Advaxis, Inc.
Form S-3
February 18, 2014

**As filed with the Securities and Exchange Commission on February 18, 2014**

**Registration No. 333-**

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM S-3**

**REGISTRATION STATEMENT**

**UNDER**

**THE SECURITIES ACT OF 1933**

**ADVAXIS, INC.**

(Exact Name of Registrant as Specified in Its Charter)

| **Delaware** | **02-0563870** |
|---|---|
| **(State or Other Jurisdiction of Incorporation or Organization)** | **(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 Offices)

Mr. Daniel J. O'Connor
Chief Executive Officer
305 College Road East
Princeton, New Jersey 08540
(609) 452-9813

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent For Service)

The Commission is requested to send copies of all communications to:

**Yvan-Claude Pierre, Esq.**

**Edward P. Bromley III, Esq.**

**Reed Smith LLP**

**599 Lexington Avenue**

**New York, NY 10022**

**Telephone: (212) 521-5400**

**Facsimile: (212) 521-5450**

**Approximate date of commencement of proposed sale to the public:** From time to time after the effective date of this registration statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ¨

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, other than securities offered only in connection with dividend or interest

reinvestment plans, check the following box. x

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, 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 registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ¨

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ¨

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 definition of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

| | |
|---|---|
| Large accelerated filer ¨ | Accelerated filer ¨ |
| Non-accelerated filer ¨ (Do not check if smaller reporting company) | Smaller reporting company x |

**CALCULATION OF REGISTRATION FEE**

| **Title of each class of securities to be registered**[1] | Amount to be registered | Proposed maximum aggregate offering price per unit | Proposed maximum aggregate offering price | **Amount of registration fee**[3] |
|---|---|---|---|---|
| Common Stock, $0.001 par value per share | N/A | [2] N/A | [2] $ 50,000,000 | $ 6,440 |

(1) Such indeterminate number of shares of Common Stock of Advaxis, Inc. as may from time to time be issued at indeterminate prices. Pursuant to Rule 416 under the Securities Act of 1933, as amended, such number of shares of Common Stock registered hereby shall include an indeterminate number of shares of Common Stock that may be issued in connection with a stock split, stock dividend, recapitalization or similar event.

(2) Omitted pursuant to General Instruction II.D of Form S-3 under the Securities Act of 1933, as amended.

(3) The registration fee has been calculated in accordance with Rule 457(o) under the Securities Act of 1933, as amended.

**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 of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

**The information in this 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 prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.**

**Subject to Completion—Dated February 18, 2014**

**PROSPECTUS**

**$50,000,000**

**Common Stock**

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

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

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

As of February 13, 2014, the aggregate market value of the voting and non-voting common equity held by non-affiliates, computed by reference to the price at which the common equity was last sold or the average bid and

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

**INVESTING IN OUR SECURITIES INVOLVES RISKS. YOU SHOULD REVIEW CAREFULLY THE RISKS AND UNCERTAINTIES DESCRIBED UNDER THE HEADING "RISK FACTORS" ON PAGE 4 AND CONTAINED IN THE APPLICABLE PROSPECTUS SUPPLEMENT AND UNDER SIMILAR HEADINGS IN THE OTHER DOCUMENTS THAT ARE INCORPORATED BY REFERENCE INTO THIS PROSPECTUS.**

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

**NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.**

The date of this prospectus is , 2014.

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**ABOUT THIS PROSPECTUS**

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

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

This prospectus and the accompanying supplement to this prospectus do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor do this prospectus and the accompanying supplement to this prospectus constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus or any applicable

prospectus supplement is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus or any applicable prospectus supplement is delivered or securities sold on a later date.

(i)

**SUMMARY**

Prospectus Summary

This summary highlights selected information from this prospectus and does not contain all of the information that you need to consider in making your investment decision. You should carefully read the entire prospectus, including the risks of investing discussed under “Risk Factors” on page 4, the information incorporated by reference, including our financial statements, and the exhibits to the registration statement of which this prospectus is a part. Unless otherwise stated or the context requires otherwise, references in this prospectus to “Advaxis,” “we,” “us,” or “our” refer to Advaxis, Inc.

**Our Company**

**Business Overview**

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

The effectiveness of our approach has been validated by numerous publications in multiple models of human disease. In the clinic, ADXS-HPV, our lead Lm- LLO immunotherapy for the treatment of HPV-associated cancers, is well-tolerated and has been administered to both young patients with pre-malignant dysplasia, as well as patients with advanced disease. Clinical efficacy has been demonstrated by apparent prolonged survival, complete and partial tumor responses, and the prolonged stabilization of advanced cancer. The preliminary data from our completed Phase 2 clinical trial of ADXS-HPV in patients with recurrent cervical cancer demonstrate that ADXS-HPV is an active agent in this disease setting with a manageable safety profile. We achieved proof of concept with this Phase 2 study, and over the next two to five years, we plan to advance ADXS-HPV through registrational Phase 3 trials and regulatory approval(s) in the United States and relevant markets for the treatment of women with cervical cancer. We are currently evaluating this same Lm -LLO immunotherapy in Phase 1/2 clinical trials for two other HPV-associated

cancers: head and neck cancer and anal cancer. In addition, we plan to advance ADXS-PSA, our second Lm -LLO immunotherapy, into a Phase 1 dose escalation trial to determine the maximum tolerated dose for the treatment of prostate cancer in the first half of 2014. A third Lm -LLO immunotherapy, ADXS-cHER2, is being evaluated for safety and efficacy in the treatment of companion dogs with HER2 over-expressing osteosarcoma. We plan to advance ADXS-cHER2 into a Phase 1 dose escalation trial to determine the maximum tolerated dose for the treatment of breast cancer.

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

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

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

Our Lm -LLO immunotherapies are based on a platform technology under exclusive license from the Trustees of the University of Pennsylvania, or Penn, that utilizes live attenuated Lm bioengineered to secrete antigen/adjuvant fusion proteins. These Lm strains use a fragment of the protein listeriolysin, or LLO, fused to a tumor associated antigen, or TAA, or other antigen of interest and we refer to these as Lm -LLO immunotherapies. Regardless of which antigen(s) is fused to LLO, the proposed mechanism of action is basically the same. We believe these Lm -LLO immunotherapies redirect the potent immune response to Lm that is inherent in humans, to the TAA or other antigen of interest. Lm -LLO immunotherapies stimulate the immune system to induce antigen-specific anti-tumor immune responses involving both innate and adaptive arms of the immune system. In addition, our technology facilitates the immune response by altering the tumor microenvironment to reduce immunologic tolerance in the tumors but leaves normal tissues unchanged. This makes the tumor more susceptible to immune attack by inhibiting the T-cells, or Tregs, and myeloid-derived suppressor cells, or MDSC, that we believe promote immunologic tolerance of cancer cells in the tumor.

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

**Our Preclinical and Clinical Development Pipeline**

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

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

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

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

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

**Corporate Information**

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

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

**The Securities We May Offer**

We may offer shares of our common stock, from time to time under this prospectus, together with any applicable prospectus supplement, at prices and on terms to be determined by market conditions at the time of offering. This prospectus provides you with a general description of the securities we may offer. Holders of our common stock are entitled to one vote for each share held of record on each matter submitted to a vote of stockholders. Each time we offer our common stock, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities. A prospectus supplement to be provided to you may also add, update or change information contained in this prospectus or in documents we have incorporated by reference. However, no prospectus

supplement will offer a security that is not registered and described in this prospectus at the time of the effectiveness of the registration statement of which this prospectus is a part.

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

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

**RISK FACTORS**

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

**Risks Related to our Business and Industry**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- competition from companies that have substantially greater assets and financial resources than we have;
- need for acceptance of our immunotherapies;
- ability to anticipate and adapt to a competitive market and rapid technological developments;
- amount and timing of operating costs and capital expenditures relating to expansion of our business, operations and infrastructure;
- need to rely on multiple levels of outside funding due to the length of drug development cycles and governmental approved protocols associated with the pharmaceutical industry; and
- dependence upon key personnel including key independent consultants and advisors.

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

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

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

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

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

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

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

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

- preclinical study results that may show the immunotherapy to be less effective than desired (e.g., the study failed to meet its primary objectives) or to have harmful or problematic side effects;
- clinical study results that may show the immunotherapy to be less effective than expected (e.g., the study failed to meet its primary endpoint) or to have unacceptable side effects;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis, or Biologics License Application preparation, discussions with the FDA, an FDA request for additional preclinical or clinical data, or unexpected safety or manufacturing issues;
- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make the immunotherapy uneconomical; and

- the proprietary rights of others and their competing products and technologies that may prevent the immunotherapy from being commercialized.

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

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

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

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

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

criminal prosecution, civil and criminal penalties, recall or seizure of products, exclusion from having our products reimbursed by federal health care programs, the curtailment or restructuring of our operations, injunctions against shipping products and total or partial suspension of production and/or refusal to allow a company to enter into governmental supply contracts.

The process of obtaining requisite FDA approval has historically been costly and time-consuming. Current FDA requirements for a new human biological product to be marketed in the United States include: (1) the successful conclusion of preclinical laboratory and animal tests, if appropriate, to gain preliminary information on the product's safety; (2) filing with the FDA of an IND to conduct human clinical trials for drugs or biologics; (3) the successful completion of adequate and well-controlled human clinical trials to establish the safety and efficacy of the investigational new drug for its recommended use; and (4) filing by a company and acceptance and approval by the FDA of a Biologic License Application, or BLA, for a biological investigational new drug, to allow commercial distribution of a biologic product. The FDA also requires that any drug or formulation to be tested in humans be manufactured in accordance with its Good Manufacturing Practices, or GMP, regulations. This has been extended to include any drug that will be tested for safety in animals in support of human testing. The GMPs set certain minimum requirements for procedures, record-keeping and the physical characteristics of the laboratories used in the production of these drugs. A delay in one or more of the procedural steps outlined above could be harmful to us in terms of getting our immunotherapies through clinical testing and to market.

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

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

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

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

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

Although we have submitted a new request for orphan drug designation for ADXS-HPV for use in the treatment of invasive cervical cancer our original request was denied and there can be no assurance that our new request will be granted. Although, we have been granted orphan drug designation for ADXS-HPV for use in the treatment of HPV-associated anal cancer and for HPV-associated head and neck cancer in the United States, and intend to request a similar designation for these uses in the European Union, we may not be granted orphan drug designation, or even if granted, we may not receive the benefits associated with orphan drug designation. This may result from a failure to maintain orphan drug status, or result from a competing product reaching the market that has an orphan designation for the same disease indication. Under U.S. rules for orphan drugs, if such a competing product reaches the market before ours does, the competing product could potentially obtain a scope of market exclusivity that limits or precludes our product from being sold in the United States for seven years. Even if we obtain exclusivity, the FDA could subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. A competitor also may receive approval of different products for the same indication for which our orphan product has exclusivity, or obtain approval for the same product but for a different indication for which the orphan product has exclusivity.

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

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

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

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

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

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

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

We own or hold licenses to a number of issued patents and U.S. pending patent applications, as well as foreign patents and foreign counterparts. Our success depends in part on our ability to obtain patent protection both in the United States and in other countries for our product candidates, as well as the methods for treating patients in the product indications using these product candidates. Such patent protection is costly to obtain and maintain, and we cannot guarantee that sufficient funds will be available. Our ability to protect our product candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Even if our product candidates, as well as methods for treating patients for prescribed indications using these product candidates are covered by valid and enforceable patents and have claims with sufficient scope, disclosure and support in the specification, the patents will provide protection only for a limited amount of time. Accordingly, rights under any issued patents may not provide us with sufficient protection for our product candidates or provide sufficient protection to afford us a commercial advantage against competitive products or processes.

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

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

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

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

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

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

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

- the patentability of our inventions relating to our product candidates; and/or
- the enforceability, validity or scope of protection offered by our patents relating to our product candidates.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may:

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

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

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

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

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

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

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

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

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

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

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

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

Management of our relationships with our collaborators will require:

- significant time and effort from our management team;
- coordination of our research and development programs with the research and development priorities of our collaborators; and
- effective allocation of our resources to multiple projects.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- price and volume fluctuations in the overall stock market from time to time;
- fluctuations in stock market prices and trading volumes of similar companies;
- actual or anticipated changes in our net loss or fluctuations in our operating results or in the expectations of securities analysts;
- the issuance of new equity securities pursuant to a future offering, including issuances of preferred stock;
- general economic conditions and trends;
- positive and negative events relating to healthcare and the overall pharmaceutical and biotech sector;
- major catastrophic events;
- sales of large blocks of our stock;
- significant dilution caused by the anti-dilutive clauses in our financial agreements;
- departures of key personnel;
- changes in the regulatory status of our immunotherapies, including results of our clinical trials;

- events affecting Penn or any future collaborators;
- announcements of new products or technologies, commercial relationships or other events by us or our competitors;
- regulatory developments in the United States and other countries;
- failure of our common stock or warrants to be listed or quoted on The NASDAQ Capital Market, NYSE Amex Equities or other national market system;
- changes in accounting principles; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

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

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

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

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

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

- with a price of less than $5.00 per share;
- that are neither traded on a "recognized" national exchange nor listed on an automated quotation system sponsored by a registered national securities association meeting certain minimum initial listing standards; and
- of issuers with net tangible assets less than $2.0 million (if the issuer has been in continuous operation for at least three years) or $5.0 million (if in continuous operation for less than three years), or with average revenue of less than $6.0 million for the last three years.

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

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

broker-dealer to:

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

- reasonably determine, based on that information, that transactions in penny stocks are suitable for the investor and that the investor has enough knowledge and experience to be able to evaluate the risks of "penny stock" transactions;

- provide the investor with a written statement setting forth the basis on which the broker-dealer made his or her determination; and

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

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

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

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

The quotation of our common stock on the NASDAQ does not assure that a meaningful, consistent and liquid trading market currently exists, and in recent years such market has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies like us. Our common stock is thus subject to this volatility. Sales of substantial amounts of common stock, or the perception that such sales might occur, could adversely affect prevailing market prices of our common stock and our stock price may decline substantially in a short time and our shareholders could suffer losses or be unable to liquidate their holdings. Also there are large blocks of restricted stock that have met the holding requirements under Rule 144 that may be sold without restriction. Our stock is thinly traded due to the limited number of shares available for trading on the market thus causing large swings in price. In addition, there is no established trading market for our warrants.

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

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

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

- investor perceptions of our company and the pharmaceutical and biotech industries generally; and

- general economic and other national conditions.

***Speculative nature of warrants.***

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

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

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

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

Our internal control over financial reporting and our disclosure controls and procedures have been ineffective in the past. We have taken steps to improve our disclosure controls and procedures and our internal control over financial reporting, and as of October 31, 2013, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures and internal control over financial reporting were effective. However, there is no assurance that our disclosure controls and procedures will remain effective or that there will be no material weaknesses in our internal control over financial reporting in the future. Additionally, as a result of the historical material weaknesses in our internal control over financial reporting and the historical ineffectiveness of our disclosure controls and procedures, current and potential stockholders could lose confidence in our financial reporting, which would harm our business and the trading price of our stock.

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

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

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

We are currently authorized to issue 25,000,000 shares of our common stock. As of February 13, 2014, we had 13,903,855 shares of our common stock issued and outstanding, excluding shares issuable upon exercise of our outstanding warrants, options, convertible promissory notes and shares of common stock earned but not yet issued under our director compensation program. Under our 2011 Employee Stock Purchase Plan, or ESPP, our employees can buy our common stock at a discounted price. To the extent the shares of common stock are issued, options and warrants are exercised or convertible promissory notes are converted, holders of our common stock will experience dilution. In addition, in the event of any future financing of equity securities or securities convertible into or exchangeable for, common stock, holders of our common stock may experience dilution. As of February 13, 2014, warrants to purchase 202,503 shares of our common stock were exercisable at approximately $9.24 per share and were

subject to "weighted-average" anti-dilution protection upon certain equity issuances below $9.24 per share (as may be further adjusted as defined in the warrant). In addition, as of February 13, 2014, we had outstanding options to purchase 467,923 shares of our common stock at a weighted average exercise price of approximately $15.86 per share and outstanding warrants to purchase 4,265,262 shares of our common stock (including the above warrants subject to weighted-average anti-dilution protection); and approximately 28,449 shares of our common stock were available for grant under the ESPP. Although we entered into agreements providing for the repayment or conversion of certain of our outstanding indebtedness, not all the holders of our outstanding convertible promissory notes have agreed to exchange their securities at this time.

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

Certain of our outstanding warrants contain, or may be deemed to contain from time to time, embedded derivative rights in accordance with U.S. generally accepted accounting principles, or GAAP. These derivative rights, or similar rights in securities we may issue in the future, need to be, or may need to be, separately valued as of the end of each accounting period in accordance with GAAP. We record these embedded derivatives as liabilities at issuance, valued using the Black-Scholes Model and are subject to revaluation at each reporting date. Any change in fair value between reporting periods is reported on our statement of operations. At October 31, 2013, and October 31, 2012, the fair value of the embedded derivative liability was $0 as the related securities were paid off, converted or reached maturity. For the twelve months ended October 31, 2013 and October 31, 2012, we reported income of $0 and approximately $400,000, respectively, due to changes in the fair value of the embedded derivative liability partially resulting from debt to equity exchanges during the period. Changes in the valuations of these rights, the valuation methodology or the assumptions on which the valuations are based could cause us to take charges to our earnings, which would adversely impact our results of operations. Moreover, the methodologies, assumptions and related interpretations of accounting or regulatory authorities associated with these embedded derivatives are complex and in some cases uncertain, which could cause our accounting for these derivatives, and as a result, our financial results, to fluctuate. There is a risk that questions could arise from investors or regulatory authorities concerning the appropriate accounting treatment of these instruments, which could require us to restate previous financial statements, which in turn could adversely affect our reputation, as well as our results of operations.

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

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

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

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

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

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

These provisions are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of our company to first negotiate with its board. These provisions

may delay or prevent someone from acquiring or merging with us, which may cause the market price of our common stock to decline.

**Item 2. Properties.**

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

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

**Item 3. Legal Proceedings.**

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

On August 19, 2013, we entered into an agreement with Maxim Group LLC, or Maxim, to terminate a July 2012 engagement agreement between the parties, pursuant to which Maxim asserted claims for unpaid fees related to the introduction of investors to us and services provided. As consideration for terminating the agreement, we agreed to pay Maxim approximately $589,000 in monthly installment payments in either cash or shares of our common stock, and a warrant to purchase 30,154 shares of our common stock at an exercise price of $4.90 per share. Additionally, in order to move the settlement forward, we reluctantly agreed to pay Maxim an additional $150,000 upon the completion of a contemplated public offering of securities. On September 17, 2013, we issued 25,582 shares of our common stock as an installment payment under this agreement and also issued the warrant to acquire 30,154 shares of our common stock at $4.90 per share, and on September 27, 2013, we issued 158,385 shares of our common stock to satisfy the remaining amount owed under this agreement. Maxim rejected the delivery of these 158,385 shares and claimed that we may not prepay our obligations under the agreement notwithstanding any language to the contrary in the agreement. Upon receipt of the rejected shares, Advaxis cancelled the issuance of such shares. Upon the completion of our public offering in October 2013, we paid the aforementioned $150,000 and commenced final settlement of the disputed amounts owed. On or about November 14, 2013, Maxim initiated a proceeding by confession of judgment in New York State Court to recover monies it believes Advaxis owes it under the Termination Agreement in the amount of $484,709.50. On November 15, 2013, the New York County Clerk's office entered a judgment in favor of Maxim. On or about November 22, 2013, Maxim mailed a Notice of Entry to Advaxis and the parties decided to settle the dispute without any admission of liability or wrongdoing and on December 23, 2013, the parties executed a Settlement Agreement and Releases. On December 27, 2013, we paid Maxim $285,000 in final settlement of all matters related to their claim.

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.

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

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

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

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

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

**USE OF PROCEEDS**

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

**PLAN OF DISTRIBUTION**

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

- the name or names of any underwriters;
- the purchase price of the securities;

- any underwriting discounts and other items constituting underwriters' compensation;
- any initial public offering price and the net proceeds we will receive from such sale;
- any discounts or concessions allowed or reallowed or paid to dealers; and
- any securities exchange or market on which the securities offered in the prospectus supplement may be listed.

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

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

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

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

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

An underwriter may engage in over-allotment, stabilizing transactions, short covering transactions and penalty bids in accordance with securities laws. Over-allotment involves sales in excess of the offering size, which creates a short position. Stabilizing transactions permit bidders to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Short covering transactions involve purchases of the securities in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a covering transaction to cover short positions. Those activities may cause the price of the securities to be higher than it would otherwise be. The underwriters may engage in these activities on any exchange or other market in which the securities may be traded. If commenced, the underwriters may discontinue these activities at any time.

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

In compliance with the guidelines of the Financial Services Regulatory Authority, Inc., or FINRA, the maximum compensation to be received by a FINRA member or independent broker-dealer may not exceed 8% of the offering

proceeds. It is anticipated that the maximum compensation to be received in any particular offering of securities will be less than this amount.

**DESCRIPTION OF COMMON STOCK**

General

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

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

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

Common Stock

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

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

**Registration Rights**

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

**Anti-Takeover Provisions**

***Delaware Law***

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

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

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

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

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or

· the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

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

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

*Amended and Restated Certificate of Incorporation and Bylaw Provisions*

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

· provide our board of directors with the ability to alter its bylaws without stockholder approval; and

· provide that vacancies on our board of directors may be filled by a majority of directors in office, although less than a quorum.

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

Transfer Agent and Registrar

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

Listing

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

LEGAL MATTERS

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

**EXPERTS**

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

Change in Our Public Accounting Firm

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

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

## WHERE YOU CAN FIND MORE INFORMATION

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

## INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

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

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

(b) Our Current Reports on Form 8-K filed with the SEC on December 13, 2013*, December 19, 2013, January 22, 2014* and February 11, 2014 (*excluding items 7.01 and 9.01, and Exhibit 99.1); and

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

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

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

**PART II**

**INFORMATION NOT REQUIRED IN THE PROSPECTUS**

## ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.

The table below itemizes the expenses payable by the registrant in connection with the registration and issuance of the securities being registered hereunder, other than underwriting discounts and commissions. All amounts except the Securities and Exchange Commission registration fee are estimated.

| | |
|---|---|
| Securities and Exchange Commission Registration Fee | $6,440 |
| Legal Fees and Expenses | $† |
| Accountants' Fees and Expenses | $† |
| Transfer agent and registrar's fees and expenses | $† |
| Printing and Duplicating Expenses | $† |
| Miscellaneous Expenses | $† |
| Total | $† |

† Estimated expenses are not presently known. The foregoing sets forth the general categories of expenses (other than underwriting discounts and commissions) that the Company anticipates it will incur in connection with the offering of securities under the registration statement. An estimate of the aggregate expenses in connection with the issuance and distribution of the securities being offered will be included in the applicable prospectus supplement.

## ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS.

*Delaware General Corporation Law*. The registrant is a Delaware corporation. Section 102(b)(7) of the Delaware General Corporation Law (the "DGCL") enables a corporation to eliminate or limit the personal liability of a director to the corporation or its stockholders for monetary damages for breach of the director's fiduciary duty, except:

- for any breach of the director's duty of loyalty to the corporation or its stockholders;

- for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;

- pursuant to Section 174 of the DGCL (providing for liability of directors for unlawful payment of dividends or unlawful stock purchases or redemptions); or

- for any transaction from which the director derived an improper personal benefit.

In accordance with Section 102(b)(7) of the DGCL, the registrant's certificate of incorporation includes a provision eliminating, to the fullest extent permitted by the DGCL, the liability of the registrant's directors to the registrant or its stockholders for monetary damages for breach of fiduciary as director. If the DGCL is subsequently amended to further eliminate or limit the liability of a director, then a director of the registrant, in addition to the circumstances in which a director is not personally liable as set forth in provision described in the preceding sentence, will not be liable to the fullest extent permitted by the amended DGCL.

Subsection (a) of Section 145 of the DGCL provides that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that he is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with such action, suit or proceeding if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful. Section 145 of the DGCL further provides that a corporation similarly may indemnify any such person serving in any such capacity who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor, against expenses (including attorneys' fees) actually and reasonably incurred in connection with the defense or settlement of such action or suit if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Delaware Court of Chancery or such other court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

*Certificate of Incorporation and Bylaws*. The registrant's amended and restated certificate of incorporation contains provisions which provide that the registrant will indemnify the registrant's directors and officers in each and every situation where, under Section 145 of the DGCL, as amended from time to time, the registrant is permitted or empowered to make such indemnification, and to the fullest extent permitted by law. The registrant may, in the sole discretion of its Board of Directors, indemnify any other person who may be indemnified pursuant to Section 145 of the DGCL to the extent the Board of Directors deems advisable, as permitted by Section 145 of the DGCL.

The registrant's bylaws contain provisions which provide, among other things, that the registrant shall indemnify any officer or director who was or is a party or is threatened to be made a party to any threatened, pending or completed (i) action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the registrant) by reason of the fact that he is or was a director, officer, employee or agent of the registrant, or is or was serving at the request of the registrant as a director, officer, employee or agent of another registrant, partnership, limited liability company, joint venture, trust, employee benefit plan or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with such action, suit or proceeding if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the registrant, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful and (ii) action or suit by or in the right of the registrant to procure a judgment in its favor by reason of the fact that he is or was a director, officer, employee or agent of the registrant, or is or was serving at the request of the registrant as a director, officer, employee or agent of another registrant, partnership, limited liability company, joint venture, trust, employee benefit plan or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by him in connection with the defense or settlement of such action or suit if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the registrant; except that no indemnification shall be made in respect of any claim, issue or matters as to which such person shall have been adjudged to be liable to the registrant unless and only to the

extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper. Any indemnification under the provisions in the bylaws (unless ordered by a court) shall be made by the registrant only as authorized in the specific case upon a determination that indemnification of the director, officer, employee or agent is proper in the circumstances because he has met the applicable standard of conduct set forth above. Such determination shall be made (i) by a majority vote of the directors who were not parties to such action, suit or proceeding even though less than a quorum, or (ii) if there are no such directors, or, if such directors so direct, by independent legal counsel in a written opinion, or (iii) by the stockholders. To the extent, however, that a director, officer, employee or agent of the registrant has been successful on the merits or otherwise in defense of any action, suit or proceeding described above, or in defense of any claim, issue or matter therein, he shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by him in connection therewith, without the necessity of authorization in the specific case.

The DGCL provides that the indemnification described above shall not be deemed exclusive of any other indemnification that may be granted by a corporation pursuant to its by-laws, disinterested directors' vote, stockholders' vote, agreement or otherwise.

*Indemnification Agreements*. In addition to the indemnification provided for in the registrant's amended and restated certificate of incorporation and bylaws, the registrant has entered into indemnification agreements with each of its directors and officers to provide the directors and officers with contractual rights to indemnification and advance payment of expenses to the fullest extent permitted by law and to further establish procedures for such indemnification.

*Insurance Policies*. The DGCL also provides corporations with the power to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation in a similar capacity for another corporation, partnership, joint venture, trust or other enterprise, against any liability asserted against him or her in any such capacity, or arising out of his or her status as such, whether or not the corporation would have the power to indemnify him or her against such liability as described above. The registrant has directors' and officers' liability insurance in an amount not less than $5 million.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers, or persons controlling the registrant pursuant to the foregoing provisions, the registrant has been informed that in the opinion of the Commission such indemnification is against public policy as expressed in such Securities Act and is therefore unenforceable.

**ITEM 16. EXHIBITS.**

| Exhibit Number | Description |
|---|---|
| 1.1 | Underwriting Agreement* |
| 4.1 | Form of common stock certificate. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on October 23, 2007. |
| 4.2 | Certificate of Designations of Preferences, Rights and Limitations of Series A Preferred Stock of the registrant, dated September 24, 2009. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on September 25, 2009. |
| 4.3 | Certificate of Designations of Preferences, Rights and Limitations of Series B Preferred Stock of the registrant, dated July 19, 2010. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on July 20, 2010. |
| 4.4 | Form of Amended and Restated Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K/A filed with the SEC on February 11, 2010. |
| 4.5 | Form of Common Stock Purchase Warrant, issued in the junior bridge financing. Incorporated by reference to Exhibit 4.12 to Registration Statement on Form S-1 (File No. 333-162632) filed with the SEC on October 22, 2009. |
| 4.6 | Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on June 19, 2009. |
| 4.7 | Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.3 to Current Report on Form 8-K/A filed with the SEC on February 11, 2010. |

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| 4.8 | Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K filed with the SEC on November 12, 2010. |
| 4.9 | Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K filed with the SEC on May 9, 2011. |
| 4.10 | Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on August 31, 2011. |
| 4.11 | Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K filed with the SEC on November 2, 2011. |

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| 4.12 | Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K filed with the SEC on January 5, 2012. |
| 4.13 | Form of Common Stock Purchase Warrant issued pursuant to the Exchange Agreements, dated as of May 14, 2012, by and between Advaxis, Inc. and each investor identified on the signature pages thereto. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on May 18, 2012. |
| 4.14 | Form of Common Stock Purchase Warrant issued pursuant to the Note Purchase Agreement, dated as of May 14, 2012, by and between Advaxis, Inc. and each investor identified on the signature pages thereto. Incorporated by reference to Exhibit 4.3 to Current Report on Form 8-K filed with the SEC on May 18, 2012. |
| 4.15 | Form of Common Stock Purchase Warrant issued to Dr. James Patton. Incorporated by reference to Exhibit 4.23 to Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-183682) filed with the SEC on September 11, 2012. |
| 4.16 | Form of Secured Promissory Note issued pursuant to the Securities Purchase Agreement, dated as of December 13, 2012, by and between Advaxis, Inc. and Tonaquint, Inc. Incorporated by reference to Exhibit 4.1 to Quarterly Report on Form 10-Q filed with the SEC on March 25, 2013. |
| 4.17 | Form of Warrant to Purchase Shares of Common Stock issued pursuant to the Securities Purchase Agreement, dated as of December 13, 2012, by and between Advaxis, Inc. and Tonaquint, Inc. Incorporated by reference to Exhibit 4.2 to Quarterly Report on Form 10-Q filed with the SEC on March 25, 2013. |
| 4.18 | Form of Warrant Agency Agreement by and between Advaxis, Inc. and Securities Transfer Corporation and Form of Warrant Certificate. Incorporated by reference to Exhibit 4.18 to Registration Statement on Form S-1/A (File No. 333-188637) filed with the SEC on September 27, 2013. |
| 4.19 | Form of Representative's Warrant. Incorporated by reference to Exhibit 4.19 to Registration Statement on Form S-1/A (File No. 333-188637) filed with the SEC on September 27, 2013. |
| 4.20 | Form of Warrant to Purchase 30,154 Shares of Common Stock issued September 17, 2013 pursuant to an engagement letter termination agreement. Incorporated by reference to Exhibit 4.20 to Registration Statement on Form S-1/A (File No. 333-188637) filed with the SEC on September 27, 2013. |
| 4.21 | Form of Warrant Agency Agreement between Advaxis, Inc. and Securities Transfer Corporation dated October 22, 2013 and Form of Warrant Certificate. Incorporated by reference to Exhibits 10.1 and 10.2 to Current Report on Form 8-K filed with the SEC on October 22, 2013. |
| 5.1 | Opinion of Reed Smith LLP. |
| 23.1 | Consent of Marcum LLP. |
| 23.2 | Consent of McGladrey LLP. |
| 23.3 | Consent of Reed Smith LLP (included in Exhibit 5.1). |

24.1 Power of Attorney (included on the signature page to this Registration Statement).

* To be filed by amendment or as an exhibit to a document to be incorporated by reference herein in connection with an offering of the securities.

**ITEM 17. UNDERTAKINGS.**

A. RULE 415 OFFERING

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b)) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

*Provided, however*, That:

(A) Paragraphs (a)(1)(i) and (a)(1)(ii) of this section do not apply if the registration statement is on Form S-8, and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement; and

(B) Paragraphs (a)(1)(i), (a)(1)(ii), and (a)(1)(iii) of this section do not apply if the registration statement is on Form S-3 or Form F-3 and the information required to be included in a post-effective amendment by those paragraphs is

contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post- effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the Registration Statement as of the date the filed prospectus was deemed part of and included in the Registration Statement; and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a Registration Statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the Registration Statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the Registration Statement relating to the securities in the Registration Statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a Registration Statement or prospectus that is part of the Registration Statement or made in a document incorporated or deemed incorporated by reference into the Registration Statement or prospectus that is part of the Registration Statement will, as to the purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the Registration Statement or prospectus that was part of the Registration Statement or made in any such document immediately prior to such effective date.

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this Registration Statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectuses relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(e) The undersigned registrant hereby undertakes to deliver or cause to be delivered with the prospectus, to each person to whom the prospectus is sent or given, the latest annual report to security holders that is incorporated by reference in the prospectus and furnished pursuant to and meeting the requirements of Rule 14a-3 or Rule 14c-3 under the Securities Exchange Act of 1934; and, where interim financial information required to be presented by Article 3 of Regulation S-X are not set forth in the prospectus, to deliver, or cause to be delivered to each person to whom the prospectus is sent or given, the latest quarterly report that is specifically incorporated by reference in the prospectus to provide such interim financial information.

(h) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

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**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Princeton, State of New Jersey, on February 17, 2014.

Advaxis, Inc.

By: /s/ Daniel J. O'Connor
Name: Daniel J. O'Connor
Title: Chief Executive Officer and President

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated. Each person in so signing also makes, constitutes and appoints Daniel J. O'Connor, Mark J. Rosenblum and Gregory T. Mayes, and each of them acting alone, his or her true and lawful attorney-in-fact, with full power of substitution, in any and all capacities, to execute and cause to be filed with the Securities and Exchange Commission pursuant to the requirements of the Securities Act of 1933, any and all amendments and post-effective amendments to this Registration Statement, with exhibits to such registration statements and amendments and other documents in connection therewith, and hereby ratifies and confirms all that said attorney-in-fact or his or her substitute or substitutes may do or cause to be done by virtue hereof.

| **Signature** | **Title** | **Date** |
|---|---|---|
| /s/ Daniel J. O'Connor<br>Daniel J. O'Connor | Chief Executive Officer and President (Principal Executive Officer) and Director | February 17, 2014 |
| /s/ Mark J. Rosenblum<br>Mark J. Rosenblum | Chief Financial Officer (Principal Financial and Accounting Officer) | February 17, 2014 |
| /s/ Dr. James P. Patton<br>Dr. James P. Patton | Chairman of the Board of Directors | February 17, 2014 |
| /s/ Roni A. Appel<br>Roni A. Appel | Director | February 17, 2014 |
| /s/ Richard Berman<br>Richard Berman | Director | February 17, 2014 |
| /s/ Dr. Thomas McKearn | Director | February 17, 2014 |

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|---|---|---|
| Dr. Thomas McKearn | | |
| /s/ Thomas A. Moore<br>Thomas A. Moore | Director | February 17, 2014 |
| /s/ Dr. David Sidransky<br>Dr. David Sidransky | Director | February 17, 2014 |

**EXHIBIT INDEX**

| Exhibit Number | Description |
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| 4.2 | Certificate of Designations of Preferences, Rights and Limitations of Series A Preferred Stock of the registrant, dated September 24, 2009. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on September 25, 2009. |
| 4.3 | Certificate of Designations of Preferences, Rights and Limitations of Series B Preferred Stock of the registrant, dated July 19, 2010. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on July 20, 2010. |
| 4.4 | Form of Amended and Restated Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K/A filed with the SEC on February 11, 2010. |
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| 4.6 | Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on June 19, 2009. |
| 4.7 | Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.3 to Current Report on Form 8-K/A filed with the SEC on February 11, 2010. |
| 4.8 | Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K filed with the SEC on November 12, 2010. |
| 4.9 | Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K filed with the SEC on May 9, 2011. |
| 4.10 | Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on August 31, 2011. |
| 4.11 | Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K filed with the SEC on November 2, 2011. |
| 4.12 | Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K filed with the SEC on January 5, 2012. |

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|---|---|
| 4.13 | Form of Common Stock Purchase Warrant issued pursuant to the Exchange Agreements, dated as of May 14, 2012, by and between Advaxis, Inc. and each investor identified on the signature pages thereto. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on May 18, 2012. |
| 4.14 | Form of Common Stock Purchase Warrant issued pursuant to the Note Purchase Agreement, dated as of May 14, 2012, by and between Advaxis, Inc. and each investor identified on the signature pages thereto. Incorporated by reference to Exhibit 4.3 to Current Report on Form 8-K filed with the SEC on May 18, 2012. |

| | |
|---|---|
| 4.15 | Form of Common Stock Purchase Warrant issued to Dr. James Patton. Incorporated by reference to Exhibit 4.23 to Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-183682) filed with the SEC on September 11, 2012. |
| 4.16 | Form of Secured Promissory Note issued pursuant to the Securities Purchase Agreement, dated as of December 13, 2012, by and between Advaxis, Inc. and Tonaquint, Inc. Incorporated by reference to Exhibit 4.1 to Quarterly Report on Form 10-Q filed with the SEC on March 25, 2013. |
| 4.17 | Form of Warrant to Purchase Shares of Common Stock issued pursuant to the Securities Purchase Agreement, dated as of December 13, 2012, by and between Advaxis, Inc. and Tonaquint, Inc. Incorporated by reference to Exhibit 4.2 to Quarterly Report on Form 10-Q filed with the SEC on March 25, 2013. |
| 4.18 | Form of Warrant Agency Agreement by and between Advaxis, Inc. and Securities Transfer Corporation and Form of Warrant Certificate. Incorporated by reference to Exhibit 4.18 to Registration Statement on Form S-1/A (File No. 333-188637) filed with the SEC on September 27, 2013. |
| 4.19 | Form of Representative's Warrant. Incorporated by reference to Exhibit 4.19 to Registration Statement on Form S-1/A (File No. 333-188637) filed with the SEC on September 27, 2013. |
| 4.20 | Form of Warrant to Purchase 30,154 Shares of Common Stock issued September 17, 2013 pursuant to an engagement letter termination agreement. Incorporated by reference to Exhibit 4.20 to Registration Statement on Form S-1/A (File No. 333-188637) filed with the SEC on September 27, 2013. |
| 4.21 | Form of Warrant Agency Agreement between Advaxis, Inc. and Securities Transfer Corporation dated October 22, 2013 and Form of Warrant Certificate. Incorporated by reference to Exhibits 10.1 and 10.2 to Current Report on Form 8-K filed with the SEC on October 22, 2013. |
| 5.1 | Opinion of Reed Smith LLP. |
| 23.1 | Consent of Marcum LLP. |
| 23.2 | Consent of McGladrey LLP. |
| 23.3 | Consent of Reed Smith LLP (included in Exhibit 5.1). |
| 24.1 | Power of Attorney (included on the signature page to this Registration Statement). |

* To be filed by amendment or as an exhibit to a document to be incorporated by reference herein in connection with an offering of the securities.