

Advaxis, Inc.  
Form 10-K  
January 06, 2015

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-K**

**ANNUAL REPORT UNDER SECTION 13 OR 15(d)**

**OF THE SECURITIES EXCHANGE ACT OF 1934**

**FOR THE FISCAL YEAR ENDED - OCTOBER 31, 2014**

**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)*

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Delaware 02-0563870  
(State or Other Jurisdiction of (I.R.S. Employer  
Incorporation or Organization) 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 [ ]

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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  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

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

As of April 30, 2014, the aggregate market value of the voting common equity held by non-affiliates was approximately \$50,339,157 based on the closing bid price of the registrant's Common Stock on the NASDAQ Capital Market. (For purposes of determining this amount, only directors, executive officers, and 10% or greater shareholders and their respective affiliates have been deemed affiliates).

The registrant had 23,644,808 shares of Common Stock, par value \$0.001 per share, issued and outstanding as of December 26, 2014.

**DOCUMENTS INCORPORATED BY REFERENCE**

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Portions of the Proxy Statement for the registrant's 2015 Annual Meeting of Stockholders (the "Proxy Statement") to be filed within 120 days of the end of the fiscal year ended October 31, 2014 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 other 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

Advaxis, Inc. (“Advaxis”, “company”, “we”, “us”, or “our”) is a clinical stage biotechnology company focused on the discovery, development and commercialization of proprietary *Lm*-LLO cancer immunotherapies. These immunotherapies are based on a platform technology that utilizes live attenuated *Listeria monocytogenes* (“*Lm*” or “Listeria”), bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm*-LLO strains are believed to be a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy as 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.

ADXS-HPV is our lead *Lm*-LLO immunotherapy product candidate for the treatment of human papilloma virus (“HPV”) associated cancers. We completed a Phase 2 study in 110 patients with recurrent cervical cancer in India that demonstrated a manageable safety profile, improved survival and objective tumor responses. We plan to advance this immunotherapy into an adequate and well-controlled clinical trial for the treatment of women with recurrent cervical cancer. ADXS-HPV has received United States Food and Drug Administration (“FDA”) orphan drug designation for

three HPV-associated cancers: cervical, head and neck, and anal cancer, and is being evaluated in three ongoing cooperative group and investigator-initiated clinical trials as follows: locally advanced cervical cancer, head and neck cancer, and anal cancer. We also plan to initiate a Phase 1/2 clinical trial alone and in combination with MedImmune's, the global biologics research and development arm of AstraZeneca, investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736, in patients with previously treated locally advanced metastatic HPV-associated cervical cancer and HPV-associated head and neck cancer. Lastly, we are evaluating higher doses and repeat cycles of ADXS-HPV in patients with recurrent cervical cancer.

We are developing two other cancer immunotherapies. ADXS-PSA is our *Lm-LLO* immunotherapy product candidate designed to target the PSA antigen associated with prostate cancer. The FDA has cleared our Investigational New Drug ("IND") application, and we now plan to initiate a Phase 1/2 clinical trial alone and in combination with KEYTRUDA® (pembrolizumab), Merck's humanized monoclonal antibody against PD-1, in patients with previously treated metastatic castration-resistant prostate cancer. ADXS-HER2 is our *Lm-LLO* immunotherapy product candidate for the treatment of Her2 expressing cancers, including human and canine osteosarcoma, breast, gastric and other cancers. We have submitted an IND application and have received orphan drug designation for ADXS-HER2 in osteosarcoma. Over twenty distinct additional constructs have been developed and are in various stages of development, developed directly by us and through strategic collaborations with recognized centers of excellence.

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

From inception through the period ended January 31, 2014, we were a development stage company. During the three months ended April 30, 2014, we exited the development stage upon our execution of a license agreement with Aratana Therapeutics Inc. ("Aratana"). This provided an upfront payment of \$1 million, which we properly recognized and earned as revenue.

## Clinical Pipeline

### *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 (“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 have the ability to 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 is designed to facilitate the immune response by altering the tumor microenvironment to reduce immunologic tolerance in the tumors but while leaving normal tissues unchanged. This makes the tumor more susceptible to immune attack by inhibiting the T-cells, or Tregs, and myeloid-derived suppressor cells, or MDSC that we believe promote immunologic tolerance of cancer cells in the tumor.

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

Our most advanced product candidates in clinical development are ADXS-HPV, ADXS-PSA and ADXS-HER2.

### *ADXS-HPV Franchise*

ADXS-HPV is a *Lm*-LLO immunotherapy directed against HPV and designed to target cells expressing the HPV gene E7. It is currently under investigation in three HPV-associated cancers: recurrent or persistent cervical cancer, head and neck cancer, and anal cancer, either as a monotherapy or in combination with investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736.

### Cervical Cancer



There are 500,000 new cases of cervical cancer caused by HPV worldwide every year, and 12,000 new cases in the U.S. alone, according to the World Health Organization (“WHO”) Human Papillomavirus and Related Cancers in the World Summary Report 2010. 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. 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.

We completed a Phase 2 clinical study that was conducted in India in 110 women with recurrent cervical cancer. The final results, were presented at the 2014 American Society of Clinical Oncology (“ASCO”) Annual Meeting, and showed that 22% (24/109) of the patients were long-term survivors (“LTS”) of greater than 18 months. 18% (16/91) of patients were alive for more than 24 months. Of the 109 patients treated in the study, LTS included not only patients with tumor shrinkage but also patients who had experienced increased tumor burden. 17% (19/109) of the patients in the trial had recurrence of disease after at least two prior treatments for their cervical cancer; these patients comprised 8% (2/24) of LTS. Among the LTS, 25% (3/11) of patients had an ECOG performance status of 2, a patient population that is often times excluded from clinical trials because of their poor survival.

We have completed an End-of-Phase 2 (“EOP2”) meeting with the FDA. The purpose of the EOP2 meeting was to discuss ADXS-HPV’s preclinical data, Chemistry, Manufacturing and Controls (“CMC”) and clinical program prior to moving ADXS-HPV forward into the next phase of clinical development in cervical cancer. At the meeting, the FDA provided guidance on our CMC activities and clinical development plan. We plan to submit our Phase 3 protocol for a Special Protocol Assessment (“SPA”), and continue to have dialogue with the FDA, incorporating their valuable guidance into our planned registration program. We are planning to initiate an adequate and well-controlled clinical trial in cervical cancer in the first half of 2015 to support a Biologics License Application (“BLA”) submission in the U.S. and in other territories around the world.

The adequate and well-controlled Phase 3 clinical trial that we are planning to conduct will be a Phase 3 study of adjuvant ADXS-HPV following chemoradiation as primary treatment for high risk locally advanced cervical cancer compared to chemoradiation alone. This population has a high risk of recurrence and once recurred there is no cure. This study will evaluate both the time it takes for the cancer to recur as well as the overall survival. Our goal is to develop a treatment to prevent recurrence of cervical cancer after primary care, which is approximately 12,000 new cases each year in the U.S.

The Gynecologic Oncology Group (“GOG”) of the National Cancer Institute (“NCI”) is independently conducting a single arm Phase 2 study of ADXS-HPV in invasive cervical cancer in the U.S., GOG-265. This study has now completed enrollment in the first stage of 26 evaluable patients. The second stage of enrollment of 38 patients is pending. We have agreed to provide clinical material to support this study but do not control the conduct of the study.

We have entered into a clinical trial collaboration agreement with MedImmune LLC (“MedImmune”), the global biologics research and development arm of AstraZeneca, where we plan to collaborate on a Phase 1/2 study to

evaluate safety and efficacy of MedImmune's investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736, in combination with our investigational *Lm*-LLO cancer immunotherapy, ADXS-HPV, as a combination treatment for patients with advanced, recurrent or refractory cervical cancer and HPV-associated head and neck cancer.

Georgia Regents University (“GRU”) Cancer Center is conducting a Phase 1/2 trial evaluating higher doses and repeat cycles of ADXS-HPV in patients with recurrent cervical cancer. This Phase 1/2 study is designed to evaluate the safety, efficacy and immunological effect of the highest-tolerated dose of ADXS-HPV administered in repeat cycles of treatment to patients with cervical cancer whose disease recurred after receiving one prior cytotoxic treatment regimen.

ADXS-HPV has received orphan drug designation for invasive Stage II-IVb cervical cancer.

### Head and Neck Cancer

Head and neck squamous cell carcinoma (“HNSCC”) is the most frequently occurring malignant tumor of the head and neck and is a major cause of morbidity and mortality worldwide. More than 90% of HNSCCs originate from the mucosal linings of the oral cavity, pharynx, or larynx. According to the American Cancer Society, head and neck cancer accounts for about 3% to 5% of all cancers in the United States. About 55,070 new cases will be diagnosed and about 12,000 people are expected to die of head and neck cancer in the United States during 2014.

The safety and efficacy of ADXS-HPV is being evaluated in a Phase 1/2 study under an investigator-sponsored IND at the Icahn School of Medicine at Mount Sinai, U.S. (“Mount Sinai”), in patients with HPV-positive head and neck cancer. This clinical trial is 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 chemotherapy or radiation for their cancer.

As stated above, we recently entered into a clinical trial collaboration agreement with MedImmune to collaborate on a Phase 1/2 study to evaluate safety and efficacy of MEDI4736 in combination with ADXS-HPV as a combination treatment for patients with advanced, recurrent or refractory cervical cancer and HPV-associated head and neck cancer. The FDA has cleared our IND application and we now plan to initiate this Phase 1/2 study in early 2015.

ADXS-HPV has received orphan drug designation for HPV-associated head and neck cancer.

### Anal Cancer

According to the American Cancer Society, most squamous cell anal cancers seem to be linked to infection by the HPV, the same virus that causes cervical cancer. In fact, women with a history of cervical cancer (or pre-cancer) have an increased risk of anal cancer. Anal cancer is fairly rare – much less common than cancer of the colon or rectum. About 7,210 new cases will be diagnosed and about 950 people are expected to die of anal cancer in the United States during 2014.

The safety and efficacy of ADXS-HPV is being evaluated in a Phase 1/2 study under an investigator-sponsored IND by Brown University in patients with HPV-associated anal cancer. Preliminary data from this study indicates a “clinical complete response” in all seven patients who have completed the treatment regimen.

ADXS-HPV has received orphan drug designation for HPV-associated anal cancer.

#### *ADXS-PSA Franchise*

##### Prostate Cancer

According to the American Cancer Society, prostate cancer is the most common type of cancer found in American men, other than skin cancer. Prostate cancer is the second leading cause of cancer death in men, behind only lung cancer. One man in six will get prostate cancer during his lifetime, and one man in 36 will die of this disease

ADXS-PSA is a *Lm-LLO* immunotherapy designed to target the PSA antigen associated with prostate cancer.

We have entered into a clinical trial collaboration and supply agreement with Merck & Co. (“Merck”) to evaluate the safety and efficacy of ADXS-PSA as monotherapy and in combination with KEYTRUDA® (pembrolizumab), Merck’s anti PD-1 antibody, in a Phase 1/2 study in patients with previously treated metastatic, castration-resistant prostate cancer. The FDA has cleared our IND application and we now plan to initiate this Phase 1/2 study in the first quarter of 2015.

#### *ADXS-HER2 Franchise*

##### HER2 Expressing Solid Tumors

ADXS-HER2 is a *Lm*-LLO immunotherapy designed to target the Her2 gene which is expressed in some solid tumor cancers such as human and canine osteosarcoma, breast, gastric and other cancers. We have submitted an IND with the FDA and plan to initiate a Phase 1b study in patients with HER2-expressing cancers in 2015. Thereafter, we intend to initiate a clinical development program with ADXS-HER2 for the treatment of pediatric osteosarcoma.

#### Pediatric Osteosarcoma

Pediatric osteosarcoma affects about 400 children and teens in the U.S. every year, representing a small but significant unmet medical need that has seen little therapeutic improvement in decades. Pediatric osteosarcoma is considered a rare disease and may qualify for regulatory incentives including, but not limited to, orphan drug designation, patent term extension, market exclusivity, and development grants. Given the limited availability of new treatment options for pediatric osteosarcoma, and that it is an unmet medical need affecting a very small number of patients in the U.S. annually, we believe that, subject to regulatory approval, the potential to be on the market may be accelerated.

Based on encouraging preliminary data from a veterinarian clinical study in which pet dogs with naturally occurring osteosarcoma were treated with ADXS-HER2, we intend to initiate a clinical development program with ADXS-HER2 for the treatment of pediatric osteosarcoma. In this veterinarian clinical study, pet dogs with naturally occurring osteosarcoma treated with ADXS-HER2 after the standard of care showed a statistically significant prolonged overall survival benefit compared with dogs that received standard of care without ADXS-HER2. Both veterinary and human osteosarcoma specialists consider canine osteosarcoma to be the best model for human osteosarcoma.

ADXS-HPV has received orphan drug designation for osteosarcoma.

### Canine Osteosarcoma

Under the direction of Dr. Nicola Mason, the University of Pennsylvania School of Veterinary is conducting a Phase 1 study in companion dogs evaluating the safety and efficacy of ADXS-HER2 in the treatment of canine osteosarcoma. The primary endpoint of the study is to determine the maximum tolerated dose of ADXS-HER2. Secondary endpoints for the study are progression-free survival and overall survival. The preliminary findings of the Phase 1 clinical trial in dogs with osteosarcoma suggest that ADXS-HER2 is safe and well tolerated at doses up to  $3 \times 10^9$  CFU with no evidence of cardiac, hematological, or other systemic toxicities. The study determined that ADXS-HER2 is able to delay or prevent metastatic disease and significantly prolong overall survival in dogs with osteosarcoma that had minimal residual disease following standard of care (amputation and follow-up chemotherapy). Dr. Mason presented data at the 2014 American College of Veterinary Internal Medicine (“ACVIM”) Forum which showed that 80% of the dogs treated (n=15) were still alive and median survival had not yet been reached; median survival in control dogs (n=13) was 316 days. Immunological analyses are also being conducted in this study to further evaluate the immune response to ADXS-HER2.

Osteosarcoma is the most common primary bone tumor in dogs, accounting for roughly 85% of tumors on the canine skeleton. Approximately 8,000-10,000 dogs a year (predominately middle to older-aged dogs and larger breeds) are diagnosed with osteosarcoma in the United States. This cancer initially presents as lameness and oftentimes visible swelling on the leg. Current standard of care treatment is amputation immediately after diagnosis, followed by chemotherapy and sometimes radiation for palliative care.

On March 19, 2014, we entered into a definitive Exclusive License Agreement with Aratana, where we granted Aratana an exclusive, worldwide, royalty-bearing, license, with the right to sublicense, certain of our proprietary technology that enables Aratana to develop and commercialize animal health products that will be targeted for treatment of osteosarcoma and other cancer indications in animals. A product license request has been filed by Aratana for ADXS-HER2 (also known as AT-014 by Aratana) for the treatment of canine osteosarcoma with the United States Department of Agriculture (“USDA”). While the USDA has no specific obligation to respond within a prescribed timeframe, the companies expect a response from the USDA to the request for a product license within the next several months. Aratana has been granted exclusive worldwide rights by us to develop and commercialize ADXS-HER2 in animals.

### *Lm-LLO Combination Franchise*

### ADXS-HPV and MEDI4736

As stated above, we have entered into a clinical trial collaboration agreement with MedImmune, the global biologics research and development arm of AstraZeneca, where we plan to collaborate on a Phase 1/2 study to evaluate safety and efficacy of MedImmune's investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736, in combination with our investigational *Lm*-LLO cancer immunotherapy, ADXS-HPV, as a combination treatment for patients with advanced, recurrent or refractory cervical cancer and HPV-associated head and neck cancer. The FDA has cleared our IND application and we now plan to initiate this Phase 1/2 in early 2015.

#### ADXS-PSA and MK-3475

As stated above, we have entered into a clinical trial collaboration agreement with Merck to evaluate the safety and efficacy of ADXS-PSA as monotherapy and in combination with KEYTRUDA® (pembrolizumab), Merck's anti PD-1 antibody, in a Phase 1/2 study in patients with previously treated metastatic, castration-resistant prostate cancer. The FDA has cleared our IND application and we now plan to initiate this Phase 1/2 in the first quarter of 2015.

#### *Lm*-LLO and GRU

We have a non-clinical research agreement with GRU which provides research collaboration of the in vitro effect of our *Lm*-LLO cancer immunotherapy technology evaluating it in combination with other immunotherapies, including, but not limited to, anti-PD-1 immune checkpoint inhibitors.

### **Corporate Information**

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

Our principal executive offices are located at 305 College Road East, Princeton, New Jersey 08540 and our telephone number is (609) 452-9813. We maintain a website at [www.advaxis.com](http://www.advaxis.com) which contains descriptions of our technology, our product candidates and the trial status of each drug.





## 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 53 issued patents and 75 pending patent applications. All of these patents and patent applications are exclusively licensed from Penn with the exception of 33 pending patent applications, which are owned by us. 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*-LLO immunotherapies for our product candidates, ADXS-HPV, ADXS-PSA, and ADXS-HER2, expire at various dates between 2015 and 2035, prior to available patent extensions.

Our approach to the intellectual property portfolio is to create, maintain, protect, enforce and defend our proprietary rights for the products we develop from 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 (“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 2025. Issued patents directed to our product candidates ADXS-HPV, and ADXS-PSA outside of the United States, will expire between 2015 and 2025. Issued patents which cover our *Lm*-based immunotherapy platform in the United States, will expire between 2016 and 2030. Issued patents directed to our *Lm*-based immunotherapy platform outside of the United States, will expire between 2018 and 2030.

We have issued patents directed to methods of treatment by using our product candidates ADXS-HPV and ADXS-PSA in the United States, which will expire between 2015 and 2026. 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 2028.

We have pending patent applications for use of our product candidates ADXS-HPV, ADXS-PSA, ADXS-HER2 covering the following indications: 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 2035, depending on the specific indications.

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 or will have 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, 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.

## **The Drug Development Process**

The product candidates in our pipeline are at various stages of preclinical and clinical development. The path to regulatory approval includes multiple phases of clinical trials in which we collect data to support an application to regulatory authorities to allow us to market a product for the diagnosis, cure, mitigation, treatment, or prevention of a specified disease. There are many difficulties and uncertainties inherent in research and development of new products, resulting in a high rate of failure. To bring a drug from the discovery phase to regulatory approval, and ultimately to market, takes many years and significant costs.

Clinical testing, known as clinical trials or clinical studies, is either conducted internally by a pharmaceutical or biotechnology company or is conducted on behalf of these companies by Clinical Research Organizations (“CRO”). The process of conducting clinical studies is highly regulated by the FDA, as well as by other governmental and professional bodies. In a clinical trial, participants receive specific interventions according to the research plan or protocol created by the investigators. Clinical trials may compare a new medical approach to a standard one that is already available or to a placebo that contains no active ingredients or to no intervention. Some clinical trials compare interventions that are already available to each other. When a new product or approach is being studied, it is not usually known whether it will be helpful, harmful, or no different than available alternatives. The investigators try to determine the safety and efficacy of the intervention by measuring certain outcomes in the participants.

*Phase 1.* Phase 1 clinical trials begin when regulatory agencies allow initiation of clinical investigation of a new drug or product candidate. They typically 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. Typically, cancer therapies are initially tested on late stage cancer patients.

*Phase 2.* Phase 2 clinical trials involve larger numbers of patients that have been diagnosed with the targeted disease or condition. Phase 2 clinical trials gather preliminary data on effectiveness (where the drug works in people who have a certain disease or condition) and to determine the common short-term side effects and risks associated with the drug. If Phase 2 clinical trials 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 clinical trials are typically controlled multi-center trials that involve a larger number of patients to ensure the study results are statistically significant. The purpose is to confirm effectiveness and safety on a large scale and to provide an adequate basis for physician labeling. These trials are generally global in nature and are designed to generate clinical data necessary to submit an application for marketing approval to regulatory agencies.

*Biologic License Application (BLA).* The results of the clinical trials using biologics are submitted to the FDA as part of a 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 follow-up requests and responses between the FDA and the Sponsor, the review time can take months to many years. Once approved through this process, a drug may be marketed in the United States, subject to any conditions imposed by the FDA.

The current state of development of our candidates in various areas are outlined in the following table:

| Product                               | Indication                             | Stage               | Development Status |         |          | Sponsor / Partner               |
|---------------------------------------|--|---------------------|--------------------|---------|----------|---------------------------------|
|                                       |  |                     | Pre-Clinical       | Phase I | Phase II |                                 |
| ADX-HPV (HPV-E7)                      | Cervical *                             | Locally Advanced    |                    |         |          | 2015 Advaxis / GOG              |
| ADX-HPV (HPV-E7)                      | Cervical *                             | 2nd Line Met        |                    |         | x        | GOG                             |
| ADX-HPV (HPV-E7)                      | Head & Neck *                          | Newly diagnosed     |                    |         | x        | Mt. Sinai                       |
| ADX-HPV (HPV-E7)                      | Anal *                                 | Met                 |                    |         | x        | BrUOG                           |
| ADX-HPV (HPV-E7)                      | Cervical/H&N                           | Met                 |                    | 2015    | 2015     | Advaxis / MedImmune             |
| ADX-HPV (HPV-E7)                      | High Dose                              | Met                 |                    | 2015    |          | Advaxis / GRU                   |
| ADX-PSA (PSA)                         | Prostate                               | mCRPC               |                    | 2015    | 2015     | Advaxis / Merck                 |
| ADX-HER2 (Her2/Neu)                   | Expressing                             | Met HER2 expressing |                    | 2015    |          | Advaxis                         |
| ADX-HER2 (Her2/Neu)                   | Osteosarcoma *                         | HER2 expressing     |                    |         | 2016     | Advaxis                         |
| Survivin                              | Lymphoma                               |                     | x                  |         |          | Aratana (Pre-Veterinary Trials) |
| Survivin                              | Pan-tumor antigen                      |                     | x                  |         |          | Advaxis                         |
| PSCA                                  | Prostate                               |                     | x                  |         |          | Advaxis                         |
| HMWW-MAA                              | Melanoma                               |                     | x                  |         |          | Advaxis                         |
| HMWW-MAA                              | Neovascularization                     |                     | x                  |         |          | Advaxis                         |
| WT-1                                  | Pan-tumor antigens                     |                     | x                  |         |          | Advaxis                         |
| CEA                                   | Ovarian                                |                     | x                  |         |          | Advaxis                         |
| CA9                                   | Renal                                  |                     | x                  |         |          | Advaxis                         |
| CA9                                   | Hypoxic Solid Tumors                   |                     | x                  |         |          | Advaxis                         |
| VEGF r2                               | Solid tumors                           |                     | x                  |         |          | Advaxis                         |
| p53                                   | Breast                                 |                     | x                  |         |          | Advaxis                         |
| IL-13R Alpha2                         | Hypoxic Solid Tumors                   |                     | x                  |         |          | Advaxis                         |
| FAP                                   | Colorectal                             |                     | x                  |         |          | Advaxis                         |
| SCCE (Kallikrein related peptidase 7) | Pan Tumors (e.g. Melanoma, Pancreatic) |                     | x                  |         |          | Advaxis                         |
| ISG-15                                | Bladder                                |                     | x                  |         |          | Advaxis                         |
| ISG-15                                | Others                                 |                     | x                  |         |          | Advaxis                         |
| Endoglin (CD-105)                     | Tumor (BrCa) anti-angiogenesis         |                     | x                  |         |          | Advaxis                         |
| PSA + HMWMAA                          | Prostate                               |                     | x                  |         |          | Advaxis                         |
| Her2/neu + HMWMAA                     | Breast                                 |                     | x                  |         |          | Advaxis                         |

|                      |        |   |         |
|----------------------|--------|---|---------|
| Her2/neu +<br>HMWMAA | Others | x | Advaxis |
| Her2/neu + CA9       | Breast | x | Advaxis |
| Her2/neu + CA9       | Others | x | Advaxis |

\* Orphan Drug Designation

## Government Regulations

### *General*

Government authorities in the United States and other countries extensively regulate, among other things, the preclinical and clinical testing, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing and distribution of biologic products. In the United States, the FDA subjects pharmaceutical and biologic products to rigorous review under the Federal Food, Drug and Cosmetic Act, the Public Health Service Act and other federal statutes and regulations.

### *Orphan Drug Designation*

Under the Orphan Drug Act (“ODA”), the FDA may grant Orphan Drug Designation (“ODD”) to a drug or biological product intended to treat a rare disease or condition, which means 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, but for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States will be recovered from domestic sales of the product.

The benefits of ODD can be substantial, 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 and that this new product has not been previously approved for the same orphan disease or condition, with or without orphan drug designation. 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 ODD 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.

We currently have ODD 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 treatment of Stage II-IV invasive cervical cancer (granted May 2014). We also have ODD with the FDA for ADXS-HER2 for the treatment of osteosarcoma (granted May 2014).



### *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 time spent in gaining approval varies from that required for FDA approval, and 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.

### **Collaborations, Partnerships and Agreements**

#### *Biocon Limited*

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

Pursuant to the Biocon Agreement, we granted Biocon an exclusive license (with a right to sublicense) to (i) use our data from clinical development activities, regulatory filings, technical, manufacturing and other information and know-how to enable Biocon to submit regulatory filings for ADXS-HPV in the following territories: India, Malaysia, 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 Biocon Agreement, Biocon has agreed to use its commercially reasonable efforts to obtain regulatory approvals for ADXS-HPV in India. In the event Phase 2 or Phase 3 clinical trials are required, we shall conduct such trials at our cost, provided that if we are unable to commence such clinical trials, Biocon may conduct such clinical trials, subject to reimbursement of costs by us. Biocon has agreed to commence commercial distribution of ADXS-HPV no later than 9 months following receipt of regulatory approvals in a country in the Territory. Biocon will be responsible for the costs of obtaining and maintaining regulatory approvals in the Territory.

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

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

The term of the Biocon Agreement will be the later of twenty years or the last to expire patent or patent application. In addition, the Biocon 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 Biocon Agreement, (ii) if the other party becomes bankrupt or insolvent or (iii) if the other party undergoes a change in control.

We continue to assist Biocon with the activities necessary to develop and ultimately commercialize ADXS-HPV in the Territory.

*Global BioPharma, Inc.*

On December 9, 2013, we 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 our lead product candidate in several other indications including lung, head and neck, and anal cancer.

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

GBP will be responsible for all clinical development and commercialization costs in the GBP territory. GBP will also reimburse us \$2.25 million toward our U.S. registrational study, where such payment will help to offset our development costs. GBP is committed to establishing manufacturing capabilities for its own territory and to serving as

a secondary manufacturing source for us in the future. Under the terms of the agreement, we will exclusively license the rights of ADXS-HPV to GBP for the Asia, Africa, and former USSR territory, exclusive of India and certain other countries, for all HPV-associated indications. We will retain exclusive rights to ADXS-HPV for the rest of the world.

*University of Pennsylvania*

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

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 by Penn as of the effective date of the license, in connection with Dr. Paterson and requires us to pay various milestone, legal, filing and licensing payments to commercialize the technology. In exchange for the license, Penn received shares of our Common Stock. However, as of October 31, 2014, Penn does not own shares of our Common Stock. In addition, Penn is entitled to receive a non-refundable initial license fee, royalty payments and milestone payments based on net sales and percentages of sublicense fees and certain commercial milestones. Under the amended licensing agreement, Penn is entitled to receive 2.5% of net sales in the territory. Should annual net sales exceed \$250 million, the royalty rate will increase to 2.75%, but only with respect to those annual net sales in excess of \$250 million. Additionally, Penn will receive tiered sales milestone payments upon the achievement of cumulative global sales ranging between \$250 million and \$2 billion, with the maximum aggregate amounts payable to Penn in the event that maximum sales milestones are achieved is \$40 million. Notwithstanding these royalty rates, upon first in-human commercial sale (US & EU), we have agreed to pay Penn a total of \$775,000 over a four-year period as an advance minimum royalty, which shall serve as an advance royalty in conjunction with the above terms. 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 31st thereafter for the remainder of the term of the agreement until the first commercial sale of a Penn licensed product. We are responsible for filing new patents and maintaining and defending the existing patents licensed to us and we are obligated to reimburse Penn for all attorney's fees, expenses, official fees and other charges incurred in the preparation, prosecution and maintenance of the patents licensed from Penn.

Upon first regulatory approval in humans (US or EU), Penn will be entitled to a milestone payment of \$600,000. 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 in-human commercial sale (US or EU) of the first product in the cancer field and \$1.0 million will be due upon the date of first in-human commercial sale (US or EU) of a product in each of the secondary strategic fields sold.

As of October 31, 2014, we had no outstanding balance with Penn under all licensing agreements.

*Merck & Co., Inc.*

On August 22, 2014, we entered into a Clinical Trial Collaboration and Supply Agreement (the “Merck Agreement”) with Merck, pursuant to which the parties will collaborate on a Phase 1/2 dose-escalation and safety study. The Phase 1 portion of the study will evaluate the safety of our *Lm*-LLO based immunotherapy for prostate cancer, ADXS31-142 (the “Advaxis Compound”) as monotherapy and in combination with KEYTRUDA®(pembrolizumab), Merck’s humanized monoclonal antibody against PD-1, (the “Merck Compound”) to determine a recommended Phase 2 combination dose. The Phase 2 portion will evaluate the safety and efficacy of the Advaxis Compound in combination with the Merck Compound. Both phases of the study will be in patients with previously treated metastatic castration-resistant prostate cancer. A joint development committee, comprised of equal representatives from both parties, is responsible for coordinating all regulatory and other activities under, and pursuant to, the Merck Agreement.

Each party is responsible for their own internal costs and expenses to support the study, while we will be responsible for all third party costs of conducting the study. Merck will be responsible for manufacturing and supplying the Merck Compound. We will be responsible for manufacturing and supplying the Advaxis Compound. We will be the sponsor of the study and hold the IND related to the study.

All data and results generated under the study (“Collaboration Data”) will be jointly owned by the parties, except that ownership of data and information generated from sample analysis to be performed by each party on its respective compound will be owned by the party conducting such testing. All rights to all inventions and discoveries, which claim or cover the combined use of the Advaxis Compound and the Merck Compound shall belong jointly to the parties. Inventions and discoveries relating solely to the Advaxis Compound, or a live attenuated bacterial vaccine, shall be the exclusive property of us. Inventions and discoveries relating solely to the Merck Compound, or a PD-1 antagonist, shall be the exclusive property of Merck.

The Merck Agreement shall continue in full force and effect until completion of all of the obligations of the parties or a permitted termination.

*MedImmune/AstraZeneca*

On July 21, 2014, we entered into a Clinical Trial Collaboration Agreement (the “MedImmune Agreement”) with MedImmune, the global biologics research and development arm of AstraZeneca, pursuant to which the parties intend to initiate a Phase 1/2 clinical study in the United States to evaluate the safety and efficacy of MedImmune’s investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736, in combination with our investigational *Lm*-LLO cancer immunotherapy, ADXS-HPV, as a combination treatment for patients with advanced, recurrent or refractory cervical cancer and HPV-associated head and neck cancer. A joint steering committee, composed of equal representatives from both parties, is responsible for various matters associated with the collaboration, including protocol approval, as well as reviewing and monitoring the progress of the study.

MedImmune will be responsible for providing MEDI4736 at no cost, as well as costs related to the proprietary assays performed by MedImmune or a third party on behalf of MedImmune. We will be the sponsor of the study and be responsible for the submission of all regulatory filings to support the study, the negotiation and execution of the clinical trial agreements associated with each study site, and the packaging and labelling of the Advaxis and MedImmune product candidates to be used in the study and the costs associated therewith.

For a period beginning upon the completion of the study and the receipt by MedImmune of the last final report for the study and ending one hundred twenty (120) days thereafter (unless extended), MedImmune will be granted first right to negotiate in good faith in an attempt to enter into an agreement with us with respect to the development, regulatory approval and commercialization of ADXS-HPV and MEDI4736 to be used in combination with each other for the treatment or prevention of cancer. Neither party is obligated to enter into such an agreement. In the event the parties do not enter an agreement and we obtain regulatory approval for ADXS-HPV in combination with any PD-1 antibody or PD-L1 antibody, we shall pay MedImmune a royalty obligation and one-time payment.

All intellectual property rights made, conceived or generated through the clinical trials that relate solely to a MedImmune development product shall be owned solely by MedImmune. All intellectual property rights made, conceived or generated through the clinical trials that relate solely to an Advaxis development product shall be owned solely by us. All intellectual property rights made, conceived or generated through the clinical trials that relate to the combination of one or more MedImmune development product and one or more Advaxis development product shall be jointly owned by both parties; provided, however that in the event the parties do not enter into a clinical development and commercialization agreement, we will not exploit, commercialize or license the joint inventions, except for the performance of its obligations under the MedImmune Agreement. MedImmune has the sole right to prosecute and enforce all patents and other intellectual property rights covering all joint inventions and all associated costs will be shared by the parties.

The MedImmune Agreement shall remain in effect until the earlier of (i) permitted termination, (ii) the parties entering into a clinical development and commercialization agreement or expiration of the negotiation period (unless

extended), except with respect to rights that survive termination. Either party may terminate the MedImmune Agreement upon thirty (30) days written notice upon material breach of the other party, unless the breach is cured in such period or reasonable actions to cure the breach are initiated and pursued (if the breach is not capable of being cured during the 30-day notice period). In addition, either party may terminate the MedImmune Agreement immediately if the party determines in good faith that the trials may unreasonably affect the safety of trial subjects.

#### *Aratana*

On March 19, 2014, we entered into a definitive Exclusive License Agreement (the “Aratana Agreement”) with Aratana. Pursuant to the Aratana Agreement, we granted Aratana an exclusive, worldwide, royalty-bearing, license, with the right to sublicense, under certain Advaxis proprietary technology that enables the design of an immunotherapy utilizing live attenuated *Lm* bioengineered to secrete fusion proteins consisting of antigen and adjuvant molecules, including certain “Constructs” and related “Compounds” (both as defined in the Aratana Agreement) in order for Aratana to develop and commercialize animal health products containing or incorporating Compounds (“Products”) for use in non-human animal health applications (the “Aratana Field”) that will be targeted for treatment of osteosarcoma and other cancer indications in animals. Our technology licensed to Aratana includes certain patents and patent applications, as well as related know-how, data, technical information, results and other information controlled by us during the term of the Aratana Agreement that are reasonably necessary for the development, manufacture or commercialization of any Construct, Compound or Product.

In addition to the Constructs licensed by Aratana upon signing of the Aratana Agreement, Aratana also has a right of first refusal to license additional constructs from us in the future if we develop (on its own or upon request of Aratana) new constructs which are reasonably believed to be suitable for treating osteosarcoma and certain other cancer indications (“Additional Constructs”). If the parties agree upon the terms pursuant to which such Additional Constructs shall be added as Constructs under the Aratana Agreement, such Additional Constructs will be added by virtue of an amendment to the Aratana Agreement.

Aratana has granted us an exclusive, worldwide, royalty-free, fully-paid, irrevocable and perpetual license, with the right to sublicense, under Aratana’s existing technology, and any related sole Aratana development or Aratana’s rights in any joint inventions which may be developed by the parties during the course of the Aratana Agreement, solely for us to develop and commercialize our products for any and all uses outside of the Aratana Field, including, without limitation, all human health applications. The Aratana technology to be licensed to us will include any patents or patent applications controlled by Aratana during the term of the Aratana Agreement that claim or cover the manufacture, use, sale, offer for sale or import of any Products as well as related know-how, data, technical information, results and other information controlled by Aratana during the term of the Aratana Agreement that is necessary or useful in the development, manufacture or commercialization of any Compound, Construct or Product.

Under the terms of the Aratana Agreement, Aratana paid an upfront payment to us in the amount of \$1,000,000 upon signing of the Aratana Agreement. Aratana will also pay us (a) up to \$36.5 million based on the achievement of milestone relating to the advancement of Products through the approval process with the USDA in the United States and the relevant regulatory authorities in the European Union (“E.U.”) in all four therapeutic areas and up to an additional \$15 million in cumulative sales milestones based on achievement of gross sales revenue targets for sales of any and all Products in the Aratana Field (regardless of therapeutic area), and (b) tiered royalties starting at 5% and going up to 10%, which will be paid based on net sales of any and all Products (regardless of therapeutic area) in the Aratana Field in the United States. Royalties for sales of Products outside of the United States will be paid at a rate equal to half of the royalty rate payable by Aratana on net sales of Products in the United States (starting at 2.5% and going up to 5%). Royalties will be payable on a Product-by-Product and country-by-country basis from first commercial sale of a Product in a country until the later of (a) the 10th anniversary of first commercial sale of such Product by Aratana, its affiliates or sub licensees in such country or (b) the expiration of the last-to-expire valid claim of our patents or joint patents claiming or covering the composition of matter, formulation or method of use of such Product in such country. Aratana will also pay us 50% of all sublicense royalties received by Aratana and its affiliates.

Furthermore, pursuant under the terms of the Aratana Agreement, we (i) issued and sold 306,122 shares of Common Stock to Aratana at a price of \$4.90 per share, which was equal to the closing price of the Common Stock on the NASDAQ Capital Market on March 19, 2014, and (ii) issued a ten-year warrant to Aratana giving Aratana the right to purchase up to 153,061 additional shares of Common Stock at an exercise price of \$4.90 per share. The warrant also contains a provision for cashless exercise if the fair market value of Advaxis’s Common Stock for the five trading days ending three trading days prior to the exercise date is higher than the exercise price. In connection with the sale of the Common Stock and warrants, we received aggregate net proceeds of \$1,500,000. We issued the shares and warrant in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933.

On July 2, 2014, we announced that a request for a product license from the USDA has been filed for ADXS-HER2 by Aratana. While the USDA has no specific obligation to respond with a prescribed timeframe, we expect that a response from the USDA to the filing will occur within the next several months.

#### *Master Services Agreement with inVentiv Health Clinical*

On May 29, 2014, we announced that we entered into a master services agreement with inVentiv Health Clinical (“inVentiv”), a leading global Clinical Research Organization (“CRO”), for the clinical development of certain immunotherapy product candidates in our proprietary pipeline.

Under the terms of the agreement, inVentiv can provide us with full CRO services to execute clinical studies for our current cancer immunotherapy product candidates including ADXS-HPV for cervical cancer, and other HPV-associated cancer; ADXS-HER2 for pediatric osteosarcoma and other HER2 over-expressing cancer and ADXS-PSA for prostate cancer. In addition, pending regulatory approval, we can leverage inVentiv’s significant



commercialization capabilities in select countries, should we seek to do so.

## **Manufacturing**

Good manufacturing practices (“GMP”) are the standards identified in order to conform to requirements by governmental agencies that control authorization and licensure for manufacture and distribution of drug products for either clinical investigations or commercial sale. GMPs identify the requirements for procurement, manufacturing, testing, storage, distribution and the supporting quality systems in order to ensure that a drug product is safe for its intended application. GMPs are enforced in the United States by the FDA, under the authorities of the Federal Food, Drug and Cosmetic Act and its implementing regulations and use the phrase “current good manufacturing practices” (“cGMP”) to describe these standards.

To support our development efforts, we have entered into agreements with various third-party organizations to handle the manufacturing of our product candidates and have secured contract manufacturing organizations with scale-up and commercial capabilities. These organizations have extensive experience in manufacturing and testing of biologic products for investigational studies and are full service manufacturing organizations that manufacture, test and supply synthetic and biologic based products for the pharmaceutical and biotech industry. These services include cell banking, GMP manufacturing and testing capabilities. We continue to invest in our existing chemistry and manufacturing process controls, including, but not limited to process optimization, test method development, and supporting quality systems. We also continue to evaluate and develop new technologies and capabilities to support the advancement of our development pipeline.

## **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 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, acceptance, availability, price and patent position.

## **Employees**

As of December 26, 2014, we had 20 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.

## **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. The agreement has a termination date of November 29, 2015. We plan to continue to rent necessary offices and laboratories to support our business.

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 clinical stage company.*

We are a clinical 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 clinical 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.

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, 2014 we had an accumulated deficit of \$86,991,137 and shareholders’ equity of \$20,629,986. 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 fail 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.

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

Product candidates are subject to extensive pre-clinical testing and clinical trials to demonstrate their safety and efficacy in humans. Conducting pre-clinical testing and clinical trials is a lengthy, time-consuming and expensive

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

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

- unforeseen safety issues (including those arising with respect to trials by third parties for compounds in a similar class as our product or product candidate), inadequate efficacy, or an unacceptable risk-benefit profile observed at any point during or after completion of the trials;

- slower than expected rates of patient enrollment, which could be due to any number of factors, including failure of our third-party vendors, including our CROs, to effectively perform their obligations to us, a lack of patients who meet the enrollment criteria or competition from clinical trials in similar product classes or patient populations;

- the risk of failure of our clinical investigational sites and related facilities, including our suppliers, to maintain compliance with the FDA's cGMP regulations or similar regulations in countries outside of the U.S., including the risk that these sites fail to pass inspections by the appropriate governmental authority, which could invalidate the data collected at that site or place the entire clinical trial at risk;

- any inability to reach agreement or lengthy discussions with the FDA, equivalent regulatory authorities, or ethical review committees on trial design that we are able to execute;

- changes in laws, regulations, regulatory policy or clinical practices, especially if they occur during ongoing clinical trials or shortly after completion of such trials.

- clinical trial record keeping or data quality and accuracy issues.

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

***Our 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 today exist as a clinical stage company. Prior thereto we conducted no business. Accordingly, we have a limited operating history. We have no approved products and therefore have not derived any significant 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, our 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.

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 research organizations, clinical investigators and medical institutions for clinical testing and 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, our agents. 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 future development of our agents.

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 our 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 product promotion, 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 Good Clinical Practices (“GCP”), 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, manufacturing 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 Statute and the federal False Claims Act, and privacy laws. Noncompliance with applicable laws and requirements can result in various adverse consequences, including delay in approving or refusal to approve product licenses or other applications, suspension or termination of clinical investigations, revocation of approvals previously granted, fines, criminal prosecution, civil and criminal penalties, recall or seizure of products, exclusion from having our products reimbursed by federal health care programs, the curtailment or restructuring of our operations, injunctions against shipping products and total or partial suspension of production and/or refusal to allow a company to enter into governmental supply contracts.

The process of obtaining requisite FDA approval has historically been costly and time-consuming. Current FDA requirements for a new human biological product to be marketed in the United States include: (1) the successful conclusion of preclinical laboratory and animal tests, if appropriate, to gain preliminary information on the product's safety; (2) filing with the FDA of an IND to conduct human clinical trials for drugs or biologics; (3) the successful completion of adequate and well-controlled human clinical trials to establish the safety and efficacy of the investigational new drug for its recommended use; and (4) filing by a company and acceptance and approval by the FDA of a 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 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 several of our candidates in a number of ongoing pre-clinical and clinical trials. However, even though the initiation and conduct of the clinical 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 a New Drug Application ("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 in-humans (US & EU) 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 been granted orphan drug designation for ADXS-HPV for use in the treatment of HPV-associated anal cancer, HPV-associated head and neck cancer, HPV-associated Stage II-IV invasive cervical cancer and for ADXS-HER2 for the treatment of osteosarcoma in the United States, and intend to request a similar designation for these uses in the European Union, we may not receive the benefits associated with orphan drug designation. This may result from a failure to maintain orphan drug status, or result from a competing product reaching the market that has an orphan designation for the same disease indication. Under U.S. rules for orphan drugs, if such a competing product reaches the market before ours does, the competing product could potentially obtain a scope of market exclusivity that limits or precludes our product from being sold in the United States for seven years. Even if we obtain exclusivity, the FDA could subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. A competitor also may receive approval of different products for the same indication for which our orphan product has exclusivity, or obtain approval for the same product but for a different indication for which the orphan product has exclusivity.

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

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

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

We have 53 patents that have been issued and 75 patent applications that are pending. All of these patents and patent applications are licensed from Penn with the exception of 33 pending patent applications, which are owned by us. 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, at the University of Pennsylvania.

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 as a result of laws, rules and guidelines that are changed due to legislative, judicial or administrative actions, or review, which render our patents unenforceable or invalid. Our patents can be challenged by our competitors who can argue that our patents are invalid, unenforceable, lack utility, 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 valid, 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 license agreement with Penn, which has been amended from time to time, 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, 2014, we had no outstanding payments to Penn. We can provide no assurance that we will be able to make all future 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 various third party manufacturing facilities 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 our clinical product candidates, and we may rely even more on strategic collaborations for research, development, marketing and commercialization for some of our immunotherapies. To date, we have been heavily reliant upon third party outsourcing for our clinical trials execution and production of drug supplies for use in clinical trials. 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. Our current collaborations, as well as any future new collaborations, may never result in the successful development or commercialization of our immunotherapies or the generation of sales revenue. To the extent that we have entered or will 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;

- financial funding to support said collaboration;

- 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 Product Liability and Clinical Trial Liability insurance coverage for each clinical trial. We do not have product liability insurance for sold commercial products because we do not have products on the market. We currently are in the process of obtaining insurance coverage and plan 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 or pollution liability or remediation insurance coverage, nor do our workers' compensation, general liability, and property and casualty insurance policies provide coverage for damages and fines/penalties 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 December 26, 2014, we had 20 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. 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 may not obtain or maintain the benefits associated with breakthrough therapy designation.***

If we apply for Breakthrough Therapy Designation (“BTD”), we may not be granted BTD, or even if granted, we may not receive the benefits associated with BTD. This may result from a failure to maintain breakthrough therapy status if

it is no longer considered to be a breakthrough therapy. For example, a drug's development program may be granted BTD 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 BTD 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 BTD 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 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 current or 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 limited public trading market may cause volatility in the price of our Common Stock.***

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.

***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, resulting in our management concluding that our disclosure controls and procedures are now effective. We also initiated a Sarbanes–Oxley assessment services, including the development of control design documents, to ensure effectiveness.

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 45,000,000 shares of our Common Stock. As of December 26, 2014, we had 23,644,808 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 December 22, 2014, warrants to purchase 53,957 shares of our Common Stock are exercisable at approximately \$7.77 per share and are subject to “weighted-average” anti-dilution protection upon certain equity issuances below \$7.77 per share (as may be further adjusted as defined in the warrant). In addition, as of December 22, 2014, we had outstanding options to purchase 487,968 shares of our Common Stock at a weighted average exercise price of approximately \$14.99 per share and outstanding warrants to purchase 4,133,797 shares of our Common Stock (including the above warrants subject to weighted-average anti-dilution protection); and approximately 29,990 shares of our Common Stock are available for grant under the ESPP.

***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.

***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. To date, we have not issued shares of preferred stock, however, 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. The agreement has a termination date of November 29, 2015. We plan to continue to rent necessary offices and laboratories to support our business.

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.**

*Iliad Research and Trading*

On March 24, 2014, Iliad Research and Trading, L.P. (“Iliad”) filed a complaint (the “Complaint”) against us in the Third Judicial District Court of Salt Lake County, Utah. Iliad alleges that we granted a participation right to Tonaquint, Inc. (“Tonaquint”) in a securities purchase agreement between Tonaquint and us, dated as of December 13, 2012 (the “Purchase Agreement”), pursuant to which Tonaquint was entitled to participate in any transaction that we structured in accordance with Section 3(a)(9) or Section 3(a)(10) of the Securities Act of 1933, as amended. Iliad further alleges that the settlement that we entered into with Ironridge Global IV, Ltd. (“Ironridge”), pursuant to which we issued certain shares of our Common Stock to Ironridge in reliance on the Section 3(a)(10) exemption, occurred without adequate notice for Tonaquint to exercise its participation right. In addition, Iliad alleges that it acquired all of Tonaquint’s rights under the Purchase Agreement in April 2013. On May 9, 2014, we filed papers in support of our motion to dismiss the Complaint in its entirety. On June 2, 2014, Iliad filed an amended complaint (the “Amended Complaint”) which purports to assert claims against us for breach of contract and breach of the implied covenant of good faith and fair dealing as well as claims under the federal and Utah securities laws and for common law fraud. In the Amended Complaint, Iliad alleges damages of greater than \$300,000 plus interest, attorneys’ fees and costs. In connection with its claim under the Utah Securities Act, Iliad has asked for punitive damages equal to three times its actual damages. We intend to continue to defend ourselves vigorously.

#### *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 (“Numoda”), to oversee Phase 2 clinical activity with ADXS-HPV for the treatment of invasive cervical cancer and CIN.

We are in a dispute regarding the amounts outstanding under these agreements. Numoda had taken the position that it was owed approximately \$540,000 while we believed that the amount due to Numoda should be substantially less than that amount. We intend to continue to defend ourselves vigorously.

*Brio Capital*

On March 22, 2013, we were notified that Brio Capital L.P. (“Brio”) had filed a lawsuit against us 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 we 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 us 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. As of October 29, 2013, this matter was fully settled and the Action dismissed with prejudice.

*Maxim Group*

On August 19, 2013, we entered into an agreement with Maxim Group LLC (“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 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, we cancelled the issuance of such shares. Upon the completion of our public offering in October 2013 we paid the aforementioned \$150,000 and commenced final settlement of the disputed amounts owed. On or about November 14, 2013, Maxim initiated a proceeding by confession of judgment in New York State Court to recover monies it believed we owed 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 us 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.



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 or proceedings against us is likely to have, individually or in the aggregate, a material adverse effect on the 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.**

Set forth below for the periods indicated are the high and low sales prices for trading in our Common Stock. Through October 2013, our Common Stock was quoted on the OTC Bulletin Board under the symbol ADXS.OB. Fiscal year 2013 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 year 2014 bid prices represent prices as reported by the NASDAQ Capital Market.

| Fiscal 2014    | High   | Low    |
|----------------|--------|--------|
| Fourth Quarter | \$4.60 | \$2.50 |
| Third Quarter  | \$3.57 | \$2.52 |
| Second Quarter | \$5.99 | \$2.46 |
| First Quarter  | \$5.70 | \$2.88 |

| Fiscal 2013    | High    | Low    |
|----------------|---------|--------|
| Fourth Quarter | \$7.96  | \$2.70 |
| Third Quarter  | \$7.50  | \$3.18 |
| Second Quarter | \$17.50 | \$8.75 |
| First Quarter  | \$8.75  | \$3.75 |

As of October 31, 2014, there were approximately 114 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. On December 26, 2014, the last reported sale price per share for our Common Stock as reported by NASDAQ was \$7.97.



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, nor do we anticipate paying cash dividends in the foreseeable future.

### **Recent Sales of Unregistered Securities**

On August 1, 2014, the registrant issued 4,869 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On August 1, 2014, the registrant issued 1,179 shares of Common Stock to an accredited investor as payment for consulting services rendered.

On August 29, 2014, the registrant issued 2,507 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On September 1, 2014, the registrant issued 1,179 shares of Common Stock to an accredited investor as payment for consulting services rendered.

On September 30, 2014, the registrant issued 2,891 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On October 1, 2014, the registrant issued 1,179 shares of Common Stock to an accredited investor as payment for consulting services rendered.

On October 13, 2014, the registrant issued 5,000 shares of Common Stock to an accredited investor as payment for consulting services rendered.

On October 20, 2014, the registrant issued 25,170 shares of Common Stock to a current Executive Officer which represents the initial vesting period of an inducement grant pursuant to his Employment Agreement.

On October 27, 2014, the registrant issued 18,937 shares of Common Stock to a current Executive Officer which represents the second of four vesting periods of an inducement grant pursuant to his Employment Agreement.

On October 31, 2014, the registrant issued 3,420 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On November 10, 2014, the registrant issued 40,000 shares of Common Stock to an accredited investor as payment for consulting services rendered.

On November 28, 2014, the registrant issued 3,868 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On December 5, 2014, the registrant issued 30,000 shares of Common Stock to an accredited investor as payment for consulting services rendered.

On December 31, 2014, the registrant issued 1,504 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

**Equity Compensation Plan Information**

The following table provides information regarding the status of our existing equity compensation plans at October 31, 2014:

| Plan category  | Number of shares of Common Stock to be issued on exercise of outstanding options, warrants and rights | Weighted-average exercise price of outstanding options, warrants and rights | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in the previous columns) |
|--|---|---|---|
| Equity compensation plans approved by security holders     | 467,968   | \$ 15.51  | 970,807   |
| Equity compensation plans not approved by security holders | -   | \$ -  | -   |
| Total  | 467,968   | \$ 15.51  | 970,807   |

**ITEM 6. Selected Financial Data.**

Not required.

**ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

*This Management's Discussion and Analysis of Financial Conditions and Results of Operations and other portions of this report contain forward-looking information that involves risks and uncertainties. Our actual results could differ materially from those anticipated by the forward-looking information. Factors that may cause such differences include, but are not limited to, availability and cost of financial resources, product demand, market acceptance and other factors discussed in this report under the heading "Risk Factors". This Management's Discussion and Analysis of Financial Conditions and Results of Operations should be read in conjunction with our financial statements and the related notes included elsewhere in this report.*

## Overview

We are a clinical-stage biotechnology company focused on the discovery, development and commercialization of proprietary *Lm*-LLO cancer immunotherapies. These immunotherapies are based on a platform technology that utilizes live attenuated *Listeria monocytogenes*, bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm*-LLO strains are believed to be a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy as 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.

### *ADXS-HPV Franchise*

ADXS-HPV is a *Lm*-LLO immunotherapy directed against HPV and designed to target cells expressing the HPV gene E7. It is currently under investigation in three HPV-associated cancers: recurrent or persistent cervical cancer, head and neck cancer, and anal cancer, either as a monotherapy or in combination with investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736.

### Cervical Cancer

There are 500,000 new cases of cervical cancer caused by HPV worldwide every year, and 12,000 new cases in the U.S. alone, according to the WHO Human Papillomavirus and Related Cancers in the World Summary Report 2010. 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. 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.

We completed a Phase 2 clinical study that was conducted in India in 110 women with recurrent cervical cancer. The final results, were presented at the 2014 ASCO Annual Meeting, and showed that 22% (24/109) of the patients were LTS of greater than 18 months. 18% (16/91) of patients were alive for more than 24 months. Of the 109 patients treated in the study, LTS included not only patients with tumor shrinkage but also patients who had experienced increased tumor burden. 17% (19/109) of the patients in the trial had recurrence of disease after at least two prior treatments for their cervical cancer; these patients comprised 8% (2/24) of LTS. Among the LTS, 25% (3/11) of patients had an ECOG performance status of 2, a patient population that is often times excluded from clinical trials because of their poor survival.

We have completed an EOP2 meeting with the FDA. The purpose of the EOP2 meeting was to discuss ADXS-HPV's preclinical data, CMC and clinical program prior to moving ADXS-HPV forward into the next phase of clinical development in cervical cancer. At the meeting, the FDA provided guidance on our CMC activities and clinical development plan. We plan to submit our Phase 3 protocol for a SPA, and continue to have dialogue with the FDA, incorporating their valuable guidance into our planned registration program. We are planning to initiate an adequate and well-controlled clinical trial in cervical cancer in the first half of 2015 to support a BLA submission in the U.S. and in other territories around the world.

The adequate and well-controlled Phase 3 clinical trial that we are planning to conduct will be a Phase 3 study of adjuvant ADXS-HPV following chemoradiation as primary treatment for high risk locally advanced cervical cancer compared to chemoradiation alone. This population has a high risk of recurrence and once recurred there is no cure. This study will evaluate both the time it takes for the cancer to recur as well as the overall survival. Our goal is to develop a treatment to prevent recurrence of cervical cancer after primary care, which is approximately 12,000 new cases each year in the U.S.

The GOG of the NCI is independently conducting a single arm Phase 2 study of ADXS-HPV in invasive cervical cancer in the U.S., GOG-265. This study has now completed enrollment in the first stage of 26 evaluable patients. The second stage of enrollment of 38 patients is pending. We have agreed to provide clinical material to support this study but do not control the conduct of the study.

We have entered into a clinical trial collaboration agreement with MedImmune, the global biologics research and development arm of AstraZeneca, where we plan to collaborate on a Phase 1/2 study to evaluate safety and efficacy of MedImmune's investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736, in combination with our investigational *Lm*-LLO cancer immunotherapy, ADXS-HPV, as a combination treatment for patients with advanced, recurrent or refractory HPV associated cervical cancer and HPV-associated head and neck cancer.

GRU Cancer Center is conducting a Phase 1/2 trial evaluating higher doses and repeat cycles of ADXS-HPV in patients with recurrent cervical cancer. This Phase 1/2 study is designed to evaluate the safety, efficacy and immunological effect of the highest-tolerated dose of ADXS-HPV administered in repeat cycles of treatment to patients with cervical cancer whose disease recurred after receiving one prior cytotoxic treatment regimen.

ADXS-HPV has received orphan drug designation for invasive Stage II-IVb cervical cancer.

### Head and Neck Cancer

HNSCC is the most frequently occurring malignant tumor of the head and neck and is a major cause of morbidity and mortality worldwide. More than 90% of HNSCCs originate from the mucosal linings of the oral cavity, pharynx, or larynx. According to the American Cancer Society, head and neck cancer accounts for about 3% to 5% of all cancers in the United States. About 55,070 new cases will be diagnosed and about 12,000 people are expected to die of head and neck cancer in the United States during 2014.

The safety and efficacy of ADXS-HPV is being evaluated in a Phase 1/2 study under an investigator-sponsored IND at Mount Sinai, in patients with HPV-positive head and neck cancer. This clinical trial is 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 chemotherapy or radiation for their cancer.

As stated above, we recently entered into a clinical trial collaboration agreement with MedImmune to collaborate on a Phase 1/2 study to evaluate safety and efficacy of MEDI4736 in combination with ADXS-HPV as a combination treatment for patients with advanced, recurrent or refractory cervical cancer and HPV-associated head and neck



cancer. The FDA has cleared our IND application and we now plan to initiate this Phase 1/2 study in early 2015.

ADXS-HPV has received orphan drug designation for HPV-associated head and neck cancer.

### Anal Cancer

According to the American Cancer Society, most squamous cell anal cancers seem to be linked to infection by the HPV, the same virus that causes cervical cancer. In fact, women with a history of cervical cancer (or pre-cancer) have an increased risk of anal cancer. Anal cancer is fairly rare – much less common than cancer of the colon or rectum. About 7,210 new cases will be diagnosed and about 950 people are expected to die of anal cancer in the United States during 2014.

The safety and efficacy of ADXS-HPV is being evaluated in a Phase 1/2 study under an investigator-sponsored IND by Brown University in patients with HPV-associated anal cancer. Preliminary data from this study indicates a “clinical complete response” in all seven patients who have completed the treatment regimen.

ADXS-HPV has received orphan drug designation for HPV-associated anal cancer.

### *ADXS-PSA Franchise*

### Prostate Cancer

According to the American Cancer Society, prostate cancer is the most common type of cancer found in American men, other than skin cancer. Prostate cancer is the second leading cause of cancer death in men, behind only lung cancer. One man in six will get prostate cancer during his lifetime, and one man in 36 will die of this disease.

ADXS-PSA is a *Lm*-LLO immunotherapy designed to target the PSA antigen associated with prostate cancer.

We have entered into a clinical trial collaboration and supply agreement with Merck to evaluate the safety and efficacy of ADXS-PSA as monotherapy and in combination with KEYTRUDA® (pembrolizumab), Merck’s anti PD-1 antibody, in a Phase 1/2 study in patients with previously treated metastatic, castration-resistant prostate cancer. The

FDA has cleared our IND application and we now plan to initiate this Phase 1/2 study in the first quarter of 2015.

## *ADXS-HER2 Franchise*

### HER2 Expressing Solid Tumors

ADXS-HER2 is a *Lm*-LLO immunotherapy designed to target the Her2 gene which is expressed in some solid tumor cancers such as human and canine osteosarcoma, breast, gastric and other cancers. We have submitted an IND with the FDA and plan to initiate a Phase 1b study in patients with HER2-expressing cancers in 2015. Thereafter, we intend to initiate a clinical development program with ADXS-HER2 for the treatment of pediatric osteosarcoma.

### Pediatric Osteosarcoma

Pediatric osteosarcoma affects about 400 children and teens in the U.S. every year, representing a small but significant unmet medical need that has seen little therapeutic improvement in decades. Pediatric osteosarcoma is considered a rare disease and may qualify for regulatory incentives including, but not limited to, orphan drug designation, patent term extension, market exclusivity, and development grants. Given the limited availability of new treatment options for pediatric osteosarcoma, and that it is an unmet medical need affecting a very small number of patients in the U.S. annually, we believe that, subject to regulatory approval, the potential to be on the market may be accelerated.

Based on encouraging preliminary data from a veterinarian clinical study in which pet dogs with naturally occurring osteosarcoma were treated with ADXS-HER2, we intend to initiate a clinical development program with ADXS-HER2 for the treatment of pediatric osteosarcoma. In this veterinarian clinical study, pet dogs with naturally occurring osteosarcoma treated with ADXS-HER2 after the standard of care showed a statistically significant prolonged overall survival benefit compared with dogs that received standard of care without ADXS-HER2. Both veterinary and human osteosarcoma specialists consider canine osteosarcoma to be the best model for human osteosarcoma.

ADXS-HPV has received orphan drug designation for osteosarcoma.

### Canine Osteosarcoma

Under the direction of Dr. Nicola Mason, the University of Pennsylvania School of Veterinary is conducting a Phase 1 study in companion dogs evaluating the safety and efficacy of ADXS-HER2 in the treatment of canine osteosarcoma.

The primary endpoint of the study is to determine the maximum tolerated dose of ADXS-HER2. Secondary endpoints for the study are progression-free survival and overall survival. The preliminary findings of the Phase 1 clinical trial in dogs with osteosarcoma suggest that ADXS-HER2 is safe and well tolerated at doses up to  $3 \times 10^9$  CFU with no evidence of cardiac, hematological, or other systemic toxicities. The study determined that ADXS-HER2 is able to delay or prevent metastatic disease and significantly prolong overall survival in dogs with osteosarcoma that had minimal residual disease following standard of care (amputation and follow-up chemotherapy). Dr. Mason presented data at the 2014 ACVIM Forum which showed that 80% of the dogs treated (n=15) were still alive and median survival had not yet been reached; median survival in control dogs (n=13) was 316 days. Immunological analyses are also being conducted in this study to further evaluate the immune response to ADXS-HER2.

Osteosarcoma is the most common primary bone tumor in dogs, accounting for roughly 85% of tumors on the canine skeleton. Approximately 8,000-10,000 dogs a year (predominately middle to older-aged dogs and larger breeds) are diagnosed with osteosarcoma in the United States. This cancer initially presents as lameness and oftentimes visible swelling on the leg. Current standard of care treatment is amputation immediately after diagnosis, followed by chemotherapy and sometimes radiation for palliative care.

On March 19, 2014, we entered into a definitive Exclusive License Agreement with Aratana, where we granted Aratana an exclusive, worldwide, royalty-bearing, license, with the right to sublicense, certain of our proprietary technology that enables Aratana to develop and commercialize animal health products that will be targeted for treatment of osteosarcoma and other cancer indications in animals. A product license request has been filed by Aratana for ADXS-HER2 (also known as AT-014 by Aratana) for the treatment of canine osteosarcoma with the USDA. While the USDA has no specific obligation to respond within a prescribed timeframe, the companies expect a response from the USDA to the request for a product license within the next several months. Aratana has been granted exclusive worldwide rights by us to develop and commercialize ADXS-HER2 in animals.

#### *Lm-LLO Combination Franchise*

#### ADXS-HPV and MEDI4736

As stated above, we have entered into a clinical trial collaboration agreement with MedImmune, the global biologics research and development arm of AstraZeneca, where we plan to collaborate on a Phase 1/2 study to evaluate safety and efficacy of MedImmune's investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736, in combination with our investigational *Lm-LLO* cancer immunotherapy, ADXS-HPV, as a combination treatment for patients with advanced, recurrent or refractory cervical cancer and HPV-associated head and neck cancer. The FDA has cleared our IND application and we now plan to initiate this Phase 1/2 in the first quarter of 2015.

#### ADXS-PSA and MK-3475

As stated above, we have entered into a clinical trial collaboration agreement with Merck to evaluate the safety and efficacy of ADXS-PSA as monotherapy and in combination with KEYTRUDA® (pembrolizumab), Merck's anti PD-1 antibody, in a Phase 1/2 study in patients with previously treated metastatic, castration-resistant prostate cancer. The FDA has cleared our IND application and we now plan to initiate this Phase 1/2 in the first quarter of 2015.

Lm-LLO and GRU

We have a non-clinical research agreement with GRU which provides research collaboration of the in vitro effect of our *Lm-LLO* cancer immunotherapy technology evaluating it in combination with other immunotherapies, including, but not limited to, anti-PD-L1 & anti-PD-1 immune checkpoint inhibitors.

*Corporate*

We continue to invest in the development of our platform technology and utilize our capital most efficiently. For example, we recently entered into an amendment with Penn, where both parties mutually agreed to eliminate a near-term milestone payment obligation we had to Penn, as well as modify others relating to the development and commercialization of our *Lm-LLO* cancer immunotherapy technology. In addition, to ensure we appropriately support our development efforts, we entered into a master service agreement with inVentiv, a leading global CRO, for the clinical development of our immunotherapy products. InVentiv is a suitable partner, providing full CRO services to execute our clinical studies while offering competitive rates and, pending regulatory approval, we have the option to leverage inVentiv's significant commercialization capabilities.

We are included in the Russell Microcap Index, which is widely used by investment managers and institutional investors for index funds and as benchmarks for active investment strategies.

**Results of Operations**

**Fiscal Year 2014 Compared to Fiscal Year 2013**

*Revenue*

During our second fiscal quarter ended April 30, 2014, we transitioned from a development stage company to an operating company. On March 19, 2014, we and Aratana entered into a definitive agreement (known as the "Aratana Agreement") pursuant to which we granted Aratana an exclusive, worldwide, royalty-bearing, license, with the right to sublicense, certain, Advaxis proprietary technology that enables Aratana to develop and commercialize animal health products that will be targeted for treatment of osteosarcoma and other cancer indications in animals. Under the terms of the Aratana Agreement, Aratana paid us an upfront payment of \$1 million. As this license has stand-alone value to Aratana (who has the ability to sublicense) and was delivered to Aratana upon execution of the Aratana Agreement, we properly recorded the \$1 million payment as licensing revenue for the year ended October 31, 2014.

We recorded no revenue for the year ended October 31, 2013.

*Research and Development Expenses*

We make significant investments in research and development in support of our development programs both clinically and pre-clinically. Research and development costs are expensed as incurred and primarily include salary and benefit costs, third-party grants, fees paid to clinical research organizations, and supply costs. Research and development expense was \$8.7 million for the year ended October 31, 2014, compared with \$5.6 million for the year ended October 31, 2013, an increase of \$3.1 million. The increase was primarily a result of higher third-party costs, specifically related to ADXS-HPV cervical cancer program and ADXS-HER2 preclinical support.

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

#### *General and Administrative Expenses*

General and administrative expenses primarily include salary and benefit costs for employees included in our finance, legal and administrative organizations, outside legal and professional services, and facilities costs. General and administrative expense was \$11.9 million for the year ended October 31, 2014, compared with \$9.1 million for the year ended October 31, 2013, an increase of \$2.8 million. The increase was primarily a result of higher stock compensation costs from Common Stock that was issued after the number of authorized shares under the 2011 Omnibus Incentive Plan was increased from 520,000 to 2,120,000, and non-cash investor relations costs.

#### *Interest Expense*

Interest expense was \$5,253 for the year ended October 31, 2014, compared with \$987,746 for the year ended October 31, 2013. The decrease was a result of the significant reduction in overall debt from approximately \$3.6 million in outstanding principal at October 31, 2013 to \$62,882 in outstanding principal at October 31, 2014. In addition, we recorded \$157,150 in non-cash interest expense, in the prior period, related to the issuance of 3.5 million shares of Common Stock under the Hanover Purchase Agreement.

#### *Other Expense/Income*

Other income was \$36,305 for the year ended October 31, 2014, compared to other expense of \$70,876 for the year ended October 31, 2013. Interest income earned for the year ended October 31, 2014 reflected interest income earned on our savings account balance. Interest income earned for the year ended October 31, 2013 reflected the result of approximately \$5,400 in interest income from payments made to us under the terms of a convertible promissory note,

more than offset by expense of approximately \$76,300 related to unfavorable changes in foreign exchange rates relating to transactions with certain vendors.



*Gain on Note Retirement, Warrant Exchanges and Accounts Payable*

Non-cash income for gain on note retirement and accounts payable was \$6,243 for the year ended October 31, 2014, compared to non-cash charges of \$3.5 million for the year ended October 31, 2013. Non-cash income earned for the year ended October 31, 2014 primarily resulted from the settlement of outstanding payables with shares of our Common Stock at a discount. Non-cash charges for the year ended October 31, 2013 primarily resulted from the conversion of approximately \$3.95 million aggregate principal value of various convertible promissory notes into shares of our Common Stock by investors.

*Changes in Fair Values*

Change in fair value was non-cash income of \$619,089 for the year ended October 31, 2014, compared with non-cash expense of \$1.5 million for the year ended October 31, 2013. The non-cash income from changes in the fair value of the warrant liability recorded for the year ended October 31, 2014 were a result of a decrease in the fair value of each liability warrant due to a decrease in our share price from \$3.74 at October 31, 2013 to \$3.18 at October 31, 2014 in addition to a lower volatility of our stock price used in the Black-Scholes Model (“BSM”). Changes in the fair value of the warrant liability recorded for the year ended October 31, 2013 were a result of non-cash expense of approximately \$0.2 million from the mark-to-market of our convertible promissory notes, accounted for under fair value accounting. In addition, we recorded non-cash expense of approximately \$1.3 million resulting from the number of outstanding liability warrants increasing during the prior period in addition to a larger range of share prices used in the calculation of the BSM volatility input.

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

*Income Tax Benefit*

We may be eligible, from time to time, to receive cash from the sale of our Net Operating Losses (“NOLs”) under the State of New Jersey NOL Transfer Program. In the year ended October 31, 2014, we received a net cash amount of \$625,563 from the sale of its state NOLs and research and development tax credits for the periods ended October 31, 2010 and 2011. In December 2014, we received a net cash amount of \$1,731,317 from the sale of our state NOLs and research and development tax credits for the years ended October 31, 2012 and 2013.

In the year ended October 31, 2013, we received a net cash amount of \$725,190 from the sale of our state NOLs and research and development tax credits for the periods through October 31, 2010.

## Liquidity and Capital Resources

Since our inception through October 31, 2014, we reported accumulated net losses of \$87.0 million and recurring negative cash flows from operations. We anticipate that we will continue to generate significant losses from operations for the foreseeable future.

Cash used in operating activities for the year ended October 31, 2014 was \$17.0 million (including proceeds from the sale of our state NOLs and R&D tax credits of approximately \$0.6 million) primarily from spending associated with our clinical trial programs and general & administrative spending. Total spending approximated \$13.9 million, including one-time non-recurring costs associated with our October 2013 financing, March 2014 financing, certain compensation costs and the settlement of legal claims.

Cash used in investing activities, for the year ended October 31, 2014, was \$439,675 resulting from legal cost spending in support of our intangible assets (patents) and costs paid to Penn for patents.

Cash provided by financing activities, for the year ended October 31, 2014, was \$14.5 million, primarily resulting from the public offering of 4,692,000 shares of Common Stock at \$3.00 per share, resulting in net proceeds of \$12.6 million. In addition, we sold 306,122 shares of Common Stock to Aratana at a price of \$4.90 per share, resulting in net proceeds of \$1.5 million. We also issued GBP 108,724 shares of Common Stock pursuant to a Stock Purchase Agreement with GBP, resulting in net proceeds of \$0.4 million.

For the year ended October 31, 2013, we issued to certain accredited investors (including JMJ Financial) convertible promissory notes in the aggregate principal amount of \$2,991,776 for an aggregate net purchase price of \$2,963,400. These convertible promissory notes were issued with either original issue discounts ranging from 15% to 25% or are interest-bearing and are convertible into shares of our Common Stock. Some of these convertible promissory notes were issued along with warrants. Most of the convertible promissory notes have subsequently converted into Common Stock. In addition, during the year ended October 31, 2013, Mr. Moore loaned us \$11,200 under the Moore Notes. We repaid Mr. Moore \$85,700 under the Moore Notes.

During the year ended October 31, 2013, we issued 17,657 shares of our Common Stock, to accredited investors, at a price per share of \$4.375, resulting in total net proceeds of \$77,250. In addition, we issued approximately 45,300 shares of its Common Stock in the third fiscal quarter of 2014, resulting in net proceeds of \$100,000.

During the year ended October 31, 2013, we issued 359,224 shares of our Common Stock to Hanover in connection with the settlement of drawdowns pursuant to the Hanover Purchase Agreement, at prices ranging from approximately \$2.81 to \$7.48 per share. The per share price for such shares was established under the terms of the Hanover Purchase Agreement. We received total net proceeds of approximately \$2,964,140 in connection with these drawdowns.

Our limited capital resources and operations to date have been funded primarily with the proceeds from public and private equity, debt financings, NOL tax sales and income earned on investments and grants. We have sustained losses from operations in each fiscal year since our inception, and we expect losses to continue for the indefinite future, due to the substantial investment in research and development. As of October 31, 2014 and October 31, 2013, we had an accumulated deficit of \$86,991,137 and \$70,465,823, respectively and shareholders' equity of \$20,629,986 and \$18,002,142, respectively.

In December 2014, we completed a registered direct offering, resulting in total proceeds, before expenses, of \$16.7 million.

We believe our current cash position is sufficient to fund our business plan through July 31, 2016. This assessment is based on current estimates and assumptions regarding our clinical development program and business needs. Actual results could differ materially from this projection. Subsequent to October 31, 2014, we may plan to continue to raise additional funds through the sales of debt and/or equity securities as needed.

We recognize it will need to raise additional capital over and above the amounts raised during the October 2013, March 2014 and December 2014 offerings in order to continue to execute its business plan. There is no assurance that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to us or whether we will become profitable and generate positive operating cash flow. If we are unable to raise sufficient additional funds, it will have to scale back its business plan, extend payables and reduce overhead until sufficient additional capital is raised to support further operations. There can be no assurance that such a plan will be successful.

### **Off-Balance Sheet Arrangements**

As of October 31, 2014, we had no off-balance sheet arrangements.

### **Critical Accounting Estimates**

The preparation of financial statements in accordance with U.S. Generally Accepted Accounting Principles ("GAAP") involves the use of estimates and assumptions that affect the recorded amounts of assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results may differ substantially from these estimates. Significant estimates include the fair value and recoverability of the carrying value of intangible assets (patents and licenses), the fair value of options, the fair value of embedded

conversion features, warrants and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates, based on historical experience and on various other assumptions that it believes to be reasonable under the circumstances. Actual results may differ from estimates. The most significant estimates impact the following transactions or account balances: stock compensation, warrant valuation and dilution caused by anti-dilution provisions in the warrants and other agreements.

### *Revenue Recognition*

The Company derived the majority of its revenue in 2014 from patent licensing. In general, these revenue arrangements provide for the payment of contractually determined fees in consideration for the grant of certain intellectual property rights for patented technologies owned or controlled by the Company. The intellectual property rights granted may be perpetual in nature, or upon the final milestones being met, or can be granted for a defined, relatively short period of time, with the licensee possessing the right to renew the agreement at the end of each contractual term for an additional minimum upfront payment. The Company recognizes licensing fees when there is persuasive evidence of a licensing arrangement, fees are fixed or determinable, delivery has occurred and collectability is reasonably assured.

An allowance for doubtful accounts is established based on the Company's best estimate of the amount of probable credit losses in the Company's existing license fee receivables, using historical experience. The Company reviews its allowance for doubtful accounts periodically. Past due accounts are reviewed individually for collectability.

Account balances are charged off against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. To date, this is yet to occur.

If product development is successful, the Company will recognize revenue from royalties based on licensees' sales of its products or products using its technologies. Royalties are recognized as earned in accordance with the contract terms when royalties from licensees can be reasonably estimated and collectability is reasonably assured. If royalties cannot be reasonably estimated or collectability of a royalty amount is not reasonably assured, royalties are recognized as revenue when the cash is received.

The Company recognizes revenue from milestone payments received under collaboration agreements when earned, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, the Company has no further performance obligations relating to the event and collection is reasonably assured. If these criteria are not met, the Company recognizes milestone payments ratably over the remaining period of the Company's performance obligations under the collaboration agreement. All such recognized revenues are included in collaborative licensing and development revenue in the Company's consolidated statements of operations.

*Stock Based Compensation*

The Company has an equity plan which allows for the granting of stock options to its employees, directors and consultants for a fixed number of shares with an exercise price equal to the fair value of the shares at date of grant. The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. For employees and directors, the fair value of the award is measured on the grant date and for non-employees, the fair value of the award is generally measured based on contractual terms. The fair value amount is then recognized over the requisite service period, usually the vesting period, in both research and development expenses and general and administrative expenses on the statement of operations.

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

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

#### *Fair Value of Financial Instruments*

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

#### *Derivative Financial instruments*

We do not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. We evaluate all of our financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the statements of operations. The determination of fair value requires the use of judgment and estimates by management. For stock-based derivative financial instruments, we used the BSM which approximated the binomial lattice options pricing model to value the derivative instruments at inception and on subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the instrument could be required within 12 months of the balance sheet date. The variables used in the model are projected based on our historical data, experience, and other factors. Changes in any of these variables could result in material adjustments to the expense recognized for changes in the valuation of the warrant derivative liability.

### *Intangible Assets*

Intangible assets primarily consist of legal and filing costs associated with obtaining patents and licenses and are amortized on a straight-line basis over their remaining useful lives which are estimated to be twenty years from the effective dates of the University of Pennsylvania (Penn) License Agreements, beginning in July 1, 2002. These legal and filing costs are invoiced to the Company through Penn and its patent attorneys.

Management has reviewed its long-lived assets for impairment whenever events and circumstances indicate that the carrying value of an asset might not be recoverable and its carrying amount exceeds its fair value, which is based upon estimated undiscounted future cash flows. Net assets are recorded on the balance sheet for patents and licenses related to ADXS-HPV, ADXS-PSA and ADXS-HER2 and other products that are in development. However, if a competitor were to gain FDA approval for a treatment before us or if future clinical trials fail to meet the targeted endpoints, the Company would likely record an impairment related to these assets. In addition, if an application is rejected or fails to be issued, the Company would record an impairment of its estimated book value.

### *Income Taxes*

The Company uses the asset and liability method of accounting for income taxes in accordance with ASC Topic 740, "Income Taxes." Under this method, income tax expense is recognized for the amount of: (i) taxes payable or refundable for the current year and (ii) deferred tax consequences of temporary differences resulting from matters that have been recognized in an entity's financial statements or tax returns. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the results of operations in the period that includes the enactment date. A valuation allowance is provided to reduce the deferred tax assets reported if based on the weight of the available positive and negative evidence, it is more likely than not some portion or all of the deferred tax assets will not be realized.

ASC Topic 740-10-30 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. ASC Topic 740-10-40 provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. The Company will classify as income tax expense any interest and penalties. The Company has no material uncertain tax positions for any of the reporting periods presented. The Company files tax returns in U.S. federal and state jurisdictions, including New Jersey, and is subject to audit by tax authorities beginning with the year ended October 31, 2011.



## New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, *Revenue from Contracts with Customers*. Amendments in this ASU create Topic 606, Revenue from Contracts with Customers, and supersede the revenue recognition requirements in Topic 605, Revenue Recognition, including most industry-specific revenue recognition guidance throughout the Industry Topics of the Codification. In addition, the amendments supersede the cost guidance in Subtopic 605-35, Revenue Recognition—Construction-Type and Production-Type Contracts, and create new Subtopic 340-40, Other Assets and Deferred Costs—Contracts with Customers. In summary, the core principle of Topic 606 is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This ASU is the final version of Proposed ASU 2011-230—Revenue Recognition (Topic 605) and Proposed ASU 2011-250—Revenue Recognition (Topic 605): Codification Amendments, both of which have been deleted. The amendments in this ASU are effective for the Company for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. The Company is currently evaluating the effects of ASU 2014-09 on the consolidated financial statements.

In June 2014, the FASB issued ASU 2014-12, *Compensation - Stock Compensation*. The amendments in this ASU apply to reporting entities that grant their employees share-based payments in which the terms of the award provide that a performance target can be achieved after the requisite service period. This ASU is the final version of Proposed ASU EITF-13D--Compensation--Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period, which has been deleted. The amendments require that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. A reporting entity should apply existing guidance in Topic 718 as it relates to awards with performance conditions that affect vesting to account for such awards. As such, the performance target should not be reflected in estimating the grant-date fair value of the award. Compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. If the performance target becomes probable of being achieved before the end of the requisite service period, the remaining unrecognized compensation cost should amount of compensation cost recognized during and after the requisite service period should reflect the number of awards that are expected to vest and should be adjusted to reflect those awards that ultimately vest. The requisite service period ends when the employee can cease rendering service and still be eligible to vest in the award if the performance target is achieved. As indicated in the definition of vest, the stated vesting period (which includes the period in which the performance target could be achieved) may differ from the requisite service period. The amendments in this ASU are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015, and early adoption is permitted. The Company does not expect ASU 2014-12 to have a material impact on the consolidated financial statements.

## Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not Required.

**Item 8: Financial Statements and Supplementary Data.**

The index to Financial Statements appears on the page immediately prior to page F-1, the Report of the Independent Registered Public Accounting Firms appears on page F-1, and the Financial Statements and Notes to Financial Statements appear on pages F-2 to F-29.

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

Not applicable.

**Item 9A: Controls and Procedures.**

As of the end of the period covered by this report, we conducted an evaluation, under the supervision and with the participation of our chief executive officer and chief financial officer of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act). Based upon this evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is: (1) accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure; and (2) recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. In conjunction with this evaluation, we initiated the development of control design documents and are currently reviewing the recommendations and will implement change as appropriate.

**Changes in Internal Control Over Financial Reporting**

In March 2014, our previous Chief Financial Officer left the Company and a new Chief Financial Officer was appointed. During the quarter ended October 31, 2014, there were no changes in our internal control over financial reporting that have materially affected, nor were there any other significant changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting during the reporting period.

### **Assessment of the Effectiveness of Internal Controls over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) under the Exchange Act. Our management assessed the effectiveness of our internal control over financial reporting as of October 31, 2014 on criteria for effective internal control over financial reporting described in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO - 1992). Based on this evaluation, management has determined that as of October 31, 2014, there were no material weaknesses in our internal control over financial reporting and that our internal control over financial reporting was effective.

### **Attestation Report of our Registered Public Accounting Firm**

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting because we are a “smaller reporting company.” Our management’s report was not subject to attestation by our independent registered public accounting firm pursuant to rules of the SEC that permit us to provide only management’s report in this annual report.

### **Item 9B: Other Information.**

None

## **PART III**

### **Item 10: Directors, Executive Officers and Corporate Governance.**

The information required under this item will be set forth in the Company’s Form 10-K/A or proxy statement to be filed with the Securities and Exchange Commission on or before March 2, 2015 and is incorporated herein by reference.

### **Item 11: Executive Compensation.**

The information required under this item will be set forth in the Company's Form 10-K/A or proxy statement to be filed with the Securities and Exchange Commission on or before March 2, 2015 and is incorporated herein by reference.

**Item 12: Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters.**

The information required under this item will be set forth in the Company's Form 10-K/A or proxy statement to be filed with the Securities and Exchange Commission on or before March 2, 2015 and is incorporated herein by reference.

**Item 13: Certain Relationships and Related Transactions, and Director Independence.**

The information required under this item will be set forth in the Company's Form 10-K/A or proxy statement to be filed with the Securities and Exchange Commission on or before March 2, 2015 and is incorporated herein by reference.

**Item 14: Principal Accountant Fees and Services.**

The information required under this item will be set forth in the Company's Form 10-K/A or proxy statement to be filed with the Securities and Exchange Commission on or before March 2, 2015 and is incorporated herein by reference.

**PART IV**

**Item 15: Exhibits and Financial Statements Schedules.**

See Index of Exhibits below. The Exhibits are filed with or incorporated by reference in this report.

**(a) Exhibits.** The following exhibits are included herein or incorporated herein by reference.

| <b>Exhibit Number</b> | <b>Description of Exhibits</b>   |
|-----------------------|--|
| 1.1                   | Underwriting Agreement, dated March 26, 2014, by and between Aegis Capital Group and Advaxis, Inc. Incorporated by reference to Exhibit 1.1 to Current Report on Form 8-K filed with the SEC on April 1, 2014.   |
| 2.1                   | Agreement Plan and Merger of Advaxis, Inc. (a Colorado corporation) and Advaxis, Inc. (a Delaware corporation). Incorporated by reference to Annex B to DEF 14A Proxy Statement filed with the SEC on May 15, 2006.  |
| 3.1                   | Amended and Restated Certificate of Incorporation. Incorporated by reference to Annex C to DEF 14A Proxy Statement filed with the SEC on May 15, 2006.   |
| 3.2                   | Certificate of Designations of Preferences, Rights and Limitations of Series A Preferred Stock of the registrant, dated September 24, 2009. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on September 25, 2009.                 |
| 3.3                   | Certificate of Designations of Preferences, Rights and Limitations of Series B Preferred Stock of the registrant, dated July 19, 2010. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on July 20, 2010.                           |
| 3.4                   | Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on August 16, 2012. Incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the SEC on August 17, 2012.                   |
| 3.5                   | Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on July 11, 2013 (reverse stock split). Incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the SEC on July 15, 2013. |
| 3.6                   | Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on July 12, 2013 (authorized share capital decrease). Incorporated by reference to  |

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Exhibit 3.2 to Current Report on Form 8-K filed with the SEC on July 15, 2013.

- 3.7 Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on July 9, 2014. Incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the SEC on July 10, 2014.
- 3.8 Amended and Restated Bylaws. Incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-QSB filed with the SEC on September 13, 2006.
- 4.1 Form of Common Stock certificate. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on October 23, 2007.
- 4.2 Form of Amended and Restated Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K/A filed with the SEC on February 11, 2010.
- 4.3 Form of Common Stock Purchase Warrant, issued in the junior bridge financing. Incorporated by reference to Exhibit 4.12 to Registration Statement on Form S-1 (File No. 333-162632) filed with the SEC on October 22, 2009.
- 4.4 Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on June 19, 2009.
- 4.5 Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.3 to Current Report on Form 8-K/A filed with the SEC on February 11, 2010.
- 4.6 Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K filed with the SEC on November 12, 2010.

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| Exhibit Number | Description of Exhibits  |
|----------------|--|
| 4.7            | Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K filed with the SEC on May 9, 2011.   |
| 4.8            | Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on August 31, 2011.   |
| 4.9            | Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K filed with the SEC on November 2, 2011.  |
| 4.10           | Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K filed with the SEC on January 5, 2012.   |
| 4.11           | Form of Common Stock Purchase Warrant issued pursuant to the Exchange Agreements, dated as of May 14, 2012, by and between Advaxis, Inc. and each investor identified on the signature pages thereto. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on May 18, 2012.     |
| 4.12           | Form of Common Stock Purchase Warrant issued pursuant to the note purchase agreement, dated as of May 14, 2012, by and between Advaxis, Inc. and each investor identified on the signature pages thereto. Incorporated by reference to Exhibit 4.3 to Current Report on Form 8-K filed with the SEC on May 18, 2012. |
| 4.13           | Form of Common Stock Purchase Warrant issued to Dr. James Patton. Incorporated by reference to Exhibit 4.23 to Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-183682) filed with the SEC on September 11, 2012.   |
| 4.14           | Form of Secured Promissory Note issued pursuant to the Securities Purchase Agreement, dated as of December 13, 2012, by and between Advaxis, Inc. and Tonaquint, Inc. Incorporated by reference to Exhibit 4.1 to Quarterly Report on Form 10-Q filed with the SEC on March 25, 2013.                                |
| 4.15           | Form of Warrant to Purchase Shares of Common Stock issued pursuant to the Securities Purchase Agreement, dated as of December 13, 2012, by and between Advaxis, Inc. and Tonaquint, Inc. Incorporated by reference to Exhibit 4.2 to Quarterly Report on Form 10-Q filed with the SEC on March 25, 2013.             |
| 4.16           | Form of Warrant Agency Agreement by and between Advaxis, Inc. and Securities Transfer Corporation and Form of Warrant Certificate. Incorporated by reference to Exhibit 4.18 to Registration Statement on Form S-1/A (File No. 333-188637) filed with the SEC on September 27, 2013.                                 |
| 4.17           | Form of Representative's Warrant. Incorporated by reference to Exhibit 4.19 to Registration Statement on Form S-1/A (File No. 333-188637) filed with the SEC on September 27, 2013.  |
| 4.18           | Form of Warrant to Purchase 30,154 Shares of Common Stock issued September 17, 2013 pursuant to an engagement letter termination agreement. Incorporated by reference to Exhibit 4.20 to Registration Statement on Form S-1/A (File No. 333-188637) filed with the SEC on September 27, 2013.                        |

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- 4.19 Form of Warrant Agency Agreement between Advaxis, Inc. and Securities Transfer Corporation dated October 22, 2013 and Form of Warrant Certificate. Incorporated by reference to Exhibits 10.1 and 10.2 to Current Report on Form 8-K filed with the SEC on October 22, 2013.
- 4.20 Common Stock purchase warrant, dated as of March 19, 2014, by and between Advaxis, Inc. and Aratana Therapeutics, Inc. Incorporated by reference to Exhibit 4.1 to Quarterly Report on Form 10-Q filed with the SEC on June 10, 2014.
- 4.21 Form of Representative's Warrant related to the Underwriting Agreement, dated as of March 31, 2014, by and between Advaxis, Inc. and Aegis Capital Group. Incorporated by reference to Exhibit 4.2 to Quarterly Report on Form 10-Q filed with the SEC on June 10, 2014.



| Exhibit Number | Description of Exhibits  |
|----------------|--|
| 10.1           | 2004 Stock Option Plan of the registrant. Incorporated by reference to Exhibit 4.1 to Report on Form S-8 filed with the SEC on December 1, 2005.   |
| 10.2           | 2005 Stock Option Plan of the registrant. Incorporated by reference to Annex A to DEF 14A Proxy Statement filed with the SEC on May 15, 2006.  |
| 10.3           | License Agreement, between the Trustees of the University of Pennsylvania and the registrant dated as of June 17, 2002, as Amended and Restated on February 13, 2007. Incorporated by reference to Exhibit 10.11 to Annual Report on Form 10-KSB filed with the SEC on February 13, 2007.  |
| 10.4           | Sponsored Research Agreement dated November 1, 2006 by and between the Trustees of the University of Pennsylvania (Dr. Paterson Principal Investigator) and the registrant. Incorporated by reference to Exhibit 10.44 to Annual Report on 10-KSB filed with the SEC on February 13, 2007. |
| 10.5           | Agreement, dated July 7, 2003, by and between Cobra Biomanufacturing PLC and Advaxis, Inc. Incorporated by reference to Exhibit 10.16 to Pre-Effective Amendment No. 4 filed on June 9, 2005 to Registration Statement on Form SB-2 (File No. 333-122504).                                 |
| 10.6           | Employment Agreement, dated March 1, 2005, by and between John Rothman and the registrant. Incorporated by reference to Exhibit 10.25 to Pre-Effective Amendment No. 2 filed on April 8, 2005 to Registration Statement on Form SB-2/A (File No. 333-122504).                              |
| 10.7           | Royalty Agreement, dated as of May 11, 2003, by and between Cobra Bio-Manufacturing PLC and the registrant. Incorporated by reference to Exhibit 10.28 to Pre-Effective Amendment No. 4 filed on June 9, 2005 to Registration Statement on Form SB-2 (File No. 333-122504).                |
| 10.8           | Employment Agreement dated August 21, 2007 between the registrant and Thomas Moore. Incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed with the SEC on August 27, 2007.   |
| 10.9           | Note purchase agreement, dated September 22, 2008 by and between Thomas A. Moore and the registrant. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on September 30, 2008.   |
| 10.10          | Technical/Quality Agreement dated May 6, 2008 by and between Vibalogics GmbH and the registrant. Incorporated by reference to Exhibit 10.57 to Annual Report on Form 10-KSB filed with the SEC on January 29, 2009.  |
| 10.11          | Master Service Agreement dated April 7, 2008 by and between Vibalogics GmbH and the registrant. Incorporated by reference to Exhibit 10.58 to Annual Report on Form 10-KSB filed with the SEC on January 29, 2009.   |
| 10.12          | Form of Senior Promissory Note as amended, between the registrant and Thomas Moore. Incorporated by reference to Exhibit 4.3 to Current Report on Form 8-K filed with the SEC on June 19, 2009.  |
| 10.13          |  |

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Form of Amended and Restated Senior Promissory Note, between the registrant and Thomas Moore. Incorporated by reference to Exhibit 4.17 to Annual Report on Form 10-K filed with the SEC on February 19, 2010.

10.14 Amended and Restated 2009 Stock Option Plan of the registrant. Incorporated by reference to Annex A to DEF 14A Proxy Statement filed with the SEC on April 30, 2010.

10.15 Second Amendment to the Amended and Restated Patent License Agreement between the registrant and the Trustees of the University of Pennsylvania dated as of May 10, 2010. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on June 3, 2010.

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| Exhibit Number | Description of Exhibits  |
|----------------|--|
| 10.16          | Series B Preferred Stock Purchase Agreement dated July 19, 2010 by and between Optimus Capital Partners, LLC and the registrant. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on July 20, 2010.  |
| 10.17          | Form of Amended and Restated Promissory Note between Optimus CG II Ltd. and the registrant. Incorporated by reference to Exhibit G to the Purchase Agreement included as Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on July 20, 2010.   |
| 10.18          | Form of Security Agreement between Optimus CG II Ltd. and the registrant. Incorporated by reference to Exhibit H to the Purchase Agreement included as Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on July 20, 2010.   |
| 10.19          | Amended and Restated Senior Promissory Note, dated March 17, 2011, between the registrant and Thomas A. Moore. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on March 17, 2011.  |
| 10.20          | Amendment No. 1 to Series B Preferred Stock Purchase Agreement dated April 4, 2011 by and between Optimus Life Sciences Capital Partners, LLC, Optimus CG II Ltd. and the registrant. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on April 7, 2011. |
| 10.21          | Form of Promissory Note between Optimus CG II Ltd. and the registrant. Incorporated by reference to Appendix 2 to the Warrant included as Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on April 7, 2011.   |
| 10.22          | Amended and Restated Security Agreement between Optimus CG II Ltd. and the registrant. Incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the SEC on April 7, 2011.  |
| 10.23          | Form of note purchase agreement, dated as of May 9, 2011, by and between Advaxis, Inc. and each investor identified on the signature pages thereto. Incorporated by reference to Exhibit 10.1 to Amendment to Current Report on Form 8-K/A filed with the SEC on May 12, 2011.                     |
| 10.24          | 2011 Omnibus Incentive Plan of registrant. Incorporated by reference to Annex A to DEF 14A Proxy Statement filed with the SEC on August 29, 2011.  |
| 10.25          | 2011 Employee Stock Purchase Plan. Incorporated by reference to Annex B to DEF 14A Proxy Statement filed with the SEC on August 29, 2011.  |
| 10.26          | Exchange and Amendment Agreement, dated as of August 29, 2011, by and between Advaxis, Inc. and Thomas A. Moore. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on August 31, 2011.  |
| 10.27          | Form of Convertible Promissory Note. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on November 2, 2011.  |
| 10.28          |  |

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Form of note purchase agreement, dated as of October 28, 2011, by and between Advaxis, Inc. and each investor identified on the signature pages thereto. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on November 2, 2011.

| Exhibit Number | Description of Exhibits  |
|----------------|--|
| 10.29          | Form of Registration Rights Agreement, dated as of October 28, 2011, by and between Advaxis, Inc. and each of the several investors signatory thereto. Incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the SEC on November 2, 2011.   |
| 10.30          | Amendment No. 1 to the Advaxis, Inc. 2011 Employee Stock Purchase Plan. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on December 20, 2011.   |
| 10.31          | Form of Convertible Promissory Note. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on January 5, 2012.   |
| 10.32          | Form of note purchase agreement, dated as of December 29, 2011, by and between Advaxis, Inc. and each investor identified on the signature pages thereto. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on January 5, 2012.   |
| 10.33          | Form of Registration Rights Agreement, by and between Advaxis, Inc. and each of the several investors signatory thereto. Incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the SEC on January 5, 2012.  |
| 10.34          | Form of Exchange Agreement, dated as of May 14, 2012, by and between Advaxis, Inc. and each investor identified on the signature pages thereto. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on May 18, 2012.  |
| 10.35          | Form of Amendment, Consent and Waiver Agreement, dated as of May 14, 2012, by and between Advaxis, Inc. and each investor identified on the signature pages thereto. Incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the SEC on May 18, 2012.                                   |
| 10.36          | Form of Convertible Promissory Note issued pursuant to the note purchase agreement, dated as of May 14, 2012, by and between Advaxis, Inc. and each investor identified on the signature pages thereto. Incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K filed with the SEC on May 18, 2012. |
| 10.37          | Form of note purchase agreement, dated as of May 14, 2012, by and between Advaxis, Inc. and each investor identified on the signature pages thereto. Incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed with the SEC on May 18, 2012.   |
| 10.38          | Form of Registration Rights Agreement, dated as of May 14, 2012, by and between Advaxis, Inc. and each investor identified on the signature pages thereto. Incorporated by reference to Exhibit 10.4 to Current Report on Form 8-K filed with the SEC on May 18, 2012.   |
| 10.39          | Stock Purchase Agreement, dated as of June 13, 2012, by and between Advaxis, Inc. and Numoda Corporation. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on June 14, 2012.   |
| 10.40          | Amendment No. 1, dated as of March 26, 2007, to the License Agreement, between the Trustees of the University of Pennsylvania and Advaxis, Inc. dated as of June 17, 2002, as amended and restated on  |

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February 13, 2007. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on June 14, 2012.

10.41 Master Agreement, dated June 19, 2009, by and between Numoda Corporation and Advaxis, Inc. Incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed with the SEC on June 14, 2012.

10.42 Form of Project Agreement by and between Numoda Corporation and Advaxis, Inc. Incorporated by reference to Exhibit 10.3 to Quarterly Report on Form 10-Q filed with the SEC on June 14, 2012.

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| Exhibit Number | Description of Exhibits   |
|----------------|---|
| 10.43          | Clinical Trial Services Agreement, dated December 13, 2009, by and between the Gynecologic Oncology Group and Advaxis, Inc. Incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-Q filed with the SEC on June 14, 2012.   |
| 10.44          | Amendment No. 3, dated as of December 12, 2011, to the License Agreement, between the Trustees of the University of Pennsylvania and Advaxis, Inc. dated as of June 17, 2002, as amended and restated on February 13, 2007. Incorporated by reference to Exhibit 10.5 to Quarterly Report on Form 10-Q filed with the SEC on June 14, 2012. |
| 10.45          | Exchange Agreement, dated as of July 5, 2012, by and between Advaxis, Inc. and Thomas A. Moore. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on July 11, 2012.  |
| 10.48          | Amendment No. 1 to 2011 Omnibus Incentive Plan of registrant. Incorporated by reference to Annex B to DEF 14A Proxy Statement filed with the SEC on July 19, 2012.  |
| 10.49          | Promissory Note issued to JLSI, LLC on July 21, 2012. Incorporated by reference to Exhibit 10.111 to Registration Statement on Form S-1 (File No. 333-183682) filed with the SEC on August 31, 2012.  |
| 10.50          | Form of Convertible Promissory Note issued to Dr. James Patton. Incorporated by reference to Exhibit 10.112 to Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-183682) filed with the SEC on September 11, 2012.  |
| 10.51          | Form of Convertible Promissory Note issued to JMJ Financial on August 27, 2012. Incorporated by reference to Exhibit 10.113 to Registration Statement on Form S-1 (File No. 333-183682) filed with the SEC on August 31, 2012.  |
| 10.52          | Form of note purchase agreement by and between Advaxis, Inc. and Dr. James Patton. Incorporated by reference to Exhibit 10.114 to Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-183682) filed with the SEC on September 11, 2012.   |
| 10.53          | Common Stock Purchase Agreement by and between Advaxis, Inc. and Hanover Holdings I, LLC, dated as of October 26, 2012. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on October 31, 2012.   |
| 10.54          | Registration Rights Agreement by and between Advaxis, Inc. and Hanover Holdings I, LLC, dated as of October 26, 2012. Incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the SEC on October 31, 2012.   |
| 10.55          | Order for Approval of Stipulation for Settlement of Claims entered by the Superior Court of the State of California for the County of Los Angeles – Central District, dated December 20, 2012. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on December 28, 2012.                             |
| 10.56          | Stipulation for Settlement of Claims between Ironridge Global IV, Ltd. and Advaxis, Inc., dated December 19, 2012. Incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with   |

the SEC on December 28, 2012.



| <b>Exhibit<br/>Number</b> | <b>Description of Exhibits</b>  |
|---------------------------|---|
| 10.57                     | Form of Securities Purchase Agreement, dated as of December 13, 2012, by and between Advaxis, Inc. and Tonaquint, Inc. Incorporated by reference to Exhibit 10.3 to Quarterly Report on Form 10-Q filed with the SEC on March 25, 2013. |
| 10.58                     | Form of Security Agreement, dated as of December 13, 2012, by Advaxis, Inc. in favor of Tonaquint, Inc. Incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-Q filed with the SEC on March 25, 2013.                |
| 10.59                     | Separation Agreement and General Release dated March 20, 2013 between Advaxis, Inc. and John Rothman. Incorporated by reference to Exhibit 10.5 to Quarterly Report on Form 10-Q filed with the SEC on March 25, 2013.                  |
| 10.60                     | Convertible Promissory Note issued to JMJ Financial on April 26, 2013. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on May 8, 2013.   |
| 10.61                     | Securities Purchase Agreement dated June 21, 2013 between Advaxis, Inc. and Redwood Management, LLC. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on June 27, 2013.                       |
| 10.62                     | 5% Convertible Debenture dated June 21, 2013 issued to Redwood Management, LLC. Incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the SEC on June 27, 2013.  |
| 10.63                     | Consulting Agreement by and between Advaxis, Inc. and Thomas A. Moore, dated August 19, 2013. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on August 20, 2013.                            |
| 10.64                     | Employment Agreement by and between Advaxis, Inc. and Daniel J. O'Connor, dated August 19, 2013. Incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the SEC on August 20, 2013.                         |
| 10.65                     | Form of Indemnification Agreement. Incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed with the SEC on August 20, 2013  |
| 10.66                     | Employment Agreement by and between Advaxis, Inc. and Mark J. Rosenblum, dated September 4, 2013. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on September 10, 2013.                     |
| 10.67                     | Securities Purchase Agreement dated September 4, 2013. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on September 10, 2013.  |
| 10.68                     | Convertible Promissory Note dated September 4, 2013. Incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the SEC on September 10, 2013.  |
| 10.69                     |   |

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Amendment No. 1 dated September 4, 2013 to Convertible Promissory Note dated April 26, 2013. Incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed with the SEC on September 10, 2013.

10.70 Employment Agreement between Advaxis, Inc. and Robert Petit, dated September 26, 2013. Incorporated by reference to Exhibit 10.70 to Registration Statement on Form S-1/A (File No. 333-188637) filed with the SEC on September 27, 2013.

10.71 Employment Agreement between Advaxis, Inc. and Chris French, dated September 26, 2013. Incorporated by reference to Exhibit 10.71 to Registration Statement on Form S-1/A (File No. 333-188637) filed with the SEC on September 27, 2013.

10.72 Debt Conversion Agreement between Advaxis, Inc. and Thomas A. Moore dated September 26, 2013. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on September 27, 2013.

| Exhibit Number | Description of Exhibits   |
|----------------|---|
| 10.73          | Form of Exchange Agreement between Advaxis, Inc. and Redwood Management, LLC dated September 27, 2013. Incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the SEC on September 27, 2013.                                |
| 10.74          | Notice of Settlement and Redemption Agreement dated September 26, 2013. Incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed with the SEC on September 27, 2013.   |
| 10.75          | Exchange and Settlement Agreement between Advaxis, Inc. and Iliad Research and Trading, LP, dated October 10, 2013. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on October 11, 2013.                     |
| 10.76          | Accelerated Conversion and Note Termination Agreement between Advaxis, Inc. and JMJ Financial, dated October 16, 2013. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on October 17, 2013.                  |
| 10.77‡         | Employment Agreement by and between Advaxis, Inc. and Gregory T. Mayes, III, dated October 25, 2013. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on October 29, 2013.                                    |
| 10.78‡         | Form of Restricted Stock Agreement between Advaxis, Inc. and Gregory T. Mayes, III, dated October 25, 2013. Incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the SEC on October 29, 2013.                             |
| 10.79          | Exclusive License and Technology Transfer Agreement by and between Advaxis, Inc. and Global BioPharma, Inc., dated December 9, 2013. Incorporated by reference to Exhibit 10.79 to Annual Report on Form 10-K/A filed with the SEC on February 6, 2014. |
| 10.80‡         | Amendment No. 1, dated as of December 19, 2013, to the Employment Agreement by and between Advaxis, Inc. and Daniel J. O'Connor. Incorporated by reference to Exhibit 10.82 to Annual Report on Form 10-K/A filed with the SEC on February 6, 2014.     |
| 10.81‡         | Amendment No. 1, dated as of December 19, 2013, to the Employment Agreement by and between Advaxis, Inc. and Gregory T. Mayes, III. Incorporated by reference to Exhibit 10.82 to Annual Report on Form 10-K/A filed with the SEC on February 6, 2014.  |
| 10.82‡         | Amendment No. 1, dated as of December 19, 2013, to the Employment Agreement by and between Advaxis, Inc. and Mark J. Rosenblum. Incorporated by reference to Exhibit 10.82 to Annual Report on Form 10-K/A filed with the SEC on February 6, 2014.      |
| 10.83‡         | Amendment No. 1, dated as of December 19, 2013, to the Employment Agreement by and between Advaxis, Inc. and Robert G. Petit. Incorporated by reference to Exhibit 10.82 to Annual Report on Form 10-K/A filed with the SEC on February 6, 2014.        |
| 10.84‡         | Amendment No. 1, dated as of December 19, 2013, to the Employment Agreement by and between Advaxis, Inc. and Chris L. French. Incorporated by reference to Exhibit 10.82 to Annual Report on Form   |

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10-K/A filed with the SEC on February 6, 2014.

- 10.85 Distribution and Supply Agreement, dated as of January 20, 2014, by and between Advaxis, Inc. and Biocon, Limited. Incorporated by reference to Exhibit 10.7 to Quarterly Report on Form 10-Q filed with the SEC on March 17, 2014.
- 10.86 Exclusive License Agreement, dated March 19, 2014, by and between Advaxis, Inc. and Aratana Therapeutics, Inc. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on June 10, 2014.
- 10.87‡ Employment Agreement, dated March 24, 2014, by and between Advaxis, Inc. and Sara M. Bonstein. Incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed with the SEC on June 10, 2014.
- 10.88‡ Separation Agreement and General Release, dated March 24, 2014, between Advaxis, Inc. and Mark J. Rosenblum. Incorporated by reference to Exhibit 10.3 to Quarterly Report on Form 10-Q filed with the SEC on June 10, 2014.
- 10.89‡ Amendment No. 2, dated as of June 5, 2014, to the Employment Agreement by and between Advaxis, Inc. and Daniel J. O'Connor. Incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-Q filed with the SEC on June 10, 2014.
- 10.90‡ Amendment No. 2, dated as of June 5, 2014, to the Employment Agreement by and between Advaxis, Inc. and Gregory T. Mayes. Incorporated by reference to Exhibit 10.5 to Quarterly Report on Form 10-Q filed with the SEC on June 10, 2014.
- 10.91‡ Amendment No. 2, dated as of June 5, 2014, to the Employment Agreement by and between Advaxis, Inc. and Robert G. Petit. Incorporated by reference to Exhibit 10.6 to Quarterly Report on Form 10-Q filed with the SEC on June 10, 2014.

| Exhibit Number | Description of Exhibits  |
|----------------|--|
| 10.92‡         | Amendment No. 2, dated as of June 5, 2014, to the Employment Agreement by and between Advaxis, Inc. and Chris L. French. Incorporated by reference to Exhibit 10.7 to Quarterly Report on Form 10-Q filed with the SEC on June 10, 2014.                                     |
| 10.93‡         | Amendment No. 1, dated as of June 5, 2014, to the Employment Agreement by and between Advaxis, Inc. and Sara M. Bonstein. Incorporated by reference to Exhibit 10.8 to Quarterly Report on Form 10-Q filed with the SEC on June 10, 2014.                                    |
| 10.94‡         | Employment Agreement, dated October 20, 2014, by and between Advaxis, Inc. and David J. Mauro. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on October 21, 2014  |
| 10.95‡         | Form of Restricted Stock Agreement between Advaxis, Inc. and David J. Mauro, dated October 20, 2014. Incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the SEC on October 21, 2014.   |
| 10.96          | Clinical Trial Collaboration Agreement, dated July 21, 2014, by and between Advaxis, Inc. and MedImmune, LLC. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on September 9, 2014.  |
| 10.97          | 5 <sup>th</sup> Amendment to the Amended & Restated License Agreement, dated July 25, 2014, by and between Advaxis, Inc. and University of Pennsylvania. Incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed with the SEC on September 9, 2014. |
| 10.98          | Amendment No. 2 to the Advaxis, Inc. 2011 Omnibus Incentive Plan, effective July 9, 2014. Incorporated by reference to Annex A to Current Report on Schedule 14A filed with the SEC on May 20, 2014.   |
| 10.99          | Amended and Restated 2011 Omnibus Incentive Plan, dated September 8, 2014. Incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-Q filed with the SEC on September 9, 2014.   |
| 10.100         | Master Services Agreement for Technical Transfer and Clinical Supply, dated February 5, 2014, by and between Advaxis, Inc. and SynCo Bio Partners B.V. Incorporated by reference to Exhibit 10.1 to Current Report to Form 8-K filed with the SEC on February 11, 2014.      |
| 10.101***      | Clinical Trial Collaboration and Supply Agreement by and between Advaxis, Inc. and Merck & Co. dated August 22, 2014.  |
| 10.102*        | Manufacturing Services Agreement by and between Advaxis, Inc. and IDT Biologika dated September 8, 2014.   |
| 10.103         | Clinical Trial Collaboration and Supply Agreement by and between Advaxis, Inc. and MedImmune, LLC dated August 22, 2014. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on September 9, 2014.                                 |

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14.1 Code of Business Conduct and Ethics dated November 12, 2004. Incorporated by reference to Exhibit 14.1 to Current Report on Form 8-K filed with the SEC on November 18, 2004.

14.2 Code of Business Conduct and Ethics dated July 9, 2014. Incorporated by reference to Exhibit 14.1 to Current Report on Form 8-K filed with the SEC on July 10, 2014.

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**Exhibit Number Description of Exhibits**

|           |  |
|-----------|--|
| 23.1*     | Consent of Marcum LLP  |
| 31.1*     | Certification of Chief Executive Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002 |
| 31.2*     | Certification of Chief Financial Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002 |
| 32.1*     | Certification of Chief Executive Officer pursuant to section 906 of the Sarbanes-Oxley Act of 2002 |
| 32.2*     | Certification of Chief Financial Officer pursuant to section 906 of the Sarbanes-Oxley Act of 2002 |
| 101.INS** | XBRL Instance Document   |
| 101.SCH** | XBRL Taxonomy Extension Schema Document  |
| 101.CAL** | XBRL Taxonomy Extension Calculation Linkbase Document  |
| 101.DEF** | XBRL Taxonomy Extension Definitions Linkbase Document  |
| 101.LAB** | XBRL Taxonomy Extension Label Linkbase Document  |
| 101.PRE** | XBRL Taxonomy Extension Presentation Linkbase Document   |

\* Filed herewith.

\*\* Furnished herewith.

Filed herewith. Confidential treatment requested under 17 C.F.R. §§200.80(b)(4) and Rule 24b-2. The confidential portions of this exhibit have been omitted and are marked accordingly. The confidential portions have been provided separately to the SEC pursuant to the confidential treatment request.

‡ Denotes management contract or compensatory plan or arrangement.

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized, in Princeton, Mercer County, State of New Jersey, on this 5<sup>th</sup> day of January 2015.

ADVAXIS, INC.

By: */s/ Daniel J. O'Connor*

Daniel J. O'Connor, Chief Executive Officer and Director

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Daniel J. O'Connor and Sara M. Bonstein (with full power to act alone), as his true and lawful attorneys-in-fact and agents, with full powers of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitute or substitutes, lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

| SIGNATURE   | Title  | DATE            |
|---|--|-----------------|
| <i>/s/ Daniel J. O'Connor</i><br>Daniel J. O'Connor | President, Chief Executive Officer and Director<br>(Principal Executive Officer)               | January 5, 2015 |
| <i>/s/ Sara Bonstein</i><br>Sara Bonstein           | Chief Financial Officer, Senior Vice President<br>(Principal Financial and Accounting Officer) | January 5, 2015 |
| <i>/s/ James Patton</i><br>James Patton             | Chairman of the Board  | January 5, 2015 |
| <i>/s/ Roni Appel</i><br>Roni Appel                 | Director   | January 5, 2015 |



*/s/ Richard Berman*

Richard Berman      Director

January 5, 2015

*/s/ Thomas McKearn*

Thomas McKearn      Director

January 5, 2015

*/s/ Samir Khleif*

Samir Khleif      Director

January 5, 2015

*/s/ David Sidransky*

David Sidransky      Director

January 5, 2015

**ADVAXIS, INC.**

**FINANCIAL STATEMENTS**

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Audit Committee of the  
Board of Directors and Shareholders of  
Advaxis, Inc.

We have audited the accompanying balance sheets of Advaxis, Inc. (the “Company”) as of October 31, 2014 and 2013, and the related statements of operations, shareholders’ equity and cash flows for the years then ended. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Advaxis, Inc., as of October 31, 2014 and 2013, in conformity with accounting principles generally accepted in the United States of America.

*/s/ Marcum LLP*

New York, NY  
January 5, 2015

**ADVAXIS, INC.****BALANCE SHEETS**

|   | October 31,<br>2014  | 2013                 |
|---|----------------------|----------------------|
| <b>ASSETS</b>   |                      |                      |
| Current Assets:   |                      |                      |
| Cash  | \$ 17,606,860        | \$ 20,552,062        |
| Prepaid Expenses  | 182,978              | 31,255               |
| Income Tax Receivable   | 1,731,317            | -                    |
| Other Current Assets  | 8,182                | 8,182                |
| Deferred Expenses - current   | 964,724              | 218,007              |
| Total Current Assets  | 20,494,061           | 20,809,506           |
| Deferred Expenses – long-term   | -                    | 129,041              |
| Property and Equipment (net of accumulated depreciation)  | 77,369               | 80,385               |
| Intangible Assets (net of accumulated amortization)   | 2,767,945            | 2,528,551            |
| Other Assets  | 38,438               | 38,438               |
| <b>TOTAL ASSETS</b>   | <b>\$ 23,377,813</b> | <b>\$ 23,585,921</b> |
| <b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>   |                      |                      |
| Current Liabilities:  |                      |                      |
| Accounts Payable  | \$ 1,411,058         | \$ 3,841,771         |
| Accrued Expenses  | 1,241,796            | 869,260              |
| Short-term Convertible Notes and Fair Value of Embedded Derivative  | 62,882               | 62,882               |
| Notes Payable – Officer (including interest payable)  | -                    | 163,132              |
| Total Current Liabilities   | 2,715,736            | 4,937,045            |
| Common Stock Warrant Liability  | 32,091               | 646,734              |
| Total Liabilities   | 2,747,827            | 5,583,779            |
| Commitments and Contingencies   |                      |                      |
| Shareholders' Equity:   |                      |                      |
| Preferred Stock, \$0.001 par value; 5,000,000 shares authorized; Series B Preferred Stock; issued and outstanding 0 at October 31, 2014 and 2013. Liquidation preference of \$0 at October 31, 2014 and 2013. | -                    | -                    |
| Common Stock - \$0.001 par value; authorized 45,000,000 shares, issued and outstanding 19,630,139 at October 31, 2014 and 13,719,861 at October 31, 2013.   | 19,630               | 13,720               |
| Additional Paid-In Capital  | 107,601,493          | 88,454,245           |
| Accumulated Deficit   | (86,991,137)         | (70,465,823)         |
| Total Shareholders' Equity  | 20,629,986           | 18,002,142           |
| <b>TOTAL LIABILITIES &amp; SHAREHOLDERS' EQUITY</b>   | <b>\$ 23,377,813</b> | <b>\$ 23,585,921</b> |

The accompanying notes should be read in conjunction with the financial statements.

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**ADVAXIS, INC.****Statements of Operations**

|   | Year Ended October 31, |                |
|---|------------------------|----------------|
|   | 2014                   | 2013           |
| Revenue   | \$1,000,000            | \$-            |
| Research and Development Expenses   | 8,687,168              | 5,621,989      |
| General and Administrative Expenses   | 11,851,410             | 9,071,613      |
| Total Operating expenses  | 20,538,578             | 14,693,602     |
| Loss from Operations  | (19,538,578)           | (14,693,602)   |
| Other Income (expense):   |                        |                |
| Interest Expense  | (5,253 )               | (987,746 )     |
| Other Income (Expense)  | 36,305                 | (70,876 )      |
| Gain (Loss) on Note Retirement  | 6,243                  | (3,455,327 )   |
| Gain (Loss) on Change in Fair Value of Common Stock Warrant Liability and Embedded Derivative Liability | 619,089                | (1,504,465 )   |
| Net Loss before Income tax Benefit  | (18,882,194)           | (20,712,016)   |
| Income Tax Benefit  | 2,356,880              | 725,190        |
| Net Loss  | (16,525,314)           | (19,986,826)   |
| Dividends Attributable to Preferred Shares  | -                      | 555,000        |
| Net Loss applicable to Common Stock   | \$(16,525,314)         | \$(20,541,826) |
| Net Loss per Common Share, Basic and Diluted  | \$(0.97 )              | \$(4.10 )      |
| <br>  |                        |                |
| Weighted average number of common shares outstanding, basic and diluted                                 | 17,106,577             | 5,012,105      |

The accompanying notes should be read in conjunction with the financial statements.

## ADVAXIS, INC.

## STATEMENTS OF SHAREHOLDERS' EQUITY

|  | Preferred Stock<br>Number of<br>Shares of<br>Outstanding | Amount | Common Stock<br>Number of<br>Shares of<br>outstanding | Amount  | Promissory<br>Note and<br>Interest<br>Receivable | Additional<br>Paid-in Capital | Accumulated<br>Deficit | Shareholders'<br>Equity |
|--|--|--------|---|---------|--|-------------------------------|------------------------|-------------------------|
| Balance at<br>October 31,<br>2012  | 740  | \$ -   | 3,158,419   | \$3,158 | \$(10,484,022)                                   | \$52,119,567                  | \$(47,601,427)         | \$(5,962,724 )          |
| Stock<br>compensation<br>to employees,<br>directors and<br>consultants                 |  |        |   |         |  | 2,855,183                     |                        | 2,855,183               |
| Issuance of<br>shares upon<br>conversion of<br>convertible<br>promissory<br>notes      |  |        | 1,285,706   | 1,286   |  | 5,763,660                     |                        | 5,764,946               |
| Fair value of<br>equity warrants<br>issued in<br>connection<br>with Rodman<br>May 2012 |  |        |   |         |  |                               |                        |                         |
| Financing<br>Common Stock<br>issued upon<br>exercise of<br>warrants                    |  |        | 493,675   | 494     |  | 2,308,006                     |                        | 2,308,500               |
| Common Stock<br>issued to<br>consultants   |  |        | 393,459   | 393     |  | 1,690,809                     |                        | 1,691,202               |
| Issuance of<br>shares to<br>employees<br>under ESPP<br>Plan                            |  |        | 6,334   | 6       |  | 28,034                        |                        | 28,040                  |
| Issuance of<br>shares to<br>investors under<br>stock purchase<br>agreements            |  |        | 36,888  | 37      |  | 127,214                       |                        | 127,251                 |

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|   |           |        |            |            |              |                |
|---|-----------|--------|------------|------------|--------------|----------------|
| Interest on Optimus Notes Receivable                                    |           |        | (149,562 ) | 149,562    |              | -              |
| Fractional shares cashed out  | (1,604 )  | (2 )   |            | 2          |              | -              |
| Issuance of shares under Hanover Equity Line                            | 387,224   | 387    |            | 3,120,902  |              | 3,121,290      |
| Issuance of shares under Ironridge Settlement                           | 267,117   | 267    |            | 934,643    |              | 934,910        |
| To record Beneficial Conversion Feature on convertible promissory notes |           |        |            | 118,190    |              | 118,190        |
| Notice of Redemption and Settlement Agreement with Optimus              | (740 )    | 33,750 | 34         | 10,633,584 | (7,756,048 ) | (2,877,570 ) - |
| Issuance of shares to Socius  | 4,981     | 5      |            | 24,902     |              | 24,907         |
| Brio Settlement   | 21,742    | 22     |            | 232,348    |              | 232,370        |
| Issuance of earned but not issued shares to former employees            | 70,554    | 71     |            | (71 )      |              | -              |
| Partial conversion of Moore Notes                                       | 40,783    | 41     |            | 150,449    |              | 150,490        |
| Issuance of shares under exchange agreement with Redwood                | 125,000   | 125    |            | 699,875    |              | 700,000        |
| Issuance of shares under exchange agreement with Redwood                | 783,333   | 783    |            | 2,803,549  |              | 2,804,332      |
| Advaxis Public Offering   | 6,612,500 | 6,613  |            | 23,083,469 |              | 23,090,081     |
| Net Loss  |           |        |            |            | (19,986,826) | (19,986,826)   |



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|   |   |      |            |          |     |               |                |              |
|---|---|------|------------|----------|-----|---------------|----------------|--------------|
| Balance at<br>October 31,<br>2013   | - | \$ - | 13,719,861 | \$13,720 | \$- | \$88,454,245  | \$(70,465,823) | \$18,002,142 |
| Stock<br>compensation<br>to employees,<br>directors and<br>consultants      |   |      | 501,651    | 502      |     | 2,879,777     |                | 2,880,279    |
| Common Stock<br>issued upon<br>exercise of<br>warrants                      |   |      | 50         | -        |     | 250           |                | 250          |
| Common Stock<br>issued to<br>consultants                                    |   |      | 247,218    | 247      |     | 1,551,186     |                | 1,551,433    |
| Issuance of<br>shares to<br>employees<br>under ESPP<br>Plan                 |   |      | 2,110      | 2        |     | 6,249         |                | 6,251        |
| Issuance of<br>shares to<br>investors under<br>stock purchase<br>agreements |   |      | 467,249    | 467      |     | 2,033,670     |                | 2,034,137    |
| Advaxis Public<br>Offering  |   |      | 4,692,000  | 4,692    |     | 12,676,116    |                | 12,680,808   |
| Net Loss  |   |      |            |          |     |               | (16,525,314)   | (16,525,314) |
| Balance at<br>October 31,<br>2014   | - | \$ - | 19,630,139 | \$19,630 | \$- | \$107,601,493 | \$(86,991,137) | \$20,629,986 |

The accompanying notes should be read in conjunction with the financial statements.

**ADVAXIS, INC.****Statement of Cash Flows**

|   | Year ended October 31, |                |
|---|------------------------|----------------|
|   | 2014                   | 2013           |
| <b>OPERATING ACTIVITIES</b>   |                        |                |
| Net Loss  | \$(16,525,314)         | \$(19,986,826) |
| Adjustments to reconcile net loss to net cash used in operating activities: |                        |                |
| Non-cash charges to consultants and employees for options and stock         | 4,428,712              | 4,545,992      |
| Amortization of deferred financing costs                                    | -                      | 85,943         |
| Amortization of discount on convertible promissory notes                    | -                      | 18,392         |
| Non-cash interest expense   | 51                     | 845,200        |
| (Gain) Loss on change in value of warrants and embedded derivative          | (619,089 )             | 1,504,465      |
| Warrant expense   | 4,446                  | 123,744        |
| Settlement expense  | 34,125                 | 764,335        |
| Employee Stock Purchase Plan  | 6,251                  | 28,055         |
| Depreciation expense  | 27,611                 | 19,299         |
| Amortization expense of intangibles   | 175,686                | 159,337        |
| (Gain) on note retirement   | (6,243 )               | 3,455,327      |
| <u>Change in operating assets and liabilities:</u>                          |                        |                |
| Prepaid expenses  | (151,723 )             | (18,387 )      |
| Taxes receivable  | (1,731,317 )           | -              |
| Deferred expenses   | (617,676 )             | 855,252        |
| Accounts payable and accrued expenses                                       | (1,948,987 )           | (1,140,901 )   |
| Interest payable  | (98,192 )              | 31,631         |
| Deferred rent   | -                      | (4,803 )       |
| Net cash used in operating activities                                       | (17,021,659)           | (8,713,945 )   |
| <b>INVESTING ACTIVITIES</b>   |                        |                |
| Proceeds from sale of property and equipment                                | -                      | 3,000          |
| Purchase of property and equipment  | (24,595 )              | (24,616 )      |
| Cost of intangible assets   | (415,080 )             | (274,133 )     |
| Net cash used in Investing Activities                                       | (439,675 )             | (295,749 )     |
| <b>FINANCING ACTIVITIES</b>   |                        |                |
| Proceeds from convertible notes   | -                      | 2,968,500      |
| Repayment of convertible notes  | -                      | (690,799 )     |
| Cash paid for deferred financing costs                                      | -                      | (66,919 )      |
| Proceeds from Officer Loan  | -                      | 11,200         |
| Repayment of Officer Loan   | (64,926 )              | (193,833 )     |
| Proceeds from the exercise of warrants                                      | 250                    | 94,444         |
| Net proceeds of issuance of Common Stock                                    | 14,580,808             | 27,438,931     |
| Net cash provided by Financing Activities                                   | 14,516,132             | 29,561,524     |
| Net increase (decrease) in cash   | (2,945,202 )           | 20,551,830     |
| Cash at beginning of year   | 20,552,062             | 232            |
| Cash at end of year   | \$ 17,606,860          | \$ 20,552,062  |

The accompanying notes should be read in conjunction with the financial statements.

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**Supplemental Disclosures of Cash Flow Information**

|                        | Year Ended<br>October 31, |            |
|------------------------|---------------------------|------------|
|                        | 2014                      | 2013       |
| Cash paid for Interest | \$ 103,445                | \$ 125,988 |
| Cash paid for Taxes    | \$-                       | \$-        |

**Supplemental Schedule of Noncash Investing and Financing Activities**

|   | Year Ended<br>October 31, |                 |
|---|---------------------------|-----------------|
|   | 2014                      | 2013            |
| Accounts Payable and Accrued Expenses settled with Common Stock               | \$ 103,012                | \$-             |
| Accounts Payable from consultants settled with Common Stock                   | \$-                       | \$ 776,302      |
| Notes payable and embedded derivative liabilities converted to Common Stock   | \$-                       | \$ 4,646,148    |
| Cancellation of Note Receivable in connection with Preferred Stock Redemption | \$-                       | \$ (10,633,584) |
| Common Stock issued in exchange for warrants                                  | \$-                       | \$ 2,308,500    |

The accompanying notes should be read in conjunction with the financial statements.

## ADVAXIS, INC.

### NOTES TO FINANCIAL STATEMENTS

#### 1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Advaxis, Inc. (“Advaxis” or, “the Company”) is a clinical stage biotechnology company focused on the discovery, development and commercialization of proprietary *Lm*-LLO cancer immunotherapies. These immunotherapies are based on a platform technology that utilizes live attenuated *Listeria monocytogenes* (“*Lm*” or “*Listeria*”), bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm*-LLO strains are believed to be a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy as 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 this comprehensive approach, but, to its knowledge, none combine all of these elements together in a single, easily administered, well-tolerated yet comprehensive immunotherapy.

ADXS-HPV is its lead *Lm*-LLO immunotherapy product candidate for the treatment of human papilloma virus (“HPV”)-associated cancers. The Company completed a Phase 2 study in 110 patients with recurrent cervical cancer in India that demonstrated a manageable safety profile, improved survival and objective tumor responses. The Company plans to advance this immunotherapy into an adequate and well-controlled clinical trial for the treatment of women with recurrent cervical cancer. ADXS-HPV has received United States Food and Drug Administration (“FDA”) orphan drug designation for three HPV-associated cancers: cervical, head and neck, and anal cancer, and is being evaluated in three ongoing cooperative group and investigator-initiated clinical trials as follows: locally advanced cervical cancer, head and neck cancer, and anal cancer. The Company also plans to initiate a Phase 1/2 clinical trial alone and in combination with MedImmune’s, the global biologics research and development arm of AstraZeneca, investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736, in patients with previously treated locally advanced metastatic HPV-associated cervical cancer and HPV-associated head and neck cancer. Lastly, the Company is evaluating higher doses and repeat cycles of ADXS-HPV in patients with recurrent cervical cancer.

The Company is developing two other cancer immunotherapies. ADXS-PSA is its *Lm*-LLO immunotherapy product candidate designed to target the PSA antigen associated with prostate cancer. The FDA has cleared its Investigational New Drug (“IND”) application, and the Company now plans to initiate a Phase 1/2 clinical trial alone and in combination with KEYTRUDA® (pembrolizumab), Merck’s humanized monoclonal antibody against PD-1, in patients with previously treated metastatic castration-resistant prostate cancer. ADXS-HER2 is its *Lm*-LLO immunotherapy product candidate for the treatment of Her2 expressing cancers, including human and canine osteosarcoma, breast, gastric and other cancers. The Company has submitted an IND application and has received orphan drug designation for ADXS-HER2 in osteosarcoma. Over twenty distinct additional constructs have been developed to various stages

of development, developed directly by the Company and through strategic collaborations with recognized centers of excellence.

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

From inception through the period ended January 31, 2014, the Company was a development stage company. During the three months ended April 30, 2014, it exited the development stage upon its execution of a license agreement with Aratana Therapeutics Inc. (“Aratana”). This provided an upfront payment of \$1 million, which the Company properly recognized and earned as revenue.

#### *Liquidity and Financial Condition*

The Company’s products are being developed and have not generated significant revenues. As a result, the Company has suffered recurring losses. These losses are expected to continue for an extended period of time. However, in the year ended October 31, 2014, the Company recorded \$1 million in revenue pursuant to a licensing agreement with Aratana. The licensing agreement provides for potentially significant revenues based on the achievement of event-based milestones in the future. In addition, the Company completed a second public offering of its Common Stock (“Common Stock”), yielding a net amount of approximately \$12.7 million and received approximately \$2 million related to the sale of its Common Stock to investors under stock purchase agreements.

On March 31, 2014, the Company closed its public offering of 4,692,000 shares of Common Stock, including 612,000 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 \$3.00 per share. Total gross proceeds from the offering were \$14 million. After deducting underwriting discounts and commissions and other offering expenses paid by the Company, net proceeds were approximately \$12.7 million.

In December 2014, the Company received \$1.7 million in net proceeds from the sale of its tax credit from the New Jersey Technology Business Tax Certificate Transfer (NOL) Program. On December 22, 2014, the Company closed a registered direct offering, receiving total proceeds, before expenses, of \$16.7 million. As of October 31, 2014, the Company had \$17.6 million of cash on hand. The Company believes its current cash position is sufficient to fund its business plan through July 31, 2016.

The Company recognizes it will need to raise additional capital over and above the amount raised during October 2013, March 2014 and December 2014 in order to continue to execute its business plan. Subsequent to October 31, 2014, the Company may plan to continue to raise additional funds through the sales of equity securities. There is no assurance that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to the Company or whether the Company will become profitable and generate positive operating cash flow. If the Company is unable to raise sufficient additional funds, it will have to scale back its business plan, delay research and development activity, extend payables and reduce overhead until sufficient additional capital is raised to support further operations. There can be no assurance that such a plan will be successful.

## **2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

### *Estimates*

The preparation of financial statements in accordance with U.S. Generally Accepted Accounting Principles ("GAAP") involves the use of estimates and assumptions that affect the recorded amounts of assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results may differ substantially from these estimates. Significant estimates include the fair value and recoverability of the carrying value of intangible assets (patents and licenses), the fair value of options, the fair value of embedded conversion features, warrants and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates, based on historical experience and on various other assumptions that it believes to be reasonable under the circumstances. Actual results may differ from estimates.

### *Reclassification*

Certain amounts in the prior period financial statements have been reclassified to conform to the presentation of the current period financial statements. These reclassifications had no effect on the previously reported net loss.

### *Revenue Recognition*

The Company derived the majority of its revenue in 2014 from patent licensing. In general, these revenue arrangements provide for the payment of contractually determined fees in consideration for the grant of certain intellectual property rights for patented technologies owned or controlled by the Company. The intellectual property rights granted may be perpetual in nature, or upon the final milestones being met, or can be granted for a defined, relatively short period of time, with the licensee possessing the right to renew the agreement at the end of each contractual term for an additional minimum upfront payment. The Company recognizes licensing fees when there is persuasive evidence of a licensing arrangement, fees are fixed or determinable, delivery has occurred and collectability is reasonably assured.

An allowance for doubtful accounts is established based on the Company's best estimate of the amount of probable credit losses in the Company's existing license fee receivables, using historical experience. The Company reviews its allowance for doubtful accounts periodically. Past due accounts are reviewed individually for collectability.

Account balances are charged off against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. To date, this is yet to occur.

If product development is successful, the Company will recognize revenue from royalties based on licensees' sales of its products or products using its technologies. Royalties are recognized as earned in accordance with the contract terms when royalties from licensees can be reasonably estimated and collectability is reasonably assured. If royalties cannot be reasonably estimated or collectability of a royalty amount is not reasonably assured, royalties are recognized as revenue when the cash is received.

The Company recognizes revenue from milestone payments received under collaboration agreements when earned, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, the Company has no further performance obligations relating to the event and collection is reasonably assured. If these criteria are not met, the Company recognizes milestone payments ratably over the remaining period of the Company's performance obligations under the collaboration agreement. All such recognized revenues are included in collaborative licensing and development revenue in the Company's consolidated statements of operations.

### *Cash and Cash Equivalents*



The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. As of October 31, 2014 and October 31, 2013, the Company did not have any cash equivalents.

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### *Concentration of Credit Risk*

The Company maintains its cash in bank deposit accounts (checking) that at times exceed federally insured limits. Approximately \$17.6 million is subject to credit risk at October 31, 2014. However, these cash balances are maintained at creditworthy financial institutions. The Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risk.

### *Deferred Expenses*

Deferred Expenses consist of advanced payments made on research and development projects. Amortization is provided for on a straight-line basis over the periods of the underlying research and development contracts ranging from six months to five years and is charged to Research and Development Expense in the Statement of Operations.

### *Property and Equipment*

Property and equipment consists of laboratory equipment and is stated at cost. Depreciation and amortization is provided for on the straight-line basis over the estimated useful lives of the respective asset ranging from 3 to 5 years. Expenditures for maintenance and repairs that do not materially extend the useful lives of the respective assets are charged to expense as incurred. The cost and accumulated depreciation of assets retired or sold are removed from the respective accounts and any gain or loss is recognized in operations.

### *Intangible Assets*

Intangible assets primarily consist of legal and filing costs associated with obtaining patents and licenses and are amortized on a straight-line basis over their remaining useful lives which are estimated to be twenty years from the effective dates of the University of Pennsylvania (Penn) License Agreements, beginning in July 1, 2002. These legal and filing costs are invoiced to the Company through Penn and its patent attorneys.

Management has reviewed its long-lived assets for impairment whenever events and circumstances indicate that the carrying value of an asset might not be recoverable and its carrying amount exceeds its fair value, which is based upon estimated undiscounted future cash flows. Net assets are recorded on the balance sheet for patents and licenses related to ADXS-HPV, ADXS-PSA and ADXS-HER2 and other products that are in development. However, if a competitor

were to gain FDA approval for a treatment before us or if future clinical trials fail to meet the targeted endpoints, the Company would likely record an impairment related to these assets. In addition, if an application is rejected or fails to be issued, the Company would record an impairment of its estimated book value.

### *Deferred Financing Costs*

The Company has recorded deferred financing costs as a result of fees incurred by the Company in conjunction with its debt financing activities. These costs are amortized using the straight-line method over the shorter of (a) the term of the related debt or (b) the expected conversion date of the debt into equity instruments, which approximates the effective interest method. The amortization of deferred financing costs is included in interest expense as a component of other expenses in the accompanying statements of operations. For the year ended October 31, 2013, amortization of deferred financing costs was immaterial, and as of October 31, 2013, deferred financing costs were fully amortized.

### *Net Loss per Share*

Basic net income or loss per common share is computed by dividing net income or loss available to common shareholders by the weighted average number of common shares outstanding during the period. Diluted earnings per share give effect to dilutive options, warrants, convertible debt and other potential Common Stock equivalents outstanding during the period. Therefore, in the case of a net loss the impact of the potential Common Stock resulting from warrants, outstanding stock options and convertible debt is not included in the computation of diluted loss per share, as the effect would be anti-dilutive. In the case of net income the impact of the potential Common Stock resulting from these instruments that have intrinsic value is included in the diluted earnings per share. The table sets forth the number of potential shares of Common Stock that have been excluded from diluted net loss per share.

|  | As of October 31, |           |
|--|-------------------|-----------|
|  | 2014              | 2013      |
| Warrants   | 4,158,092         | 4,265,262 |
| Stock Options                                    | 467,968           | 467,923   |
| Convertible Debt (using the if-converted method) | 3,354             | 3,354     |
| Total  | 4,629,414         | 4,736,539 |

### *Research and Development Expenses*

Research and development costs are expensed as incurred and include but are not limited to clinical trial and related manufacturing costs, payroll and personnel expenses, lab expenses, and related overhead costs.

*Advertising Expense*

Advertising costs are charged to operations as incurred. For the years ended October 31, 2014 and 2013 the Company did not incur any advertising costs.

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### *Stock Based Compensation*

The Company has an equity plan which allows for the granting of stock options to its employees, directors and consultants for a fixed number of shares with an exercise price equal to the fair value of the shares at date of grant. The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. For employees and directors, the fair value of the award is measured on the grant date and for non-employees, the fair value of the award is generally measured based on contractual terms. The fair value amount is then recognized over the requisite service period, usually the vesting period, in both research and development expenses and general and administrative expenses on the statement of operations depending on the nature of the services provided by the employees or consultants.

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

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

### *Fair Value of Financial Instruments*

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

### *Derivative Financial Instruments*

The Company does not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. The Company evaluates all of its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the statements of operations. For stock-based derivative financial instruments, the Company used the Black Scholes valuation model which approximated the binomial lattice options pricing model to value the derivative instruments at inception and on subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the instrument could be required within 12 months of the balance sheet date.

#### *Hybrid Financial Instruments*

For certain hybrid financial instruments, the Company elected to apply the fair value option to account for these instruments. The Company made an irrevocable election to measure such hybrid financial instruments at fair value in their entirety, with changes in fair value recognized in earnings at each balance sheet date. The election may be made on an instrument by instrument basis.

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

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

#### *Recent Accounting Pronouncements*

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, *Revenue from Contracts with Customers*. Amendments in this ASU create Topic 606, Revenue from Contracts with Customers, and supersede the revenue recognition requirements in Topic 605, Revenue Recognition, including most industry-specific revenue recognition guidance throughout the Industry Topics of the Codification. In addition, the amendments supersede the cost guidance in Subtopic 605-35, Revenue Recognition—Construction-Type and Production-Type Contracts, and create new Subtopic 340-40, Other Assets and Deferred Costs—Contracts with Customers. In summary, the core principle of Topic 606 is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This ASU is the final version of Proposed ASU 2011-230—Revenue Recognition (Topic 605) and Proposed ASU 2011-250—Revenue Recognition (Topic 605): Codification Amendments, both of which have been deleted. The amendments in this ASU are effective for the Company for annual reporting

periods beginning after December 15, 2016, including interim periods within that reporting period. The Company is currently evaluating the effects of ASU 2014-09 on the consolidated financial statements.

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In June 2014, the FASB issued ASU 2014-12, *Compensation - Stock Compensation*. The amendments in this ASU apply to reporting entities that grant their employees share-based payments in which the terms of the award provide that a performance target can be achieved after the requisite service period. This ASU is the final version of Proposed ASU EITF-13D--Compensation--Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period, which has been deleted. The amendments require that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. A reporting entity should apply existing guidance in Topic 718 as it relates to awards with performance conditions that affect vesting to account for such awards. As such, the performance target should not be reflected in estimating the grant-date fair value of the award. Compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. If the performance target becomes probable of being achieved before the end of the requisite service period, the remaining unrecognized compensation cost should amount of compensation cost recognized during and after the requisite service period should reflect the number of awards that are expected to vest and should be adjusted to reflect those awards that ultimately vest. The requisite service period ends when the employee can cease rendering service and still be eligible to vest in the award if the performance target is achieved. As indicated in the definition of vest, the stated vesting period (which includes the period in which the performance target could be achieved) may differ from the requisite service period. The amendments in this ASU are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015, and early adoption is permitted. The Company does not expect ASU 2014-12 to have a material impact on the consolidated financial statements.

Management does not believe that any other recently issued, but not yet effective accounting pronouncements, if adopted, would have a material impact on the accompanying consolidated financial statements.

#### *Income Taxes*

The Company uses the asset and liability method of accounting for income taxes in accordance with ASC Topic 740, "Income Taxes." Under this method, income tax expense is recognized for the amount of: (i) taxes payable or refundable for the current year and (ii) deferred tax consequences of temporary differences resulting from matters that have been recognized in an entity's financial statements or tax returns. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the results of operations in the period that includes the enactment date. A valuation allowance is provided to reduce the deferred tax assets reported if based on the weight of the available positive and negative evidence, it is more likely than not some portion or all of the deferred tax assets will not be realized.

### **3. PROPERTY AND EQUIPMENT**



Property and equipment consists of the following:

|                            | October 31, |           |
|----------------------------|-------------|-----------|
|                            | 2014        | 2013      |
| Laboratory Equipment       | \$333,727   | \$309,132 |
| Accumulated Depreciation   | (256,358)   | (228,747) |
| Net Property and Equipment | \$77,369    | \$80,385  |

Depreciation expense for the years ended October 31, 2014 and 2013 was \$27,611 and \$19,229, respectively.

#### 4. INTANGIBLE ASSETS

Under the University of Pennsylvania (“Penn”) license agreements, the Company is billed actual patent expenses as they are passed through from Penn and are billed directly from the Company’s patent attorney. The following is a summary of intangible assets as of the end of the following fiscal periods:

|                          | October 31, |             |
|--------------------------|-------------|-------------|
|                          | 2014        | 2013        |
| License                  | \$651,992   | \$651,992   |
| Patents                  | 3,111,624   | 2,696,543   |
| Total intangibles        | 3,763,616   | 3,348,535   |
| Accumulated Amortization | (995,671 )  | (819,984 )  |
| Intangible Assets        | \$2,767,945 | \$2,528,551 |

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The expirations of the existing patents range from 2015 to 2028 but the expirations can be extended based on market approval if granted and/or based on existing laws and regulations. Capitalized costs associated with patent applications that are abandoned without future value are charged to expense when the determination is made not to pursue the application. No patent applications having a future value were abandoned or expired and charged to expense for either of the years ended October 31, 2014 or 2013. Amortization expense for licensed technology and capitalized patent cost is included in general and administrative expenses and aggregated \$175,686 and \$159,337 for the years ended October 31, 2014 and 2013.

Estimated amortization expense for the next five years is as follows:

| Year ending October 31, |           |
|-------------------------|-----------|
| 2015                    | \$188,000 |
| 2016                    | \$188,000 |
| 2017                    | \$188,000 |
| 2018                    | \$188,000 |
| 2019                    | \$188,000 |

## 5. ACCRUED EXPENSES:

The following table represents the major components of accrued expenses:

|                                 | October 31, |           |
|---------------------------------|-------------|-----------|
|                                 | 2014        | 2013      |
| Salaries and other compensation | \$890,069   | \$752,248 |
| Vendors                         | 121,200     | -         |
| Professional Fees               | 208,000     | 17,000    |
| Withholding taxes payable       | 22,527      | -         |
| Share Purchase                  | -           | 100,012   |
|                                 | \$1,241,796 | \$869,260 |

## 6. CONVERTIBLE NOTES AND FAIR VALUE OF EMBEDDED DERIVATIVE

### Junior Subordinated Convertible Promissory Notes

The Company refers to all Junior Subordinated Convertible Promissory Notes as “Bridge Notes”.

The Bridge Notes are convertible into shares of the Company’s Common Stock at a fixed exercise price. For every dollar invested in the Company’s Bridge Notes, each Investor received warrant coverage ranging from approximately 23% to 75%, subject to adjustments upon the occurrence of certain events as more particularly described below and in the form of Warrant. As of October 31, 2012, substantially all of the Bridge Warrants have an exercise price of \$18.75 per share. The Bridge Notes may be prepaid in whole or in part at the option of the Company without penalty at any time prior to the Maturity Date. The warrants may be exercised on a cashless basis under certain circumstances.

During the twelve months ended October 31, 2013, pursuant to the terms of various Assignment Agreements, the Company delivered convertible notes to Magna in aggregate principal amounts of \$170,589 (including \$11,765 of junior subordinated convertible promissory notes plus the above December 2011 Note in the principal amount of \$158,824) and \$111,111 (consisting of one junior subordinated convertible promissory note), convertible into shares of Common Stock, which bears interest at a rate of 6% per annum, which interest accrues, but does not become payable until maturity. The Company converted the exchange note, which it refers to as the Third Magna Exchange Note, in the principal amount of \$111,111 into 34,241 shares of its Common Stock at a conversion price of \$3.25 per share, recording non-cash expense of approximately \$106,000 to the loss on retirement account, on the statement of operations, for the difference between the amount of the principal converted and the fair value of the shares issued as a result of the conversion. As of October 31, 2013, approximately \$63,000 in principal remained outstanding on the junior unsubordinated convertible promissory notes, as the notes had matured on October 22, 2011. As of October 31, 2014, these notes are recorded as current liabilities on the balance sheet. The Company is in discussion with note holders to convert these notes in full during fiscal year 2015.

JMJ Financial

On August 27, 2012, in a private placement pursuant to a Note Purchase Agreement, the Company issued MJJ Financial a convertible promissory note in the aggregate principal amount of \$100,000 for a purchase price of \$100,000, which it refers to as the MJJ August 2012 Note. As of October 31, 2012, the MJJ August 2012 Note remained outstanding. Due to the conversion feature into a variable number of shares, the MJJ August 2012 Note is valued at fair value at each reporting period. As of October 31, 2012, the fair value of the MJJ August 2012 Note was \$73,590.

During the twelve months ended October 31, 2013, the Company converted the MJJ August 2012 Note totaling \$100,000 into 24,744 shares of its Common Stock. The Company recorded non-cash income of approximately \$70,114 upon conversion. This non-cash income was recorded to the gain on retirement account, on the statement of operations, representing the difference between the fair value of the MJJ August 2012 Note, as reported on the balance sheet, and the fair value of the shares issued as a result of the conversion.

On December 28, 2012, in a private placement pursuant to a note purchase agreement, the Company issued MJJ Financial a one month convertible promissory note, which it refers to as the MJJ December 2012 Note, in the aggregate principal amount of \$100,000 for a purchase price of \$100,000 . If repaid before January 31, 2013, the principal amount of the MJJ December 2012 Note would be \$125,000. If the MJJ December 2012 Note was to be rolled into a future financing, the principal amount would be \$115,000.

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

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

outstanding shares of Common Stock as of such date. The Company agreed to reserve at least 160,000 shares of its Common Stock for conversion of the note. The note also provides for penalties and rescission rights if the Company does not deliver shares of its Common Stock upon conversion within the required timeframes.

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

The Company also granted MJM Financial the right, at its election, to participate in the next public offering of its securities by exchanging, in whole or in part, the funded portion of this note for a subscription to such public offering in an amount equal to 125% of the sum of the funded portion of the principal amount being exchanged plus all accrued and unpaid interest, liquidated damages, fees, and other amounts due on such exchanged principal amount. However, the note was subsequently amended in September 2013 to remove this right. If the Company completes a public offering of \$10,000,000 or more, MJM Financial has the right, at its election, to require repayment of the note, in whole or in part, in amount equal to 125% of the sum of the funded principal amount being repaid plus all accrued and unpaid interest liquidated damages, fees, and other amounts due on such principal amount. In September 2013, this note was amended to lower this threshold to \$5,000,000 in connection with the sale of the new convertible promissory note to MJM Financial.

On August 14, 2013, the Company borrowed an additional \$100,000 under the JMJ April 2013 convertible promissory note. At this date, the Company has borrowed 625,000 under the JMJ April 2013 Note. JMJ Financial has no obligation to lend the Company the remaining \$95,000 of available principal amount under the note and may never do so. The Company has no obligation to pay JMJ Financial any amounts on the unfunded portion of the note and may not prepay any portion of the note without JMJ Financial's consent. During August and September 2013, JMJ Financial converted \$145,833 in principal and interest on its April 2013 Note into 71,438 shares of Common Stock at conversion rates ranging from \$1.89 to \$2.20. After these conversions, \$583,333 in principal and interest remained outstanding under the JMJ April 2013 Note.

On September 4, 2013, in a private placement, the Company issued JMJ Financial a convertible promissory note ("JMJ September 2013 Note"). The face amount of the note reflects an aggregate principal amount of \$800,000 for total consideration of \$720,000 (or a 10% original issue discount). However, JMJ Financial has only paid us \$500,000 in cash as consideration for the note to date. The Company also issued JMJ Financial 19,231 restricted shares of its Common Stock as a \$50,000 origination fee for this convertible promissory note. JMJ Financial has no obligation to lend us the remaining \$220,000 of available consideration under the note and may never do so. The convertible promissory note matures September 4, 2014 and, in addition to the 10% original issue discount, provides for payment of a one-time interest charge of 5% on funded amounts. The convertible promissory note is convertible at any time, in whole or in part, at JMJ Financial's option into shares of the Company's Common Stock at the lesser of \$2.65 or 70% of the average of the lowest two closing prices in the 20-day pricing period preceding a conversion. However, at no time will JMJ Financial be entitled to convert any portion of the note to the extent that after such conversion, JMJ Financial (together with its affiliates) would beneficially own more than 4.99% of the Company's outstanding shares Common Stock as of such date. The Company agreed to reserve at least 2,000,000 shares of the Company's Common Stock for conversion of the note. \$583,333 in principal and interest remained outstanding under the JMJ September 2013 Note.

As of October 16, 2013, the Company owed JMJ Financial approximately \$ 1,167,000 in principal and interest under its convertible promissory notes with JMJ Financial. On October 16, 2013, the Company entered into an Accelerated Conversion and Note Termination Agreement with JMJ Financial whereby it agreed to exchange all of its outstanding convertible promissory notes (which had an aggregate principal amount of approximately \$1,167,000), plus fees of approximately \$400,000 (recorded as non-cash interest expense), for accelerated conversion, note termination and a lock-up, for an aggregate of 783,333 restricted shares of its Common Stock at an effective conversion price of \$2.00. The Company recorded non-cash expense of approximately \$922,000 upon conversion. This non-cash expense was recorded to the loss on retirement account, on the statement of operations representing the difference between the fair value of the JMT April and September Notes and the fair value of the shares issued as a result of the conversion. JMJ Financial also agreed to certain lock-up restrictions with respect to such shares. Accordingly, JMJ Financial agreed not to sell any of such shares until 60 days after the date of the agreement, following which, until 90 days after the date of the agreement, it agreed to limit the number of such shares it sells on any day to 10% of the trading volume on such day. JMJ Financial also agreed not to engage in any short sales of the Company's Common Stock at any time.

At October 31, 2014, there were no remaining convertible promissory notes outstanding with JMJ Financial.

Hanover Holdings Notes

On September 19, 2012, in a private placement pursuant to a note purchase agreement, the Company issued Hanover a convertible promissory note in the aggregate principal amount of \$132,500, for a purchase price of \$132,500, which the Company refers to as the Initial Hanover PIPE Note. On October 19, 2012, in a private placement pursuant to a note purchase agreement, the Company issued Hanover a convertible promissory note in the aggregate principal amount of \$132,500, for a purchase price of \$132,500, which is referred to as the Second Hanover PIPE Note, which, together with the Initial Hanover PIPE Note is referred to as the Hanover PIPE Notes. The Hanover PIPE Notes bear interest at a rate of 12%, which interest accrues, but does not become payable until maturity or acceleration of the principal of such Hanover PIPE Notes. The Hanover PIPE Notes are convertible into shares of the Company's Common Stock at a conversion price equal to 65% of the arithmetic average of the five lowest closing trading prices for the Common Stock during the 10 trading day period ending on the latest complete trading day prior to the applicable conversion date. The Hanover PIPE Notes mature eight months from their respective issuance dates. To the extent Hanover does not elect to convert the Hanover PIPE Notes as described above, the principal amount and interest of such Hanover PIPE Notes shall be payable in cash at maturity. The Hanover PIPE Notes may be converted at any time by Hanover, at its option, in whole or in part. The Hanover PIPE Notes include a limitation on conversion, which provides that at no time will Hanover be entitled to convert any portion of the Hanover PIPE Notes, to the extent that after such conversion, Hanover (together with its affiliates) would beneficially own more than 4.99% of the outstanding shares of the Common Stock as of such date.

Unrealized losses on the mark-to-market of the notes which amounted to \$97,791, for the period from the dates of issuance (September 19 and October 19, 2012) through October 31, 2013 were recorded as non-cash expense. The Hanover PIPE Notes were recorded on the balance sheet, at fair value, of approximately \$363,000.

During the twelve months ended October 31, 2013, the note-holder converted principal of \$365,000 into 97,333 shares of the Company's Common Stock at a conversion rate of \$3.75 per share. During the twelve months ended October 31 2013, the Company recognized interest expense of approximately \$72,000 in order to accrete the unamortized debt discount back to the notes' principal through the dates of conversion.

As of October 31, 2014, there were no remaining Hanover PIPE Notes.

Magna Note

In October 2012, pursuant to the terms of various Assignment Agreements, which the Company refers to as the Assignment Agreements, Magna Group, LLC, an affiliate of Hanover, which is referred to as Magna, acquired \$400,076 in aggregate principal amount of the Company's outstanding convertible notes from certain third parties and entered into agreements to acquire an additional \$340,523 in aggregate principal amount of its outstanding convertible notes from other third parties. Pursuant to the terms of such Assignment Agreements, the Company delivered two convertible notes to Magna in an aggregate principal amount of \$740,599, in anticipation of the closing of all of the transactions contemplated by such Assignment Agreements. On October 25, 2012, the convertible note in the aggregate principal amount of \$617,723 previously delivered to Magna was exchanged for a new convertible note in the aggregate principal amount of \$400,076, convertible into shares of Common Stock, which the Company refers to as the Magna Exchange Note, to reflect such portion of the convertible notes actually issued as of October 25, 2012 pursuant to the Assignment Agreements, and the remaining convertible note in the aggregate principal amount of \$122,876 previously delivered to Magna was returned to us and cancelled. The Magna Exchange Note bears interest at a rate of 6%, which interest accrues, but does not become payable until maturity or acceleration of the principal of the Magna Exchange Note. The Magna Exchange Note is convertible into shares of the Company's Common Stock at a conversion price equal to 73% of the arithmetic average of the five lowest closing trading prices for the Common Stock during the 10 trading day period ending on the lowest complete trading day prior to the applicable conversion date. The Magna Exchange Note matures on October 17, 2013. To the extent Magna does not elect to convert the Magna Exchange Note as described above, the principal amount and interest of the Magna Exchange Note shall be payable in cash at maturity. Upon the closing of the remaining transactions contemplated by such applicable Assignment Agreements, the Company is obligated to issue additional convertible notes in the form of the Magna Exchange Note with respect to the outstanding \$ 340,523 in aggregate principal amount of convertible notes held by the third party signatories to the other Assignment Agreements.

The Magna Exchange Note may be converted at any time by Magna, at its option, in whole or in part. The Magna Exchange Note includes a limitation on conversion, which provides that at no time will Magna be entitled to convert any portion of the Magna Exchange Note, to the extent that after such conversion, Magna (together with its affiliates) would beneficially own more than 4.99% of the outstanding shares of the Common Stock as of such date.

During the twelve months ended October 31, 2013, Magna converted the remaining approximately \$300,000 in principal into 80,992 shares of the Company's Common Stock at prices ranging from \$3.21 to \$4.14, resulting in non-cash expense for the period of approximately \$ 44,000 resulting from the difference between the amount of principal converted and the fair value of the shares issued as a result of the conversion. In addition, Magna converted another approximately \$341,000 in principal into 182,344 shares of the Company's Common Stock at prices ranging from \$3.16 to \$3.49, resulting in non-cash expense of approximately \$281,000 resulting from the difference between the amount of principal converted and the fair value of the shares issued as a result of these conversions.

As of October 31, 2014, the Magna Exchange Note had been converted in full and no longer remained outstanding.



Chris French

On September 27, 2012, in a private placement pursuant to a note purchase agreement, the Company issued its employee Christine French a convertible promissory note in the aggregate principal amount of \$25,000, for a purchase price of \$25,000, which is referred to as the French Note. The French Note bears interest at a rate of 12%, compounded annually. The French Note is convertible into shares of the Company's Common Stock at a conversion price equal to the arithmetic average of the five lowest closing trading prices for the Common Stock during the 10 trading day period ending on the latest complete trading day prior to the applicable conversion date. The French Note matures one month from its issuance date. Additionally, Ms. French will receive a warrant, which the Company refers to as the French Warrant, to purchase such number of shares of its Common Stock equal to 50% of such number of shares of its Common Stock issuable upon conversion of the French Note at an exercise price equal to the conversion price then in effect. These warrants have not yet been issued. The French Warrant may be exercised on a cashless basis under certain circumstances. The French Note and the French Warrant each include a limitation on conversion or exercise, as applicable, which provides that at no time will Ms. French be entitled to convert any portion of the French Note or French Warrant, to the extent that after such conversion or exercise, as applicable, Ms. French (together with her affiliates) would beneficially own more than 4.99% of the outstanding shares of the Common Stock as of such date.

During the twelve months ended October 31, 2013, the Company converted principal of \$25,000 of a note issued to Chris French plus accrued interest of approximately \$633, into 4,527 shares of its Common Stock at a conversion price of \$5.625 per share. In addition, the Company issued a warrant to acquire 2,263 shares, which expires on October 26, 2015 and revalued the warrant liability, at October 31, 2013, with an exercise price of \$5.625, resulting in non-cash expense of approximately \$21,000 resulting from the difference between the fair value of the note as shown on the balance sheet plus accrued interest to-date and the fair value of the shares issued as a result of the conversion.

As of October 31, 2014, the French Note no longer remained outstanding.

Asher

On September 11, 2012, in a private placement pursuant to a note purchase agreement, the Company issued Asher Enterprises, Inc., which is referred to as Asher, a convertible promissory note in the aggregate principal amount of \$103,500, for a purchase price of \$100,000, which is referred to as the Asher Note. The Asher Note bears interest at a rate of 8%, which interest accrues, but does not become payable until maturity or acceleration of the principal of the Asher Note. The Asher Note is convertible into shares of the Company's Common Stock at a conversion price equal to 61% of the arithmetic average of the five lowest closing trading prices for the Common Stock during the 10 trading day period ending on the latest complete trading day prior to the applicable conversion date. The Asher Note matures on June 13, 2013, nine months from its issuance date. The Asher Note may be converted by Asher, at its option, in whole or in part. The Asher Note includes a limitation on conversion, which provides that at no time will Asher be entitled to convert any portion of the Asher Note, to the extent that after such conversion, Asher (together with its

affiliates) would beneficially own more than 4.99% of the outstanding shares of the Common Stock as of such date.

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During the year ended October 31, 2013, Asher converted the above principal of \$153,500 and accrued interest of \$6,140 into approximately 44,161 shares of the Company's Common Stock at a conversion prices ranging from \$3.43 /share to \$3.90 /share.

On May 1, 2013, in a private placement pursuant to a note purchase agreement, the Company issued Asher a convertible promissory note in the aggregate principal amount of \$203,500, for a purchase price of \$200,000, which it refers to as the Third Asher Note. The Third Asher Note bears interest at a rate of 8%, which interest accrues, but does not become payable until maturity or acceleration of the principal of the Third Asher Note. The Third Asher Note is convertible into shares of the Company's Common Stock at a conversion price equal to 65% of the arithmetic average of the five lowest closing trading prices for the Common Stock during the 10 trading day period ending on the latest complete trading day prior to the applicable conversion date. The Third Asher Note matures on February 3, 2014, nine months from its issuance date. The Third Asher Note may be converted by Asher, at its option, in whole or in part and included a limitation on conversion, which provides that at no time would Asher be entitled to convert any portion of the Third Asher Note, to the extent that after such conversion, Asher (together with its affiliates) would beneficially own more than 4.99% of the outstanding shares of the Common Stock of the Company as of such date.

The Company recorded interest expense of \$77,737 resulting from the prepayment penalty associated with the Third Asher Note. During the twelve months ended October 31, 2013, the Company paid off the Third Asher Note in the amount of \$281,237.

As of October 31, 2014, the Third Asher Note no longer remained outstanding.

On July 12, 2013, in a private placement pursuant to a note purchase agreement, the Company issued Asher a convertible promissory note in the aggregate principal amount of \$103,500, for a purchase price of \$100,000, which it refers to as the Fourth Asher Note. The Fourth Asher Note bears interest at a rate of 8%, which interest accrues, but does not become payable until maturity or accelerations of the principal of the Fourth Asher Note. The Fourth Asher Note is convertible into shares of the Company's Common Stock at a conversion price equal to 65% of the arithmetic average of the five lowest closing trading prices for the Common Stock during the 10 trading day period ending on the latest complete trading day prior to the applicable conversion date. The Fourth Asher Note matures on April 16, 2014, nine months from its issuance date. The Fourth Asher Note may be converted by Asher, at its option, in whole or in part and included a limitation on conversion, which provides that at no time will Asher be entitled to convert any portion of the Fourth Asher Note, to the extent that after such conversion, Asher (together with its affiliates) would beneficially own more than 4.99% of the outstanding shares of the Common Stock of the Company as of such date.

The Company recorded interest expense of \$27,917 resulting from the prepayment penalty associated with the Fourth Asher Note. During the twelve months ended October 31, 2013, the Company paid off the Fourth Asher Note in the amount of \$131,417.

As of October 31, 2014, the Fourth Asher Note no longer remained outstanding.

Yvonne Paterson

On September 25, 2012, in a private placement pursuant to a note purchase agreement, the Company issued its affiliate Dr. Yvonne Paterson a convertible promissory note in the aggregate principal amount of \$100,000, for a purchase price of \$100,000, which is referred to as the Paterson Note. The Paterson Note bears interest at a rate of 12%, compounded annually. The Paterson Note is convertible into shares of the Company's Common Stock at a conversion price equal to the arithmetic average of the five lowest closing trading prices for the Common Stock during the 10 trading day period ending on the latest complete trading day prior to the applicable conversion date. The Paterson Note matures one month from its issuance date. Additionally, Dr. Paterson will receive a warrant, which is referred to as the Paterson Warrant, to purchase such number of shares of the Company's Common Stock equal to 50% of such number of shares of its Common Stock issuable upon conversion of the Patterson Note at an exercise price equal to the conversion price then in effect. These warrants have not yet been issued. The Paterson Warrant may be exercised on a cashless basis under certain circumstances. The Paterson Note and the Paterson Warrant each include a limitation on conversion or exercise, as applicable, which provides that at no time will Dr. Paterson be entitled to convert any portion of the Paterson Note or Paterson Warrant, to the extent that after such conversion or exercise, as applicable, Dr. Paterson (together with her affiliates) would beneficially own more than 4.99% of the outstanding shares of the Common Stock as of such date.

During the twelve months ended October 31, 2013, the Company converted principal of \$100,000 of a note issued to Yvonne Paterson plus accrued interest of approximately \$2,532, into 18,107 shares of its Common Stock at a conversion price of \$5.625 per share. In addition, the Company issued a warrant to acquire 9,054 shares, which expires on October 26, 2015 and revalued the warrant liability, at October 31, 2013, with an exercise price of \$5.625, resulting in non-cash expense of \$32,000 resulting from the difference between the fair value of the note as shown on the balance sheet plus accrued interest to-date and the fair value of the shares issued as a result of the conversion.

As of October 31, 2014, the Paterson Note no longer remained outstanding.

James Patton

On August 2, 2012, in a private placement pursuant to a note purchase agreement, the Company issued Dr. James Patton, a member of its board of directors, a convertible promissory note, which is referred to as the Patton Note, in the principal amount of \$66,667 for a purchase price of \$50,000. The Patton Note was issued with an original issue discount of 25%. Dr. Patton paid \$0.75 for each \$1.00 of principal amount of the Patton Note purchased. The Patton Note is convertible into shares of the Company's Common Stock at a per share conversion price equal to \$0.15. Additionally, Dr. Patton received a warrant, which is referred to as the Patton Warrant, to purchase such number of

shares of the Company's Common Stock equal to 50% of such number of shares of its Common Stock issuable upon conversion of the Patton Note at an exercise price of \$0.15 per share. The Patton Note and Patton Warrant also provide that on December 1, 2012, solely to the extent the conversion price of the Patton Note or the exercise price of the Patton Warrant, as applicable, is less than the Market Price (as defined in the Patton Note or the Patton Warrant, as applicable), such conversion price or exercise price, as applicable, shall be reduced to such Market Price. The Patton Note matures on August 2, 2013. The Company may redeem the Patton Note under certain circumstances. The Patton Warrant is exercisable at any time on or before August 2, 2017. The Patton Warrant may be exercised on a cashless basis under certain circumstances. The Patton Note and the Patton Warrant each include a limitation on conversion or exercise, as applicable, which provides that at no time will Dr. Patton be entitled to convert any portion of the Patton Note or Patton Warrant, to the extent that after such conversion or exercise, as applicable, Dr. Patton (together with his affiliates) would beneficially own more than 4.99% of the outstanding shares of the Common Stock as of such date.

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During the twelve months ended October 31, 2013, the Company converted the principal amount of the Patton Note, of \$66,667, into 21,092 shares at a conversion price of \$3.16. The Company recorded non-cash income of approximately \$94,000 for the twelve months ended October 31, 2013, respectively. Accretion of the discount amounted to \$3,355, for the twelve months ended October 31, 2013. The Patton Warrants, in the amount of 1,778, remained outstanding at October 31, 2014 and were revalued as part of the warrant liability at October 31, 2014 and 2013.

As of October 31, 2014, the Patton Note no longer remained outstanding.

#### Redwood Management LLC

On June 21, 2013, the Company entered into a bridge financing arrangement with Redwood Management, LLC (“Redwood”), an accredited investor, for which Aegis Capital Corp. acted as placement agent and received an 8 % fee based on the consideration paid to the Company. Accordingly, on June 21, 2013, the Company entered into a Securities Purchase Agreement with Redwood Management LLC, which it refers to as Redwood, and in a private placement thereunder issued Redwood a convertible promissory note in the aggregate principal amount of \$277,777, for a purchase price of \$250,000 (or a 10% original issue discount), which it refers to as the Redwood Note. The Redwood Note bears interest at a rate of 5%, which interest accrues, but does not become payable until maturity or acceleration of the principal of the Redwood Note. The Redwood Note is convertible into shares of the Company’s Common Stock at a conversion price equal to the lesser of (i) \$6.25, or (ii) 70% of the ten day average value weighted average price (“VWAP”) for the ten trading days immediately preceding the conversion date. The Redwood Note matures on December 30, 2013, six months from its issuance date. The Redwood Note may be converted by Redwood, at its option, in whole or in part. The Redwood Note includes a limitation on conversion, which provides that at no time will Redwood be entitled to convert any portion of the Redwood Note, to the extent that after such conversion, Redwood (together with its affiliates) would beneficially own more than 4.99% of the outstanding shares of the Common Stock as of such date.

The Company agreed to reserve at least 2.5 times the number of shares of its Common Stock actually issuable upon full conversion of the Redwood Note, and not to take certain actions without Redwood’s consent and granted Redwood the right, at its election, to participate in future financings subject to certain limited exceptions. So long as the Company is not in default, and provided it has given 20 days prior written notice, it may prepay the Redwood Note in full at any time at a premium of 110% of the amount owed (which multiple increases 4 months after the issuance date). In addition, if the Company completes a financing of \$7,000,000 or more, Redwood has the right, at its election, to require the Company to repay the Redwood Note in full on the closing date of such financing on the same payment terms as noted in the preceding sentence. The Redwood Note includes customary event of default provisions, and provide for a default rate of 14%.

During the twelve months ended October 31, 2013, the Company converted the Redwood Note, with a principal amount of \$ 277,777 and accrued interest of approximately \$ 4,300 into 125,000 shares of its Common Stock, at an conversion price of \$ 2.33 per share.

As of October 31, 2014, the Redwood Note no longer remained outstanding.

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

On August 20, 2013, in a private placement pursuant to a note purchase agreement, the Company 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 Company borrowed an additional \$150,000 from this accredited investor and amended and restated the terms of the August note and issued this investor 12,000 shares of its Common Stock. As amended and restated, this note has an aggregate principal amount of \$258,000, bears interest at a rate of 20% per annum and is due February 21, 2014, nine months after its original issuance date. To secure prompt payment under the note, the Company granted the holder a continuing security interest in all net proceeds the Company receives up to the aggregate amount of \$258,000 plus accrued interest from the sale of its net operating loss and or research and development tax credits through the New Jersey Economic Development Program. In October 2013, the Company paid approximately \$278,000 (principal and accrued interest) in full satisfaction of its obligation under this note.

As of October 31, 2014, this note no longer remained outstanding.

## 7. NOTES PAYABLE- FORMER OFFICER:

### *Moore Notes*

The Company has agreed to sell senior promissory notes, which it refers to as the Moore Notes, to Mr. Moore, a former director of the Company and its former chief executive officer, from time to time, under an agreement which the Company refers to as the Moore Agreement. The Moore Notes bear interest at the rate of 12% per annum. Under the terms of the amended and restated Moore Notes, the maturity date was the earlier of (i) the date of consummation of an equity financing in an amount of \$6.0 million or more or (ii) the occurrence of any event of default as defined in the Moore Notes. As of October 31, 2012, the Company owed Mr. Moore approximately \$477,000 in principal and interest under the Moore Notes.

On September 26, 2013, the Company entered into a debt conversion and repayment agreement of the Moore Notes, with respect to the repayment and partial conversion of amounts owed to Mr. Moore under the Moore Agreement. As provided in the agreement, following the closing of the Company's October 22, 2013 public offering: (a) the Company paid Mr. Moore \$100,000 in cash as partial repayment of the Moore Notes, (b) the Company converted one-half of the remaining balance (approximately \$163,132 ) using the same terms as securities being offered and sold in the October 22, 2013 offering and issued Mr. Moore 40,783 shares of its Common Stock and a five year warrant to purchase 20,392 shares of its Common Stock at an exercise price of \$5.00 on October 31, 2013 and (c) within three months of the closing of the offering, the Company will pay Mr. Moore in cash the then remaining outstanding balance under the Moore Notes (after taking into account the \$100,000 payment and automatic conversion into its securities). Following the cash payments and partial conversion into the Company's securities, there will no longer be any outstanding balances under the Moore Notes and the Company will no longer have any obligations under the Moore Notes. Securities received by Mr. Moore upon conversion will be restricted securities and subject to customary lock-up restrictions.

For the twelve months ended October 31, 2013, Mr. Moore loaned the Company \$11,200 under the Moore Notes. The Company paid Mr. Moore \$193,833 principal on the Moore Notes for the twelve months ended October 31, 2013. As of October 31, 2013, the Company was not in default under the terms of the Moore Agreement. As of October 31, 2013, the Company owed \$163,132 in principal and accrued interest Mr. Moore. On February 4, 2014, the Company paid Mr. Moore \$168,280 in principal and accrued interest, in full satisfaction of these notes. During the twelve months ended October 31, 2014 and 2013, the Company recorded interest expense of approximately \$7,200 and \$1,600, respectively.

As of October 31, 2014, this note no longer remained outstanding.



**8. COMMON STOCK PURCHASE WARRANTS AND WARRANT LIABILITY***Warrants*

As of October 31, 2014, there were outstanding warrants to purchase 4,158,092 shares of the Company's Common Stock with exercise prices ranging from \$2.76 to \$21.25 per share. Information on the outstanding warrants is as follows:

| Type                          | Exercise Price | Amount    | Expiration Date            | Type of Financing                                    |
|-------------------------------|----------------|-----------|----------------------------|--|
| Common Stock Purchase Warrant | \$18.75        | 28,632    | May 2015                   | May 2011 Convertible Debt Financing                  |
| Common Stock Purchase Warrant | \$18.75        | 10,059    | October 2015               | Oct 2011 Convertible Debt Financing                  |
| Common Stock Purchase Warrant | \$18.75        | 17,706    | May 2015 – January 2016    | December 2011 Convertible Debt Financing             |
| Common Stock Purchase Warrant | \$18.75        | 13,333    | May 2017                   | May 2012 Convertible Debt Financing                  |
| Common Stock Purchase Warrant | \$7.77-21.25   | 112,460   | December 2014 – April 2015 | Bridge Notes   |
| Common Stock Purchase Warrant | \$18.75        | 376       | N/A                        | Vendor & Other                                       |
| Common Stock Purchase Warrant | \$10.625-18.75 | 7,855     | January 2015 – May 2017    | Placement Agent – Convertible Debt Financing         |
| Common Stock Purchase Warrant | \$5.00         | 20,392    | October 2018               | Former Officer                                       |
| Common Stock Purchase Warrant | \$4.90         | 30,154    | September 2015             | Consultant   |
| Common Stock Purchase Warrant | \$2.76-5.52    | 277,055   | December 2015 – March 2024 | Stock Purchase Agreement                             |
| Common Stock Purchase Warrant | \$ 5.625-18.75 | 13,095    | October 2015 – August 2017 | August – September 2012 Convertible Promissory Notes |
| Common Stock Purchase Warrant | \$5.00         | 3,306,200 | October 2018               | Advaxis Public Offering                              |
| Common Stock Purchase Warrant | \$3.75-5.00    | 320,775   | October 2018 – March 2019  | Representative – Advaxis Public Offering             |
|                               | Grand Total    | 4,158,092 |                            |  |

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As of October 31, 2013, there were outstanding warrants to purchase 4,265,262 shares of the Company's Common Stock with exercise prices ranging from \$2.76 to \$21.25 per share. Information on the outstanding warrants is as follows:

| Type                               | Exercise Price  | Amount    | Expiration Date             | Type of Financing                                    |
|------------------------------------|-----------------|-----------|-----------------------------|--|
| Exchange Warrants - Nonexercisable | \$ 18.75        | 278,329   | October 2014                | July 2012 Exchanges                                  |
| Common Stock Purchase Warrant      | \$ 18.75        | 28,632    | May 2015                    | May 2011 Convertible Debt Financing                  |
| Common Stock Purchase Warrant      | \$ 18.75        | 11,628    | October 2014 – October 2015 | Oct 2011 Convertible Debt Financing                  |
| Common Stock Purchase Warrant      | \$ 18.75        | 17,706    | May 2015 – January 2016     | December 2011 Convertible Debt Financing             |
| Common Stock Purchase Warrant      | \$ 18.75        | 13,333    | May 2017                    | May 2012 Convertible Debt Financing                  |
| Common Stock Purchase Warrant      | \$9.24-21.25    | 293,115   | December 2013 – April 2015  | Bridge Notes   |
| Common Stock Purchase Warrant      | \$ 18.75        | 376       | N/A                         | Vendor & Other                                       |
| Common Stock Purchase Warrant      | \$ 10.625-18.75 | 29,883    | May 2014 – May 2017         | Placement Agent – Convertible Debt Financing         |
| Common Stock Purchase Warrant      | \$ 5.00         | 20,392    | October 2018                | Former Officer                                       |
| Common Stock Purchase Warrant      | \$ 4.90         | 30,154    | September 2015              | Consultant   |
| Common Stock Purchase Warrant      | \$ 2.76-4.375   | 23,994    | December 2015 – August 2016 | Stock Purchase Agreement                             |
| Common Stock Purchase Warrant      | \$ 5.625-18.75  | 13,095    | October 2015 – August 2017  | August – September 2012 Convertible Promissory Notes |
| Common Stock Purchase Warrant      | \$ 5.00         | 3,306,250 | October 2018                | Advaxis Public Offering                              |
| Common Stock Purchase Warrant      | \$ 5.00         | 198,375   | October 2018                | Representative – Advaxis Public Offering             |
|                                    | Grand Total     | 4,265,262 |                             |  |

A summary of changes in warrants for the year ended October 31, 2014 is as follows:

| Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life In Years | Aggregate Intrinsic Value |
|--------|---------------------------------|--|---------------------------|
|--------|---------------------------------|--|---------------------------|

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|  |            |          |      |           |
|--|------------|----------|------|-----------|
| Outstanding and Exercisable Warrants at October 31, 2013 | 4,265,262  | \$ 6.71  | 4.22 | \$ 22,208 |
| Issued   | 412,693    | \$ 4.97  |      |           |
| Exercised  | (50 )      | \$ 5.00  |      |           |
| Expired  | (519,813 ) | \$ 15.01 |      |           |
| Outstanding and Exercisable Warrants at October 31, 2014 | 4,158,092  | \$ 5.42  | 3.94 | \$ 9,518  |

At October 31, 2014, the Company had approximately 4.0 million of its total 4.2 million outstanding warrants classified as equity (equity warrants). At October 31, 2013, the Company had approximately 3.7 million of its total 4.3 million outstanding warrants classified as equity (equity warrants). At issuance, equity warrants are recorded at their relative fair values, using the Relative Fair Value Method, in the shareholders equity section of the balance sheet. The Company's equity warrants can only be settled through the issuance of shares and are not subject to anti-dilution provisions.

At October 31, 2014, the Company had approximately 123,000 of its total 4.2 million outstanding warrants classified as liability warrants (Common Stock warrant liability). The fair value of the warrant liability, as of October 31, 2014 was approximately \$32,000. At October 31, 2013, the Company had approximately 0.6 million of its total 4.3 million outstanding warrants classified as liability warrants (Common Stock warrant liability). The fair value of the warrant liability, as of October 31, 2013, was approximately \$0.6 million. In fair valuing the warrant liability, at October 31, 2014 and October 31, 2013, the Company used the following inputs in its BSM:

|                 | 10/31/2014       | 10/31/2013       |
|-----------------|------------------|------------------|
| Exercise Price: | \$2.76-21.25     | \$2.76-21.25     |
| Stock Price     | \$3.18           | \$3.74           |
| Expected term:  | 4 -1006 days     | 61-1371 days     |
| Volatility %    | 55.41% -129.38 % | 98.89% -186.24 % |
| Risk Free Rate: | .01%-1.62 %      | .035%-.94 %      |

*Warrant Liability/Embedded Derivative Liability*

*Warrant Liability*

As of October 31, 2014, the Company had approximately 123,000 of its total approximately 4.2 million total warrants classified as liabilities (liability warrants). All of these 123,000 liability warrants are outstanding. The Company utilizes the BSM to calculate the fair value of these warrants at issuance and at each subsequent reporting date. For those warrants with exercise price reset features (anti-dilution provisions), the Company computes multiple valuations, each quarter, using an adjusted BSM, to account for the various possibilities that could occur due to changes in the inputs to the BSM as a result of contractually-obligated changes (for example, changes in strike price to account for down-round provisions). The Company effectively weights each calculation based on the likelihood of occurrence to determine the value of the warrants at the reporting date. At October 31, 2014, approximately 60,000 of the 123,000 liability warrants are subject to weighted-average anti-dilution provisions. A certain number of liability warrants contain a cash settlement provision in the event of a fundamental transaction (as defined in the Common Stock purchase warrant). Any changes in the fair value of the warrant liability (i.e. - the total fair value of all outstanding liability warrants at the balance sheet date) between reporting periods will be reported on the statement of operations.

As of October 31, 2013, the Company had approximately 565,000 of its total approximately 4.3 million total warrants classified as liabilities (liability warrants). Of these 565,000 liability warrants, approximately 287,000 warrants are outstanding and approximately 278,000 warrants are exchange warrants – nonexercisable. The Company utilizes the BSM to calculate the fair value of these warrants at issuance and at each subsequent reporting date. For those warrants with exercise price reset features (anti-dilution provisions), the Company computes multiple valuations, each quarter, using an adjusted BSM, to account for the various possibilities that could occur due to changes in the inputs to the BSM as a result of contractually-obligated changes (for example, changes in strike price to account for down-round provisions). The Company effectively weights each calculation based on the likelihood of occurrence to determine the value of the warrants at the reporting date. At October 31, 2013, approximately 203,000 of the 565,000 liability warrants are subject to anti-dilution provisions. A certain number of liability warrants contain a cash settlement provision in the event of a fundamental transaction (as defined in the Common Stock purchase warrant). Any changes in the fair value of the warrant liability (i.e. - the total fair value of all outstanding liability warrants at the balance sheet date) between reporting periods will be reported on the statement of operations.

At October 31, 2014 and October 31, 2013, the fair value of the warrant liability was \$32,091 and \$646,734, respectively. For the twelve months ended October 31, 2014 and 2013, the Company reported income of \$619,089 and a loss of \$1,504,465, respectively, due to changes in the fair value of the warrant liability.

*Exercise of Warrants*

During the twelve months ended October 31, 2014, an accredited investor exercised 50 warrants at an exercise price of \$5.00, resulting in net proceeds to the Company of \$250. During the twelve months ended October 31, 2013, an accredited investor exercised 8,889 warrants at an exercise price of \$10.625, resulting in net proceeds to the Company of \$94,444. During the twelve months ended October 31, 2013, the Company issued 484,876 shares to Tonaquint as a result of cashless exercises of 189,415 warrants per the terms of the December 2012 promissory note in addition to the settlement agreement entered into in October 2013.

#### *Expiration of Warrants*

During the twelve months ended October 31, 2014, the Company had 60,069 warrants with anti-dilution provisions, and 459,744 warrants, with no such anti-dilution provisions, expire unexercised.

During the twelve months ended October 31, 2013, the Company had 500 warrants with no anti-dilution provisions, expire unexercised.

#### *Warrants with anti-dilution provisions*

Some of the Company's warrants (approximately 60,000) contain anti-dilution provisions originally set at an exercise price of \$25.00 with a term of five years. As of October 31, 2014, these warrants had an exercise price of approximately \$7.71. As of October 31, 2013, these warrants had an exercise price of approximately \$9.24. If the Company issues any Common Stock, except for exempt issuances as defined in the warrant agreement for consideration less than the exercise price then the exercise price and the amount of warrant shares available would be adjusted to a new price and amount of shares per the "weighted average" formula included in the warrant agreement. For the twelve months ended October 31, 2014, this anti-dilution provision required the Company to issue approximately 37,200 additional warrant shares and the exercise price to be lowered to \$7.71. Any future financial offering or instrument issuance below the current exercise price of \$7.71 will cause further anti-dilution and re-pricing provisions in approximately 60,000 of the Company's total outstanding warrants.

For those warrants with exercise price reset features (anti-dilution provisions), the Company computes multiple valuations, each quarter, using an adjusted BSM, to account for the various possibilities that could occur due to changes in the inputs to the BSM as a result of contractually-obligated changes (for example, changes in strike price to account for down-round provisions). The Company utilized different exercise prices of \$7.71 and \$6.50, weighting the possibility of warrants being exercised at \$7.71 between 40% and 50% and warrants being exercised at \$6.50 between 60% and 50%.



As of October 31, 2014, there were outstanding warrants to purchase 4,158,092 shares of the Company's Common Stock with exercise prices ranging from \$2.76 to \$21.25 per share.

### *Embedded Derivative Liability*

The Company has convertible features (known as "Embedded Derivatives") in its outstanding convertible promissory notes. The Embedded Derivatives are recorded as liabilities at issuance. These Embedded Derivatives are valued using the BSM and are subject to revaluation at each reporting date. Any change in fair value between reporting periods will be reported on the statement of operations.

At October 31, 2014 and October 31, 2013, the fair value of the Embedded Derivative Liability was \$0 as the related notes were paid off, converted or reached maturity.

The fair value of the Warrants and Embedded Derivatives are estimated using an adjusted BSM model. The Company computes multiple valuations, each quarter, using the BSM model for each derivative instrument to account for the various possibilities that could occur due to changes in the inputs to the BSM model as a result of contractually-obligated changes (for example, changes in strike price to account for down-round provisions). The Company effectively weights each calculation based on the likelihood of occurrence to determine the value of the derivative at the reporting date. As of October 31, 2014, the fair value of the Warrants and Embedded Derivatives was determined to be approximately \$32,000 and \$0, respectively. As of October 31, 2013, the fair value of the Warrants and Embedded Derivatives was determined to be approximately \$647,000 and \$0, respectively. Change in the fair value of the Common Stock warrant liability for the year ended October 31, 2014 was a gain of \$619,089 and a loss of \$1,504,465 for October 31, 2013.

## **9. STOCK OPTIONS:**

Total compensation cost for the Company's stock option plans recognized in the statement of operations for the year ended October 31, 2014 was approximately \$926,000, of which approximately \$357,000 was included in research and development expenses and approximately \$569,000 was included in general and administrative expenses.

Total compensation cost for Company's stock plans recognized in the statement of operations for the year ended October 31, 2013 was approximately \$3.5 million, of which approximately \$1.2 million was included in research and development expenses and approximately \$2.3 million was included in general and administrative expenses.

The fair value of options granted for the years ended October 31, 2014 and 2013 amounted to \$144,640 and \$1,215,875, respectively.

As of October 31, 2014, there was approximately \$807,000 of unrecognized compensation cost related to non-vested stock option awards, which is expected to be recognized over a remaining average vesting period of 80 days.

A summary of the grants, cancellations and expirations (none were exercised) of the Company's outstanding options for the periods starting with October 31, 2012 through October 31, 2014 is as follows:

|  | Shares    | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Life<br>In Years | Aggregate<br>Intrinsic<br>Value |
|--|-----------|--|---|---------------------------------|
| Outstanding as of October 31, 2012       | 358,459   | \$ 20.00                                 | 8.0   | -                               |
| Granted                                  | 134,600   | \$ 9.38                                  | 9.5   | -                               |
| Cancelled or Expired                     | (25,136 ) | \$ 12.50                                 | -   | -                               |
| Outstanding as of October 31, 2013       | 467,923   | \$ 15.86                                 | 7.28  | -                               |
| Granted                                  | 36,000    | \$ 4.02                                  | 9.16  | -                               |
| Cancelled or Expired                     | (35,955 ) | \$ 8.57                                  | -   | -                               |
| Outstanding as of October 31, 2014       | 467,968   | \$ 15.51                                 | 6.34  | -                               |
| Vested & Exercisable at October 31, 2014 | 406,017   | \$ 15.89                                 | 5.82  | \$ -                            |

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The fair value of each option granted from the Company's stock option plans during the years ended October 31, 2014 and 2013 was estimated on the date of grant using the Black-Scholes option-pricing model. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of the Company's Common Stock price, (ii) the periods of time over which employees and Board Directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on the Company's Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. The Company used their own historical volatility in determining the volatility to be used. Expected lives are based on contractual terms given the early stage of the business and lack of intrinsic value. The expected dividend yield is zero as the Company has never paid dividends to common shareholders and does not currently anticipate paying any in the foreseeable future.

|                         | Year Ended<br>October 31,<br>2014 | Year<br>Ended<br>October<br>31,<br>2013 |   |  |
|-------------------------|-----------------------------------|---|---|--|
| Expected volatility     | 151.38-171.12%                    | 138.05%                                 |   |  |
| Expected Life           | 5                                 | 5.5                                     |   |  |
| Dividend yield          | 0                                 | 0                                       |   |  |
| Risk-free interest rate | 1.39-1.72                         | % 2.04                                  | % |  |
| Forfeiture Rate         | 4.4                               | % 4.4                                   | % |  |

### 2011 Employee Stock Purchase Plan

The Company's board of directors adopted the Advaxis, Inc. 2011 Employee Stock Purchase Plan, which the Company refers to as the ESPP, on August 22, 2011, and the Company's shareholders approved the ESPP on September 27, 2011. The ESPP allows employees to purchase Common Stock of the Company at a 15% discount to the market price on designated exercise dates. Employees were eligible to participate in the ESPP beginning December 30, 2011. 40,000 shares of the Company's Common Stock are reserved for issuance under the ESPP.

During the twelve months ended October 31, 2014, \$6,251 was withheld from employees, on an after-tax basis, in order to purchase 2,110 shares of the Company's Common Stock. During the twelve months ended October 31, 2013 approximately \$28,040 was withheld from employees, on an after-tax basis, in order to purchase an aggregate of 6,334 shares of Company's Common Stock. As of October 31, 2014, 29,890 shares of Company's Common Stock remain available for issuance under the ESPP.

### 10. COMMITMENTS AND CONTINGENCIES:

*Employment Agreements*

In December, 2013, each of the Company's then executive officers requested to purchase stock directly from the Company at market price. To facilitate such requests, the Company amended each of the then executive officer's employment agreements so that such officers could make periodic purchases of the Company's Common Stock at fair market value. Listed below are the annual amounts to be purchased by each executive. On June 5, 2014, the Company and each of Daniel J. O'Connor, Chief Executive Officer and President, Gregory T. Mayes, Executive Vice President, Chief Operating Officer and Secretary, Robert G. Petit, Executive Vice President and Chief Scientific Officer, Sara M. Bonstein, Senior Vice President, Chief Financial Officer and Chris L. French, Vice President, Regulatory & Medical Affairs (each an "Executive"), voluntarily entered into a further amendment (each, an "Amendment" and collectively, the "Amendments") to their respective Employment Agreements (each, an "Employment Agreement"). The Amendments now provide that the respective stock purchases will occur on the last business day of each calendar month and will be effected through a direct purchase from the Company at a purchase price equal to the closing price of the Common Stock on the purchase date. The Company has not filed a Registration Statement on Form S-8 (or any other registration form) to cover the shares of Common Stock issuable pursuant to the Amendments.

The allocation between the cash and equity components of each Executive's base salary is as follows:

|                    | ANNUALIZED<br>Annual<br>Amount to be<br>Purchased | For the Year Ended October 31,<br>2014 |                |              |                |
|--------------------|---|--|----------------|--------------|----------------|
|                    |   | Gross Purchase                         |                | Net Purchase |                |
| Executive Officer  | \$  | \$                                     | # of<br>shares | \$           | # of<br>shares |
| Daniel J. O'Connor | \$ 81,250   | \$68,750                               | 21,687         | \$50,891     | 15,950         |
| David J. Mauro     | \$ 15,750   | \$606                                  | 190            | \$527        | 165            |
| Gregory T. Mayes   | \$ 19,875   | \$16,818                               | 5,305          | \$13,801     | 4,333          |
| Robert G. Petit    | \$ 24,225   | \$20,498                               | 6,466          | \$16,363     | 5,159          |
| Sara M. Bonstein   | \$ 16,875   | \$10,384                               | 3,355          | \$8,038      | 2,585          |
| Chris L. French    | \$ 10,750   | \$8,837                                | 2,785          | \$7,475      | 2,352          |

For the twelve months ended October 31, 2014, the Company recorded stock compensation expense of \$128,241 on the statement of operations representing 40,320 shares of its Common Stock (31,026 shares on a net basis after employee payroll taxes).

As to preserve the Company's cash resources, in his current Amendment, Mr. O'Connor voluntarily requested to waive and hence forego the scheduled increases in his base salary that were required under his Employment Agreement. Therefore, Mr. O'Connor did not receive a base salary increase or a salary increase for closing a licensing or other strategic transaction.

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In addition to the purchases of Common Stock set forth in the above table, Mr. O'Connor has also purchased an additional 72,676 shares of Common Stock out of his personal funds for an aggregate consideration of approximately \$313,419. These purchases consisted of the conversion of amounts due under a promissory note of approximately \$66,500 for 21,091 shares, 2013 base salary which he elected to receive in Common Stock of approximately \$182,919 for 34,752 shares, and purchases of the Company's Common Stock in the October 2013 and March 2014 public offerings of 13,500 shares for \$54,000 and 3,333 shares for \$10,000.

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### *Stock Awards*

In December 2013, the Company granted stock awards and restricted stock units (“RSUs”) to employees, executive officers and directors under the 2011 Omnibus Incentive Plan.

**Management Team Bonuses:** Executive officers received a portion of their year-end performance bonus (with a total fair value of approximately \$129,000) in the aggregate amount of 31,846 shares of the Company’s Common Stock (21,389 on a net basis after employee payroll taxes).

**Equity grant to executive officers:** The Company granted 525,000 shares of its Common Stock to its executive officers. Of these shares, 105,000 shares of its our Common Stock (63,949 shares on a net basis after employee payroll taxes) vested immediately, with a total fair value of \$423,150, and were issued and recorded as a charge to income during the twelve months ended October 31, 2014. The remaining 420,000 shares represent RSUs and are to vest in equal installments over twelve quarters such that 100% of the RSUs have vested by the third anniversary of the grant date. These RSU’s are subject to availability of shares under the 2011 Omnibus Incentive Plan and are subject to forfeiture under certain conditions. During the twelve months ended October 31, 2014, \$879,883 was charged to stock compensation expense, representing 218,333 shares of the Company’s Common Stock (133,903 shares on a net basis after employee payroll taxes), and 80,000 shares were forfeited. During the twelve months ended October 31, 2014, the 2011 Omnibus Incentive Plan was increased from 520,000 to 2,120,000.

**Equity grant to non-executive employees:** The Company granted approximately \$101,250 of the aggregate base salary compensation, or 25,124 shares of Common Stock, to be issued to its non-executive employees. Of this grant, \$20,250 vested immediately and 5,025 shares of Common Stock (3,685 shares on a net basis after employee payroll taxes) were issued to non-executive employees. The remaining \$81,250, or 20,099 shares of Common Stock, represents RSUs and are to vest in equal installments over twelve quarters such that 100% of the RSUs have vested by the third anniversary of the grant date. In addition an employee received 100 shares of the Company’s Common Stock (91 shares on a net basis after employee payroll taxes) with a total fair value of \$336 award for employee excellence. During the twelve months ended October 31, 2014, \$45,719 was charged to stock compensation expense, representing 11,362 shares of the Company’s Common Stock (8,758 shares on a net basis after employee payroll taxes) and 2,316 shares of Common Stock were forfeited.

All of these non-executive equity grants are currently available under the 2011 Omnibus Incentive Plan. As of October 31, 2014, all vested shares have been issued.

The Company recognizes the fair value of those vested shares in the statement of operations in the period earned.

### *Director Compensation*

During December 2013, the Board of Directors deemed it advisable and in the best interests of the Company to issue shares of RSUs as compensation for all 2013 Board of Director committee meetings and to cancel any options designated for issuance related to those 2013 committee and board meetings and to further issue shares of RSUs for all fiscal years 2013 through 2016 Board of Director committee meetings in the aggregate amount of 50,000 shares of RSUs to each non-employee director (excluding Mr. Moore). The RSU grant will vest quarterly over three years such that 100% of the RSU will be vested on the third anniversary date (December 2016). During the twelve months ended October 31, 2014, \$340,039 was charged to stock compensation expense, representing 84,377 shares of the Company's Common Stock.

During December 2013, the Board of Directors deemed it advisable and in the best interests of the Company to amend a certain provision of the consulting agreement with Mr. Moore, which took effect August 19, 2013 and issue 37,500 restricted stock units (RSU's). The RSU grant will vest quarterly over three years such that 100% of the RSU will be vested on the third anniversary date (December 2016). Since Mr. Moore was not nominated for re-election, only 10,976 RSUs vested through his current term on the Board. Accordingly, \$46,099 was charged to stock compensation expense for the year ended October 31, 2014.

#### *Legal Proceedings*

##### *Iliad Research and Trading*

On March 24, 2014, Iliad Research and Trading, L.P. ("Iliad") filed a complaint (the "Complaint") against the Company in the Third Judicial District Court of Salt Lake County, Utah, purporting to assert claims for breach of express and implied contract. Specifically, Iliad alleged that the Company granted a participation right to Tonaquint, Inc. ("Tonaquint") in a securities purchase agreement between Tonaquint and the Company, dated as of December 13, 2012 (the "Purchase Agreement"), pursuant to which Tonaquint was entitled to participate in any transaction that the Company structured in accordance with Section 3(a)(9) or Section 3(a)(10) of the Securities Act of 1933, as amended. Iliad further alleged that the settlement that the Company entered into with Ironridge Global IV, Ltd. ("Ironridge"), pursuant to which the Company issued certain shares of its Common Stock to Ironridge in reliance on the Section 3(a)(10) exemption, occurred without adequate notice for Tonaquint to exercise its participation right. In addition, Iliad alleged that it acquired all of Tonaquint's rights under the Purchase Agreement in April 2013. On May 9, 2014, the Company filed papers in support of its motion to dismiss the Complaint in its entirety. On June 2, 2014, Iliad filed an amended complaint (the "Amended Complaint"), which purported to add claims against the Company under the federal and Utah securities laws and for common law fraud. On June 30, 2014, the Company removed the action to the United States District Court for the District of Utah. On August 1, 2014, after the Court issued its Order Granting Stipulated Motion for Leave to File Second Amended Complaint, Iliad filed a Second Amended Complaint (the "SAC"), which purports to add a sixth claim for conversion. Iliad seeks "damages in an amount to be determined at trial" (though the common law fraud damages alone are alleged to be "greater than \$300,000") plus interest, attorneys' fees and costs. Iliad has also asked for punitive damages in connection with its claims under the Utah Securities Act (equal to three times its actual damages), common law fraud and conversion. The Company intends to continue to defend itself vigorously.



*Brio Capital L.P.*

On March 22, 2013, the Company was notified that Brio Capital L.P. which the Company refers 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 the Company refers 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 its Common Stock that was 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 the Company to issue to Brio 21,742 shares of the Company's 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, the Company 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, the Company 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 October 29, 2013.

*Maxim Group, LLC*

On August 19, 2013, the Company 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 the Company and services provided. As consideration for terminating the agreement, the Company agreed to pay Maxim approximately \$589,000 in monthly installment payments in either cash or shares of its Common Stock, and a warrant to purchase 30,154 shares of its Common Stock at an exercise price of \$4.90 per share. Additionally, in order to move the settlement forward, the Company reluctantly agreed to pay Maxim an additional \$150,000 upon the completion of a contemplated public offering of securities. On September 17, 2013, the Company issued 25,582 shares of its Common Stock as an installment payment under this agreement and also issued the warrant to acquire 30,154 shares of its Common Stock at \$4.90 per share, and on September 27, 2013, the Company issued 158,385 shares of its Common Stock to satisfy the remaining amount owed under this agreement. Maxim rejected the delivery of these 158,385 shares and claimed that the Company may not prepay its 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 its public offering in October, 2013 the Company paid the aforementioned \$150,000 and commenced final settlement of the disputed amounts owed. On or about November 14, 2013 Maxim initiated a proceeding by confession of judgment in New York State Court to recover monies it believed Advaxis owed it under the Termination Agreement in the amount of \$484,710. 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 the Company paid Maxim \$285,000 in final settlement of all matters related to their claim.

The Company is from time to time involved in legal proceedings in the ordinary course of its business. The Company does 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 its financial condition or results of operations.

*Consulting Agreement; Debt Conversion/Repayment*

On August 19, 2013, the Company entered into a consulting agreement with Mr. Thomas A. Moore, a former director of the Company and its former Chief Executive Officer, pursuant to which Mr. Moore will continue to assist the Company in exchange for (i) receiving an aggregate of approximately \$350,000, paid in installments over the course of the one year consulting period, (ii) reimbursement by the Company for any costs associated with or incurred by Mr. Moore for participation in a group health plan and (iii) a grant of 37,500 RSUs that will vest quarterly over three years. Since Mr. Moore was not nominated for re-election, only 10,976 RSUs vested through his current term on the Board. The one-year consulting agreement automatically terminated on August 18, 2014.

Following Mr. Moore's termination of his engagement as a consultant as provided in the agreement, Mr. Moore was entitled to payment of any earned or accrued but unpaid compensation and, provided that Mr. Moore executes a separation agreement and general release, a one-time lump sum \$350,000 disengagement payment, subject to all applicable withholdings and deductions. As of October 27, 2014, the disengagement payment was paid in full.



*Numoda*

On June 19, 2009, the Company entered into a master agreement and on July 8, 2009, the Company entered into a Project Agreement with Numoda Corporation (“Numoda”), to oversee Phase 2 clinical activity with ADXS-HPV for the treatment of invasive cervical cancer and CIN.

Numoda and the Company are in a dispute regarding the amounts outstanding under these agreements. Numoda had taken the position that it was owed approximately \$540,000 while the Company believed that the amount due to Numoda should be substantially less than that amount. The Company intends to continue to defend itself vigorously.

*Merck & Co., Inc.*

On August 22, 2014, we entered into a Clinical Trial Collaboration and Supply Agreement (the “Merck Agreement”) with Merck, pursuant to which the parties will collaborate on a Phase 1/2 dose-escalation and safety study. The Phase 1 portion of the study will evaluate the safety of our Lm-LLO based immunotherapy for prostate cancer, ADXS31-142 (the “Advaxis Compound”) as monotherapy and in combination with KEYTRUDA® (pembrolizumab), Merck’s humanized monoclonal antibody against PD-1, (the “Merck Compound”) to determine a recommended Phase 2 combination dose. The Phase 2 portion will evaluate the safety and efficacy of the Advaxis Compound in combination with the Merck Compound. Both phases of the study will be in patients with previously treated metastatic castration-resistant prostate cancer. A joint development committee, comprised of equal representatives from both parties, is responsible for coordinating all regulatory and other activities under, and pursuant to, the Merck Agreement.

Each party is responsible for their own internal costs and expenses to support the study, while we will be responsible for all third party costs of conducting the study. Merck will be responsible for manufacturing and supplying the Merck Compound. We will be responsible for manufacturing and supplying the Advaxis Compound. We will be the sponsor of the study and hold the IND related to the study.

All data and results generated under the study (“Collaboration Data”) will be jointly owned by the parties, except that ownership of data and information generated from sample analysis to be performed by each party on its respective compound will be owned by the party conducting such testing. All rights to all inventions and discoveries, which claim or cover the combined use of the Advaxis Compound and the Merck Compound shall belong jointly to the parties. Inventions and discoveries relating solely to the Advaxis Compound, or a live attenuated bacterial vaccine, shall be the exclusive property of us. Inventions and discoveries relating solely to the Merck Compound, or a PD-1 antagonist, shall be the exclusive property of Merck.

The Merck Agreement shall continue in full force and effect until completion of all of the obligations of the parties or a permitted termination.

*MedImmune/AstraZeneca*

On July 21, 2014, we entered into a Clinical Trial Collaboration Agreement (the “MedImmune Agreement”) with MedImmune, the global biologics research and development arm of AstraZeneca, pursuant to which the parties intend to initiate a Phase 1/2 clinical study in the United States to evaluate the safety and efficacy of MedImmune’s investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736, in combination with our investigational Lm-LLO cancer immunotherapy, ADXS-HPV, as a combination treatment for patients with advanced, recurrent or refractory cervical cancer and HPV-associated head and neck cancer. A joint steering committee, composed of equal representatives from both parties, is responsible for various matters associated with the collaboration, including protocol approval, as well as reviewing and monitoring the progress of the study.

MedImmune will be responsible for providing MEDI4736 at no cost, as well as costs related to the proprietary assays performed by MedImmune or a third party on behalf of MedImmune. We will be the sponsor of the study and be responsible for the submission of all regulatory filings to support the study, the negotiation and execution of the clinical trial agreements associated with each study site, and the packaging and labelling of the Advaxis and MedImmune product candidates to be used in the study and the costs associated therewith. For a period beginning upon the completion of the study and the receipt by MedImmune of the last final report for the study and ending one hundred twenty (120) days thereafter (unless extended), MedImmune will be granted first right to negotiate in good faith in an attempt to enter into an agreement with us with respect to the development, regulatory approval and commercialization of ADXS-HPV and MEDI4736 to be used in combination with each other for the treatment or prevention of cancer. Neither party is obligated to enter into such an agreement. In the event the parties do not enter an agreement and we obtain regulatory approval for ADXS-HPV in combination with any PD-1 antibody or PD-L1 antibody, we shall pay MedImmune a royalty obligation and one-time payment.

All intellectual property rights made, conceived or generated through the clinical trials that relate solely to a MedImmune development product shall be owned solely by MedImmune. All intellectual property rights made, conceived or generated through the clinical trials that relate solely to an Advaxis development product shall be owned solely by us. All intellectual property rights made, conceived or generated through the clinical trials that relate to the combination of one or more MedImmune development product and one or more Advaxis development product shall be jointly owned by both parties; provided, however that in the event the parties do not enter into a clinical development and commercialization agreement, we will not exploit, commercialize or license the joint inventions, except for the performance of its obligations under the MedImmune Agreement. MedImmune has the sole right to prosecute and enforce all patents and other intellectual property rights covering all joint inventions and all associated costs will be shared by the parties.

The MedImmune Agreement shall remain in effect until the earlier of (i) permitted termination, (ii) the parties entering into a clinical development and commercialization agreement or expiration of the negotiation period (unless extended), except with respect to rights that survive termination. Either party may terminate the MedImmune Agreement upon thirty (30) days written notice upon material breach of the other party, unless the breach is cured in such period or reasonable actions to cure the breach are initiated and pursued (if the breach is not capable of being cured during the 30-day notice period). In addition, either party may terminate the MedImmune Agreement immediately if the party determines in good faith that the trials may unreasonably affect the safety of trial subjects.

*Office & Laboratory Lease*

In April 2011, the Company entered into a sublease agreement and relocated its current offices and laboratory to an approximately 10,000 square foot leased facility in Princeton, NJ which approximates \$21,000 per month plus utilities. Utility costs are estimated to be approximately \$7,200 per month and are capped at approximately \$10,700 per month. The Company made an initial payment of approximately \$54,000 prior to entering the new facility. Approximately \$8,000 of the initial \$54,000 payment was for the security deposit and was recorded on the balance sheet as a long-term asset. The sublease agreement has a termination date of November 29, 2015. The Company expects its annual lease costs to approximate \$338,000 per year (approximately \$1.02 million in the aggregate) until the termination of this agreement in November 2015.

Rent expense for the years ended October 31, 2014 and 2013 was \$330,000 and \$229,416, respectively.

*Sale of Net Operating Losses (NOLs)*

The Company may be eligible, from time to time, to receive cash from the sale of its Net Operating Losses under the State of New Jersey NOL Transfer Program. In January 2014, the Company received a net cash amount of \$625,563 from the sale of its state NOLs and research and development tax credits for the periods ended October 31, 2010 and 2011. In December 2014, the Company received a net cash amount of \$1,731,317 from the sale of its state NOLs and research and development tax credits for the periods ended October 31, 2012 and 2013.

**11. INCOME TAXES:**

The income tax provision (benefit) consists of the following:

|         | October 31,<br>2014 | October 31,<br>2013 |
|---------|---------------------|---------------------|
| Federal |                     |                     |

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|                                |               |              |
|--------------------------------|---------------|--------------|
| Current                        | \$-           | \$-          |
| Deferred                       | (5,777,937)   | (3,725,144)  |
| State and Local                |               |              |
| Current                        | (2,356,880)   | (725,190 )   |
| Deferred                       | 1,008,338     | (202,712 )   |
| Change in valuation allowance  | 4,769,599     | 3,927,856    |
| Income tax provision (benefit) | \$(2,356,880) | \$(725,190 ) |

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The Company has U.S. federal net operating loss carryovers (NOLs) of approximately \$75,320,000 and \$58,447,000 at October 31, 2014 and 2013, respectively, available to offset taxable income which expire beginning in 2023. If not used, these NOLs may be subject to limitation under Internal Revenue Code Section 382 should there be a greater than 50% ownership change as determined under the regulations. The Company plans on undertaking a detailed analysis of any historical and/or current Section 382 ownership changes that may limit the utilization of the net operating loss carryovers. The Company also has New Jersey State Net Operating Loss carryovers of \$18,123,000 and \$17,563,000, as of October 31, 2014 and October 31, 2013, respectively, available to offset future taxable income through 2034.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon future generation for taxable income during the periods in which temporary differences representing net future deductible amounts become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. After consideration of all the information available, Management believes that significant uncertainty exists with respect to future realization of the deferred tax assets and has therefore established a full valuation allowance. For the year ended October 31, 2014 and 2013, the change in the valuation allowance was approximately \$4,770,000 and \$3,928,000.

The Company evaluated the provisions of ASC 740 related to the accounting for uncertainty in income taxes recognized in an enterprise's financial statements. ASC 740 prescribes a comprehensive model for how a company should recognize, present, and disclose uncertain positions that the company has taken or expects to take in its tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. Differences between tax positions taken or expected to be taken in a tax return and the net benefit recognized and measured pursuant to the interpretation are referred to as "unrecognized benefits." A liability is recognized (or amount of net operating loss carry forward or amount of tax refundable is reduced) for unrecognized tax benefit because it represents an enterprise's potential future obligation to the taxing authority for a tax position that was not recognized as a result of applying the provisions of ASC 740.

If applicable, interest costs related to the unrecognized tax benefits are required to be calculated and would be classified as "Other expenses – Interest" in the statement of operations. Penalties would be recognized as a component of "General and administrative."

No interest or penalties on unpaid tax were recorded during the years ended October 31, 2014 and October 31, 2013, respectively. As of October 31, 2014 and October 31, 2013, no liability for unrecognized tax benefits was required to be reported. The Company does not expect any significant changes in its unrecognized tax benefits in the next year.

The Company files tax returns in the U.S. federal and state jurisdictions and is subject to examination by tax authorities beginning with the year ended October 31, 2011.

The Company's deferred tax assets (liabilities) consisted of the effects of temporary differences attributable to the following:

|  | Years Ended         |                     |
|--|---------------------|---------------------|
|  | October 31,<br>2014 | October 31,<br>2013 |
| <b>Deferred Tax Assets</b>                     |                     |                     |
| Net operating loss carryovers                  | \$26,685,000        | \$21,994,270        |
| Stock-based compensation                       | 3,467,000           | 3,772,857           |
| Other deferred tax assets                      | 2,094,000           | 1,603,056           |
| Total deferred tax assets                      | \$32,246,000        | \$27,370,183        |
| Valuation allowance                            | (31,112,000)        | (26,342,495)        |
| Deferred tax asset, net of valuation allowance | \$1,134,000         | \$1,027,688         |
| <b>Deferred Tax Liabilities</b>                |                     |                     |
| Other deferred tax liabilities                 | (1,134,000 )        | (1,027,688 )        |
| Total deferred tax liabilities                 | \$(1,134,000 )      | \$(1,027,688 )      |
| Net deferred tax asset (liability)             | \$-                 | \$-                 |

The expected tax (expense) benefit based on the statutory rate is reconciled with actual tax expense benefit as follows:

|   | Years Ended         |                     |
|---|---------------------|---------------------|
|   | October 30,<br>2014 | October 31,<br>2013 |
| US Federal statutory rate                                 | 34.00%              | 34.00               |
| State income tax, net of federal benefit                  | 5.9                 | 5.9                 |
| Deferred tax true-up - permanent differences              | 0.2                 | (9.8 )              |
| Non-deductible loss on note retirement                    | 0.0                 | (9.4 )              |
| Deferred tax adjustment                                   | (13.3 )             | (0.7 )              |
| Change in valuation allowance                             | (25.3 )             | (19.0 )             |
| Income tax benefit from sale of New Jersey NOL carryovers | 12.5                | 3.5                 |
| Other permanent differences                               | (1.5 )              | (1.0 )              |
| Income tax (provision) benefit                            | 12.5 %              | 3.5 %               |



## 12. SHAREHOLDERS' EQUITY:

### *Amendments*

At the Annual Meeting of Stockholders of the Company held on July 9, 2014, the stockholders ratified and approved an amendment to the Company's 2011 Omnibus Incentive Plan to increase the aggregate number of shares of common stock authorized for issuance under such plan by from 520,000 shares to 2,120,000 shares. Furthermore, the stockholders approved an amendment to the Company's Certificate of Incorporation to increase the total number of authorized shares of common stock from 25,000,000 shares of common stock to 45,000,000 shares of common stock.

### *Equity Enhancement Program*

On October 26, 2012, the Company entered into a Common Stock Purchase Agreement, which it refers to as the Hanover Purchase Agreement, with Hanover, which requires Hanover to purchase up to \$10.0 million of shares of its Common Stock over the 24-month term following the effectiveness of the resale registration statement. The purchase price for such shares of Common Stock will be the higher of (i) the minimum price, which the Company refers to as the Floor Price, set forth in its notice electing to effect such issuance, and (ii) 90% of the arithmetic average of the five lowest closing sale prices of the Common Stock during the applicable ten trading day pricing period (or, if less, the arithmetic average of all trading days with closing sale prices in excess of the Floor Price), subject to adjustment. Each trading day with a closing sale price less than the Floor Price is excluded from the calculation of the purchase price and automatically reduces the number of trading days in the applicable pricing period.

In consideration for Hanover's execution and delivery of the Hanover Purchase Agreement, in connection with the execution and delivery of the Hanover Purchase Agreement, the Company issued Hanover 28,000 Commitment Fee Shares in November 2012. The Company recognized non-cash expense of approximately \$157,000 related to the issuance of the Commitment Fee Shares in the twelve months ended October 31, 2013. The Company has also agreed to issue Hanover additional Maintenance Fee Shares of its Common Stock in the event that no shares of Common Stock have been purchased or sold pursuant to the Hanover Purchase Agreement during any calendar quarter during the 24 month term per the terms of the Hanover Purchase Agreement.

The Hanover Purchase Agreement provides for indemnification of Hanover and its affiliates in the event that the Company breaches any of its representations and warranties under the Hanover Purchase Agreement.



In connection with the Hanover Purchase Agreement, on October 26, 2012, the Company entered into a registration rights agreement, which it refers to as the Hanover Registration Rights Agreement, with Hanover, and granted to Hanover certain registration rights related to the Commitment Fee Shares, the Maintenance Fee Shares, and the shares issuable under the Hanover Purchase Agreement. Under the Hanover Registration Rights Agreement, the Company filed with the SEC a registration statement for the purpose of registering the resale of the Common Stock issued to Hanover.

During the twelve months ended October 31, 2013, the Company sold 359,224 shares of its Common Stock under the Equity Enhancement Program for proceeds totaling \$2,964,140.

On September 27, 2013, the Company notified Hanover Holdings LLC that it irrevocably commits to suspend any draw-downs under the Common Stock Purchase Agreement without the prior written consent of Aegis Capital Corp. for a six month period from the closing. During the twelve months ended October 31, 2014, the Company and Hanover agreed to terminate the Common Stock Purchase Agreement in exchange for the issuance of 7,080 shares of the Company's Common Stock valued at \$34,126.

#### *Reverse Stock Split*

At the annual meeting of shareholders held on June 14, 2013, the Company's shareholders approved the filing of a Certificate of Amendment to effect a reverse stock split of its issued and outstanding Common Stock, and the filing of a Certificate of Amendment to decrease the total number of its authorized shares of Common Stock. On July 11, 2013, the Company's Board of Directors authorized a reverse stock split at a ratio of 1-for-125 and approved the implementation of the authorized share capital decrease after the effectiveness of the reverse stock split. Accordingly, the Company amended its Amended and Restated Certificate of Incorporation by the filing of two Certificates of Amendment with the Delaware Secretary of State as follows:(a) on July 11, 2013, to effect a 1-for-125 reverse stock split of its outstanding Common Stock, par value \$0.001 per share, to take effect on July 12, 2013 at 4:30 p.m. EDT, and (b) on July 12, 2013, to decrease the total number of authorized shares of Common Stock on a post-reverse stock split basis, so that the total number of shares that the Company has the authority to issue is 30,000,000 shares, of which 25,000,000 shares are Common Stock and 5,000,000 shares are 'blank check' preferred stock. The reverse stock split was effective at approximately 4:30 p.m. EDT on July 12, 2013, and the share capital decrease took effect thereafter upon filing with the Delaware Secretary of State. All references in this report to number of shares, price per share and weighted average number of shares of Common Stock outstanding prior to this reverse stock split have been adjusted to reflect the reverse stock split on a retroactive basis, unless otherwise noted.

#### *Licensing Agreement – 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's 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 of \$400,000 by purchasing from the Company 108,724 shares of its Common Stock at a price of \$3.68 per share, GBP also received 100,000 warrants at an exercise price of \$5.52 which expire in December 2018.

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GBP will be responsible for all clinical development and commercialization costs in the GBP territory. GBP will also reimburse the Company \$2.25 million toward its U.S. registrational study, where such payment will help to offset development costs. 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 of ADXS-HPV to GBP for Asia, Africa, and former USSR territory, exclusive of India and certain other countries, for all HPV-associated indications. Advaxis retains exclusive rights to ADXS-HPV for the rest of the world.

#### *Licensing Agreement – Aratana Therapeutics*

On March 19, 2014, the Company and Aratana entered into a definitive Exclusive License Agreement (the “Aratana Agreement”). Pursuant to the Agreement, Advaxis granted Aratana an exclusive, worldwide, royalty-bearing, license, with the right to sublicense, certain Advaxis proprietary technology that enables Aratana to develop and commercialize animal health products that will be targeted for treatment of osteosarcoma and other cancer indications in animals. Under the terms of the Aratana Agreement, Aratana paid an upfront payment to the Company, of \$1 million. As this license has stand-alone value to Aratana (who has the ability to sublicense) and was delivered to Aratana, upon execution of the Aratana Agreement, the Company recorded the \$1 million payment as licensing revenue in the three months ended April 30, 2014. Aratana will also pay the Company up to an additional \$36.5 million based on the achievement of certain milestones with respect to the advancement of products pursuant to the terms of the Aratana Agreement. In addition, Aratana may pay the Company an additional \$15 million in cumulative sales milestones pursuant to the terms of the Aratana Agreement.

Advaxis (i) issued and sold 306,122 shares of Advaxis’s Common Stock to Aratana at a price of \$4.90 per share, which was equal to the closing price of the Common Stock on the NASDAQ Capital Market on March 19, 2014, and (ii) issued a ten-year warrant to Aratana giving Aratana the right to purchase up to 153,061 additional shares of Advaxis’s Common Stock at an exercise price of \$4.90 per share. In connection with the sale of the Common Stock and warrants, Advaxis received aggregate net proceeds of \$1,500,000.

Based on the above licensing agreement, the Company expects to derive the majority of revenue from patent licensing if clinical development is successful. In general, these revenue arrangements provide for the payment of contractually determined fees in consideration for the grant of certain intellectual property rights for patented technologies owned or controlled by the Company. The intellectual property rights granted may be perpetual in nature, or upon the final milestones being met, or can be granted for a defined, relatively short period of time, with the licensee possessing the right to renew the agreement at the end of each contractual term for an additional minimum upfront payment. The Company recognizes licensing fees when there is persuasive evidence of a licensing arrangement, fees are fixed or determinable, delivery has occurred and collectability is reasonably assured.

#### *JLS Ventures*

During the twelve months ended October 31, 2014 the Company issued 200,000 shares of its Common Stock valued at \$756,000 to JLS Ventures pursuant to the underlying agreement for investor relations services. As of October 31, 2014, there were no outstanding obligations under this agreement.

#### *Stock Purchase Agreements*

During the twelve months ended October 31, 2013, the Company sold 62,981 shares of its Common Stock, to accredited investors, for proceeds totaling approximately \$177,250. The Company recorded a liability on its balance sheet for approximately \$100,000 (included in proceeds of \$177,250) for 45,323 shares (included in the above 62,981 shares), that were not yet delivered to Yenson Co. Ltd as of October 31, 2013 pursuant to a Securities Purchase dated August 28, 2013.

On May 15, 2014, the Company issued 45,323 shares of its Common Stock pursuant to the Securities Purchase Agreement with Yenson.

#### *Series B Preferred Stock Financing*

On July 19, 2010, the Company entered into a Series B Preferred Stock Purchase Agreement with Optimus (the "Series B Purchase Agreement"), pursuant to which Optimus agreed to purchase, upon the terms and subject to the conditions set forth therein and described below, up to \$7.5 million of the Company's newly authorized, non-convertible, redeemable Series B preferred stock ("Series B Preferred Stock") at a price of \$10,000 per share. Under the terms of the Series B Purchase Agreement, subject to the Company's ability to maintain an effective registration statement for the Warrant Shares (as defined below), the Company may from time to time until July 19, 2013, present Optimus with a notice to purchase a specified amount of Series B Preferred Stock. Subject to satisfaction of certain closing conditions, Optimus is obligated to purchase such shares of Series B Preferred Stock on the 10th trading day after the date of the notice.

Holders of Series B preferred stock will be entitled to receive dividends, which will accrue in shares of Series B preferred stock on an annual basis at a rate equal to 10% per annum from the issuance date. Accrued dividends will be payable upon redemption of the Series B preferred stock or upon the liquidation, dissolution or winding up of the Company. In the event the Company redeems all or a portion of any shares of the Series B Preferred Stock then held by Optimus, Optimus shall apply, and the Company may offset, the proceeds of any such redemption to pay down the accrued interest and outstanding principal of the Promissory Note from Optimus.

On September 26, 2013, the Company entered into a Notice of Redemption and Settlement Agreement with Optimus Capital Partners, LLC, a Delaware limited liability company, dba Optimus Life Sciences Capital Partners, LLC, Optimus CG II, Ltd., a Cayman Islands exempted Company and Socius CG II, Ltd., a Bermuda exempted Company, pursuant to which it agreed to redeem the Company's outstanding shares of Series B Preferred Stock. Pursuant to the agreement, the Company agreed to cancel an outstanding receivable in the amount of \$10,633,584 as of the date of the agreement as payment in full of the redemption payment due under the terms of the Series B Preferred Stock and agreed to issue 33,750 shares of its Common Stock having a fair value of \$221,400 to settle a disagreement regarding the calculation of the settlement amount under a July 2012 Order and Stipulation. In connection with the redemption, the Company agreed to cancel the outstanding warrant held by Optimus. The Company recorded a charge to Retained Earnings for the accrued dividends payable to date, of \$2,877,570 were canceled as part of the redemption transaction. The difference between the accrued dividends payable to-date and the outstanding receivable was written off to Additional Paid-In Capital. The loss on the aforementioned transaction was not material. Accordingly, following such redemption, there are no longer any shares of the Company's Series B Preferred Stock issued and outstanding.

As of October 31, 2013, the Series B preferred stock had a liquidation preference of \$0 due to its redemption as described above. During the twelve months ended October 31, 2014 and 2013, the Company accrued dividends of \$0 and \$555,000 respectively. The Company also recorded \$0 and \$149,562 in accrued interest on the promissory notes through the twelve months ended October 31, 2014 and 2013, respectively. The promissory bears interest at 2% per annum which is credited directly to capital.

### **13. FAIR VALUE**

The authoritative guidance for fair value measurements defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or the most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Market participants are buyers and sellers in the principal market that are (i) independent, (ii) knowledgeable, (iii) able to transact, and (iv) willing to transact. The guidance describes a fair value hierarchy based on the levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

Level 1 — Quoted prices in active markets for identical assets or liabilities

Level 2— Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or corroborated by observable market data or substantially the full term of the assets or liabilities

Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the value of the assets or liabilities

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The following table provides the liabilities carried at fair value measured on a recurring basis as of October 31, 2014 and 2013:

| October 31, 2014   | Level 1 | Level 2 | Level 3  | Total    |
|--|---------|---------|----------|----------|
| Common Stock warrant liability, warrants exercisable at \$5.63 - \$21.25 from October 2014 through August 2017 | \$ -    | \$ -    | \$32,091 | \$32,091 |

  

| October 31, 2013   | Level 1 | Level 2 | Level 3   | Total     |
|--|---------|---------|-----------|-----------|
| Common Stock warrant liability, warrants exercisable at \$5.63 - \$21.25 from October 2013 through August 2017 | \$ -    | \$ -    | \$646,734 | \$646,734 |

The following table summarizes the changes in fair value of the Company's Level 3 instruments for the twelve months ended October 31, 2014 and October 31, 2013.

**Common Stock warrant liability:**

|   | October 31, 2014 | October 31, 2013 |
|---|------------------|------------------|
| Beginning balance   | \$646,734        | \$434,136        |
| Issuance of Common Stock warrants                               | -                | 1,460,867        |
| Exercises and exchanges of warrants                             | -                | (1,026,131)      |
| Issuance of additional warrants due to anti-dilution provisions | 4,446            | 123,744          |
| Change in fair value  | (619,089)        | (345,882)        |
| Ending Balance  | \$32,091         | \$646,734        |

**14. SUBSEQUENT EVENTS**

*Recent Sales of Unregistered Securities*

On November 10, 2014, the registrant issued 40,000 shares of Common Stock to an accredited investor as payment for consulting services rendered.

On November 28, 2014, the registrant issued 3,868 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On December 5, 2014, the registrant issued 30,000 shares of Common Stock to an accredited investor as payment for consulting services rendered.

*Consulting Agreement*

On November 25, 2014, the registrant granted 20,000 Stock Options to an advisor pursuant to a consulting agreement.

*Registered Direct Offering*

On December 19, 2014, the registrant priced a registered direct offering of 3,940,801 shares of its Common Stock. The transaction closed on December 22, 2014, and the Company received total proceeds, before expenses, of \$16.7 million from the offering.

*Employment Agreements*

On December 31, 2014, the registrant issued 1,504 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

