Advaxis, Inc.
Form 10-K
January 29, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

x ANNUAL REPORT UNDER SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED - OCTOBER 31, 2013

OR

¨ TRANSITION REPORT UNDER SECTION 13 OR 15 (d)
OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NUMBER 000-28489

ADVAXIS, INC.
(Name of Registrant 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
(Address of Principal Executive Offices)	*(Zip Code)*
(609) 452-9813 *(Issuer's Telephone Number)*	

Securities registered under Section 12(b) of the Exchange Act:	Common Stock - $.001 par value NASDAQ Capital Market
Securities registered under Section 12(g) of the Exchange Act:	[None]

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act.

Yes ¨ No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨	Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

As of April 30, 2013, the aggregate market value of the voting common equity held by non-affiliates was approximately $69,373,577 based on the closing bid price of the registrant's common stock on the Over the Counter Bulletin Board. (For purposes of determining this amount, only directors, executive officers, and 10% or greater shareholders and their respective affiliates have been deemed affiliates). x

The registrant had 13,872,182 shares of Common Stock, par value $0.001 per share, issued and outstanding as of January 17, 2014.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the registrant's 2014 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed within 120 days of the end of the fiscal year ended October 31, 2013 are incorporated by reference in Part III hereof. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as a part hereof.

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PART 1

FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. When used in this Annual Report, statements that are not statements of current or historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "plan", "intend", "may," "will," "expect," "believe", "could," "anticipate," "estimate," or "continue" or similar expressions or ot comparable terminology are intended to identify such forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the Company undertakes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 1. Business.

General

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

The effectiveness of our approach has been validated by numerous publications in multiple models of human disease. In the clinic, ADXS-HPV, our lead *Lm*- LLO immunotherapy for the treatment of HPV-associated cancers, is well-tolerated and has been administered to both young patients with pre-malignant dysplasia, as well as patients with advanced disease. Clinical efficacy has been demonstrated by apparent prolonged survival, complete and partial tumor responses, and the prolonged stabilization of advanced cancer. The preliminary data from our 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.

To date, we have outsourced many functions of drug development including manufacturing and clinical trial management. Accordingly, the expenses of these outsourced services account for a significant amount of our

accumulated loss. We cannot predict when, if ever, any of our immunotherapies will become commercially viable or approved by the United States Food and Drug Administration, which we refer to as the FDA. We expect to spend substantial additional sums on the continued research and development of proprietary products and technologies, including conducting clinical trials for our immunotherapies, with no certainty that our immunotherapies will become commercially viable or profitable as a result of these expenditures.

History of the Company

We were originally incorporated in the State of Colorado on June 5, 1987 under the name Great Expectations, Inc. In 1999, we became a reporting company under the Exchange Act. We were a publicly-traded "shell" company without any business until November 12, 2004 when we acquired Advaxis, Inc., a Delaware corporation, through Share Exchange. As a result of such acquisition, Advaxis 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 shareholders approved the reincorporation of the company from the state of Colorado to the state of Delaware by merging us into its wholly-owned subsidiary. Our date of inception, for financial statement purposes, is March 1, 2002. Our statements of income and cash flows disclose our accumulated losses and net cash increases (decreases), respectively since inception. Our principal executive offices are located at 305 College Road East, Princeton, NJ 08540 and our telephone number is (609) 452-9813.

We maintain a website at *www.advaxis.com* that contains descriptions of our technology, our drugs and the trial status of each drug. The information on, or that can be accessed through, our website is not part of this Annual Report on Form 10-K.

We currently trade on NASDAQ under the ticker symbol ADXS.

Recent Developments

Biocon Limited

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

Pursuant to the Agreement, Advaxis granted Biocon an exclusive license (with a right to sublicense) to (i) use Advaxis' data from clinical development activities, regulatory filings, technical, manufacturing and other information and know-how to enable Biocon to submit regulatory filings for ADXS-HPV in certain territories ("Territory") and (ii) import, promote, market, distribute and sell pharmaceutical products containing ADXS-HPV.

Under the Agreement, Biocon has agreed to use its commercially reasonable efforts to obtain regulatory approvals for ADXS-HPV in India. In the event Phase II or Phase III clinical trials are required, Advaxis shall conduct such trials at its cost, provided that if Advaxis is unable to commence such clinical trials, Biocon may conduct such clinical trials, subject to reimbursement of costs by Advaxis. Biocon has agreed to commence commercial distribution of ADXS-HPV no later than 9 months following receipt of regulatory approvals in a country in the Territory. Biocon will be responsible for the costs of obtaining and maintaining regulatory approvals in the Territory.

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

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

The term of the Agreement will be the later of twenty years or the last to expire patent or patent application. In addition, the Agreement may be terminated by either party upon thirty days' written notice (i) in the event of a material breach by the other party of its obligations under the Agreement, (ii) if the other party becomes bankrupt or insolvent or (iii) if the other party undergoes a change in control (see also Item 1- Collaborations, Partnerships and Agreements).

Public Offering

On October 22, 2013, the Company closed its public offering of 6,612,500 shares of common stock, and warrants to purchase up to an aggregate of 3,306,250 shares of its common stock, including 862,500 shares and warrants to purchase 431,250 shares that were offered and sold by the Company pursuant to the full exercise of the underwriters' over-allotment option, at a price to the public of $4.00 per share and $0.001 per warrant. The warrants have a per share exercise price of $5.00, 125% of the public offering price of the common stock, are exercisable immediately, and expire five years from the date of issuance Aegis, as the representative, received warrants to purchase 198,375 shares of the Company's common stock (equal to 3% of total shares offered), which warrants are exercisable at $5.00 per share and shall expire five years from the date of issuance. Total gross proceeds from the offering were approximately $26,500,000, before deducting underwriting discounts and commissions and other offering expenses payable by the Company.

Licensing Agreement

On December 9, 2013, the Company entered into an exclusive licensing agreement for the development and commercialization of ADXS-HPV with Global BioPharma, Inc. (GBP), a Taiwanese based biotech company funded by a group of investors led by Taiwan Biotech Co., Ltd (TBC). TBC is one of the top five pharmaceutical companies in Taiwan and formed GBP solely to focus on the development and commercialization of ADXS-HPV for the treatment of human papillomavirus (HPV)-associated diseases. The GBP territory covers over 4 billion people with over 200,000 annual diagnoses of cervical cancer, accounting for roughly 40% of the world's cases, according to WHO statistics.

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

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

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

Appointment of Greg Mayes as Executive Vice President and Chief Operating Officer

On October 28, 2013, Advaxis, Inc. (the "Company"), announced the appointment of Gregory T. Mayes, age 45, as Executive Vice President and Chief Operating Officer ("COO") of the Company.

Mr. Mayes is the former Executive Vice President, Human Resources for Dendreon Corporation, the leading pioneer in the field of immuno-oncology research and development, where he was a member of the Executive Committee. Prior to Dendreon, Mr. Mayes was the President of Unigene Laboratories Inc. (2010 to 2012) where he primarily led out-licensing efforts for the company's novel oral peptide drug delivery platform. Prior to Unigene, Mr. Mayes served as the Vice President, General Counsel and Chief Compliance Officer at ImClone Systems Corporation, a wholly owned subsidiary of Eli Lilly (2004 to 2010). While serving at ImClone in positions of increasing responsibility, Mr. Mayes supported the clinical development and commercialization of ERBITUX (cetuximab), led the development and oversight of the company's first corporate compliance program and contributed significantly to activities related to Eli Lilly's $6.5 billion acquisition of ImClone in 2008. Mr. Mayes also served as Senior Counsel at AstraZeneca Pharmaceuticals LP, where he provided a wide range of legal services in connection with the development and commercialization of five approved products in the company's oncology portfolio (2001 to 2004). Earlier Mr. Mayes worked in private practice at Morgan Lewis LLP, a national law firm. He earned his B.S. degree from Syracuse University cum laude, where he was recognized as a Remembrance Scholar, and he earned his J.D. degree from the Temple University School of Law where he was the Articles Editor on the Temple Law Review.

Following the approval of a majority of the independent members of the Board of Directors of the Company, the Company entered into an employment agreement with Mr. Mayes on October 25, 2013, which took effect as of such date. The employment agreement provides for an initial term of one year, after which it will be automatically renewed for one year periods unless otherwise terminated by the Company. Mr. Mayes is entitled to an annual base salary of $265,000 per year (plus annual cost-of-living adjustments), which salary will be reviewed on an annual basis. Beginning in fiscal 2014, Mr. Mayes is also eligible to receive an annual bonus of 10-50% of his base salary, which amount, if any, will be determined by the Compensation Committee based on achievement of certain goals to be established by such committee and Mr. Mayes at the beginning of each fiscal year, in consultation with the Company's Chief Executive Officer. In addition, upon execution and delivery of the employment agreement, Mr. Mayes received an inducement grant of 150,000 restricted shares of the Company's common stock, 37,500 shares (25%) of which are fully vested and not subject to forfeiture as of the grant date, with the remaining shares vesting 37,500 annually beginning with the first anniversary of the grant date such that the entire award is fully vested and not subject to forfeiture as of October 25, 2016. Vesting will be accelerated in the event of Mr. Mayes's death or disability, or in the event of a "Change of Control" as defined in the restricted stock award agreement. The restricted stock award agreement also includes other terms and conditions and restrictions regarding the award. Mr. Mayes is eligible to participate in the Company's benefit plans, is entitled to four weeks of vacation and sick leave, as well as reimbursement of reasonable expenses incurred in fulfilling his duties under the agreement.

Employment Agreement Amendments

On December 19, 2013, the Company and each of its Executives, voluntarily entered into an amendment to their respective employment agreements.

Under the terms of each Amendment, all of the Executives voluntarily agreed to utilize a percentage of their base salary for stock compensation. Common stock of the Company will be acquired by each Executive based on the fair market value of the Common Stock on the date of acquisition. The allocation between the cash and equity components of each Executive's base salary is as follows:

Executive	% of base salary in cash	% of base salary in Common Stock

Daniel J. O'Connor	75.0	25.0
Gregory T. Mayes, III	92.5	7.5
Mark J. Rosenblum	92.5	7.5
Robert G. Petit	91.5	8.5
Chris L. French	95.0	5.0

The stock compensation will be acquired by the Executives on the last business day of each fiscal quarter of the Company in accordance with the terms and provisions of the Company's 2011 Omnibus Incentive Plan..

The Amendments also clarify several other matters related to severance, purchases of Company stock, and base salary changes as more fully described in Form 8K filed on December 19, 2013.

Regulatory Affairs

In August 2013, the FDA granted our orphan drug designation request for ADXS-HPV for HPV-associated anal cancer. In January 2014, a teleconference meeting was conducted with the FDA to discuss the orphan drug designation request and subsequent denial for ADXS-HPV for the treatment of invasive cervical cancer. We intend to submit a new application based on the discussions.

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. 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.

Clinical Research

In October 2013, we completed *Lm*-LLO-E7-15. This randomized Phase 2 study evaluated the safety and efficacy of ADXS-HPV (1 cycle of three doses at $1x10^9$ cfu) with and without cisplatin (40 mg/m2, weekly x5) in 110 patients in India with recurrent cervical cancer in two treatment arms of 55 patients each. The primary endpoint of the study is overall survival.

On November 9, 2013, we announced final 18-month survival data from *Lm*-LLO-E7-15 at the 2013 Society for Immunotherapy of Cancer (SITC) Annual Meeting in National Harbor, MD. The final 18-month survival data was 28% (31/110) and the final 12-month survival was 36% (39/110). ADXS-HPV was well-tolerated in patients with recurrent cervical cancer. 42% (46/110) of patients reported predominately Grade 1 and 2 mild/moderate transient adverse events associated with infusion; 2 SAEs (1 Grade 3 and 1 Grade 4) were reported in 110 patients. Tumor responses were equivalent in both treatment groups with an 11% objective response rate (including 6 complete responses, 6 partial responses and 35 patients with stable disease) for a disease control rate of 41% (47/110) for greater than 3 months. The average duration of response was ~10.5 months with once cycle (3 doses) of treatment.

In January 2014, we announced that the first patient was dosed in the Phase 1/2 "window of opportunity" study being conducted by the Icahn School of Medicine at Mount Sinai. Patients diagnosed with HPV-associated head and neck cancer will receive ADXS-HPV immunotherapy during the "window" of time between initial diagnosis and minimally invasive transoral robotic surgery (TORS) to remove their tumors. This investigator-initiated clinical study is designed to enroll 25 patients with HPV-positive stage II-IV squamous cell carcinoma of the oropharynx who are scheduled to undergo TORS. TORS is an FDA-approved technology developed at Mount Sinai for patients with head and neck cancer and is considered to be the standard of care therapy in appropriate patients. Fifteen patients will receive ADXS-HPV treatment followed by TORS and ten patients will serve as the control group and receive only TORS. The primary objective of this study is to assess the safety, efficacy and immunogenicity of ADXS-HPV in this patient population prior to undergoing surgery.

Conversion of Debt

During the twelve months ended October 31, 2013, the Company converted approximately $5 million in outstanding principal of convertible promissory notes into approximately 2.2 million shares of our common stock. As of October 31, 2013, the Company only had approximately $220,000 in outstanding principal (including the Moore Notes).

New Jersey Economic Development Authority

On December 20, 2013 the Company received notice from the New Jersey Economic Development Authority that it had been preliminarily approved to transfer and sell its available Net Operating Losses ("NOL") and R&D tax credits for the years ended October 31, 2009, 2010 and 2011. On January 17, 2014 the Company received $625,563 from the transfer and sale of these NOL's and R&D tax credits.

Preclinical Research

In September 2013, we announced the e-publication of a paper titled "Anti-PD-1 antibody significantly increases therapeutic efficacy of *Listeria monocytogenes* (*Lm*)-LLO immunotherapy" by Mkrtichyan et. al., in the Journal of Immunotherapy of Cancer. The research was conducted by Dr. Samir N. Khleif and his research team at the Georgia Regents University Cancer Center and demonstrated that treatment with an *Lm*-LLO immunotherapy, in combination with an anti-PD-1 antibody, significantly improved immune and therapeutic efficacy in preclinical mouse models. In addition, the study showed that a significant reduction of regulatory T cells (Treg) and myeloid-derived suppressor cells (MDSC) in both the spleen and the tumor microenvironment were mediated solely by the *Lm*-LLO immunotherapy. The addition of anti-PD-1 antibody to the *Lm*-LLO immunotherapy treatment resulted in a significant increase in antigen-specific immune responses in the periphery and in CD8 T cell infiltration into the tumor. As a result, this treatment combination led to significant inhibition of tumor growth and prolonged survival/complete regression of tumors in treated animals. Separate studies were conducted to evaluate activity in human cells where *Lm*-LLO immunotherapy was found to significantly upregulate surface PD-L1 expression on human monocyte-derived dendritic cells isolated from healthy volunteers. This finding suggests that the combination of *Lm*-LLO immunotherapy with an anti-PD-1 antibody could have clinical application.

Icahn School of Medicine at Mount Sinai

On December 5, 2013, we entered into a clinical trial agreement with the Icahn School of Medicine to evaluate the safety, effectiveness and immunogenicity of ADXS-HPV in 25 patients with head and neck cancer. This clinical trial will be the first study to evaluate the effects of ADXS-HPV in patients when they are initially diagnosed with HPV-associated head and neck cancer, prior to receiving any standard of care (surgery, chemotherapy, radiation or a combination thereof) to remove and/or treat their tumors. This study will be an important first step towards understanding ADXS-HPV's potential to treat this type of cancer before chemotherapy and/or radiation and its potential to reduce the need for these treatments.

Research and Development Program

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 and holds tremendous promise to generate more effective and better tolerated treatments for cancer than the more traditional, high dose chemotherapy and radiation therapies that have been the mainstay of cancer treatment thus far. There are many approaches toward immunotherapy that have been recently approved or are in development:

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

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

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

Based on their mechanisms of action, all immunotherapy products on the market or in development, fall into the category of one or more of the first 3 of the four essential elements of immunotherapy shown in the boxes in the graphic below: Box 1 - Access to antigen presenting cells to direct and target the immune response; Box 2 Ability to generate a strong T-cell response against tumor antigens; and Box 3 Ability to get past immune check-points and negative regulators of cellular immunity. The problem is that none of the current treatments meet all of these four elements and thereby have limitations. Box 1 - Accessing the dendritic cell is only part of the solution; Box 2 - many vaccines are able to generate T-cell responses but without overcoming tolerance, T-cells cannot do their jobs; Box 3 checkpoints are one of the many mechanisms of tolerance and if the product blocks them systemically, autoimmunity can result, thereby limiting application. What makes Lm-LLO-E7 immunotherapies different is that our one treatment meets the challenges of all four elements while avoiding the negative characteristics that limit the application of previous immunotherapies. In addition is the only treatment that addresses Box 4, which is the key differentiating factor from other immunotherapies. Our technology changes the tumor microenvironment and reduces the number and function of immune tolerance cells that are inside the tumor protecting it from anti-tumor immunity. We believe that we are the only technology that integrates all of these elements into a single, well-tolerated, low cost to manufacture, and easy to administer immunotherapy.

Mechanism of Action

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

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

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Lm -LLO immunotherapies are bioengineered with multiple copies of a plasmid that encode a fusion protein sequence that includes a fragment of LLO joined to the TAA of interest. Some *Lm* escape from the phagolysosome via LLO, which forms pores in the membrane of the phagolysosome and allows the *Lm* to escape into the cytosol and secrete antigen-LLO fusion proteins. These fusion protein antigens are presented via the MHC class I pathway to generate activated CD8+ T cells, or killer T cells. The majority of *Lm* are broken down in the phagolysosome and the *Lm* fragments are processed via the MHC class II pathway generating antigen-specific CD4+ T cells, or helper T cells. We believe the activated T cells will then find and infiltrate tumors and destroy the tumor cells. Immunologic tolerance in the tumor microenvironment is mediated by Tregs and MDSC is reduced. Thus we believe *Lm* -LLO immunotherapies may simultaneously stimulate innate and adaptive tumor-specific immunity while simultaneously reducing immune tolerance to tumors. We believe our *Lm* -LLO immunotherapies integrate all four of what we consider to be the essential elements of a cancer immunotherapy into a comprehensive, single, well-tolerated, easy to manufacture and administer immunotherapy.

Our Development Pipeline

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

Our first *Lm* -LLO based immunotherapy, ADXS-HPV, uses HPV-E7, an antigen that is present in Human Papilloma Virus (HPV). HPV-associated cancers account for approximately 6-8% of all cancers worldwide, including cervical cancer, head and neck cancers, anal cancer and others. ADXS-PSA is directed against prostate cancer. ADXS-cHER2 is directed against HER2, an antigen found in HER2 overexpressing cancers such as breast, gastric and other cancers, as well as canine osteosarcoma. By varying the antigen, we believe we will be able to create different immunotherapies that may be useful across multiple therapeutic areas and tumor types such as ADXS-PSA for the treatment of prostate cancer and ADXS-cHER2, for the treatment of HER2 over-expressing cancers such as breast, gastric and other human cancers as well as canine osteosarcoma.

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

Immunotherapy	Indication	Stage of Clinical Development
ADXS-HPV	**Cervical Cancer**	**Phase 1** We sponsored and completed in 2007 with 15 patients.
	Cervical Cancer	**Phase 2** We sponsored this study which was initiated in November 2010 in India in 110 patients with recurrent cervical cancer. We completed the study in October 2013.
	Cervical Cancer	**Phase 2** The GOG of the NCI is conducting a study in 67 patients with recurrent/refractory cervical cancer.
	Head & Neck Cancer	**Phase 1** CRUK is funding a study of 27 patients with head and neck cancer at 3 U.K. sites.
	Head & Neck Cancer	**Phase 1/2** The Icahn School of Medicine at Mount Sinai is conducting a study in 25 patients with head and neck cancer.
ADXS-HPV	**Anal Cancer**	**Phase 1/2** The BrUOG is funding and conducting a study in 25 patients with anal cancer at Brown University, M.D. Anderson Cancer Center, Montefiore Medical Center and Boston Medical Center.
ADXS-PSA	**Prostate Cancer**	**Phase 1** We plan to initiate a Phase 1 study in the first half of 2014.
ADXS-cHER2	**Canine Osteosarcoma**	**Phase 1** We are sponsoring a study of 15 dogs with osteosarcoma. We plan to initiate a Phase 1 study in the second half of 2014.

Overview of Product Candidates

ADXS-HPV Franchise

Published studies have shown that of the more than 100 strains of HPV, 15 are known to be sexually transmitted "high-risk" oncogenic types of HPV that are responsible for 5% of all cancers worldwide and 10% of cancers in women. HPV infection can cause cells to become cancerous through the expression of the E6 and E7 genes. According to data extrapolated from the incidence rates reported in the WHO Human Papillomavirus and Related Cancers in the World Summary Report 2010, the worldwide annual incidence of HPV-associated cancers is approximately 527,000 cervical cancer; 99,000 anal cancer, 86,000 penile cancer, 80,000 head and neck cancer, 27,000 vulvar cancer and 13,000 vaginal cancer. Current preventative vaccines cannot protect the 20 million women who are already infected with HPV; and of the high risk oncogenic strains, only HPV 16 and 18 are present in these vaccines. According to a study published by Trimble, et. al. in Lancet Oncology, 80% of sexually active Americans will have contracted at least one strain of HPV by age 50. Challenges with acceptance, accessibility and compliance have resulted in only a third of

young women being vaccinated in the United States and even less in other countries around the world. HPV is associated with 99% of cervical cancer, which in late stage is a highly aggressive malignancy with poor prognosis, no standard of care, and for which traditional cancer therapy is ineffective. HPV-associated head and neck cancer is growing at an epidemic rate in western countries; and occurs more frequently (3:1) in men than women due to changes in sexual practices. HPV is associated with over 25% of head and neck cancers in the United States, the number of HPV-positive head and neck cancer cases has already equaled the number of cases of cervical cancer and continues to increase in frequency and current therapies lead to poor quality of life. HPV is associated with over 80% of anal cancers and is also increasing in frequency. Current therapies are toxic and have long-term side effects with no approved therapy for recurrent disease.

In addition, 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 prostate-specific antigen, or PSA. ADXS-PSA is designed to target cells expressing PSA. ADXS-PSA secretes the PSA antigen, fused to LLO, directly inside the APC that are capable of driving a cellular immune response to PSA expressing cells. In preclinical analysis, the localized effect is the inhibition of the Treg and MDSC cells that we believe may promote immunologic tolerance of the PSA cancer cells of the tumor. We have conducted a pre-IND, meeting with the FDA to discuss the chemistry, manufacturing and controls, pharmacology, toxicity and clinical plans for ADXS-PSA. We will finalize the toxicology reports and GMP documentation required for the IND we plan to submit to the FDA, and advance ADXS-PSA into a Phase 1 dose escalation trial to determine the maximum dose for the treatment of prostate cancer in the first half of 2014. Future plans for the ADXS-PSA clinical program are contingent upon a number of variables including available resources, types and number of studies, study initiation, patient enrollment, clinical and safety data generated, regulatory interactions and changing competitive landscape.

ADXS-cHER2

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

The preliminary data from the canine osteosarcoma study provides the rational to advance ADXS-cHER2 into a Phase 1 study in the second half of 2014 to determine the maximum tolerated dose in breast cancer.

Recent Clinical Research Developments

We have completed dosing in *Lm* -LLO-E7-15, a Phase 2 randomized trial designed to assess the safety and efficacy of ADXS-HPV ($1x10^9$ cfu) with and without cisplatin (40 mg/m2, weekly x5). 110 patients were randomized to one of two treatment arms with 55 patients per treatment. The primary endpoint of the study is overall survival.

As reported at the SITC Annual Meeting in November 2013, the trial was completed in October 2013 with 110 patients receiving 264 doses of ADXS11-001. The final 18-month survival was 28% (31/110) and the final 12 month survival was 36% (39/110). The National Comprehensive Cancer Network Guidelines and/or GOG published studies cite historical 12 month survival data of 0 22% with single agent therapy in recurrent cervical cancer. This study shows 12 month survival of 36% (39/110) and is consistent with an active agent in recurrent cervical cancer:

- Published Phase 2 single agent trials report 12 months survival of 0 22%*

* NCCN Guidelines:

Plaxe SC, et. al., 2002, Cancer Chemother Pharmacol; 50: 151-4.
Garcia AA, et. al., 2007, Am J Clin Oncol; 30: 428-431.

Survival results were not significantly different between treatment groups. Survival outcomes and tumor responses were not affected by ECOG performance status (0 2); type of prior therapy (radiation alone, chemotherapy alone, or a combination of both); or aggressiveness of disease (defined as recurrence ≤2 years from initial diagnosis) versus non-aggressive disease (defined as recurrence >2 years from initial diagnosis).

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

Prognostic Factors for Overall Survival in Cervical Cancer

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

  ECOG performance status,

  Number of prior therapies,

  Interval from initial therapy to time of recurrence, and

  Local recurrence vs. distant metastases*

* *Monk 2009, JCO*

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Tumor responses have been observed in 11% of the patients in the study with six complete responses, or CR: four in the ADXS alone treatment arm; two in the ADXS+ cisplatin treatment arm; and six partial responses, or PR; three in the ADXS alone treatment arm; three in the ADXS+ cisplatin treatment arm. 35 patients had durable stable disease for at least 3 months as indicated by the orange dashed lines in the waterfall plot below for a disease control rate of 43% (47/110). Activity against different high risk HPV strains beyond HPV 16 and HPV 18 have been observed, including HPV 16, 18, 31, 33 and 45.

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

Patient 110-002: Major Tumors Eliminated

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

ADXS-HPV continues to demonstrate a well-tolerated and manageable safety profile with 41% (45/110) of patients reporting predominately cytokine-release syndrome (CRS) Grade 1 or 2 transient, non-cumulative side effects related/possibly related to ADXS-HPV. Side effects either responded to symptomatic treatment or self-resolved. Less than 2% of patients reported serious adverse events associated with ADXS-HPV (1 Grade 3 CRS with dyspnea and 1 Grade 4 CRS with fever). Serious adverse events may result in death, are life-threatening, cause significant disability or require inpatient hospitalization.

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

As part of our review of all ongoing clinical and preclinical research projects and evaluating the fit with our revised, and more focused corporate strategy, we have decided to discontinue our support of any clinical trial that evaluates ADXS-HPV in a setting where patients do not have an active malignancy, and have a high likelihood of being “cured” by their primary definitive treatment before receiving ADXS-HPV. The REALISTIC clinical trial falls into this category and we have therefore notified the principal investigator in December 2013 that we have withdrawn our support of the REALISTIC trial.

Our research and development costs decreased from approximately $6.6 million for the year ending October 31, 2012 to approximately $5.6 million for the year ending October 31, 2013 (please also see Item7- Management’s Discussion and Analysis of Financial Condition and Results of Operations).

Business Strategy

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

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

- ***Develop and commercialize ADXS-HPV in multiple HPV-associated cancers.*** We plan to advance ADXS-HPV through registrational Phase 3 trials and regulatory approval in the United States and relevant markets for the treatment of cervical cancer. If successful, we plan to submit a Biologics License Application, or BLA, to the FDA as the basis for marketing approval in the United States of ADXS-HPV for the treatment of cervical cancer. HPV, the target for ADXS-HPV, is expressed on a wide variety of cancers including cervical, head and neck, anal, vulva, vaginal, and penile. Accordingly, we believe that ADXS-HPV should be active in these HPV-associated cancers and these indications could represent significant market opportunities for ADXS-HPV.

- ***Obtain Orphan Drug Designation with the FDA and the EMEA for ADXS-HPV for use in the treatment of invasive cervical cancer, head and neck cancer and anal cancer.*** In June 2013, we filed three applications for Orphan Drug Designation with the FDA for ADXS-HPV for the treatment of anal cancer (granted August 2013), head and neck cancer (granted November 2013), invasive cervical cancer (denied in October 2013 as the target population estimate exceeded the statutory maximum allowed. In January 2014, a telecon meeting

was conducted with the FDA to discuss the orphan drug designation request and subsequent denial for ADXS-HPV for invasive cervical cancer. We intend to submit a new application based on the discussions.with the FDA); Orphan status is granted by the FDA to promote the development of products that demonstrate promise for the treatment of rare diseases affecting fewer than 200,000 individuals in the United States annually, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation would entitle our company to a seven-year period of marketing exclusivity in the United States to the extent our request is approved by the FDA, and would enable us to apply for research funding, tax credits for certain research expenses, and a waiver from the FDA's application user fee. Orphan drug status in the European Union has similar but not identical benefits in that jurisdiction.

- ***Obtain Breakthrough Therapy Designation for ADXS-HPV for the treatment of invasive cervical cancer.*** 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. 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. A drug that is designated as a breakthrough therapy drug is: intended alone or in combination with one or more other drugs to treat a serious or life threatening disease or condition; and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If our drug is designated as breakthrough therapy, it will receive all the benefits of fast track designation (opportunities for frequent interactions with the FDA review team, opportunity for a 6-month priority review if supported by clinical data at the time of the BLA submission), potential for a review of portions of the marketing application prior to submitting a complete BLA), intensive guidance on an efficient drug development program, organizational commitment involving senior managers at the FDA in a proactive, collaborative, cross-disciplinary review, will expedite the development and review of such drug.

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

  Develop ADXS-cHER2 in breast cancer. We plan to advance ADXS-cHER2 into a Phase 1 dose escalation trial in the second half of 2014 to determine the maximum tolerated dose for the treatment of patients with breast cancer.

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

- ***Expand the market for Advaxis Lm-LLO immunotherapies to the treatment of companion animals.*** We intend to enter into partnerships with animal health companies to develop and commercialize Advaxis *Lm*-LLO immunotherapies for companion animals.

- ***Leverage our proprietary discovery platform to identify new therapeutic immunotherapies.*** We intend to utilize our proprietary discovery platform to identify new antigen-associated product candidates. We may conduct some of these efforts internally and/or leverage our platform to forge strategic collaborations. We have utilized our proprietary discovery platform to identify a number of preclinical product candidates and may initiate studies to support IND submissions either alone or in collaboration with strategic partners. Specifically, we intend to conduct research relating to the development of the next generations of our *Lm* -LLO immunotherapies using new antigens of interest; improving the *Lm* -LLO based platform technology by developing new strains of *Listeria* that may be more suitable as live vaccine vectors; developing bivalent *Lm* -LLO immunotherapies; further evaluating synergy of *Lm* -LLO immunotherapies with cytotoxic therapies and

continuing to develop the use of LLO as a component of a fusion protein based immunotherapy. We currently have over 15 distinct immunotherapies in various stages of development, developed directly by us and through strategic collaborations with recognized centers of excellence. These include but are not limited to the following Advaxis immunotherapy and corresponding tumor antigen: ADXS11-001/HPV16-E7, ADXS31-142/Prostate Specific Antigen, ADXS31-164/HER2/neu Chimera, *Lm* -LLO-HMW-MAA/HMW-MAA, C-terminus fragment, *Lm* -LLO-ISG15/ISG15, *Lm* -LLO CD105/Endoglin, *Lm* -LLO-flk/VEGF and Bivalent Therapy, HER-2-Chimera/HMW-MAA-C. We will continue to conduct preclinical research to develop additional *Lm* -LLO constructs to expand our platform technology and may develop additional distinct immunotherapies in the future. Our growth strategy is to expand from the ADXS-HPV franchise into larger cancer indications such as prostate and breast cancer to further validate the robustness and versatility of the platform technology and to develop immunotherapies that we believe to be of interest to big pharmaceutical partners. We also intend to further expand the research and development programs to provide multiple biomarker-specific products with applications across multiple tumor types that express those biomarkers. Additionally, we plan to partner with or acquire a target discovery company, develop multiple constructs targeting numerous biomarker targets to deliver the promise of biomarker driven multi-targeted immunotherapies. The overall goal with each patient is to: biopsy the patient's tumor; identify which biomarkers are expressed; treat the patient with our immunotherapies that hit multiple targets simultaneously, adding in the ability to adjust an individual's immunotherapy over time based on changes in the tumor. We believe that if successful, this has the potential to revolutionize the treatment of cancer.

- ***Enter into commercialization collaborations for ADXS-HPV.*** If ADXS-HPV is approved by the FDA and other regulatory authorities for first use, we plan to either enter into commercial partnerships, joint ventures, or other arrangements with competitive or complementary companies, including pharmaceutical companies or commercialize these products ourselves in North America and Europe through direct sales and distribution.

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

- ***Continue to both leverage and strengthen our intellectual property portfolio.*** We believe we have a strong intellectual property position relating to the development and commercialization of *Lm* -LLO immunotherapies. We plan to continue to leverage this portfolio to create value. In addition to strengthening our existing intellectual property position, we intend to file new patent applications, in-license new intellectual property and take other steps to strengthen, leverage, and expand our intellectual property position.

Short-Term Strategic Goals and Objectives

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

- Report final results from the completed Phase 2 clinical trial conducted in India with ADXS-HPV in the treatment of recurrent cervical cancer;
- Initiate Phase 1/2 high-dose clinical trial in patients with recurrent cervical cancer;
- Conduct an end of Phase 2 meeting with the FDA and submit a Special Protocol Assessment for ADXS-HPV;
- Initiate global Phase 3 study in recurrent cervical cancer with ADXS-HPV;
- Initiate Phase 1 study with ADXS-PSA in prostate cancer;
- Initiate Phase 1 study with ADXS-cHER2 in breast cancer;
- Initiate Phase 1 study with ADXS-HPV in HPV-associated lung cancer through our partner GBP in Asia;
- Continue to support the Phase 2 clinical trial of ADXS-HPV in the treatment of advanced cervical cancer with the GOG, largely underwritten by the NCI;
- Continue our collaboration with the BrUOG to support the Phase 1/2 clinical trial of ADXS-HPV in the treatment of anal cancer, entirely underwritten by the BrUOG;
- Continue our collaboration with the Icahn School of Medicine at Mount Sinai (ISMMS) to support the Phase 1/2 study with ADXS-HPV in patients with head and neck cancer; seek to conduct Advisory Board with key opinion leaders;
- Report data from Mount Sinai Phase 1 study;

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

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

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

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

- Submit IND for ADXS-cHER2 for the treatment of breast cancer;

- Secure a contract manufacturing organization with GMP scale-up and commercialization capabilities;

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

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

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

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

Collaborations, Partnerships and Agreements

Biocon Limited

On January 20, 2104 the Company and Biocon Limited, a company incorporated under the laws of India ("Biocon") entered into a Distribution and Supply Agreement ("Agreement") .

Pursuant to the Agreement, Advaxis granted Biocon an exclusive license (with a right to sublicense) to (i) use Advaxis' data from clinical development activities, regulatory filings, technical, manufacturing and other information and know-how to enable Biocon to submit regulatory filings for ADXS-HPV in the following territories: India, Malaysia, Kenya, Bangladesh, Bhutan, Maldives, Myanmar, Nepal, Pakistan, Sri Lanka, Bahrain, Jordan, Kuwait, Oman, Saudi Arabia, Qatar, United Arab Emirates, Algeria, Armenia, Egypt, Eritrea, Iran, Iraq, Lebanon, Libya, Sudan, Syria, Tunisia and Yemen (collectively, the "Territory") and (ii) import, promote, market, distribute and sell pharmaceutical products containing ADXS-HPV. ADXS-HPV is based on a novel platform technology using live, attenuated bacteria that are bio-engineered to secrete an antigen/adjuvant fusion protein(s) that is designed to redirect the powerful immune response all human beings have to the bacterium against their cancer.

Under the Agreement, Biocon has agreed to use its commercially reasonable efforts to obtain regulatory approvals for ADXS-HPV in India. In the event Phase II or Phase III clinical trials are required, Advaxis shall conduct such trials at its cost, provided that if Advaxis is unable to commence such clinical trials, Biocon may conduct such clinical trials, subject to reimbursement of costs by Advaxis. Biocon has agreed to commence commercial distribution of ADXS-HPV no later than 9 months following receipt of regulatory approvals in a country in the Territory. Biocon will be responsible for the costs of obtaining and maintaining regulatory approvals in the Territory.

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

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

The term of the Agreement will be the later of twenty years or the last to expire patent or patent application. In addition, the Agreement may be terminated by either party upon thirty days' written notice (i) in the event of a material breach by the other party of its obligations under the Agreement, (ii) if the other party becomes bankrupt or insolvent or (iii) if the other party undergoes a change in control.

Global BioPharma, Inc.

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

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

GBP will pay Advaxis event-based financial milestones, an annual development fee, and annual net sales royalty payments in the high single to double digits. In addition, as an upfront payment, GBP made an investment in Advaxis by purchasing from the Company shares of its common stock at market price. GBP has an option to purchase

additional shares of Advaxis stock from the Company at a 150% premium to the stock price on the effective date of the agreement.

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

University of Pennsylvania

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

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

The license provides us with the exclusive commercial rights to the patent portfolio developed at the University of Pennsylvania as of the effective date of the license, in connection with Dr. Paterson and requires us to pay various milestone, legal, filing and licensing payments to commercialize the technology. In exchange for the license, Penn received shares of our common stock, which currently represent approximately 0.2% of our common stock outstanding on a fully-diluted basis. As of October 31, 2013, Penn owns 28,468 shares of our common stock. In addition, Penn is entitled to receive a non-refundable initial license fee, license fees, royalty payments and milestone payments based on net sales and percentages of sublicense fees and certain commercial milestones. Under the licensing agreement, Penn is entitled to receive 1.5% royalties on net sales in all countries. Notwithstanding these royalty rates, we have agreed to pay Penn a total of $525,000 over a three-year period as an advance minimum royalty after the first commercial sale of a product under each license (which we are not expecting to begin paying within the next five years). In addition, under the license, we are obligated to pay an annual maintenance fee of $100,000 commencing on December 31, 2010, and each December 31 st thereafter for the remainder of the term of the agreement until the first commercial sale of a Penn licensed product. Overall, the amended and restated agreement payment terms reflect lower near term requirements but the savings are offset by higher long term milestone payments for the initiation of a Phase 3 clinical trial and the regulatory approval for the first Penn licensed product. We are responsible for filing new patents and maintaining and defending the existing patents licensed to use and we are obligated to reimburse Penn for all attorneys fees, expenses, official fees and other charges incurred in the preparation, prosecution and maintenance of the patents licensed from Penn.

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

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

As part of the Second Amendment, dated May 10, 2010, we exercised our option for the rights to seven additional patent dockets, including 56 additional patent applications, for (i) an option exercise fee payable in the form of $35,000 in cash and $70,000 in our common stock (approximately 3,111 shares of our common stock based on a price of $22.50 per share) and (ii) the assumption of certain historical costs of approximately $462,000 associated with the 56 additional patent applications acquired under the second amendment. As of October 31, 2013, approximately $325,000 of costs related to all licensing agreements remained outstanding.

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

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

Dr. Yvonne Paterson

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

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

Recipharm Cobra Biologics Limited (formerly Cobra Biomanufacturing PLC)

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

Vibalogics GmbH

In April 2008, we entered into a series of agreements with Vibalogics GmbH in Cuxhaven Germany to provide fill and finish services for our final clinical materials that were made for our scheduled clinical trials described above. These agreements cover the fill and finish operations as well as specific tests required in order to release the clinical drug supplies for human use. We have entered into agreements with Vibalogics to produce two *Lm* -LLO immunotherapies, ADXS-PSA and ADXS-cHER2 for research and/or clinical development. In April 2013, we entered into a settlement agreement with Vibalogics for payment of past-due amounts and used a portion of the proceeds from the October 2013 offering to pay down amounts owing to Vibalogics, resulting in no amounts being owed by Advaxis as of October 31, 2013. We continue to use the services of Vibalogics to provide fill and finish services for our clinical materials.

Numoda Corporation

On June 19, 2009, we entered into a Master Agreement and on July 8, 2009 we entered into a Project Agreement with Numoda Corporation, which we refer to as Numoda, a leading clinical trial and logistics management company, to oversee Phase 2 clinical activity with ADXS-HPV for the multicenter Phase 2 U.S. trial of ADXS-HPV in CIN 2/3 and to act as our U.S. CRO for the multicenter Phase 2 study of ADXS-HPV in recurrent cervical cancer being conducted in India. The scope of the Project Agreement covers over three years, with an estimated cost of

approximately $12.2 million for both trials. As of October 31, 2013, we have paid Numoda approximately $8.8 million in cash for clinical trial activities. The Master Agreement with Numoda terminated on June 12, 2012. The Project Agreement with Numoda continues until the project that is the subject of such agreement is completed, unless earlier terminated in accordance with the Master Agreement with Numoda.

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

As of October 31, 2013, the Company owed Numoda approximately $300,000, which is recorded in our Accounts Payable.

National Cancer Institute Gynecologic Oncology Group

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

Cancer Research U.K.

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

School of Veterinary Medicine at the University of Pennsylvania

On August 17, 2010, we entered into a clinical trial agreement with the School of Veterinary Medicine at Penn to investigate the use of ADXS-cHER2 for the treatment of canine osteosarcoma in 15 dogs. This study commenced dosing in July of 2012.

Georgia Reagents University

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

Brown University Oncology Group

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

Icahn School of Medicine at Mount Sinai

On December 5, 2013, we entered into a clinical trial agreement with the Icahn School of Medicine at Mount Sinai to evaluate the safety, effectiveness and immunogenicity of ADXS-HPV in 25 patients with head and neck cancer. This clinical trial will be the first study to evaluate the effects of ADXS-HPV in patients when they are initially diagnosed with HPV-associated head and neck cancer, prior to receiving any standard of care (surgery, chemotherapy, radiation or a combination thereof) to remove and/or treat their tumors. This study will be an important first step toward understanding ADXS-HPV's potential to treat this type of cancer before chemotherapy and/or radiation and its potential to reduce the need for these treatments.

Intellectual Property

Protection of our intellectual property is important to our business. We have a robust and extensive patent portfolio that protects our product candidates and Lm-based immunotherapy technology. Currently, our patent portfolio includes 42 issued patents and 40 pending patent applications. All of these patents and patent applications are licensed from Penn with the exception of 17 pending patent applications, which are owned by our company. We continuously add to this portfolio by filing applications to protect our ongoing research and development efforts. We aggressively prosecute and defend our patents and proprietary technology. Our material patents that cover the compositions of matter, use, and methods thereof, of our *Lm* immunotherapies for our product candidates , ADXS-HPV, ADXS-PSA, and ADXS-cHER2, expire at various dates between 2014 and 2033, prior to available patent extensions.

Our approach to the intellectual property portfolio is to create protect and defend our proprietary rights for our products we develop form our immunotherapy technology platform. We endeavor to maintain a coherent and aggressive strategic approach to building our patent portfolio with an emphasis in the field of cancer vaccines.

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

Issued patents which are relevant to and cover our product candidates ADXS-HPV, and ADXS-PSA in the United States, will expire between 2015 and 2017. Issued patents directed to our product candidates ADXS-HPV, and ADXS-PSA outside of the United States, will expire between 2015 and 2018. Issued patents which cover our Lm-based immunotherapy platform in the United States, will expire between 2016 and 2027. Issued patents directed to our Lm-based immunotherapy platform outside of the United States, will expire 2021.

We have pending patent applications for formulations of our product candidates ADXS-HPV, ADXS-PSA, and ADXS-cHER2 that, if issued, would expire in the United States and in countries outside of the United States between 2020 and 2030, depending on the specific compositions and formulations. Issued patents directed to methods of treatment using our product candidates ADXS-HPV and ADXS-PSA in the United States, will expire between 2014 and 2017, depending on the specific indication: infectious disease, any tumor including leukemia, melanoma, breast cancer, pancreatic cancer, and cervical cancer. Issued patents directed to use of our product candidates: ADXS-HPV and ADXS-PSA for indications outside of the United States, will expire between 2015 and 2018, depending on the specific indication: infectious disease, any tumor including leukemia, melanoma, breast cancer, pancreatic cancer, and cervical cancer. We have pending patent applications for use of our product candidates ADXS-HPV, ADXS-PSA, ADXS-cHER2 covering the following indications: any tumor/cancer, including, a her2/neu-expressing cancer, a prostate cancer, cervical dysplasia, and cervical cancer that, if issued would expire in the United States and in countries outside of the United States between 2020 and 2033, depending on the specific indications and formulations.

We will be able to protect our technology from unauthorized use by third parties only to the extent it is covered by valid and enforceable patents or is effectively maintained as trade secrets. Patents and other proprietary rights are an essential element of our business.

Our success will depend in part on our ability to obtain and maintain proprietary protection for our product candidates, technology, and know-how, to operate without infringing on the proprietary rights of others, and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions, and improvements that are important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation, and in-licensing opportunities to develop and maintain our proprietary position.

Any patent applications which we have filed or will file or to which we have licensed or will license rights may not issue, and patents that do issue may not contain commercially valuable claims. In addition, any patents issued to us or our licensors may not afford meaningful protection for our products or technology, or may be subsequently circumvented, invalidated or narrowed, or found unenforceable. Our processes and potential products may also conflict with patents which have been or may be granted to competitors, academic institutions or others. As the pharmaceutical industry expands and more patents are issued, the risk increases that our processes and potential

products may give rise to interferences filed by others in the U.S. Patent and Trademark Office, or to claims of patent infringement by other companies, institutions or individuals. These entities or persons could bring legal actions against us claiming damages and seeking to enjoin clinical testing, manufacturing and marketing of the related product or process. In recent years, several companies have been extremely aggressive in challenging patents covering pharmaceutical products, and the challenges have often been successful. If any of these actions are successful, in addition to any potential liability for damages, we could be required to cease the infringing activity or obtain a license in order to continue to manufacture or market the relevant product or process. We may not prevail in any such action and any license required under any such patent may not be made available on acceptable terms, if at all. Our failure to successfully defend a patent challenge or to obtain a license to any technology that we may require to commercialize our technologies or potential products could have a materially adverse effect on our business. In addition, changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

We also rely upon unpatented proprietary technology, and in the future may determine in some cases that our interests would be better served by reliance on trade secrets or confidentiality agreements rather than patents or licenses. We may not be able to protect our rights to such unpatented proprietary technology and others may independently develop substantially equivalent technologies. If we are unable to obtain strong proprietary rights to our processes or products after obtaining regulatory clearance, competitors may be able to market competing processes and products.

Others may obtain patents having claims which cover aspects of our products or processes which are necessary for, or useful to, the development, use or manufacture of our services or products. Should any other group obtain patent protection with respect to our discoveries, our commercialization of potential therapeutic products and methods could be limited or prohibited.

Governmental Regulation

The Drug Development Process

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

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

Protocols .

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

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

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

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

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

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

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

Biologic License Application. The results of the clinical trials using biologics are submitted to the FDA as part of Biologic License Application, which we refer to as BLA. Following the completion of Phase 3 studies, if the Sponsor of a potential product in the United States believes it has sufficient information to support the safety and effectiveness of the investigational new drug, the Sponsor submits a BLA to the FDA requesting that the investigational new drug be approved for sale. The application is a comprehensive, multi-volume filing that includes the results of all preclinical and clinical studies, information about the drug's composition, and the Sponsor's plans for manufacturing, packaging, labeling and testing the investigational new drug. The FDA's review of an application is designated either as a standard review with a target review time of 10 months or a priority review with a target of 6 months. Depending upon the completeness of the application and the number and complexity of requests and responses between the FDA and the Sponsor, the review time can take months to many years, with the mean review lasting 13.1 months. Once approved, drugs and other products may be marketed in the United States, subject to any conditions imposed by the FDA.

The drug approval process is time-consuming, involves substantial expenditures of resources, and depends upon a number of factors, including the severity of the illness in question, the availability of alternative treatments, and the risks and benefits demonstrated in the clinical trials.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. If a sponsor demonstrates that a drug is intended to treat a rare disease or condition, the FDA grants orphan drug designation to the product for that use. The benefits of orphan drug designation can obtain substantial incentives, including research and development tax credits and exemption from user fees, enhanced access to advice from the FDA while the drug is being developed, and market exclusivity once the product reaches approval and begins sales, provided that the new product is first to market. In order to qualify for these incentives, a company must apply for designation of its product as an “Orphan Drug” and obtain approval from the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. A drug that is approved for the orphan drug designated indication is granted seven years of orphan drug exclusivity. During that period, the FDA generally may not approve any other application for the same product for the same indication, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity.

In June 2013, we filed three applications for Orphan Drug Designation with the FDA for ADXS-HPV for treatment of HPV-associated anal cancer (granted August 2013), HPV-associated head and neck cancer (granted November 2013); and invasive cervical cancer (denied in October 2013 as the target population estimate exceeded the statutory maximum allowed. In January 2014, a telecon meeting was conducted with the FDA to discuss the orphan drug designation request and subsequent denial for ADXS-HPV for the treatment of invasive cervical cancer. We intend to submit a new application based on the discussions).

Orphan drug status in the European Union has similar but not identical benefits in that jurisdiction. The applicable exclusivity period, for example, is ten years in Europe, and can be reduced to six years if the drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

Breakthrough Therapy Designation

On July 9, 2012 the Food and Drug Administration Safety and Innovation Act was signed. FDASIA Section 902 provides for a new designation Breakthrough Therapy Designation. A breakthrough therapy is a drug: intended alone or in combination with one or more other drugs to treat a serious or life threatening disease or condition; and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If our drug is designated as breakthrough therapy, it will receive all the benefits of fast track designation (opportunities for frequent interactions with the FDA review team, opportunity for a 6-month priority review if supported by clinical data at the time of the BLA submission), potential for a review of portions of the marketing application prior to submitting a complete BLA), intensive guidance on an efficient drug development program, organizational commitment involving senior managers at the FDA in a proactive, collaborative, cross-disciplinary review, will expedite the development and review of such drug.

Over the course of drug development, it is foreseeable that certain products in breakthrough therapy development programs will no longer be considered 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. Additionally, if the sponsor recognizes that the development program designated as breakthrough therapy will no longer be pursued, the sponsor should inform the FDA of this change.

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.

On October 7, 2013, we submitted a request for breakthrough therapy designation to the IND for ADXS-HPV in the treatment of invasive cervical cancer. 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.

Non-U.S. Regulation

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

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

While we intend to market our products outside the United States in compliance with our respective license agreements, we have not made any applications with non-U.S. authorities. Our current business strategy, however, includes filing three applications to request Orphan Drug Designation with the EMEA for ADX-HPV for use in the treatment of invasive cervical cancer, head and neck cancer and anal cancer.

Manufacturing

The FDA requires that any drug or formulation to be tested in humans be manufactured in accordance with its GMP regulations. This has been extended to include any drug that will be tested for safety in animals in support of human testing. The GMPs set certain minimum requirements for procedures, record-keeping and the physical characteristics of the laboratories used in the production of these drugs.

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

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

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

Competition

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, our actual or proposed immunotherapies could become obsolete before we recoup any portion of our related research and development and commercialization expenses. The biotechnology and biopharmaceutical industries are highly competitive, and this competition comes from both biotechnology firms and from major pharmaceutical companies, including: Aduro Biotech, Agenus Inc., Bristol-Myers Squibb, Celgene Corporation, Celldex Therapeutics, Dendreon Corporation, Inovio Pharmaceutical Inc., Oncolytics Biotech Inc., Oncothyreon Inc., et al., each of which is pursuing cancer vaccines and/or immunotherapies.

Many of these companies have substantially greater financial, marketing, and human resources than we do (including, in some cases, substantially greater experience in clinical testing, manufacturing, and marketing of pharmaceutical products). We also experience competition in the development of our immunotherapies from universities and other research institutions and compete with others in acquiring technology from such universities and institutions. In addition, certain of our immunotherapies may be subject to competition from investigational new drugs and/or products developed using other technologies, some of which have completed numerous clinical trials.

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

Employees

As of January 17, 2014, we had 17 employees, all of which were full time employees. None of our employees is represented by a labor union, and we consider our relationship with our employees to be good.

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

Description of Property

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

On March 13, 2013, we entered into a modification of the Sublease Agreement whereby all unpaid accrued lease amounts and future lease amounts through June 30, 2013, which we estimated to be approximately $450,000, would be satisfied by a payment in total of $200,000, with $100,000 paid on March 13, 2013 and $100,000 paid upon the close of our public offering in October 2013. 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 1A: Risk Factors.

You should carefully consider the risks described below as well as other information provided to you in this annual report, including information in the section of this document entitled "Forward-Looking Statements." The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also impair our business operations. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected, the value of our common stock could decline, and you may lose all or part of your investment.

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 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 Form 10-K, 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 January 17, 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 Stock Market, NYSE Amex Equities or other national market system;

- changes in accounting principles; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

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

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 $5.33 per share on January 17, 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 Stock 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 Marketplace, 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 January 17, 2014, we had 13,872,182 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 January 17, 2014, warrants to purchase 202,503 shares of our common stock are exercisable at approximately $9.24 per share and are 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 January 17, 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 30,320 shares of our common stock are available for grant under the ESPP. Although we entered into agreements providing for the repayment or conversion of certain of our outstanding indebtedness, not all the holders of our outstanding convertible promissory notes have agreed to exchange their securities at this time.

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. In addition, the terms of our Series B Preferred Stock prohibit the payment of dividends on our common stock for so long as any

shares of our Series B Preferred Stock are outstanding.

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

On October 19, 2012, we entered into a committed equity line financing facility, or financing arrangement, under which we may sell up to $10.0 million of our common stock to Hanover over a 24-month period subject to a maximum of 920,000 shares of our common stock. In connection with such financing arrangement, we issued 28,000 shares of common stock to Hanover upon receipt of their commitment to purchase our common stock in the financing arrangement and we agreed to pay up to 14,400 additional shares of our common stock to Hanover to maintain such financing arrangement for the 24-month term, which together with the other 877,600 shares of our common stock, represents approximately 6.3% of our outstanding shares of our common stock as of January 17, 2014.

Hanover may resell some or all of the shares we issued to them pursuant to the financing arrangement and such sales could cause the market price of our common stock to decline significantly with advances under the financing arrangement.

On September 27, we notified Hanover that we irrevocably commit to suspend any draw downs under the Purchase Agreement without the prior written consent of Aegis Capital Corp. for a six month period beginning from the closing of our October, 2013 offering. Our intent is to terminate the equity line financing commitment in January, 2014 and issue 7,080 shares of our common stock pursuant to the terms of the agreement.

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

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

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

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

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

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

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

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

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

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

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

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

Our certificate of incorporation, Bylaws and Delaware law contain provisions which could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our 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. 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 2103 we paid the aforementioned $150,000 and commenced final settlement of the disputed amounts owed. On or about November 14, 2013, Maxim initiated a 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.

Item 4. Mine Safety Disclosures.

None.

PART II

Item 5. Market For Our Common Stock and Related Shareholder Matters.

From July 28, 2005, until October 2013 our common stock was quoted on the OTC Bulletin Board under the symbol ADXS.OB. In October 2013, the company began trading on NASDAQ. The following table shows, for the periods indicated, the high and low bid prices per share of our common stock as reported by the OTC Bulletin Board; no NASDAQ price was required for presentation. These bid prices represent prices quoted by broker-dealers on the OTC Bulletin Board. The quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions, and, particularly because our common stock is traded infrequently, may not necessarily represent actual transactions or a liquid trading market.

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

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

As of October 31, 2013, there were approximately 95 shareholders of record. Because shares of our common stock are held by depositaries, brokers and other nominees, the number of beneficial holders of our shares is substantially larger than the number of shareholders of record. Based on information available to us, we believe there are approximately 3,500 beneficial owners of our shares of our common stock in addition to the shareholders of record. On January 17, 2014, the last reported sale price per share for our common stock as reported by NASDAQ was $5.33.

We have not paid or declared any cash dividends during the past two fiscal years or subsequent period prior to the filing of this annual report.

Recent Sales of Unregistered Securities

On November 5, 2012, the registrant issued and delivered to Socius 4,981 shares of its common stock in connection with a settlement agreement.

On November 12, 2012, the registrant issued and sold to Asher a convertible promissory note in the aggregate principal face amount of $153,500, for an aggregate purchase price of $153,500.

On November 14, 2012, the registrant delivered a convertible note to Magna in an aggregate principal amount of $58,823.53.

On November 23, 2012, the registrant delivered a convertible note to Magna in an aggregate principal amount of $111,111.11.

On December 5, 2012, Hanover exchanged the September 2012 Hanover Pipe Note and the October 2012 Hanover Pipe Note for notes that are convertible into shares of our common stock at a conversion price of $3.75 per share.

On December 6, 2012, the registrant delivered a convertible note to Magna in an aggregate principal amount of $170,588.22.

On December 6, 2012, the registrant issued and sold to Hanover a convertible promissory note in the aggregate principal face amount of $100,000, for an aggregate purchase price of $100,000. This note was converted into 26,667 shares of the registrant's common stock in June 2013.

On December 13, 2012, the registrant entered into a securities purchase agreement with Tonaquint, Inc. pursuant to which it issued Tonaquint a convertible promissory note for the initial principal sum of $890,000. The registrant also issued Tonaquint a warrant to purchase that number of shares equal to 75% of the principal sum of $890,000 under the note issued to Tonaquint, which warrant expires 5-years from the issue date and provides for a variable exercise price per share as defined in the warrant agreement.

On December 21, 2012, the registrant issued an aggregate 360,000 shares of its common stock to Ironridge Global IV, Ltd. pursuant to a settlement agreement (92,883 of which were returned to the registrant as contemplated by the settlement agreement).

On January 2, 2013, the registrant granted Daniel J. O'Connor, its Chief Executive Officer, options to acquire 8,000 shares of its common stock at an exercise price of $3.63 per share, which expire 10-years after the grant date. No consideration was paid to the registrant by the recipient of the foregoing options for the grant of stock options.

On January 15, 2013, the registrant issued an accredited investor 2,400 shares of its common stock as payment for consulting services rendered.

On January 31, 2013, the registrant issued and sold an aggregate of 1,670 shares of its common stock to Mark J. Rosenblum, Robert G. Petit Ph.D., and Chris L. French, three of its executive officers, pursuant to its Employee Stock Purchase Plan for an aggregate purchase price of $8,769 in cash.

On February 11, 2013 the registrant issued and sold 3,428 shares of its common stock in a private placement to an accredited investor for a purchase price of $15,000.

On February 12, 2013, the registrant issued 64,000 shares of common stock to Hanover Holdings in connection with the settlement of a draw down pursuant to the Hanover Purchase Agreement, at a price of approximately $8.05 per share. The per share price for such shares was established under the terms of the Hanover Purchase Agreement. Total net proceeds of $515,520 were received in connection with this draw down.

On March 1, 2013, the registrant issued 96,000 shares of its common stock to Hanover in connection with the settlement of a draw down pursuant to the Purchase Agreement, at a price of approximately $11.87 per share. The per share price for such shares was established under the terms of the Purchase Agreement. Total net proceeds of $1,134,000 were received in connection with this draw down.

On March 14, 2013, the registrant granted options to certain of its officers and directors and employees to acquire an aggregate 134,600 shares of its common stock at an exercise price of $9.37 per share, which expire 10-years after the grant date. No consideration was paid to the registrant by the recipients of the foregoing options for the grant of stock options.

On April 29, 2013, the registrant issued 16,026 shares of its common stock to a former executive officer that had been earned but not previously issued.

On April 26, 2013, in a private placement, the registrant issued JMJ Financial a convertible promissory note with an aggregate principal amount of $800,000 for total consideration of $720,000 (or a 10% original issue discount). As of April 26, 2013, the registrant had only borrowed $425,000 from JMJ Financial under this convertible promissory note. JMJ Financial paid us $300,000 in cash and exchanged a promissory note with an aggregate principal amount of $125,000 that was issued to JMJ Financial on December 26, 2012 as consideration for the note. On June 27, 2013, the registrant borrowed an additional $116,667 under this convertible promissory note in exchange for $100,000 cash. On August 14, 2013, the registrant borrowed an additional $116,667 under this convertible promissory note in exchange for $100,000 cash.

On May 1, 2013, in a private placement pursuant to a note purchase agreement, the registrant issued Asher a convertible promissory note in the aggregate principal amount of $203,500, for a purchase price of $200,000.

On May 1, 2013, the registrant issued an accredited investor 3,600 shares of its common stock as payment for consulting services rendered.

On May 1, 2013, the registrant issued and sold an aggregate 1,291 shares of its common stock to certain employees, including Mark J. Rosenblum and Robert G. Petit, Ph.D, two of its executive officers, pursuant to its Employee Stock Purchase Plan for an aggregate purchase price of $6,779 in cash.

On May 23, 2013, the registrant issued an accredited investor 1,969 shares of its common stock as payment for consulting services rendered.

On May 22, 23, 28 and 29, 2013, the registrant issued 6,410, an aggregate 13,244, 7,092 and an aggregate 17,412 shares of its common stock, respectively, to Asher, upon conversion of $25,000, an aggregate $50,000, $25,000 and an aggregate $59,640, respectively, of principal amount of a convertible promissory note with an aggregate principal face amount of $153,500 that the registrant issued to Asher on November 12, 2012.

On June 11, 2013, the registrant issued 26,667 shares of its common stock upon conversion of the principal amount of a convertible promissory note with an aggregate principal face amount of $100,000 that was issued to Hanover in December 6, 2012.

On June 12, 2013, the registrant issued an aggregate 54,475 shares of its common stock to its non-employee Directors, which shares had been earned under the registrant's Directors' compensation program but not previously issued.

On June 17, 2013, the registrant issued an accredited investor 32,600 shares of its common stock as payment for consulting services rendered.

On June 21, 2013 the registrant entered into a Securities Purchase Agreement with Redwood Management, LLC, or Redwood, providing for the issuance and sale of up to $555,555.55 of aggregate principal amount of 5% convertible debentures to Redwood, and, pursuant to the exemption from registration provided by Section 4(2), it issued Redwood Bridge notes with a stated principal amount of $277,777.77 for total consideration of $250,000 in cash.

On July 24, 2013, in a private placement pursuant to a note purchase agreement, the registrant issued Asher a convertible promissory note in the aggregate principal amount of $103,500, for a purchase price of $100,000.

On July 25, 2013, the registrant issued Tonaquint an aggregate 27,583 shares of its common stock upon partial conversion of the notes issued to Tonaquint in December 2012.

On August 9, 2013, the registrant issued 30,000 shares of its common stock to JMJ Financial upon conversion of $67,515 of principal and interest of a convertible promissory note issued to JMJ Financial in April 2013.

On August 14, 2013, the registrant issued Tonaquint an aggregate 33,309 shares of its common stock upon partial conversion of the notes issued to Tonaquint in December 2012.

On August 20, 2013, in a private placement pursuant to a note purchase agreement, the registrant issued an accredited investor a secured convertible promissory note in the aggregate principal amount of $108,000, for a purchase price of $100,000. On September 18, 2013, the promissory note was amended and restated to increase the aggregate principal amount to $258,000 and remove the conversion feature for which the registrant received $150,000 in cash. The registrant also issued the accredited investor lender 12,000 shares of its common stock.

On August 28, 2013, pursuant to a Securities Purchase Agreement, the registrant issued Yenson Company Ltd., an accredited investor, 45,353 shares of its common stock and warrants to purchase 22,161 shares of its common stock, at an exercise price of $2.76 per share, which warrant expires 3 years from the date of the agreement, for $100,000 in cash.

On September 4, 2013, the registrant issued JMJ Financial, in a private placement, an $800,000 convertible promissory note and 19,231 restricted shares of its common stock. The face amount of the note reflects an aggregate principal amount of $800,000 for total consideration of $720,000 (or a 10% original issue discount). However, the registrant has currently only borrowed $500,000 from JMJ Financial under this convertible promissory note, all of which JMJ Financial paid in cash.

On September 9, 2013, the registrant issued 21,000 shares of its common stock to JMJ Financial upon conversion of $39,690 of principal and interest of a convertible promissory note issued to JMJ Financial in April 2013.

On September 11, September 12 and September 25, 2013, the registrant issued Tonaquint an aggregate 55,387, 46,816 and 49,157 shares, respectively, of its common stock upon conversion of an aggregate $334,736 of notes issued to Tonaquint in December 2012.

On September 17, 2013, the registrant issued 25,582 shares of its common stock to Maxim, an accredited investor as an installment payment under an engagement letter termination agreement and also issued the accredited investor a 2-year warrant to acquire 30,154 shares of its common stock at $4.90 per share pursuant to such agreement, and on Sept