in the 2009 plan. All options granted under the 2009 plan must be evidenced by a written agreement. The agreement will contain such terms and conditions as the Compensation Committee shall prescribe, consistent with the 2009 plan, including, without limitation, the exercise price, term and any restrictions on the exercisability of the options granted. For any option granted under the 2009 plan, the exercise price per share of common stock may be any price determined by the Compensation Committee; however, the exercise price per share of any incentive stock option may not be less than the fair market value of the common stock on the date such incentive stock option is granted.

The Compensation Committee may permit the exercise price of an option to be paid for in cash, by certified or official bank check or personal check, by money order, with already owned shares of common stock that have been held by the optionee for at least six (6) months (or such other shares as we determine will not cause us to recognize for financial accounting purposes a charge for compensation expense), the withholding of shares of common stock issuable upon exercise of the option, by delivery of a properly executed exercise notice together with such documentation as shall be required by the Compensation Committee (or, if applicable, the broker) to effect a cashless exercise, or a combination of the above. If paid in whole or in part with shares of already owned common stock, the value of the shares surrendered is deemed to be their fair market value on the date the option is exercised.

No incentive stock option, and unless the prior written consent of our Compensation Committee is obtained (which consent may be withheld for any reason) and the transaction does not violate the requirements of Rule 16b-3 of the Exchange Act, no non-qualified stock option granted under the 2009 plan is assignable or transferable, other than by will or by the laws of descent and distribution. During the lifetime of an optionee, an option is exercisable only by him or her, or in the case of a non-qualified stock option, by his or her permitted assignee.

The expiration date of an option under the 2009 plan will be determined by Compensation Committee at the time of grant, but in no event may such an option be exercisable after 10 years from the date of grant. An option may be exercised at any time or from time to time or only after a period of time in installments, as determined by our Compensation Committee. Our Compensation Committee may in its sole discretion accelerate the date on which any option may be exercised. Each outstanding option granted under the 2009 plan may become immediately fully exercisable in the event of certain transactions, including certain changes in control of us, certain mergers and reorganizations, and certain dispositions of substantially all our assets.

Unless otherwise provided in the option agreement, the unexercised portion of any option granted under the 2009 plan shall automatically be terminated (a) three months after the date on which the optionee's employment is terminated for any reason other than (i) cause (as defined in the 2009 plan), (ii) mental or physical disability, or (iii) death; (b) immediately upon the termination of the optionee's employment for cause; (c) one year after the date on which the optionee's employment is terminated by reason of mental or

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physical disability; or (d) one year after the date on which the optionee's employment is terminated by reason of optionee's death, or if later, three months after the date of optionee's death if death occurs during the one year period following the termination of the optionee's employment by reason of mental or physical disability.

Unless earlier terminated by our board, the 2009 plan will terminate at the earliest of (a) such time as no shares of common stock remain available for issuance under the 2009 plan, (b) termination of the 2009 plan by our board, or (c) the tenth anniversary of the effective date of the 2009 plan. Options outstanding upon expiration of the 2009 plan shall remain in effect until they have been exercised or terminated, or have expired.

As of September 27, 2011, the date on which the Advaxis, Inc. 2011 Omnibus Incentive Plan was approved by our stockholders, no further awards may be made under the 2009 plan.

**2011 Omnibus Incentive Plan**

During any 12-month period, no participant in the 2011 Omnibus Incentive Plan may be granted (i) stock options or stock appreciation rights with respect to more than 32,000 shares of our common stock, or (ii) shares of restricted stock, restricted stock units, performance shares and other stock based-awards with respect to more than 32,000 shares of our common stock. The maximum amount that may be paid out as performance units with respect to any 12-month performance period is \$2,500,000 (pro-rated for any 12-month performance period that is less than 12 months), and with respect to any performance period that is more than 12 months, \$2,000,000 multiplied by the number of full 12 month periods that are in the performance period.

The Committee, as defined below, is authorized to adjust the limitations described above and is authorized to adjust outstanding awards (including adjustments to exercise prices of options and other affected terms of awards) in the event that a dividend or other distribution, recapitalization, forward or reverse split, reorganization, merger, consolidation, spin-off, combination, repurchase, share exchange or other similar corporate transaction or event affects our common stock so that an adjustment is appropriate. The Committee is also authorized to adjust performance conditions and other terms of awards in response to these kinds of events or in response to changes in applicable laws, regulations or accounting principles.

The persons eligible to receive awards under the 2011 Omnibus Incentive Plan are the officers, directors, employees, consultants and other persons who provide services to us on a full-time basis. The foregoing notwithstanding, only our full-time employees, or any of our parent corporations or subsidiary corporations, shall be eligible for purposes of receiving any incentive stock options.

The 2011 Omnibus Incentive Plan is to be administered by a committee designated by our Board of Directors consisting of not less than two directors (the Committee), provided, however, that except as otherwise expressly provided in the 2011 Omnibus Incentive Plan, our Board of Directors may exercise any power or authority granted to the Committee under the 2011 Incentive Plan. Subject to the terms of the 2011 Omnibus Incentive Plan, the Committee is authorized to select eligible persons to receive awards, determine the type, number and other terms and conditions of, and all other matters relating to, awards, prescribe award agreements, and the rules and regulations for the administration of the 2011 Omnibus Incentive Plan, construe and interpret the 2011 Omnibus Incentive Plan and award agreements, correct defects, supply omissions or reconcile inconsistencies therein, and make all other decisions and determinations as the Committee may deem necessary or advisable for the administration of the 2011 Omnibus Incentive Plan.

The Committee is authorized to grant stock options, including both incentive stock options and non-qualified stock

options, and stock appreciation rights entitling the participant to receive the amount by which the fair market value of a share of our common stock on the date of exercise exceeds the grant price of the stock appreciation right. The exercise price of stock options and the grant price for stock appreciation rights are determined by the Committee, provided that such exercise or grant price may not be less than 100% of the fair market value on the grant date. The maximum term of each option or stock appreciation right, the times at which each option or stock appreciation right will be exercisable, and provisions requiring forfeiture of unexercised options or stock appreciation rights at or following termination of employment generally are fixed by the Committee, except that no option or stock appreciation right may have a term exceeding ten years. Methods of exercise and settlement and other terms of the options and stock appreciation right are

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determined by the Committee. The Committee, thus, may permit the exercise price of options awarded under the 2011 Omnibus Incentive Plan to be paid in cash, shares, other awards or other property (including loans to participants).

The Committee is authorized to grant restricted stock and restricted stock units. Restricted stock is a grant of shares of our common stock which may not be sold or disposed of, and which shall be subject to such risks of forfeiture and other restrictions as the Committee may impose. An award of restricted stock units confers upon a participant the right to receive shares of our common stock or cash equal to the fair market value of the specified number of shares of our common stock covered by the restricted stock units at the end of a specified deferral period, subject to such risks of forfeiture and other restrictions as the Committee may impose. Prior to settlement, an award of restricted stock units carries no voting or dividend rights or other rights associated with share ownership, although dividend equivalents may be granted, as discussed below.

The Committee is authorized to grant dividend equivalents conferring on participants the right to receive, currently or on a deferred basis, cash, shares of our common stock, other awards or other property equal in value to dividends paid on a specific number of shares of our common stock or other periodic payments. Dividend equivalents may be granted alone or in connection with another award, may be paid currently or on a deferred basis and, if deferred, may be deemed to have been reinvested in additional shares of our common stock, awards or otherwise as specified by the Committee.

The Committee is authorized to grant shares of our common stock as a bonus free of restrictions, or to grant shares of our common stock or other awards in lieu of our obligations to pay cash under the 2011 Omnibus Incentive Plan or other plans or compensatory arrangements, subject to such terms as the Committee may specify.

The Committee or our Board of Directors is authorized to grant awards that are denominated or payable in, valued by reference to, or otherwise based on or related to shares of our common stock. The Committee determines the terms and conditions of such awards.

The Committee is authorized to grant performance awards to participants on terms and conditions established by the Committee. The performance criteria to be achieved during any performance period and the length of the performance period are determined by the Committee upon the grant of the performance award. Performance awards may be settled by delivery of cash, shares or other property, or any combination thereof, as determined by the Committee. The Committee may, in its discretion, determine that the amount payable as a performance award will be reduced from the amount of any potential award.

Awards may be settled in the form of cash, shares of our common stock, other awards or other property, in the discretion of the Committee. The Committee may require or permit participants to defer the settlement of all or part of an award in accordance with such terms and conditions as the Committee may establish, including payment or crediting of interest or dividend equivalents on deferred amounts, and the crediting of earnings, gains and losses based on deemed investment of deferred amounts in specified investment vehicles. The Committee may condition any payment relating to an award on the withholding of taxes and may provide that a portion of any shares of our common stock or other property to be distributed will be withheld (or previously acquired shares of our common stock or other property be surrendered by the participant) to satisfy withholding and other tax obligations.

The Committee may, in its discretion, accelerate the exercisability, the lapsing of restrictions or the expiration of deferral or vesting periods of any award, and such accelerated exercisability, lapse, expiration and if so provided in the award agreement or otherwise determined by the Committee, vesting shall occur automatically in the case of a change in control of the company, as defined in the 2011 Omnibus Incentive Plan (including the cash settlement of stock appreciation rights which may be exercisable in the event of a change in control).

Our Board of Directors may amend, alter, suspend, discontinue or terminate the 2011 Omnibus Incentive Plan or the Committee's authority to grant awards without further stockholder approval, except that stockholder approval must be obtained for any amendment or alteration if such approval is required by law or regulation or under the rules of any stock exchange or quotation system on which shares of our common stock are then listed or quoted. Thus, stockholder approval may not necessarily be required for every amendment to

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the 2011 Omnibus Incentive Plan which might increase the cost of the 2011 Omnibus Incentive Plan or alter the eligibility of persons to receive awards. Stockholder approval will not be deemed to be required under laws or regulations, such as those relating to incentive stock options, that condition favorable treatment of participants on such approval, although our Board of Directors may, in its discretion, seek stockholder approval in any circumstance in which it deems such approval advisable. Unless earlier terminated by our board of directors, the 2011 Omnibus Incentive Plan will terminate at the earliest of (a) such time as no shares of our common stock remain available for issuance under the 2011 Omnibus Incentive Plan, (b) termination of the 2011 Omnibus Incentive Plan by our Board of Directors, or (c) the tenth anniversary of the effective date of the 2011 Omnibus Incentive Plan. Awards outstanding upon expiration of the 2011 Omnibus Incentive Plan shall remain in effect until they have been exercised or terminated, or have expired.

### **2011 Employee Stock Purchase Plan**

Our Board of Directors adopted the Advaxis, Inc. 2011 Employee Stock Purchase Plan, which we refer to as the ESPP, on August 22, 2011, and our stockholders approved the ESPP on September 27, 2011. The ESPP initially became effective November 1, 2011. 40,000 shares of our common stock are reserved for issuance under the ESPP. On December 14, 2011, our Board of Directors approved an amendment to the ESPP effective as of October 31, 2011. The ESPP was amended to change the first offering date that our employees were eligible to participate in the ESPP from November 1, 2011 to December 30, 2011. As of September 27, 2013, approximately 32,000 shares of our common stock are available for grant under the ESPP.

The Compensation Committee of our Board of Directors administers the ESPP. The ESPP vests the Compensation Committee with the authority to interpret the ESPP, to prescribe, amend and rescind rules and regulations relating to the ESPP, and to make all other determinations necessary or advisable for the administration of the ESPP; however, our Board of Directors may exercise that authority in lieu of the Compensation Committee. The ESPP is required to be administered in a manner consistent with Rule 16b-3 of the Exchange Act and subject to the provisions of Section 423 of the Internal Revenue Code (the Code).

Our employees that have been designated by our Board of Directors as eligible to participate in the ESPP are eligible to become participants if they have been employed by us or any of our subsidiaries for six months and are scheduled to work at least 20 hours per week and more than five months per calendar year. Individuals who satisfy these requirements after November 1, 2011, would be eligible to become participants on the February 1, May 1, August 1, or November 1, as the case may be, immediately following their completion of these eligibility requirements. These eligible employees may become participants in the ESPP by completing an enrollment agreement and filing it with us.

The ESPP generally is implemented through a series of 24-month-long offering periods, beginning on November 1 and ending on the October 31 that is 24 months later. Shares of our common stock are available for purchase under the ESPP on periodic exercise dates within each offering period. Exercise dates are the last business days in January, April, July and October during each offering period. On the first business day of each offering period (or if later, the first day within the offering period on which a participant becomes eligible to participate), a participant is granted the option to purchase shares of our common stock on the exercise dates within that offering period.

If the share price is ever lower on an exercise date than it was on the first business day of the offering period in which that exercise date falls, then the offering period in progress ends immediately after the close of trading on that exercise date, and a new offering period begins on the next February 1, May 1, August 1 or November 1, as the case may be, and extends for a new 24-month-long period ending on January 31, April 30, July 31 or October 31, as the case may be.

No participant is eligible for the grant of any option under the ESPP if, immediately after the grant, the participant would own, directly or indirectly, stock possessing 5% or more of the total combined voting power or value of all classes of our stock or of any of our subsidiaries. Additionally, no participant may be granted any option that would permit the participant to buy our common stock that accrues at a rate that exceeds \$25,000 (based on the fair market value of our common stock on the date the option is granted) for each calendar year in which such option is outstanding at any time. Finally, no participant may purchase more than 1,333 shares of our common stock on any one exercise date.

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The enrollment agreement that each participant must submit authorizes after-tax payroll deductions from the participant's compensation during each payroll period. Participants may elect a payroll deduction amount of at least 1%, and up to 15%, of their compensation. A participant may change or terminate his or her payroll deductions at any time during an offering period, but may only begin payroll deductions on specified dates.

The exercise price per share at which shares are sold in an offering under the ESPP is the lower of (i) 85% of the fair market value of a share of our common stock on the first day of the offering period or, (ii) 85% of the fair market value of a share of our common stock on the exercise date. Unless otherwise determined by the Compensation Committee, the term fair market value is defined to mean the ratio of the value traded (the price of a share of our common stock multiplied by number of shares of common stock traded) to total volume traded over the 10-day period ending on the valuation date.

A participant may withdraw from participation in the ESPP at any time by completing a withdrawal form and delivering it to us. If a participant's employment terminates for any reason, he or she is treated as having withdrawn from the ESPP. All options granted to the participant under the ESPP, but not yet exercised, automatically terminate, and no further purchases of common stock are made for the participant's account following the effectiveness of the participant's withdrawal. After a participant withdraws, or is treated as having withdrawn, the participant is not permitted to participate again in the ESPP until the next entry date that is at least six months after his or her date of withdrawal. In order to rejoin the ESPP, a former participant must submit a new enrollment agreement.

The ESPP will terminate following the last exercise date before 10<sup>th</sup> anniversary of its effective date, or if sooner, on the date on which all shares reserved for issuance under the ESPP have been sold. Additionally, our Board of Directors may terminate the ESPP earlier. Our Board of Directors or the Compensation Committee may amend the ESPP at any time, provided that no amendment may change any option in a way that adversely affects the rights of the holder of the option, no amendment may in any way cause rights issued under the ESPP to fail to meet the requirements for employee stock purchase plans under Section 423 of the Code, and no amendment may cause the ESPP to fail to comply with Rule 16b-3 under the Exchange Act. To the extent necessary to comply with Rule 16b-3 under the Exchange Act, Section 423 of the Code, or any other applicable law or regulation, we will obtain stockholder approval of any such amendment.

40,000 shares of our common stock are reserved for issuance under the ESPP. That amount will be increased each year by the lowest of (i) 4,000 shares, (ii) one percent of all shares of common stock outstanding at the end of the previous year, or (iii) an amount determined by the board. If any option granted under the ESPP expires or terminates for any reason without having been exercised in full, the unpurchased shares subject to that option will again be available for issuance under the ESPP.

The ESPP provides for appropriate adjustment of the number of shares of common stock for which options may be granted, the number of shares subject to outstanding options and the exercise price of outstanding options in the event of any increase or decrease in the number of issued and outstanding shares of our common stock as a result of one or more reorganizations, restructurings, recapitalizations, reclassifications, stock splits, reverse stock splits, or stock dividends.

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# SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of September 27, 2013 of:

each person who is known by us to be the beneficial owner of more than 5% of our outstanding common stock;  
 each of our directors;  
 each of our named executive officers and current executive officers; and  
 all of our current directors and executive officers as a group.

As used in the table below and elsewhere in this prospectus, the term beneficial ownership with respect to our common stock consists of sole or shared voting power (which includes the power to vote, or to direct the voting of shares of our common stock) or sole or shared investment power (which includes the power to dispose, or direct the disposition of, shares of our common stock) through any contract, arrangement, understanding, relationship or otherwise, including a right to acquire such power(s) during the 60 days following September 27, 2013.

Unless otherwise indicated in the footnotes to this table, and subject to community property laws where applicable, we believe each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. Applicable percentages are based on 5,534,596 shares of common stock outstanding as of September 27, 2013, adjusted as required by the rules promulgated by the SEC. Unless otherwise indicated, the address for each of the individuals and entities listed in this table is 305 College Road East, Princeton, New Jersey 08540.

Name and Address of Beneficial Owner	Number of Shares of Common Stock Beneficially Owned	Percentage of Class Beneficially Owned
Thomas A. Moore	274,098 <sup>(1)</sup>	4.8 %
Roni A. Appel	73,357 <sup>(2)</sup>	1.3 %
Richard Berman	31,863 <sup>(3)</sup>	*
Dr. James Patton	77,220 <sup>(4)</sup>	1.4 %
Dr. Thomas McKearn	25,753 <sup>(5)</sup>	*
Dr. John Rothman	80,761 <sup>(6)</sup>	1.4 %
Dr. David Sidransky	0	*
Daniel J. O Connor	63,961 <sup>(7)</sup>	1.1 %
Chris L. French	23,335 <sup>(8)</sup>	*
Dr. Robert G. Petit	22,287 <sup>(9)</sup>	*
Mark J. Rosenblum	34,596 <sup>(10)</sup>	*
All Current Directors and Executive Officers as a Group (10 people)	626,470 <sup>(11)</sup>	11.2 %

\*

Less than 1%.

(1) Represents 124,898 issued shares of our common stock, options to purchase 71,200 shares of our common stock exercisable within 60 days and warrants to purchase 78,000 shares of our common stock exercisable within 60 days

(assuming conversion of \$162,659 of principal amount of Moore Notes into shares and warrants upon the closing of this offering at an assumed offer price of \$6.60 per share, the closing price on September 25, 2013 and \$0.01 per warrant). However, it excludes warrants to purchase 22,840 shares of our common stock, which are limited by a 4.99% beneficial ownership provision in the warrants and notes that would prohibit him from exercising any of such warrants to the extent that upon such exercise he, together with his affiliates, would beneficially own more than 4.99% of the total number of shares of our common stock then issued and outstanding (unless Mr. Moore provides us with 61 days' notice of the holders' waiver of such provisions).

(2) Represents 44,523 issued shares of our common stock and options to purchase 28,834 shares of our common stock exercisable within 60 days.

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- (3) Represents 14,530 issued shares of our common stock and options to purchase 17,333 shares of our common stock exercisable within 60 days.
- (4) Represents 62,909 issued shares of our common stock, options to purchase 12,533 shares of our common stock exercisable within 60 days, and warrants to purchase 1,778 shares of our common stock exercisable within 60 days.
- (5) Represents 13,220 issued shares of our common stock and options to purchase 12,533 shares of our common stock exercisable within 60 days.  
Represents 18,281 issued shares of our common stock and options to purchase 62,480 shares of our common stock exercisable within 60 days. On March 6, 2013, we announced the departure of Dr. John Rothman effective March 1, 2013. Dr. Rothman will continue to assist us as a consultant for a period of one year.
- (6) Represents 21,091 issued shares of our common stock, options to purchase 8,667 shares of our common stock exercisable within 60 days, 32,425 shares earned but not yet issued and warrants to purchase 1,778 shares of our common stock exercisable within 60 days.
- (7) Represents 6,005 issued shares of our common stock, options to purchase 15,067 shares of our common stock exercisable within 60 days and warrants to purchase 2,263 shares of our common stock exercisable within 60 days.
- (8) Represents 3,487 issued shares of our common stock and options to purchase 18,800 shares of our common stock exercisable within 60 days.
- (9) Represents 8,196 issued shares of our common stock and options to purchase 26,400 shares of our common stock exercisable within 60 days.
- (10) Represents an aggregate of 298,859 shares of our common stock, options to purchase 211,367 shares of our common stock exercisable within 60 days, warrants to purchase 83,819 shares of our common stock exercisable within 60 days and 32,425 shares of our common stock earned but not yet issued.
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## **CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

Our policy is to enter into transactions with related parties on terms that, on the whole, are no more favorable, or no less favorable, than those available from unaffiliated third parties. Based on our experience in the business sectors in which we operate and the terms of our transactions with unaffiliated third parties, we believe that all of the transactions described below met this policy standard at the time they occurred.

### **Thomas Moore**

From time to time, Mr. Moore, our Director, and former Chairman and Chief Executive Officer, has loaned our company operating funds, either pursuant to the Moore Notes (as defined below) or as an investor in other offerings by our company. The following summarizes any related party transactions with Mr. Moore since November 1, 2010 (the first day of our fiscal 2011 year).

On September 22, 2008, we entered into agreement to provide for the sale, from time to time, of senior promissory notes (the Moore Notes ) to Mr. Moore, which promissory notes and agreement have subsequently been amended.

Under the current terms of the Moore Notes (most recently amended and restated on March 17, 2011): (i) the promissory notes bear interest at the rate of 12% per annum and (ii) the maturity date is the earlier of the date of consummation of an equity financing in an amount of \$6.0 million or more or the occurrence of any event of default as defined in the Moore Notes. As of October 31, 2011, we owed Mr. Moore approximately \$408,000 in principal and interest under the Moore Notes.

On August 29, 2011, we entered into an exchange agreement with Mr. Moore, pursuant to which warrants to purchase up to an aggregate of 21,333 shares of our common stock, issued to Mr. Moore on or about October 17, 2007, and certain rights of Mr. Moore to receive additional warrants in the future under the September 22, 2008 purchase agreement for the Moore Notes, were exchanged for a warrant to purchase up to an aggregate of 61,396 shares of our common stock at an exercise price of \$18.75 per share, which warrant expires on August 29, 2014.

On October 28, 2011, we entered into a note purchase agreement with Mr. Moore (and Mr. Rosenblum, as described below) and other accredited investors in connection with the private placement of an aggregate \$2.3 million convertible promissory notes and warrants. We refer to this offering as the October 2011 offering. Accordingly, on October 31, 2011 we issued \$470,588 of convertible promissory notes to Mr. Moore for a purchase price of \$400,000, representing an original issue discount of 15%, which was paid for in exchange for the cancellation of \$400,000 of outstanding indebtedness owed by us under the Moore Notes. We also issued Mr. Moore a warrant to purchase that number of shares of our common stock equal to 50% of the number of shares of our common stock issuable upon conversion of the \$470,588 of convertible promissory notes, at an exercise price of \$18.75 per share, which warrant expires on October 31, 2014.

As of October 31, 2011, we owed Mr. Moore an aggregate amount of approximately \$879,000 in principal and interest under the Moore Notes and the convertible promissory notes issued in the October 2011 offering.

Effective May 14, 2012, we entered into a note purchase agreement with Mr. Moore (and Mr. O Connor, as described below) and other accredited investors in connection with the private placement of an aggregate \$953,333 convertible promissory notes and warrants. We refer to this offering as the May 2012 offering. Accordingly, on May 18, 2012, we issued \$120,000 of convertible promissory notes to Mr. Moore for a purchase price of \$90,000 in cash, representing

an original issue discount of 25%. Mr. Moore converted these notes in full for 37,964 shares of our common stock in May 2013. We also issued Mr. Moore a warrant to purchase that number of shares of our common stock equal to 50% of such number of shares of our common stock issuable upon conversion of the \$120,000 convertible promissory notes, based on the original conversion price of \$18.75 per share, which warrant expires on May 18, 2017. The warrant had an original exercise price of \$18.75 per share but was adjusted, pursuant to its terms, on December 1, 2012 to \$10.625 per share. The warrant includes a limitation on conversion or exercise, as applicable, which provides that at no time will Mr. Moore be entitled to exercise any portion of the warrant, to the extent that after such exercise, Mr. Moore (together with his affiliates) would beneficially own more than 4.99% of our outstanding shares of common stock as of such date. In June 2012, Mr. Moore exchanged the warrants received in this transaction for new warrants with different terms.

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Effective May 14, 2012, we also entered into an exchange agreement with Mr. Moore, pursuant to which Mr. Moore received approximately 43,200 shares of our common stock in exchange for (i) surrendering the convertible promissory notes (with a principal amount of \$470,588) and warrants to purchase an aggregate of approximately 12,549 shares of our common stock that Mr. Moore acquired in the October 2011 offering, and (ii) amending the October 2011 note purchase agreement to terminate (x) Mr. Moore's right to liquidated damages if we fail for any reason to satisfy the current public information requirement under Rule 144(c) promulgated under the Securities Act, (y) Mr. Moore's right to participate in any proposed or intended issuance or sale or exchange of the our securities, and (z) the prohibition on our ability to effect, or enter into an agreement to effect, any issuance of our securities for cash consideration involving a variable rate transaction.

Effective June 8, 2012, we entered into an exchange agreement with Mr. Moore, pursuant to which warrants to purchase an aggregate of 88,516 shares of our common stock, issued to Mr. Moore between August 2007 and May 2012, were exchanged for new warrants to purchase the same amount of shares of our common stock. These new warrants have an exercise price of \$18.75 and expire in August 2014. These new warrants were not able to be exercised by Mr. Moore until we amended our certificate of incorporation to increase the authorized number of shares of our common stock to permit exercise in full of the new warrants (which amendment was effected August 16, 2012). In connection with the warrant exchange, Mr. Moore also waived our obligation to keep reserved from our authorized and available shares of common stock, such number of shares of common stock necessary to effect the exercise or conversion, in full, of (i) the original warrants exchanged for these new warrants, and (ii) the convertible promissory note in the aggregate principal amount of \$120,000 issued to Mr. Moore in the May 2012 offering.

Additionally, for the twelve months ended October 31, 2012, Mr. Moore loaned us \$74,500 under the Moore Notes.

We paid Mr. Moore \$35,000 in principal on the Moore Notes. As of October 31, 2012 and October 31, 2011, respectively, we were not in default under the terms of the agreement relating to the Moore Notes. As of October 31, 2012, we owed Mr. Moore an aggregate amount of approximately \$597,000 in principal and interest under the Moore Notes and the convertible promissory notes acquired in the May 2012 offering.

For the period from November 1, 2012 through September 27, 2013, Mr. Moore loaned us \$11,200 under the Moore Notes. In that same period, we repaid Mr. Moore \$85,700 in principal on the Moore Notes.

As of September 27, 2013, we owed Mr. Moore an aggregate amount of approximately \$431,000 in principal and interest under the Moore Notes.

Under the terms of the Moore Notes, the principal amount of the Moore Notes, with interest, is due and payable by us upon the date of consummation of an equity financing in an amount of \$6,000,000 or more. However, in August 2013, in connection with Mr. Moore's resignation as our Chairman and Chief Executive Officer, we entered into a consulting agreement with Mr. Moore, which provides that we will repay at least \$100,000 of the Moore Notes if we close a financing greater than \$5 million (or up to approximately \$429,076 at our discretion, if the financing exceeds \$15 million). If we do not repay the Moore Notes in full upon closing of a financing in excess of \$15 million, we agreed to pay the Moore Notes in full upon the earlier of (i) six months from the closing or (ii) the next subsequent underwritten financing (not currently contemplated). The terms of that consulting agreement are described under Management Summary Compensation Table Discussion of Summary Compensation Table.

Subsequent to the entry into the consulting agreement, on September 26, 2013 we entered into a debt conversion and repayment agreement with Mr. Moore with respect to the repayment and partial conversion of amounts owed to Mr.

Moore under the Moore Notes. Under this agreement, after the closing of this offering, we will pay Mr. Moore \$100,000 in partial payment of the Moore Notes, and approximately \$162,659 (one half of the remaining balance after taking into the \$100,000 payment) will automatically convert upon the closing of this offering into restricted shares of

our common stock and warrants to acquire our common stock at a conversion price equal to the public offer price in this offering. We agreed to repay the remaining outstanding balance on the Moore Notes after the payment and conversion within three months of the closing of this offering.

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## **Mark Rosenblum**

In connection with the October 2011 offering, we issued \$58,823.53 of convertible promissory notes to an IRA account in the name of our Chief Financial Officer, Mark J. Rosenblum, for a purchase price of \$50,000.00. Additionally, Mr. Rosenblum received a warrant to purchase that number of shares of our common stock equal to 50% of such number of shares of our common stock issuable upon conversion of the \$58,823.53 convertible promissory notes, at an exercise price of \$18.75 per share, which expire on October 31, 2014. On May 18, 2012, Mr. Rosenblum exchanged his convertible promissory notes and warrant for 5,490 shares of our common stock.

## **James Patton**

On August 2, 2012, in a private placement pursuant to a note purchase agreement, we issued Dr. James Patton, Chairman of our Board of Directors, a convertible promissory note in the principal amount of \$66,667 for a purchase price of \$50,000, representing an original issue discount of 25%. On June 25, 2013, Dr. Patton converted his note into 21,092 shares of our common stock. Additionally, Dr. Patton received a warrant to purchase that number of shares of our common stock equal to 50% of the number of shares of our common stock issuable upon conversion of his note, at an exercise price of \$10.62 per share. This warrant expires on August 2, 2017 and may be exercised on a cashless basis in certain circumstances. The warrants issued to Dr. Patton limit his ability to exercise to the extent that after such exercise Dr. Patton (together with his affiliates) would beneficially own more than 4.99% of our outstanding shares of common stock as of such date.

## **Daniel O Connor**

In connection with the May 2012 offering, on May 18, 2012 we issued Mr. O Connor, an executive of our company as of January 1, 2013, a convertible promissory note in the principal amount of \$66,667 for a purchase price of \$50,000, which represents an original issue discount of 25%. On May 20, 2013, Mr. O Connor converted his note into 21,091 shares of our common stock. Additionally, Mr. O Connor received a warrant to purchase that number of shares of our common stock equal to 50% of such number of shares of our common stock issuable upon conversion of his note, based on the original conversion price of \$18.75 per share. The warrant had an original exercise price of \$18.75 per share but was adjusted, pursuant to its terms, on December 1, 2012 to \$10.625 per share. This warrant expires on May 18, 2017 and may be exercised on a cashless basis in certain circumstances. In addition, the warrants issued to Mr. O Connor limit his ability to exercise to the extent that after such exercise Mr. O Connor (together with his affiliates) would beneficially own more than 4.99% of our outstanding shares of common stock as of such date.

## **Chris French**

On September 27, 2012 in a private placement pursuant to a note purchase agreement, we issued Chris French, an executive officer of our company as of August 19, 2013, a convertible promissory note in the principal amount of \$25,000 for a purchase price of \$25,000. On December 19, 2012, Ms. French converted her note into 4,526 shares of our common stock. Upon conversion of the note, Ms. French received a warrant to purchase 2,263 shares of our common stock at an exercise price of \$5.625 per share, which expires on October 26, 2015 and may be exercised on a cashless basis in certain circumstances. In addition, the warrants issued to Ms. French limit her ability to exercise to the extent that after such exercise Ms. French (together with her affiliates) would beneficially own more than 4.99% of our outstanding shares of common stock as of such date.



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## DESCRIPTION OF SECURITIES

### 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, and 5,000,000 shares of blank check preferred stock, par value \$0.001 per share. As of September 27, 2013, there were 5,534,596 shares of common stock, no shares of Series A preferred stock and 740 shares of Series B preferred stock outstanding. 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.

### 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 cumulative voting rights, 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.

### Warrants

*The following summary of certain terms and provisions of the warrants offered hereby is not complete and is subject to, and qualified in its entirety by the provisions of the form of the warrant, which is filed as an exhibit to the registration statement of which this prospectus is a part of. Prospective investors should carefully review the terms and provisions set forth in the form of warrant.*

*Exercisability.* The warrants are exercisable immediately upon issuance and at any time up to the date that is five years from the date of issuance. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). Unless otherwise specified in the warrant, the holder will not have the right to exercise any portion of the warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants.

*Cashless Exercise.* In the event that a registration statement covering shares of common stock underlying the warrants, or an exemption from registration, is not available for the resale of such shares of common stock underlying the warrants, the holder may, in its sole discretion, exercise the warrant in whole or in part and, in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, elect instead to receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant. In no event shall we be required to make any cash payments or net cash settlement to the registered holder in lieu of issuance of common stock underlying the warrants.

*Exercise Price.* The initial exercise price per share of common stock purchasable upon exercise of the warrants is \$ per share [[125%] of the public offering price of the common stock]. The exercise price is

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subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

*Certain Adjustments.* The exercise price and the number of shares of common stock purchasable upon the exercise of the warrants are subject to adjustment upon the occurrence of specific events, including stock dividends, stock splits, combinations and reclassifications of our common stock.

*Transferability.* Subject to applicable laws, the warrants may be transferred at the option of the holders upon surrender of the warrants to us together with the appropriate instruments of transfer.

*Warrant Agent and Exchange Listing.* The warrants will be issued in registered form under a warrant agency agreement between Securities Transfer Corporation, as warrant agent and us.

*Fundamental Transaction.* If, at any time while the warrants are outstanding, (1) we consolidate or merge with or into another corporation and we are not the surviving corporation, (2) we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets, (3) any purchase offer, tender offer or exchange offer (whether by us or another individual or entity) is completed pursuant to which holders of our shares of common stock are permitted to sell, tender or exchange their shares of common stock for other securities, cash or property and has been accepted by the holders of 50% or more of our outstanding shares of common stock, (4) we effect any reclassification or recapitalization of our shares of common stock or any compulsory share exchange pursuant to which our shares of common stock are converted into or exchanged for other securities, cash or property, or (5) we consummate a stock or share purchase agreement or other business combination with another person or entity whereby such other person or entity acquires more than 50% of our outstanding shares of common stock, each a 'Fundamental Transaction,' then upon any subsequent exercise of the warrants, the holders thereof will have the right to receive the same amount and kind of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of the number of warrant shares then issuable upon exercise of the warrant, and any additional consideration payable as part of the Fundamental Transaction.

*Rights as a Stockholder.* Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

## **Representative s Warrants**

Please see *Underwriting Representative s Warrants* for a description of the warrants we have agreed to issue to the representative of the underwriters in this offering, subject to the completion of the offering. We expect to enter into a warrant agreement in respect of the Representative s Warrants prior to the closing of this offering.

## **Preferred Stock**

### *General*

We are authorized to issue up to 5,000,000 shares of blank check preferred stock. Preferred stock may be issued in one or more series and having the rights, privileges and limitations, including voting rights, conversion privileges and redemption rights, as may, from time to time, be determined by our board of directors. Preferred stock may be issued

in the future in connection with acquisitions, financings, or other matters as our board of directors deems appropriate.

In the event that any shares of preferred stock are to be issued, a certificate of designation containing the rights, privileges and limitations of such series of preferred stock will be filed with the Secretary of State of the State of Delaware. The effect of such preferred stock is that, subject to Federal securities laws and Delaware law, our board of directors alone, may be able to authorize the issuance of preferred stock which could have the effect of delaying, deferring, or preventing a change in control of us without further action by the stockholders, and may adversely affect the voting and other rights of the holders of our common stock. The issuance of preferred stock with voting and conversion rights may also adversely affect the voting power of holders of our common stock, including the loss of voting control to others.

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Our board of directors has designated 1,000 shares as Series A Preferred Stock, \$0.001 par value per share and 2,500 shares as Series B Preferred Stock, \$0.001 par value per share.

As of September 25, 2013, there were no shares of Series A Preferred Stock and 740 shares of Series B Preferred Stock were issued and outstanding.

***Series B Preferred Stock***

***Ranking.*** Our Series B Preferred Stock, with respect to dividend rights and rights upon liquidation, winding-up or dissolution, ranks senior to our common stock and any other class or series of our Preferred Stock other than our Series A Preferred Stock or a class or series of our Preferred Stock of that we intend to cause to be listed for trading or quoted on any one of the NASDAQ Capital Market, the NASDAQ Global Market, the NASDAQ Global Select Market, the NYSE Amex, or the New York Stock Exchange; *pari passu* to our Series A Preferred Stock; and junior to all existing and future indebtedness and any class or series of our Preferred Stock that we intend to cause to be listed for trading or quoted on any one of the NASDAQ Capital Market, the NASDAQ Global Market, the NASDAQ Global Select Market, the NYSE Amex, or the New York Stock Exchange.

***Dividends.*** Generally, holders of our Series B Preferred Stock are entitled to receive dividends on each outstanding share of Series B Preferred Stock, which dividends accrue in shares of our Series B Preferred Stock at a rate equal to 10.0% per annum. In addition, so long as any shares of our Series B Preferred Stock are outstanding, no dividends or other distributions will be paid, declared or set apart with respect to any junior shares (such as our common stock).

Our Series B Preferred Stock prohibits us from redeeming our common stock while it is outstanding.

***Protective Provisions.*** So long as any shares of our Series B Preferred Stock are outstanding, we may not, without the affirmative approval of the holders of a majority of the shares of our Series B Preferred Stock then outstanding, (a) alter or change adversely the powers, preferences or rights given to the Series B Preferred Stock or alter or amend the Certificate of Designations for the Series B Preferred Stock, (b) authorize or create any class of stock ranking as to distribution of assets upon a liquidation senior to or otherwise *pari passu* with the Series B Preferred Stock (other than Senior Shares (as defined in the Certificate of Designations)), (c) amend our certificate or articles of incorporation or other charter documents in breach of any of the provisions of the Certificate of Designations, (d) increase the authorized number of shares of Series B Preferred Stock, (e) liquidate, dissolve or wind-up our business and affairs, or effect any Deemed Liquidation Event (as defined in the Certificate of Designations), or (f) enter into any agreement with respect to the foregoing.

***Liquidation Preference.*** Generally, holders of shares of our Series B Preferred Stock are entitled to \$10,000.00 per share, plus any accrued but unpaid dividends in the event of any liquidation, dissolution or winding up, whether voluntary or involuntary, after payment or provision for payment of our debts and other liabilities. As of July 31, 2013, the Series B Preferred Stock had a liquidation preference of \$10,277,570 comprised of \$10,000 per share plus the total of the cumulative accrued dividends in the amount of \$2,877,570. All of our outstanding shares of Series B Preferred Stock which issued pursuant to the terms the Series B Preferred Stock Purchase Agreement dated July 19, 2010 with Optimus (which expired in accordance with its terms in July 2013). In connection with each sale of Series B Preferred Stock to Optimus under that agreement, Optimus exercised a portion a 3-year warrant for shares of our common stock and issued us a promissory note as payment of the exercise price. The value of the promissory note and interest receivable was \$10,633,584 as of July 31, 2013. The promissory note bears interest at 2% per annum which is credited directly to capital. For additional information relating to the arrangement with Optimus, see Note 14 to our audited financial statements included elsewhere in this prospectus.

*Redemption Rights.* Upon or after the fourth anniversary of the applicable issuance date, we have the right, at our option, to redeem all or a portion of the shares of Series B Preferred Stock at a price per share equal to the Series B Liquidation Value (as defined in the Certificate of Designations), or approximately \$10,000 per share plus any accrued but unpaid dividends. In addition, prior to such time, we have the right, at our option, to redeem all or a portion of the shares of Series B Preferred Stock, at a price per share equal to: (i) 136% of the Series B Liquidation Value if redeemed in the first year following issuance, (ii) 127% of the

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Series B Liquidation Value if redeemed on or after the first anniversary but prior to the second anniversary of the applicable issuance date, (iii) 118% of the Series B Liquidation Value if redeemed on or after the second anniversary but prior to the third anniversary of the applicable issuance date, and (iv) 109% of the Series B Liquidation Value if redeemed on or after the third anniversary but prior to the fourth anniversary of the applicable issuance date.

On September 26, 2013, we entered into a Notice of Redemption and Settlement Agreement with Optimus Capital Partners, LLC, a Delaware limited liability company, dba Optimus Life Sciences Capital Partners, LLC, Optimus CG II, Ltd., a Cayman Islands exempted Company and Socius CG II, Ltd., a Bermuda exempted Company, pursuant to which we agreed to redeem our outstanding shares of Series B Preferred Stock. Pursuant to the agreement, we agreed to cancel an outstanding receivable in the amount of \$10,633,584 as of the date of the agreement as payment in full of the redemption payment due under the terms of the Series B Preferred Stock and agreed to issue 33,750 shares of our common stock to settle a disagreement regarding the calculation of the settlement amount under a July 2012 Order and Stipulation. In connection with the redemption, we agreed to cancel the outstanding warrant held by Optimus. Accordingly, following such redemption, there are no longer any shares of our Series B Preferred Stock issued and outstanding.

## **Warrants**

As of September 27, 2013, we had outstanding warrants to purchase an aggregate of 747,829 shares of common stock.

## **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;

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;

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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, 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 OTCQB Marketplace under the symbol ADXS. We have applied

to list our common stock and warrants on The NASDAQ Capital Market under the symbols ADXS and ADXSW, respectively. On September 25, 2013, the last reported sale price per share for our common stock as reported by the OTCQB Marketplace was \$6.60.

TABLE OF CONTENTS**UNDERWRITING**

Aegis Capital Corp. is acting as the representative of the underwriters of the offering. We have entered into an underwriting agreement dated \_\_\_\_\_, 2013 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 and warrants listed next to its name in the following table:

Underwriter	Number of Shares	Number of Warrants
Aegis Capital Corp.		
Total		

The underwriters are committed to purchase all the shares of common stock and warrants offered by us other than those covered by the option to purchase additional shares and warrants described below, if they purchase any shares and warrants. 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, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters propose to offer the shares and warrants 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 and warrants to other securities dealers at such price less a concession of \$ \_\_\_\_\_ per share. If all of the shares and warrants 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 Share	Per Warrant	Without Over-Allotment	With Over-Allotment
Public offering price	\$	\$	\$	\$
Underwriting discount (7%)	\$	\$	\$	\$
Non-accountable expense allowance (1%)	\$	\$	\$	\$
Proceeds, before expense, to us	\$	\$	\$	\$

We have paid an expense deposit of \$15,000 to the representative for out-of-pocket-accountable expenses, which will be applied against the non-accountable expense allowance that will be paid by us to the underwriters in connection with this offering. The underwriting agreement, however, provides that in the event the offering is terminated, the \$15,000 expense deposit paid to the representative will be returned to the extent such out-of-pocket accountable

expenses are not actually incurred in accordance with FINRA Rule 5110(f)(2)(C).

We have also 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 per individual, but no more than \$15,000 in the aggregate; (b) all fees and disbursements of counsel for the underwriters incurred in clearing this offering with FINRA, up to \$5,000 (excluding filing fees); (c) 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; (d) upon successfully completing this offering, \$21,775 for the underwriters' use of Ipreo's book-building, prospectus

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tracking and compliance software for this offering; and (e) upon successfully completing this offering, up to \$20,000 of the representative's actual accountable road show expenses for the offering (less the \$15,000 deposit).

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

*Over-allotment Option.* We have granted the underwriters an over-allotment option. This option, which is exercisable for up to 45 days after the date of this prospectus, permits the underwriters to purchase a maximum of additional shares and additional warrants (15% of the shares and warrants 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 and warrants covered 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 and certain of our stockholders 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 effective date of the registration statement of which this prospectus is a part 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 effective date of the offering, which period shall not extend further than five years from the effective date of the offering 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. 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, nor will they engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the warrants or the underlying securities for a period of 180 days from the effective date of the offering. In addition, the warrants provide

for registration rights upon request, in certain cases. The demand registration right provided will not be greater than five years from the effective date of the offering in compliance with FINRA Rule 5110(f)(2)(H)(iv). The piggyback registration right provided will not be greater than seven years from the effective date of the offering 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

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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. However, the warrant exercise price or underlying shares will not be adjusted for issuances of shares of common stock at a price below the warrant exercise price.

*Right of First Refusal.* Until eighteen months from the effective date of this offering the representative, or any subsidiary or successor, shall have a right of first refusal to act as lead underwriter 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 and warrants 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 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

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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 or on the OTC QB 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 with Redwood of 5% convertible debentures, which was consummated on June 21, 2013. We received gross proceeds of \$250,000 in the bridge financing and paid to Aegis a commission of \$20,000.

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, 18th 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.

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**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 and warrants 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.

An offer to the public of common stock and warrants 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 and warrants have 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 and warrants 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 and warrants 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.

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**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 and warrants have 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(l) of the Prospectus Regulations and (ii) fewer than 100 natural or legal persons who are not qualified investors.

**Israel**

The common stock and warrants offered by this prospectus have 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 and warrants 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 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 and warrants being offered. Any resale in Israel, directly or indirectly, to the public of the common stock and warrants 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 and warrants 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 and warrants 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 ( Decree 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 and warrants or distribution of any offer document relating to the common stock and warrants 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 and warrants 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 and warrants being declared null and void and in the liability of the entity transferring the common stock and warrants for any damages suffered by the investors.

## Japan

The common stock and warrants have 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

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the regulations promulgated thereunder). Accordingly, the common stock and warrants 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 and warrants 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 and warrants 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 and warrants 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 and warrants 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 offers, sales and distributions of common stock and warrants 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 and warrants 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 and warrants 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 and warrants may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering material relating to the common stock and warrants have 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 and warrants 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 and warrants have 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 and warrants 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 and warrants, including the receipt of applications and/or the allotment or redemption of such shares, may be rendered within the United Arab Emirates by us.

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No offer or invitation to subscribe for common stock and warrants 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 and warrants 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 and warrants 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.

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.

## **EXPERTS**

Our financial statements included in this prospectus and registration statement as of and for the fiscal year ended October 31, 2012 (as indicated in its report) have been audited by Marcum LLP, an independent registered public accounting firm (the report on the financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern) and is included herein in reliance upon the authority as experts in giving said report. The financial statements as of and for the fiscal year ended October 31, 2011 and for the cumulative period from March 1, 2002 (inception) to October 31, 2011 appearing in this prospectus and registration statement have been audited by McGladrey LLP (formerly McGladrey & Pullen, LLP), an independent registered public accounting firm, as stated in their report appearing elsewhere herein and are included 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.

## **WHERE YOU CAN FIND ADDITIONAL INFORMATION**

We are a reporting company and file annual, quarterly and special reports, and other information with the Securities and Exchange Commission, or the SEC. Copies of the reports and other information may be read and copied at the SEC's Public Reference Room at 100 F Street NE, Washington, D.C. 20549. You can request copies of such documents by writing to the SEC and paying a fee for the copying cost. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a web site at <http://www.sec.gov> that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC.

This prospectus is part of a registration statement on Form S-1 that we filed with the SEC. Certain information in the registration statement has been omitted from this prospectus in accordance with the rules and regulations of the SEC.

We have also filed exhibits and schedules with the registration statement that are excluded from this prospectus. For further information you may:

read a copy of the registration statement, including the exhibits and schedules, without charge at the SEC's Public Reference Room; or

obtain a copy from the SEC upon payment of the fees prescribed by the SEC.

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**ADVAXIS, INC.**

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**ADVAXIS, INC.**  
**(A Development Stage Company)**  
**BALANCE SHEETS**

	July 31, 2013 (unaudited)	October 31, 2012
<b>ASSETS</b>		
Current Assets:		
Cash	\$40	\$232
Prepaid expenses	55,111	25,798
Other current assets	33,182	8,182
Deferred expenses - current	1,323,511	860,293
Total Current Assets	1,411,844	894,505
Deferred expenses - long term	289,834	342,007
Property and equipment (net of accumulated depreciation)	61,442	78,068
Intangible assets (net of accumulated amortization)	2,499,791	2,413,755
Deferred financing cost (net of accumulated amortization)	62,034	49,024
Other assets	38,438	38,438
<b>TOTAL ASSETS</b>	<b>\$4,363,383</b>	<b>\$3,815,797</b>
<b>LIABILITIES AND SHAREHOLDERS' DEFICIENCY</b>		
Current Liabilities:		
Accounts payable	\$5,541,431	\$5,155,797
Accrued expenses	1,242,464	1,367,412
Short term convertible notes and fair value of embedded derivative	2,037,962	2,089,099
Notes payable - former officer	427,606	477,274
Notes payable - other		250,000
Total Current Liabilities	9,249,463	9,339,582
Deferred rent		4,803
Long-term convertible note	1,104,680	
Common stock warrant liability	736,059	434,136
Total Liabilities	11,090,202	9,778,521
Commitments and Contingencies		
Shareholders' Deficiency:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; Series B Preferred Stock; issued and outstanding 740 at July 31, 2013 and at October 31, 2012. Liquidation preference of \$10,277,570		
Common stock - \$0.001 par value; authorized 25,000,000 shares, issued and outstanding 4,898,248 at July 31, 2013 and 3,158,433 at October 31, 2012.	4,898	3,158
Additional paid-in capital	64,083,331	52,119,567
Promissory note receivable	(10,633,584)	(10,484,022)
Deficit accumulated during the development stage	(60,181,464)	(47,601,427)
Total Shareholders' Deficiency	(6,726,819)	(5,962,724)

TOTAL LIABILITIES AND SHAREHOLDERS DEFICIENCY	\$4,363,383	\$3,815,797
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**(A Development Stage Company)**  
**STATEMENTS OF OPERATIONS**  
**(unaudited)**