

Advaxis, Inc.  
Form 10-K  
January 09, 2017

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-K**

**[X] ANNUAL REPORT UNDER SECTION 13 OR 15(d)**

**OF THE SECURITIES EXCHANGE ACT OF 1934**

**FOR THE FISCAL YEAR ENDED - OCTOBER 31, 2016**

**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)*

Edgar Filing: Advaxis, Inc. - Form 10-K

Delaware  
(State or Other Jurisdiction of  
Incorporation or Organization)

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

305 College Road East  
Princeton, New Jersey  
(Address of Principal Executive Offices)

08540  
(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 ☒

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 ☒

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 ☒ No ☐

Edgar Filing: Advaxis, Inc. - Form 10-K

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, 2016, the aggregate market value of the voting common equity held by non-affiliates was approximately \$256,799,000 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 40,147,145 shares of Common Stock, par value \$0.001 per share, outstanding as of January 5, 2017.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Proxy Statement for the registrant's 2017 Annual Meeting of Stockholders (the "Proxy Statement") to be filed within 120 days of the end of the fiscal year ended October 31, 2016 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.

Table of Contents

**Form 10-K Index**

**PART 1**

Item 1:	<u>Business</u>	4
Item 1A:	<u>Risk Factors</u>	19
Item 1B:	<u>Unresolved Staff Comments</u>	30
Item 2:	<u>Properties</u>	30
Item 3:	<u>Legal Proceedings</u>	30
Item 4:	<u>Mine Safety Disclosures</u>	30

**PART II**

Item 5:	<u>Market for Registrant’s Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities</u>	30
Item 6:	<u>Selected Financial Data</u>	32
Item 7:	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	33
Item 7A:	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	39
Item 8:	<u>Financial Statements and Supplementary Data</u>	39
Item 9:	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosures</u>	39
Item 9A:	<u>Controls and Procedures</u>	39
Item 9B:	<u>Other Information</u>	42

**PART III**

Item 10:	<u>Directors, Executive Officers, and Corporate Governance</u>	43
Item 11:	<u>Executive Compensation</u>	43
Item 12:	<u>Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters</u>	43
Item 13:	<u>Certain Relationships and Related Transactions, and Director Independence</u>	43
Item 14:	<u>Principal Accounting Fees and Services</u>	43

**Part IV**

Item 15:	<u>Exhibits, Financial Statements Schedules</u>	44
----------	---	----

	<u>Signatures</u>	50
--	-------------------	----

## PART 1

### FORWARD LOOKING STATEMENTS

*This annual report on Form 10-K (“Form 10-K”) includes statements that are, or may be deemed, “forward-looking statements.” In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms “believes,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “should,” “approximately” or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Form 10-K and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned discovery and development of drug candidates, the strength and breadth of our intellectual property, our ongoing and planned preclinical studies and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, the degree of clinical utility of our product candidates, particularly in specific patient populations, expectations regarding clinical trial data, our results of operations, financial condition, liquidity, prospects, growth and strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the industry in which we operate and the trends that may affect the industry or us.*

*By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Form 10-K, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Form 10-K. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Form 10-K, they may not be predictive of results or developments in future periods.*

*Some of the factors that we believe could cause actual results to differ from those anticipated or predicted include:*

*the success and timing of our clinical trials, including patient accrual;  
our ability to obtain and maintain regulatory approval and/or reimbursement of our product candidates for marketing;  
our ability to obtain the appropriate labeling of our products under any regulatory approval;  
our plans to develop and commercialize our products;  
the successful development and implementation of our sales and marketing campaigns;*

*the loss of key scientific or management personnel;*  
*the size and growth of the potential markets for our product candidates and our ability to serve those markets;*  
*our ability to successfully compete in the potential markets for our product candidates, if commercialized;*  
*regulatory developments in the United States and foreign countries;*  
*the rate and degree of market acceptance of any of our product candidates;*  
*new products, product candidates or new uses for existing products or technologies introduced or announced by our competitors and the timing of these introductions or announcements;*  
*market conditions in the pharmaceutical and biotechnology sectors;*  
*our available cash;*  
*the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;*  
*our ability to obtain additional funding;*  
*our ability to obtain and maintain intellectual property protection for our product candidates;*  
*the success and timing of our preclinical studies including IND enabling studies;*  
*the ability of our product candidates to successfully perform in clinical trials;*  
*our ability to obtain and maintain approval of our product candidates for trial initiation;*  
*our ability to manufacture and the performance of third-party manufacturers;*  
*the performance of our clinical research organizations, clinical trial sponsors and clinical trial investigators; and*  
*our ability to successfully implement our strategy.*

*Any forward-looking statements that we make in this Form 10-K speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Form 10-K. You should also read carefully the factors described in the “Risk Factors” section of this Form 10-K to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Form 10-K will prove to be accurate.*

*This Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third-parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data.*

*We qualify all of our forward-looking statements by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.*

## **Item 1. Business.**

### **General**

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*” or “*Lm* Technology<sup>TM</sup>”) 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.

Axalimogene filolisbac (“AXAL”) is our lead *Lm*-LLO immunotherapy product candidate for the treatment of Human Papilloma Virus (“HPV”) - associated cancers. The Company completed a randomized Phase 2 study in 110 patients with recurrent cervical cancer that was shown to have a manageable safety profile, apparent improved survival and objective tumor responses. In addition, the Gynecologic Oncology Group (“GOG”) Foundation, Inc., now part of NRG Oncology, conducted a cooperative group / Company sponsored Phase 2 open-label clinical study of AXAL in patients with persistent or recurrent cervical cancer with documented disease progression. The study, known as GOG-0265, has successfully completed the first and second stages in its Simon 2-stage design. The results from both stages combined demonstrate a 38% 12-month overall survival. Upon early closure of this study, a total of 50 patients were dosed resulting in a 12-month survival rate of 38.0% with a manageable safety profile. The Company has initiated a registrational Phase 3 clinical trial for the adjuvant treatment of women with high-risk locally advanced cervical cancer and is planning to initiate a registrational Phase 3 clinical trial in 2017 in the metastatic cervical cancer setting. The Company also plans to pursue registrational opportunities in Europe in 2017 for the metastatic cervical cancer.

AXAL 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 has received European Medicines Agency (“EMA”) orphan drug designation for anal cancer. AXAL has been designated by the FDA as a Fast Track product for adjuvant therapy for high-risk locally advanced cervical cancer patients. It has also been classified as an advanced-therapy medicinal product (“ATMP”) for the treatment of cervical cancer by the European Medicines Agency’s Committee for Advanced Therapies (“CAT”). AXAL is subject to an agreement with the FDA, under the Special Protocol Assessment (“SPA”) process, for the Phase 3 AIM2CERV trial in patients with high-risk, locally advanced



cervical cancer. It is also being evaluated in Company-sponsored trials executed under an Investigational New Drug (“IND”) which include the following: (i) a Phase 1/2 clinical trial alone and in combination with MedImmune, LLC’s (“MedImmune”) investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab (MEDI4736), in patients with previously treated metastatic cervical cancer or patients with HPV-associated head and neck cancer; and (ii) a single arm Phase 2 monotherapy study in patients with metastatic anal cancer. In addition to the Company-sponsored trials, AXAL is also being evaluated in two investigator-initiated clinical trials as follows: neoadjuvant treatment of HPV-positive head and neck cancer (Mount Sinai & Baylor College of Medicine), and locally advanced high risk anal cancer (Brown University).

ADX-PSA is the Company’s *Lm*-LLO immunotherapy product candidate designed to target the Prostate Specific Antigen (“PSA”) associated with prostate cancer which is being evaluated in a Phase 1/2 clinical trial alone and in combination with KEYTRUDA® (pembrolizumab), Merck & Co.’s (“Merck”) humanized monoclonal antibody against PD-1, in patients with previously treated metastatic castration-resistant prostate cancer.

ADX-HER2 is the Company’s *Lm*-LLO immunotherapy product candidate designed for the treatment of Human Epidermal Growth Factor Receptor 2 (“HER2”) expressing cancers, including human and canine osteosarcoma. ADX-HER2 is being evaluated in a Phase 1b clinical trial in patients with metastatic HER2 expressing solid tumors. The Company received orphan drug designation from both the FDA and EMA for ADX-HER2 in osteosarcoma and have received Fast Track designation from the FDA for patients with newly-diagnosed, non-metastatic, surgically-resectable osteosarcoma. Clinical research with ADX-HER2 in canine osteosarcoma is being developed by the Company’s pet therapeutic partner, Aratana Therapeutics Inc. (“Aratana”), who holds exclusive rights to develop and commercialize ADX-HER2 and three other *Lm* -LLO immunotherapies for pet health applications. Aratana has announced that a product license application for use of ADX-HER2 in the treatment of canine osteosarcoma has been filed with the United States Department of Agriculture (“USDA”). Aratana received communication from the USDA in March 2015 stating that the previously submitted efficacy data for product licensure for AT-014 (ADX-HER2), the cancer immunotherapy for canine osteosarcoma, was accepted and that it provides a reasonable expectation of efficacy that supports conditional licensure. While additional steps need to be completed, including in the areas of manufacturing and safety, Aratana anticipates that AT-014 could receive conditional licensure from the USDA in 2017.

In October of 2015, the Company received notification from the FDA that the INDs for AXAL were put on clinical hold in response to its submission of a safety report to the FDA. The clinical hold also included the INDs for ADX-PSA and ADX-HER2. Following discussions with the FDA and in accordance with their recommendations, the Company agreed to implement certain risk mitigation measures, including revised study protocol inclusion / exclusion criteria, post-administration antibiotic treatment and patient surveillance and monitoring measures. In December 2015, the FDA notified the Company that the hold had been lifted with respect to its INDs.

The Company has focused its development efforts on establishing a drug development pipeline that incorporates this technology into therapeutic cancer immunotherapies, with clinical trials currently targeting HPV-associated cancers (cervical cancer, head and neck cancer, and anal cancer), prostate cancer, and osteosarcoma. Although no immunotherapies have been commercialized to date, the Company continues to invest in research and development to advance the technology and make it available to patients with many different types of cancer. 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 it continues conducting and expanding its clinical development programs. In addition to its existing single antigen vectors that target one tumor associated antigen, the Company is actively engaged in the development of new constructs that will address multiple targets that are common to tumor types, as well as mutation-associated epitopes that are specific to an individual patient's tumor. The Company is also leveraging its *Lm* Technology™ to target common (public or shared) mutations (hotspots) in tumor driver genes. The Company is exploring a preclinical infectious disease program as well to examine potential applications of its *Lm* Technology.™ Lastly, the Company is continuing to build-out its manufacturing capabilities at the state-of-the-art manufacturing facility in Princeton, NJ, to produce supplies for its neoepitope and other development programs.

## Clinical Pipeline

We are a clinical stage biotechnology company focused on the discovery, development and commercialization of proprietary *Lm*-LLO immunotherapies with our lead program in Phase 3 development. 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.

### *AXAL Franchise*

AXAL is an *Lm*-LLO immunotherapy directed against HPV and designed to target cells expressing the HPV. It is currently under investigation in three HPV-associated cancers: cervical cancer, head and neck cancer, and anal cancer, either as a monotherapy or in combination.

### Cervical Cancer

There are 527,624 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 2016

(“WHO”). Current preventative vaccines cannot protect all women who are infected with this very common virus. Challenges with acceptance, accessibility, and compliance have resulted in approximately a third of young women being vaccinated in the United States and even less in other countries around the world.

We completed a randomized Phase 2 clinical study (*Lm-LLO-E7-15*), conducted exclusively in India, in 110 women with recurrent/refractory cervical cancer. The final results were presented at the 2014 American Society of Clinical Oncology (“ASCO”) Annual Meeting, and showed that 32% (35/109) of patients were alive at 12 months, 22% (24/109) of patients were Long-term Survivors (“LTS”) alive greater than 18 months, and 18% (16/91) evaluable with adequate follow-up 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 stable disease or 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% (3/12) of patients had a baseline ECOG performance status of 2, a patient population that is often times excluded from clinical trials. Furthermore, a 10% objective response rate (including 5 complete responses and 6 partial responses) and a disease control rate of 38% (42/109) were observed. The addition of cisplatin chemotherapy to AXAL in this study did not significantly improve overall survival or objective tumor response ( $p=0.9981$ ).

In this study, 109 patients received 254 doses of AXAL. AXAL was found to be well tolerated with 38% (41/109) of patients experiencing mild to moderate Grade 1 or 2 transient adverse events associated with infusion; 1 patient experienced a Grade 3 Serious Adverse Events (“SAE”). All observed treatment-related adverse events either self-resolved or responded readily to symptomatic treatment.

We have reached an agreement with the FDA, under the Special Protocol Assessment (“SPA”) process, for a Phase 3 trial evaluating AXAL in patients with high-risk, locally advanced cervical cancer (“AIM2CERV” or “Advaxis Immunotherapy 2 Prevent Cervical Recurrence”). In collaboration with the GOG/NRG Oncology, an independent international non-profit organization with the purpose of promoting excellence in the quality and integrity of clinical and basic scientific research in the field of gynecologic malignancies, we have initiated the AIM2CERV study to support a Biologics License Application (“BLA”) submission in the U.S. and in other territories around the world.

AIM2CERV is a double-blind, randomized, placebo-controlled, Phase 3 study of adjuvant AXAL, following primary chemoradiation treatment of women with high-risk locally advanced cervical cancer (“HRLACC”). The primary objective of AIM2CERV is to compare the disease free survival of AXAL to placebo administered in the adjuvant setting following standard concurrent chemotherapy and radiotherapy (“CCRT”) administered with curative intent to patients with HRLACC. Secondary endpoints include examining overall survival and safety. Our goal is to develop a treatment to prevent or reduce the risk of cervical cancer recurrence after primary, standard of care treatment in women who are at high risk of recurrence.

Biocon Limited (“Biocon”), our co-development and commercialization partner for AXAL in India and key emerging markets, filed a Marketing Authorization Application (“MAA”) for licensure of this immunotherapy in India. The Drug Controller General of India (“DCGI”) accepted this MAA for review. The filing of the MAA was driven by several factors: (i) results from the *Lm* -LLO-E7-15 Phase 2 trial indicated that AXAL was well tolerated and showed significant clinical activity in recurrent/refractory cervical cancer; (ii) cervical cancer is the second most common cancer among Indian women (according to WHO, there are 122,844 new cases per year with 67,544 deaths reported); and (iii) current treatment options for non-operable refractory/recurrent disease are limited in India. As part of the MAA review process, Biocon met with the Scientific Expert Committee (the “Committee”). The Committee indicated that proof of concept for this novel immunotherapy has been established. The Committee advised Biocon to obtain data from a Phase 3 clinical trial in patients with recurrent cervical cancer who have failed prior chemo and radiation therapies. The face-to-face interaction with the Committee provided Biocon and Advaxis with valuable insight for future development and the companies are evaluating next steps.

We have a clinical trial collaboration agreement with MedImmune, the global biologics research and development arm of AstraZeneca, and are conducting a Phase 1/2, open-label, multicenter, two-part study to evaluate the safety and efficacy of AXAL, in combination with MedImmune’s investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab, as a combination treatment for patients with metastatic squamous or non-squamous carcinoma of the cervix and metastatic HPV-associated Squamous Cell Carcinoma of the Head and Neck (“SCCHN”). For the AXAL and durvalumab dose escalation portion of the study, the dose-escalation phase has been completed. As reported at the Society for Immunotherapy of Cancer (“SITC”) 2016 annual meeting, preliminary results from the dose escalation portion of the study showed that there were no dose limiting toxicities observed, and the safety profile was consistent with previous findings for both AXAL and durvalumab. The recommended phase 2 dose was established as  $1 \times 10^9$  CFU for AXAL and 10 mg/kg for durvalumab. One patient with cervical cancer achieved a complete response, which remains ongoing after 12 months of follow-up and one patient, also with cervical cancer, achieved a partial response with subsequent disease progression. In addition, two patients with HNSCC achieved stable disease. Treatment related adverse events (“TRAE”) were reported in 91 percent of patients; the majority were either grade 1 or grade 2 events such as chills, fever, nausea and hypotension. Grade 3 TRAEs occurred in three patients, and one patient experienced a grade 4 event. We have commenced enrollment in the Part A (20 patients with SCCHN) and B (90 patients with cervical cancer) expansion phases. Accrual is ongoing.

The GOG Foundation, Inc. (now a member of NRG Oncology), under the sponsorship of the Cancer Therapy Evaluation Program (“CTEP”) of the National Cancer Institute (“NCI”), conducted GOG-0265, an open-label, single arm Phase 2 study of AXAL in persistent or recurrent cervical cancer (patients must have received at least 1 prior chemotherapy regimen for the treatment of their recurrent/metastatic disease, not including that administered as a component of primary treatment) at numerous clinical sites in the U.S. The study was a Simon 2-stage design. The first stage of enrollment in GOG-0265 was successfully completed with 26 patients treated and met the predetermined safety and efficacy criteria required to proceed into the second stage of patient enrollment. Clinical data from the first stage of GOG-0265 was presented at the American Gynecological & Obstetrical Society (“AGOS”) annual meeting on September 17, 2015. Overall survival at 12 months was 38.5% (10/26) (the predefined criteria for 12-month survival in order to progress to Stage 2 was  $\geq 20\%$ ), and, among patients who had received the full treatment regimen of 3 doses of AXAL, the 12-month survival rate was 55.6% (10/18). The adverse events observed in the first stage of the study have been consistent with those reported in other clinical studies with AXAL. It was well-tolerated, with Grade 1-2 fatigue, chills, and fever the most commonly reported Adverse Events (“AE”); six patients experienced a treatment-related Grade 3 or Grade 4 AE, which was considered possibly-related to AXAL.

Stage 2 of the study began enrollment in February 2015 which included a protocol amendment to allow patients to continue to receive repeat cycles of therapy until disease progression. Stage 2 enrollment was temporarily suspended with the clinical hold in October 2015. Prior to re-initiating enrollment of a new cohort of Stage 2 patients, Advaxis and the GOG Foundation/NRG Oncology examined the 12-month survival and safety data obtained from the 24 patients who had previously enrolled in Stage 2. The Stage 2 population demonstrated that treatment with AXAL resulted in a 37.5% 12-month overall survival rate. This data was consistent with the findings in Stage 1 that showed a 38.5% 12-month survival, despite a greater proportion of Stage 2 patients having failed bevacizumab treatment. Taken together, the available data from both stages of GOG-0265 comprise a Phase 2 clinical trial with 50 subjects with a 12 month OS of 38%. Based on the GOG database and specific patient factors and eligibility criteria of the participants in this trial, the expected 12-month survival rate would have been 25%. Comparing this expected 25% 12-month overall survival rate to the observed actual 38% 12-month overall survival, treatment with AXAL resulted in a 52% increase in 12-month overall survival. In the second stage of the study, 15 out of 24 patients experienced a Grade 1 or Grade 2 TRAE associated with AXAL infusion. The most common Grade 1 or Grade 2 TRAEs were hypotension and symptoms related to cytokine release (e.g., nausea, chills, fever). Nine out of 24 patients experienced a Grade 3 TRAE and two out of 24 patients experienced a Grade 4 TRAE, which were hypotension and symptoms related to cytokine release.

In October 2016, upon review of these findings, the Company announced early closure of GOG-0265. Based on these data, the Company plans on pursuing regulatory opportunities for this unmet medical need in Europe in 2017, and is planning to initiate a Phase 3 registrational trial in 2017 in the metastatic cervical cancer setting.

AXAL has received FDA orphan drug designation for invasive FIGO Stage II-IV cervical cancer, and has received Fast Track designation from the FDA for high-risk locally advanced cervical cancer patients. AXAL has also been classified as an advanced-therapy medicinal product ("ATMP") for the treatment of cervical cancer by the European Medicines Agency's Committee for Advanced Therapies ("CAT"). The CAT is the EMA's committee responsible for assessing the quality, safety and efficacy of ATMPs. The Company has commenced the CAT certification procedure and review of preclinical and CMC information is underway for potential inclusion in the Marketing Authorization Application.

## Head and Neck Cancer

SCCHN 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 SCCHNs originate from the mucosal linings of the oral cavity, pharynx, or larynx and 70% of these cancers are caused by HPV, with the incidence increasing every year. According to the American Cancer Society, head and neck cancer accounts for about 3% of all cancers in the United States. Approximately 12,000 new cases will be diagnosed in the United States in 2016 according to the Surveillance, Epidemiology, and End Results ("SEER") database.

The safety and immunogenicity of AXAL is being evaluated in a Phase 2 study under an investigator-sponsored IND at Mount Sinai and Baylor College of Medicine in a pre-surgery "window of opportunity" trial in patients with HPV-positive head and neck cancer. This clinical trial is the first study to evaluate the immunologic and pathologic effects of AXAL in patients when they are initially diagnosed with HPV-associated head and neck cancer. The study is designed to show that AXAL is highly immunogenic and worth further investigation if the overall rate of vaccine-induced T-cell responses is 75 percent or more. Preliminary clinical data from this trial was presented at the American Association of Cancer Research ("AACR") annual meeting on April 18, 2016. The data from eight of the nine patients enrolled in Stage 1 who were treated with AXAL confirmed that the study met the target for the overall rate of vaccine-induced T-cell response. The results demonstrated that, HPV E7- and/or E6-specific T cell responses increased in the peripheral blood in five of the study patients. Increased infiltration of both CD4+ and CD8+ T cells were observed in the Tumor Immune Microenvironment ("TME") of four patients, with a reduction of FOXP3+ regulatory T cells within the tumors of 3/6 patients. Increased T cell responses to HPV E6 supports enhanced immune activity against additional tumor targets. Changes to the TME included cytotoxic T cell infiltration into the post-resection tumor, increased immune activation, a reduction of regulatory T cells, infiltration of cytotoxic T cells, and increased expression of inflammatory activation markers. In addition, fluctuations of circulating serum cytokine (IL-15, IL-9, TNF $\alpha$ , IL-2 and MIP-1b) levels were observed potentially suggesting consumption by activated T cells and migration of T cells to the TME. This study met its Stage 1 primary objective and is now advancing into the second stage of the clinical study. Stage 2 of the clinical study is currently accruing patients.

As stated above, we have entered into a clinical trial collaboration agreement with MedImmune to collaborate on a Phase 1/2, open-label, multicenter, two part study to evaluate safety and efficacy of AXAL, in combination with durvalumab (MEDI4736), for patients with metastatic squamous or non-squamous carcinoma of the cervix and metastatic HPV-associated SCCHN.

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

## Anal Cancer

According to the American Cancer Society, nearly all squamous cell anal cancers are linked to infection by HPV, the same virus that causes cervical cancer. According to the SEER database, approximately 7,500 new cases will be diagnosed in the United States in 2016.

The safety and efficacy of AXAL is being evaluated in a Phase 2 study under an investigator-sponsored IND by Brown University in patients with high-risk locally advanced anal cancer. As of December 2016, all patients who have completed treatment experienced a six-month complete response (n=9), with no evidence of recurrence. Expected complete response rate at six-months is approximately 50% and the complete response rate in this study is 82% (9 out of 11 patients). The follow-up duration is six-months to 33 months. In consideration of these preliminary data, the investigator at Brown University is evaluating the opportunity to transition this study into a NCI-funded cooperative group trial to evaluate the safety and efficacy of AXAL in a pivotal Phase 2/3 anal cancer trial, to be conducted by NRG Oncology. In advance of the foregoing, we have entered into a clinical trial collaboration agreement with the Radiation Therapy Oncology Group (“RTOG”) Foundation for the conduct of such study. Depending on the Company’s ability to agree upon the study design and budget, the Company plans to initiate a registrational study in high-risk locally advanced anal cancer.

We are conducting a Phase 2 multi-center, open-label, Simon two-stage study (“FAWCETT” or “Fighting Anal-Cancer with CTL Enhancing Tumor Therapy”), testing AXAL in patients with persistent or recurrent metastatic anal cancer. FAWCETT is designed to evaluate the efficacy and safety of AXAL as a monotherapy in patients with HPV-associated metastatic anal cancer who have received at least one prior treatment regimen for the advanced disease. Stage 1 of the trial will enroll 31 patients with anal cancer whose disease recurred after receiving treatment. Enrollment of Stage 2 will begin following the evaluation of Stage 1 and is targeting enrollment of 60 patients. Patients will receive AXAL  $1 \times 10^9$  CFU doses every three weeks for up to two years.

AXAL has received FDA and EMA orphan drug designation for anal cancer.

#### *ADXS-PSA Franchise*

#### Prostate Cancer

According to the American Cancer Society, prostate cancer is the second most common type of cancer found in American men. Prostate cancer is the second leading cause of cancer death in men, behind only lung cancer. One man in seven will get prostate cancer during his lifetime, and one man in 36 will die of this disease. About 180,890 new cases will be diagnosed in the United States in 2016 according to the SEER database and accounts for approximately 11% of all new cancer cases.

ADXS-PSA is an *Lm* -LLO immunotherapy designed to target the PSA antigen commonly overexpressed in 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<sup>®</sup> (pembrolizumab), Merck’s anti PD-1 antibody, in a Phase 1/2, open-label, multicenter, dose escalation and expansion study in patients with previously treated metastatic, castration-resistant prostate cancer. For the ADXS-PSA monotherapy dose escalation portion of the study, cohorts were successfully escalated to higher dose levels of  $5 \times 10^9$  CFU and  $1 \times 10^{10}$  CFU without achieving a maximum tolerated dose. Side effects noted at these higher dose levels were generally consistent with those observed at the lower dose level, other than a higher occurrence rate of predominantly Grade 2/3 hypotension. The Company believes it has gained a sufficient understanding of the safety profile of higher dose levels based on the results from this as well as other ongoing Advaxis studies. Additional patients at the  $1 \times 10^9$  CFU dose level have been enrolled to complete the dose escalation phase of the study. After ensuring adequate safety of this dose in the prostate cancer patient population, the study has enrolled patients into the combination phase with KEYTRUDA<sup>®</sup> (pembrolizumab).

### *ADXS-HER2 Franchise*

#### HER2 Expressing Solid Tumors

HER2 is overexpressed in a percentage of solid tumors including osteosarcoma. According to the SEER database and recent published literature, approximately 60-70% of osteosarcoma are HER2 positive, which is associated with poor outcomes for patients.

ADXS-HER2 is an *Lm*-LLO immunotherapy designed to target HER2 expressing solid tumors including human and canine osteosarcoma. The FDA has cleared our IND application and we have initiated a Phase 1b study in patients with metastatic HER2-expressing cancers. Thereafter, we intend to initiate a clinical development program with ADXS-HER2 for the treatment of pediatric osteosarcoma.

#### Osteosarcoma

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. 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 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 data discussed below 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 human osteosarcoma. Both veterinary and human osteosarcoma specialists consider canine osteosarcoma to be the best model for human osteosarcoma.

ADXS-HER2 has received FDA and EMA orphan drug designation for osteosarcoma and has received Fast Track designation from the FDA for patients with newly-diagnosed, non-metastatic, surgically-resectable osteosarcoma.

### Canine Osteosarcoma

Osteosarcoma is the most common primary bone tumor in dogs, accounting for roughly 85% of tumors on the canine skeleton. Approximately 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. Median survival time with standard of care is ten to twelve months. For dogs that cannot undergo amputation, palliative radiation and analgesics are frequently employed and median survival times range from three to five months.

Under the direction of Dr. Nicola Mason, the University of Pennsylvania School of Veterinary Medicine is conducting studies in companion dogs evaluating the safety and efficacy of ADXS-HER2 in the treatment of naturally occurring canine osteosarcoma. In the initial study, the primary endpoint was to determine the maximum tolerated dose of ADXS-HER2. Secondary endpoints for the study were progression-free survival and overall survival. The findings of the Phase 1 clinical trial in dogs with osteosarcoma suggest that ADXS-HER2 is safe and well tolerated at doses up to  $3.3 \times 10^9$  CFU with no evidence of significant 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). This work was recently published in the September 2016 issue of Clinical Cancer Research. Dogs receiving ADXS-HER2 following standard of care (n=18) had a progression free survival of 615 days and a median survival time of 956 days. These results compared favorably to a historical control group where the median survival time was 423 days. A second study conducted by Dr. Mason has evaluated the effects of combination palliative radiation with ADXS-HER2 on dogs with primary osteosarcoma who were unsuitable for amputation (n=15). Preliminary data was presented at the 2015 ACVIM Forum and showed that repeat doses of ADXS-HER2 administered after palliative radiation were well tolerated with no systemic or cardiac toxicity. In long-term follow-up, several dogs have experienced prolonged survival times ranging from 21 to 30 months.

On March 19, 2014, we entered into a definitive Exclusive License Agreement with Aratana Therapeutics Inc. (“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. Aratana received communication from the USDA in March 2015 stating that the previously submitted efficacy data for product licensure for AT-014 (ADXS-HER2), the cancer immunotherapy for canine osteosarcoma, was accepted and that it provides a reasonable expectation of efficacy that supports conditional licensure. While additional steps need to be completed, including in the areas of manufacturing and safety, Aratana anticipates that AT-014 could receive conditional licensure from the USDA in 2017. Aratana has been granted exclusive worldwide rights by us to develop and commercialize ADXS-HER2 in animals. Aratana is further responsible for the conduct of clinical research with ADXS-Survivin in canine/feline lymphoma, as well as pending investigations of two additional Advaxis constructs in animals.

#### *ADXS-NEO Franchise (preclinical)*

In August 2016, we entered into a global agreement (the “Agreement”) with Amgen Inc. (“Amgen”) for the development and commercialization of ADXS-NEO, a novel, preclinical investigational cancer immunotherapy treatment, using our proprietary *Lm* Technology™ attenuated bacterial vector which activates a patient’s immune system to respond against multiple potential unique mutations, or neoepitopes, contained in and identified from an individual patient’s tumor through DNA sequencing.

In February 2016, we had a productive pre-IND meeting with the FDA. Following this meeting, we intend to file an IND application for ADXS-NEO in 2017 and to initiate Company-sponsored studies, as well as external collaborations, under a program entitled “MINE™” (My Immunotherapy Neo-Epitopes).

The goal of MINE™ is to use our *Lm* Technology™ to develop patient specific neo-epitope targeted immunotherapies based on mutations found in an individual patient’s tumor (“ADXS-NEO”). MINE™ will first focus on a preclinical study of our new construct approach to evaluate the immunologic effects and anti-tumor activity of a personalized immunotherapy in mouse tumor models. We will use learnings from the preclinical and non-clinical investigations to refine and develop patient specific immunotherapy construct treatments that incorporate the neoepitope sequences identified in the patient’s tumor cells through comparative DNA sequencing. Clinical studies using ADXS-NEO are in active development in collaboration with our partner, Amgen. Further, we have entered into various research collaboration, including the Parker Institute for Cancer Immunotherapy, to advance the study of neoepitope-based, personalized cancer therapy.

#### *ADXS-HOT Franchise (preclinical)*

We are developing *Lm-LLO* constructs that could target common (public or shared) mutations in tumor driver genes. ADXS-HOT products may target acquired public mutations in tumor driver genes that are shared by multiple patients, and could have greater immunogenicity than the natural sequence peptides in normal cells. ADXS-HOT products are expected to be “off the shelf” and ready to administer for multiple patients. DNA sequencing is not required and presence of the hot-spot target can usually be determined by a rapid biomarker test. The ability to combine multiple constructs may increase coverage and the potential for clinical benefit.

#### *Lm-LLO Combination Franchise*

#### AXAL and Durvalumab

As further described above, we have entered into a clinical trial collaboration agreement with MedImmune to conduct a Phase 1/2, open-label, multicenter, two part study to evaluate safety and efficacy of AXAL, in combination with MedImmune’s investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab (MEDI4736), as a combination treatment for patients with metastatic squamous or non-squamous carcinoma of the cervix and metastatic HPV-associated SCCHN. For the AXAL and durvalumab dose escalation portion of the study, the dose-escalation cohort has been completed. We have commenced enrollment in the Part A (20 patients with SCCHN) and B (90 patients with cervical cancer) expansion phases. Accrual is ongoing.

#### ADXS-PSA and KEYTRUDA® (pembrolizumab)

As further described 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, open-label, multicenter, dose escalation and expansion study in patients with previously treated metastatic, castration-resistant prostate cancer. For the ADXS-PSA monotherapy dose escalation portion of the study, cohorts were successfully escalated to higher dose levels of  $5 \times 10^9$  CFU and  $1 \times 10^{10}$  CFU without achieving a maximum tolerated dose. Side effects noted at these higher dose levels were generally consistent with those observed at the lower dose level, other than a higher occurrence rate of predominantly Grade 2/3 hypotension. The Company believes it has gained a sufficient understanding of the safety profile of higher dose levels based on the results from this as well as other ongoing Advaxis studies. Additional patients at the  $1 \times 10^9$  CFU dose level were enrolled to complete the dose escalation phase of the study. After ensuring adequate safety of this dose in the prostate cancer patient population, the study has enrolled patients into the combination phase with KEYTRUDA® (pembrolizumab).

*Lm-LLO Immunotherapy (preclinical)*

We are developing other ways to exploit the potential of our *Lm* Technology™ including, but not limited to, the use of *Lm* Technology™ in Infectious Disease. We have various preclinical collaborations with academic and other centers of excellence to explore the potential opportunities in this disease area. Preclinical data of detoxified Listeriolysin O (“dtLLO”) shows potential use as an immunologic adjuvant or carrier for vaccinations. We intend to continue to explore the potential of dtLLO as an adjuvant molecule in the development of vaccines for infectious diseases.

**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 and the Company was uplisted to NASDAQ in 2014.

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 corporate website at [www.advaxis.com](http://www.advaxis.com) which contains descriptions of our technology, our product candidates and the development status of each drug. We make available free of charge through our Internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to these reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the SEC. We are not including the information on our website as a part of, nor incorporating it by reference into, this report. You may read and copy any materials we file at the SEC’s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 on official business days during the hours of 10:00 a.m. to 3:00 p.m. Please call the SEC at 1-800-SEC-0330 for information on the Public Reference Room. Additionally, the SEC maintains a website that contains annual, quarterly, and current reports, proxy statements, and other information that issuers (including us) file electronically with the SEC. The SEC’s website address is <http://www.sec.gov>.

## 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, we own or have rights to approximately 246 patents and applications, which are owned, licensed from, or co-owned with Penn, Merck, NIH, and/or Augusta University. We continuously grow this portfolio by filing new applications to protect our ongoing research and development efforts. We aggressively prosecute and defend our patents and proprietary technology. Our patents and applications are directed to the compositions of matter, use, and methods thereof, of our *Lm*-LLO immunotherapies for our product candidates, including AXAL, ADXS-PSA, ADXS-HER2, ADXS-NEO, and ADXS-HOT.

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 directed to our product candidates AXAL, ADXS-PSA, and ADXS-HER2 in the United States, will expire between 2017 and 2032. Issued patents directed to our product candidates AXAL, ADXS-PSA, and ADXS-HER2 outside of the United States, will expire in 2032. Issued patents directed to our *Lm*-based immunotherapy platform in the United States, will expire between 2017 and 2031. Issued patents directed to our *Lm*-based immunotherapy platform outside of the United States, will expire between 2018 and 2033.

We have issued patents directed to methods of using our product candidates AXAL, ADXS-PSA and ADXS-HER2 in the United States, which will expire between 2017 and 2032. Issued patents directed to use of our product candidates: AXAL, ADXS-PSA and ADXS-HER2 for indications outside of the United States, will expire between 2018 and 2032.

We have pending patent applications directed to our product candidates AXAL, ADXS-PSA, ADXS-HER2, ADXS-NEO and ADXS-HOT that, if issued would expire in the United States and in countries outside of the United States between 2020 and 2037. We have pending patent applications directed to methods of using of our product candidates AXAL, ADXS-PSA, ADXS-HER2, ADXS-NEO and ADXS-HOT directed to the following indications and others: her2/neu-expressing cancer, 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 2037, 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 that will ultimately 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 both high costs and 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 pharmaceutical or biotechnology companies or is managed 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 study sponsor and implemented by study 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 clinical 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 marketing. 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 and post-approval studies may be required.

## **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, import, 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; however, an ODD product may be eligible for priority review. 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 AXAL for treatment of 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).

In Europe, the Committee for Orphan Medicinal Products (“COMP”) issued a positive opinion on the application for ODD of AXAL for the treatment of anal cancer (December 2015) and on the application for ODD of ADXS-HER2 for osteosarcoma (November 2015).

### *Expedited Programs for Serious Conditions*

Four FDA programs are intended to facilitate and expedite development and review of new drugs to address unmet medical need in the treatment of serious or life-threatening conditions: fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation. We intend to avail ourselves of any and all of these programs as applicable to our products.

*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**

*Amgen*

On August 1, 2016, the Company entered into a global agreement (the “Amgen Agreement”) with Amgen for the development and commercialization of the Company’s ADXS-NEO, a novel, preclinical investigational immunotherapy, using the Company’s proprietary *Listeria monocytogenes* attenuated bacterial vector which activates a patient’s immune system to respond against unique mutations, or neoepitopes, contained in and identified from an individual patient’s tumor. Under the terms of the Amgen Agreement, Amgen receives an exclusive worldwide license to develop and commercialize ADXS-NEO. Amgen made an upfront payment to Advaxis of \$40 million and purchased \$25 million of Advaxis common stock. Advaxis and Amgen will collaborate through a joint steering committee for the development and commercialization of ADXS-NEO. Under the Amgen Agreement, Amgen will fund the clinical development and commercialization of ADXS-NEO and Advaxis will retain manufacturing responsibilities. Advaxis will also receive development, regulatory and sales milestone payments of up to \$475 million and high single digit to double digit royalty payments based on worldwide sales.

In connection with the Amgen Agreement, Amgen purchased directly from Advaxis 3,047,446 shares of the Company’s Common Stock, at approximately \$8.20 per share (representing a purchase at market using a 20 day VWAP methodology). The gross proceeds to Advaxis from the sale of the shares was \$25 million.

*Especificos Stendhal SA de CV*

On February 3, 2016, the Company entered into a Co-Development and Commercialization Agreement (the “Stendhal Agreement”) with Especificos Stendhal SA de CV (“Stendhal”), for Advaxis’ lead *Lm* Technology™ immunotherapy, AXAL, in HPV-associated cancers. Under the terms of the Stendhal Agreement, Stendhal will pay \$10 million towards the expense of AIM2CERV. This payment will be made over the duration of the trial. Stendhal will also work with the Company to complete the clinical trial of AXAL in Mexico, Brazil, Colombia and other investigational sites in Latin American countries. Stendhal will manage and is responsible for the costs associated with the regulatory approval process, promotion, commercialization and market access for AXAL in these markets. Upon approval and commercialization of AXAL, Advaxis and Stendhal will share profits on a pre-determined basis.

*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.

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 AXAL 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 AXAL. AXAL 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.

We will have the exclusive right to supply AXAL to Biocon and Biocon will be required to purchase its requirements of AXAL 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 AXAL 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.

Biocon filed a MAA for licensure of this immunotherapy in India. The DCGI accepted this MAA for review. The filing of the MAA was driven by several factors: i) results from the *Lm-LLO-E7-15* Phase 2 trial indicated that AXAL was well tolerated and showed significant clinical activity in recurrent/refractory cervical cancer; ii) cervical cancer is the second most common cancer among Indian women (according to WHO, there are 122,844 new cases per year with 67,544 deaths reported); and iii) current treatment options for non-operable refractory/recurrent disease are limited in India. As part of the MAA review process, Biocon met with the Scientific Expert Committee (the "Committee"). The Committee indicated that proof of concept for this novel immunotherapy has been established. The Committee advised Biocon to obtain data from a Phase 3 clinical trial in patients with recurrent cervical cancer who have failed prior chemo and radiation therapies. The face-to-face interaction with the Committee provided Biocon and Advaxis with valuable insight for future development.

*Global BioPharma, Inc.*

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

GBP is planning to conduct a randomized Phase 2, open-label, controlled study in HPV-associated NSCLC in patients following first-line induction chemotherapy. GBP has obtained Taiwanese regulatory approval for this study and plans to initiate this study in 2017. This trial will be fully funded exclusively by GBP. GBP will continue to explore the use of our lead product candidate in several other indications including head and neck, and anal cancer. GBP also plans to conduct registration trials with AXAL for the treatment of advanced cervical 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 AIM2CERV. GBP is committed to establishing manufacturing capabilities for its own. Under the terms of the agreement, we will exclusively license the rights of AXAL 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 AXAL 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 latter 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, 2016, 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 (U.S. & E.U.), 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, 2016, 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, AXAL, 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 negotiate negotiation period in an attempt to enter into an agreement with Advaxis with respect to the development, regulatory approval and commercialization of AXAL 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 AXAL 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.

#### *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 to 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' 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.

Aratana has filed a product license request for ADXS-HER2 (also known as AT-014 by Aratana) for the treatment of canine osteosarcoma with the USDA. Aratana received communication from the USDA in March 2015 stating that the previously submitted efficacy data for product licensure for AT-014, the cancer immunotherapy for canine osteosarcoma, was accepted and that it provides a reasonable expectation of efficacy that supports conditional licensure. While additional steps need to be completed, including in the areas of manufacturing and safety, Aratana anticipates that AT-014 could receive conditional licensure from the USDA in 2017.

*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 AXAL for cervical cancer, and other HPV-associated cancer; ADXS-HER2 for pediatric osteosarcoma 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.

*Agreement with Knight Therapeutics Inc.*

On August 26, 2015, we announced that we had entered into an agreement with Knight Therapeutics Inc. (“Knight”), a Canadian-based specialty pharmaceutical company, to commercialize in Canada Advaxis’ product candidates.

In connection with the agreement, Knight purchased 359,454 shares of our common stock at \$13.91 per share, which represents a seven percent premium to the price of our common stock at market close on August 25, 2015. In addition, Sectoral Asset Management, a leading Canadian-based global healthcare investment advisor, purchased 1,437,815 shares at \$13.91 per share directly from us on behalf of its clients. The combined gross proceeds to us from these direct investments was \$25 million.

Under the terms of the agreement, Knight will be responsible to conduct and fund all regulatory and commercial activities in Canada. We are eligible to receive double digit royalty as well as approximately \$33 million in cumulative sales milestones.

**Manufacturing**

Current Good Manufacturing Practices (“cGMPs”) 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. cGMPs 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.

We have entered into agreements with multiple third-party organizations to handle the manufacturing, testing, and distribution of our product candidates. These organizations have extensive experience within the biologics space and with the production of clinical and commercial GMP supplies. In parallel, we have also continued to invest in our internal process/analytical development, quality systems, manufacturing, and quality control infrastructure with the goal of accelerating and advancing our pipeline. We have constructed a manufacturing plant capable of producing early phase clinical trial GMP supplies and capable of supporting process optimization/scale-up at our New Jersey headquarter and further build-out of the space remains underway to allow us to produce supplies for our neoepitope and our other programs. Our strategy is to continue to leverage both our partner's capabilities and our internal capabilities in order to build a supply chain that is reliable, flexible, and cost competitive.

## **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., Celldex Therapeutics, Inovio Pharmaceutical Inc., ISA Pharmaceuticals, MedImmune LLC, Neon Therapeutics, 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, administration, reliability, acceptance, availability, price and patent position.

## **Experience and Expertise**

Our management team has extensive experience in oncology development, including contract research, development, manufacturing and commercialization across a board range of science, technologies, and process operations. We have built internal capabilities supporting research, clinical, medical, manufacturing and compliance operations and have extended our expertise with collaborations.

## **Employees**

As of January 5, 2017, we had 90 employees, all of which were full time employees. None of our employees are represented by a labor union, and we consider our relationship with our employees to be good.

We plan to further increase our capacity to include in-house clinical and commercial manufacturing capabilities, where we first intend to manufacture clinical supplies for our ADXS-NEO program. We will continue to rent necessary offices and laboratories to support our growing business.

## **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, 2016, we had an accumulated deficit of \$207,706,825 and shareholders' equity of \$119,302,194. 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 larger or 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:

safety issues up to and including patient death (whether 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, or onerous treatment administration requirements;

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, conduct additional trials, 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 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. 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 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, regulators and other parties. 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, a lawsuit, 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-applicable, 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, clinical holds, 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 which could materially harm our business, results of operations and prospects.

***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 regulatory 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, or place our products on temporary or permanent hold, 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 Statue and the federal False Claims Act, and privacy laws. Noncompliance with applicable laws and requirements can result in various adverse consequences, including delay in approving or refusal to approve product licenses or other applications, suspension or termination of clinical investigations, revocation of approvals previously granted, fines, criminal prosecution, civil and criminal penalties, recall or seizure of products, exclusion from having our products reimbursed by federal health care programs, the curtailment or restructuring of our operations, injunctions against shipping products and total or partial suspension of production and/or refusal to allow a company to enter into governmental supply contracts.

The process of obtaining requisite FDA approval has historically been costly and time-consuming. Current FDA requirements for a new human biological product to be marketed in the United States include: (1) the successful conclusion of preclinical laboratory and animal tests, if appropriate, to gain preliminary information on the product’s safety; (2) filing with the FDA of an IND to conduct human clinical trials for drugs or biologics; (3) the successful completion of adequate and well-controlled human clinical trials to establish the safety and efficacy of the investigational new drug for its recommended use; and (4) filing by a company and acceptance and approval by the FDA of a BLA for marketing approval of a biologic, 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 cGMP regulations. This has been extended to include any drug that will be tested for safety in animals in support of human testing. The cGMPs 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 FDA orphan drug designation for AXAL for use in the treatment of anal cancer, HPV-associated head and neck cancer, Stage II-IV invasive cervical cancer and for ADXS-HER2 for the treatment of osteosarcoma in the United States, as well as EMA orphan drug designation for AXAL for the treatment of anal cancer and for ADXS-HER2 for the treatment of osteosarcoma in the EU, and intend to continue to expand our designation for these uses where applicable, 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.

Currently, we own or have rights to approximately 246 patents and applications, which are owned, licensed from, or co-owned with Penn, Merck, NIH, and/or Augusta University. 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, 2016, 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 business, 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 limited to no manufacturing, sales, marketing or distribution capability and we must rely upon third parties for such.***

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 January 5, 2017, we had 90 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, unable to commercialize any 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., Celldex Therapeutics, Inovio Pharmaceutical Inc., ISA Pharmaceuticals, MedImmune LLC, Neon Therapeutics, Oncolytics Biotech Inc. and 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.

***Approval of our product candidates does not ensure successful commercialization and reimbursement.***

We are not currently marketing our product candidates, however we are seeking commercialize opportunities for AXAL. We cannot assure you that we will be able to commercialize ourselves or find a commercialization partner or that we will be able to agree to acceptable terms with any partner to launch and commercialize our products.

The commercial success of our product candidates is subject to risks in both the United States and European countries. In addition, in European countries, pricing and payment of prescription pharmaceuticals is subject to more extensive governmental control than in the United States. Pricing negotiations with European governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. If reimbursement is unavailable in any country in which reimbursement is sought, limited in scope or amount, or if pricing is set at or reduced to unsatisfactory levels, our ability or any potential partner’s ability to successfully commercialize in such a country would be impacted negatively. Furthermore, if these measures prevent us or any potential partner from selling on a

profitable basis in a particular country, they could prevent the commercial launch or continued sale in that country and could adversely impact the commercialization market opportunity in other countries.

Moreover, as a condition of approval, the regulatory authorities may require that we conduct post-approval studies. Those studies may reveal new safety or efficacy findings regarding our drug that could adversely impact the continued commercialization or future market opportunity in other countries.

In addition, Advaxis relies on a network of suppliers and vendors to manufacture its products. Should a regulatory authority make any significant findings on an inspection of those companies, the ability of Advaxis to continue producing its products could be adversely impacted and further production could cease.

Our potential revenues from the commercialization of our product candidates are subject to these and other factors, and therefore we may never reach or maintain profitability.

## 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.

***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.

***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.

***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 65,000,000 shares of our Common Stock. As of January 5, 2017, we had 40,147,145 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 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. In addition, as of January 5, 2017, we had outstanding options to purchase 3,897,558 shares of our Common Stock at a weighted average exercise price of approximately \$12.50 per share and outstanding warrants to purchase 3,110,575 shares of our Common Stock (including the above warrants subject to weighted-average anti-dilution protection); and approximately 11,807 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.

***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 1B: Unresolved Staff Comments .**

None.

**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 had a termination date of November 29, 2015. In May 2015, we signed a direct lease for an expansion area, as well as a direct lease for the existing office, lab and vivarium space upon the expiration of the sublease agreement, which is approximately 20,000 square feet of space in total. The lease term is seven years and expires on November 30, 2022. The lease requires base annual rent of approximately \$442,000 with annual increases in increments between 2% and 4% throughout the remainder of the lease. The lease contains two options to renew for five years each.

Effective February 1, 2016, the Company entered into an amendment to its office lease. On August 29, 2016, the Company entered into a second amendment to its office lease that will become effective January 1, 2017. The first and second amendments increased the leased space by approximately 25,000 and 4,000 square feet respectively, to a total of approximately 48,500 square feet. The additional space will allow the Company to expand manufacturing, testing, and product development capabilities, accelerate execution of pipeline related projects, strengthen the supply chain, and continue to ensure reliable and cost competitive supply of product. The lease term was extended by three years and is now scheduled to expire on November 30, 2025. The amended lease requires an annual rent of approximately \$962,000 with annual increases in increments between 2% and 11% throughout the remainder of the lease.

We plan to further increase our capacity to include in-house clinical and commercial manufacturing capabilities, where we first intend to manufacture clinical supplies for our ADXS-NEO program. We will continue to rent necessary offices and laboratories to support our growing business.

### **Item 3. Legal Proceedings.**

The information required under this item is set forth in Footnote 11. Commitments and Contingencies – Legal Proceedings with this Form 10-K and is incorporated herein by reference.

### **Item 4. Mine Safety Disclosures.**

None.

## **PART II**

### **Item 5. Market for Our Common Stock and Related Shareholder Matters.**

Our common stock is listed on the NASDAQ Global Select Market under the symbol “ADXS”. The following table sets forth for the periods indicated the high and low sales prices per share of our common stock as reported on the NASDAQ Stock Market:

Fiscal 2016	High	Low
Fourth Quarter	\$15.98	\$7.87
Third Quarter	\$9.66	\$7.01
Second Quarter	\$9.99	\$5.46
First Quarter	\$14.45	\$6.64

Fiscal 2015	High	Low
Fourth Quarter	\$19.71	\$9.76
Third Quarter	\$28.77	\$15.82
Second Quarter	\$23.61	\$7.02
First Quarter	\$13.51	\$2.75

Fiscal 2014	High	Low
Fourth Quarter	\$4.27	\$2.56
Third Quarter	\$3.45	\$2.56
Second Quarter	\$5.52	\$2.51
First Quarter	\$5.53	\$3.09

As of October 31, 2016, there were approximately 101 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 January 4, 2017, the last reported sale price per share for our Common Stock as reported by NASDAQ was \$7.94.

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 11, 2016, the registrant issued 28,838 shares of Common Stock to accredited investors as payment for consulting services.

On August 31, 2016, the registrant issued 974 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On September 30, 2016, the registrant issued 962 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On October 19, 2016, the registrant issued 20,000 shares of Common Stock to an accredited investor as payment for consulting services.

On October 31, 2016, the registrant issued 972 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On November 15, 2016, the registrant issued 32,500 shares of Common Stock to accredited investors as payment for consulting services.

On November 30, 2016, the registrant issued 1,205 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On December 30, 2016, the registrant issued 2,011 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, 2016:

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	3,351,795	\$ 13.31	1,145,264

## Treasury Share Repurchases

The following table represents treasury share repurchases during the year ended October 31, 2016:

Period	(a) Total Number of Shares Purchased (1)	(b) Average Price Paid Per Share	(c) Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Dollar Value of Shares that May Yet Be Purchased Under the Program
November 1, 2015 – November 30, 2015	2,009	\$ 12.49	N/A	N/A
December 1, 2015 – December 31, 2015	3,434	11.91	N/A	N/A
January 1, 2016 – January 31, 2016	89,008	7.11	N/A	N/A
February 1, 2016 – February 29, 2016	42,682	8.37	N/A	N/A
March 1, 2016 – March 31, 2016	22,943	6.02	N/A	N/A
April 1, 2016 – April 30, 2016	24,739	8.08	N/A	N/A
May 1, 2016 – May 31, 2016	11,726	7.12	N/A	N/A
June 1, 2016 – June 30, 2016	5,058	8.49	N/A	N/A
July 1, 2016 – July 31, 2016	48,849	8.33	N/A	N/A
August 1, 2016 – August 31, 2016	3,783	14.49	N/A	N/A
September 1, 2016 – September 30, 2016	10,969	11.59	N/A	N/A
October 1, 2016 – October 31, 2016	67,337	9.21	N/A	N/A
Total	332,537	\$ 8.21	N/A	N/A

(1) Consists of shares repurchased by the Company for certain employees' restricted stock units that vested to satisfy minimum tax withholding obligations that arose on the vesting of the restricted stock units.

## Common Stock Performance Graph

The following graph compares the cumulative total stockholder return on our common stock for the period from October 17, 2013 through October 31, 2016, with the cumulative total return over such period on (i) the U.S. Index of The NASDAQ Stock Market and (ii) the Biotechnology Index of The NASDAQ Stock Market. The graph assumes an investment of \$100 on October 17, 2013, in our common stock (at the closing market price) and in each of the indices listed above, and assumes the reinvestment of dividends.

**COMPARISON OF CUMULATIVE TOTAL RETURN\***

Among Advaxis, Inc., the NASDAQ Composite Index

and the NASDAQ Biotechnology Index

\* \$100 invested on October 17, 2013 in stock or index, including reinvestment of dividends.

Fiscal year ending October 31.

**ITEM 6. Selected Financial Data.**

The selected financial data included in this section are not intended to replace the consolidated financial statements included elsewhere in this Annual Report on Form 10-K. We derived the selected statements of operations data for the years ended October 31, 2016, 2015 and 2014 and the selected balance sheet data at October 31, 2016 and 2015 from our audited financial statements included elsewhere in this report. We derived the selected statements of operations data for the years ended October 31, 2013 and 2012 and the selected balance sheet data at October 31, 2014, 2013 and 2012 from our audited financial statements which are not included in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of the results that may be expected in the future. You should read the selected historical consolidated financial data below in conjunction with the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the audited consolidated financial statements included elsewhere in this report.

	Year Ended October 31,				
	2016	2015	2014	2013	2012
Statements of Operations Data:					
Revenue	\$3,994,856	\$-	\$1,000,000	\$-	\$-
Operating Expenses:					
Research and Development Expenses	48,774,589	24,426,967	8,862,854	5,621,989	6,646,094
General and Administrative Expenses	31,712,505	24,243,690	11,675,724	9,071,613	5,688,677
Total Operating Expenses	80,487,094	48,670,657	20,538,578	14,693,602	12,334,771
Loss from Operations	(76,492,238)	(48,670,657)	(19,538,578)	(14,693,602)	(12,334,771)
Other Income (Expense):					
Interest Income	331,529	114,219	36,305	(987,746 )	(4,536,528 )



Edgar Filing: Advaxis, Inc. - Form 10-K

Net Changes in Fair Value of Derivative Liabilities	69,055	(48,950 )	619,089	(1,504,465 )	6,630,610
(Loss) on Note Retirement	-	-	-	(3,455,327 )	(2,187,787 )
Other Income (Expense), Net	(201 )	(35,079 )	990	(70,876 )	12,002
Net Loss Before Income Tax Benefit	(76,091,855)	(48,640,467)	(18,882,194)	(20,712,016)	(12,416,474)
Income Tax Benefit	2,535,625	1,609,349	2,356,880	725,190	346,787
Dividends Attributable to Preferred Shares	-	-	-	(555,000 )	(740,000 )
Net Loss Applicable to Common Stock	\$(73,556,230)	\$(47,031,118)	\$(16,525,314)	\$(20,541,826)	\$(12,809,687)
Net Loss	(73,556,230)	(47,031,118)	(16,525,314)	(19,986,826)	(12,069,687)
Net Loss per Common Share, Basic and Diluted	\$(2.08 )	\$(1.68 )	\$(0.97 )	\$(4.10 )	\$(4.99 )
Weighted Average Number of Common Shares Outstanding, Basic and Diluted	35,400,980	28,026,197	17,106,577	5,012,105	2,564,820

	October 31, 2016	2015	2014	2013	2012
Balance Sheet Data:					
Cash and Cash Equivalents and Investments – Held-to-Maturity	\$ 152,087,528	\$ 112,156,178	\$ 17,606,860	\$ 20,552,062	\$ 232
Working Capital	132,168,809	111,096,966	17,778,325	15,872,461	(8,445,077 )
Total Assets	169,044,060	119,605,693	23,377,813	23,585,921	3,815,797
Common Stock Warrant Liability	20,156	89,211	32,091	646,734	434,136
Accumulated Deficit	(207,706,825 )	(134,054,259 )	(86,991,137 )	(70,465,823 )	(47,601,427 )
Total Shareholders' Equity	119,302,194	115,598,875	20,629,986	18,002,142	(5,962,724 )

## 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 with our lead program in Phase 3 development. 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.

### Results of Operations

### Fiscal Year 2016 Compared to Fiscal Year 2015

### *Revenue*

During the year ended October 31, 2016, the Company recorded revenue of \$3,994,856. The Company recognized \$3,744,856 of revenue from the collaboration agreement with Amgen related to amortization of the upfront fees received. In addition, \$250,000 of revenue was due to the receipt of an annual exclusive license fee from GBP for the development and commercialization of AXAL.

We did not record any revenue for the year ended October 31, 2015.

### *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 \$48.8 million for the year ended October 31, 2016, compared with \$24.4 million for the year ended October 31, 2015, an increase of \$24.4 million. The increase was primarily a result of higher third-party costs, specifically related to AXAL support of clinical trial expenses, manufacturing, and consulting costs, for the cervical, anal, and head & neck cancer programs, as well as ADXS-PSA Phase 1/2 trial support and preclinical support of ADXS-NEO. Stock based compensation for existing and past employees increased by approximately \$2.7 million due to increases in the number of awards. Moreover, the increase in overall research and development expense was also a result of an increased number of employees to support the research and development initiatives.

We anticipate a significant increase in research and development expenses on a continuous basis 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 \$31.7 million for the year ended October 31, 2016, compared with \$24.2 million for the year ended October 31, 2015, an increase of \$7.5 million. There was an increase of approximately \$6.9 million in compensation related expense, including a non-cash increase in stock based compensation costs of approximately \$2.6 million, attributable to increases in our employees, the grant date fair value of stock awards and the number of awards. Costs pertaining to the Company's infrastructure expansion, including leased space and information technology related costs, increased by approximately \$1.6 million. Business development costs increased by approximately \$1.5 million. This was partially offset by a decrease in non-cash investor relations costs of approximately \$2.2 million.

We anticipate general and administrative expenses in the near term to remain comparable to current levels, exclusive of the impact of future stock awards and one-time expenses.

### *Interest Income*

Interest income was \$331,529 for the year ended October 31, 2016, compared with \$114,219 for the year ended October 31, 2015. The increase in interest income earned was attributable to an increase in cash resulting from sales of the Company's common shares. The cash was invested in held-to-maturity investments and a savings account.

### *Changes in Fair Values*

For the year ended October 31, 2016, the Company recorded non-cash income from changes in the fair value of the warrant liability of \$69,055 due to a decrease in the fair value of liability warrants as a smaller range of share prices were used in the calculation of the BSM volatility input as well as a decrease in our share price from \$11.09 at October 31, 2015 to \$8.09 at October 31, 2016.

For the year ended October 31, 2015, the Company recorded non-cash expense from changes in the fair value of the warrant liability of \$48,950 due to an increase in the fair value of liability warrants primarily resulting from a larger range of share prices used in the calculation of the Black-Scholes Model ("BSM") volatility input, as well as a significant increase in our share price from \$3.18 at October 31, 2014 to \$11.09 at October 31, 2015. This was partially offset by the expiration of some warrants.

### *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.

During the year ended October 31, 2016, the Company recorded Income Tax Receivable of \$2,549,862 from the sale of its state NOLs and research and development tax credits for the period ended October 31, 2015. In addition, the Company received a net cash amount of \$35,764 in excess of what was recorded as Income Tax Receivable at October 31, 2015. We paid \$50,000 in Taiwanese withholding taxes in connection with the revenue generated from an annual exclusive license fee from GBP.

During the year ended October 31, 2015, the Company recorded Income Tax Receivable of \$1,609,349 from the sale of its state NOLs and research and development tax credits for the period ended October 31, 2014.

### *Net Loss*

We reported a net loss of \$73.6 million, or \$2.08 per share basic and diluted for the year ended October 31, 2016 as compared to a net loss of \$47.0 million, or \$1.68 per share basic and diluted, for the year ended October 31, 2015.

## **Fiscal Year 2015 Compared to Fiscal Year 2014**

### *Revenue*

We did not record any revenue for the year end October 31, 2015.

During the year end October 31, 2014, we transitioned from a development stage company to an operating company. On March 19, 2014, we and Aratana entered into the 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 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 Agreement, we properly recorded the \$1 million payment as licensing revenue in the year ended October 31, 2014.

### *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 \$24.4 million for the year ended October 31, 2015, compared with \$8.9 million for the year ended October 31, 2014, an increase of \$15.5 million. The increase was primarily a result of higher third-party costs, specifically related to AXAL support of clinical trial expense and manufacturing costs, for the cervical, anal, and head & neck cancer programs, as well as ADXS-PSA Phase 1/2 trial support. In addition, stock based compensation costs rose by approximately \$5.0 million due to a rise in our share price and an increase in the number of shares awarded as a result of an increased headcount.

We anticipate a significant increase in research and development expenses on a continuous basis 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 \$24.2 million for the year ended October 31, 2015, compared with \$11.7 million for the year ended October 31, 2014, an increase of \$12.5 million. The increase was due to greater stock based compensation costs of approximately \$11.0 million attributable to a rise in our share price and an increase in the number of shares awarded as a result of an increased headcount. Furthermore, greater legal costs of approximately \$0.6 million for consultation on a variety of corporate matters and \$1.4 million in cash payments for investor relations. The aforementioned was partially offset by \$0.5 million in severance costs related to a former employee in the prior period.

We anticipate general and administrative expenses in the near term to remain comparable to current levels, exclusive of the impact of future stock awards and one-time expenses.

### *Interest Income*

Interest income was \$114,219 for the year ended October 31, 2015, compared with \$36,305 for the year ended October 31, 2014. Interest income earned for the year ended October 31, 2015 reflected interest income earned on the Company's held-to-maturity investments and savings account balance. Interest income earned for the year ended October 31, 2014 reflected interest income earned on the Company's savings account balance.

#### *Changes in Fair Values*

For the year ended October 31, 2015, the Company recorded non-cash expense from changes in the fair value of the warrant liability of \$48,950 due to an increase in the fair value of liability warrants primarily resulting from a larger range of share prices used in the calculation of the Black-Scholes Model ("BSM") volatility input, as well as a significant increase in our share price from \$3.18 at October 31, 2014 to \$11.09 at October 31, 2015. This was partially offset by the expiration of some warrants.

For the year ended October 31, 2014, the Company recorded non-cash income from changes in the fair value of the warrant liability of \$619,089 due to a decrease value of liability warrants due to a decrease in our share price from \$3.74 at October 31, 2013 to \$3.18 at October 31, 2014, a smaller range of share prices used in the calculation of the BSM volatility input and the expiration of some warrants.

#### *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 December 2015, the Company received a net cash amount of \$1,609,349 from the sale of its state NOLs and research and development tax credits for the period ended October 31, 2014.

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.

#### *Net Loss*

We reported a net loss of \$47.0 million, or \$1.68 per share basic and diluted for the year ended October 31, 2015 as compared to a net loss of \$16.5 million, or \$0.97 per share basic and diluted, for the year ended October 31, 2014.





## **Liquidity and Capital Resources**

Our major sources of cash have been proceeds from various public and private offerings of our common stock, option and warrant exercises, and interest income. From October 2013 through December 2016, we raised approximately \$221.8 million in gross proceeds from various public and private offerings of our common stock. We have not yet commercialized any drug, and we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain regulatory approvals for our drug, successfully complete any post-approval regulatory obligations, successfully compete with other available treatment options in the marketplace, overcome any clinical holds that the FDA may impose and successfully manufacture and commercialize our drug alone or in partnership. We may continue to incur substantial operating losses even after we begin to generate revenues from our drug candidates. As of October 31, 2016, the Company had approximately \$152.1 million in cash, cash equivalents and investments on its balance sheet. We believe our current cash position is sufficient to fund our business plan approximately through the second quarter of fiscal 2019. The actual amount of cash that we will need to operate is subject to many factors.

Since our inception through October 31, 2016, we reported accumulated net losses of approximately \$207.7 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 Flows***

#### ***Operating Activities***

Cash used in operating activities for the year ended October 31, 2016 was approximately \$9.1 million. Spending associated with our clinical trial programs and general and administrative spending was partially offset by a \$40 million upfront payment received from Amgen in connection with the collaboration agreement as well as proceeds from the sale of our state NOLs and Research and Development (R&D) tax credits of approximately \$1.6 million.

Cash used in operating activities for the year ended October 31, 2015 was approximately \$24.1 million (including proceeds from the sale of our state NOLs and R&D tax credits of approximately \$1.7 million) primarily from spending associated with our clinical trial programs and general and administrative spending.

Cash used in operating activities for the year ended October 31, 2014 was approximately \$16.1 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 and 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.

### *Investing Activities*

Cash provided by investing activities for the year ended October 31, 2016 was approximately \$1.6 million resulting from net proceeds from investments in held-to-maturity investments, purchases of property and equipment, construction of cleanroom and laboratory facilities, legal cost spending in support of our intangible assets (patents) and costs paid to Penn for patents.

Cash used in investing activities for the year ended October 31, 2015 was approximately \$47.4 million resulting from investments in held-to-maturity investments, purchases of property and equipment to support expansion, legal cost spending in support of our intangible assets (patents) and costs paid to Penn for patents.

Cash used in investing activities, for the year ended October 31, 2014, was approximately \$440,000 resulting from legal cost spending in support of our intangible assets (patents) and costs paid to Penn for patents.

### *Financing Activities*

Cash provided by financing activities for the year ended October 31, 2016 was approximately \$53.7 million, resulting from the sale of 3,047,446 shares of our Common Stock to Amgen resulting in net proceeds of approximately \$25 million and a registered direct offering of 2,244,443 shares of our Common Stock resulting in net proceeds of approximately \$28.2 million. In addition, approximately \$614,000 in proceeds was received on option and warrant exercises. This was partially offset by approximately \$36,000 of taxes paid related to the net share settlement of equity awards.

Cash provided by financing activities for the year ended October 31, 2015 was approximately \$120.5 million, resulting primarily from registered direct offerings of 8,806,165 shares of our Common Stock resulting in net proceeds of approximately \$63.1 million and a public offering of 2,800,000 shares of Common Stock resulting in net proceeds of approximately \$56.7 million. In addition, the Company received approximately \$2.4 million from the proceeds received on option and warrant exercises. This was partially offset by approximately \$1.6 million of taxes paid related to the net share settlement of equity awards.

Cash provided by financing activities, for the year ended October 31, 2014, was approximately \$13.6 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 approximately \$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 approximately \$0.4 million. This was partially offset by approximately \$0.9 million of taxes paid related to the net share settlement of equity awards.

Our capital resources and operations to date have been funded primarily with the proceeds from public, private equity and debt financings, NOL tax sales and income earned on investments and grants. We have sustained losses from operations in each fiscal year since our inception, and we expect losses to continue for the indefinite future, due to the substantial investment in research and development. As of October 31, 2016 and October 31, 2015, we had an accumulated deficit of \$207,706,825 and \$134,054,259, respectively and shareholders' equity of \$119,302,194 and \$115,598,875, respectively.

The Company believes its current cash position is sufficient to fund its business plan approximately through the second quarter of fiscal 2019. We have based this estimate on assumptions that may prove to be wrong, and we could use available capital resources sooner than currently expected. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amount of increased capital outlays and operating expenses associated with completing the development of our current product candidates.

The Company recognizes it may need to raise additional capital 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 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, 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.

#### Tabular Disclosure of Contractual Obligations

Contractual Obligations	Payments Due by Period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating Leases	\$11,408,963	\$961,796	\$2,149,280	\$2,550,547	\$5,747,340
Employment Agreements Subject to Annual Renewal	\$1,414,433	\$1,414,433			
Consulting and other Services	\$1,663,783	\$1,055,960	\$607,823		

We enter into agreements in the normal course of business with contract research organizations for clinical trials and with vendors for preclinical studies and other services and products for operating purposes which are cancelable at any time by us, generally upon 30 days prior written notice. These payments are not included in this table of contractual obligations.

We are obligated to make future payments to third parties under in-license agreements, including sublicense fees, royalties and payments that become due and payable on the achievement of certain development and commercialization milestones. As the amount and timing of sublicense fees and the achievement and timing of these milestones are not probable and estimable, such commitments have not been included on our consolidated balance sheets or in the contractual obligations table above.

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

As of October 31, 2016, we had no off-balance sheet arrangements.

### **Critical Accounting Estimates**

The preparation of financial statements in accordance with GAAP accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts and related disclosures in the financial statements. Management considers an accounting estimate to be critical if:

it requires assumptions to be made that were uncertain at the time the estimate was made, and

changes in the estimate of difference estimates that could have been selected could have material impact in our results of operations or financial condition.

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

### *Revenue Recognition*

The Company is expected to derive the majority of its revenue 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.

Revenue associated with nonrefundable upfront license fees under arrangements where the license fees and research and development activities cannot be accounted for as separate units of accounting is deferred and recognized as revenue on a straight-line basis over the expected period of performance.

Revenues from the achievement of research and development milestones, if deemed substantive, are recognized as revenue when the milestones are achieved and the milestone payments are due and collectible. If not deemed substantive, the Company recognizes such milestones as revenue on a straight-line basis over the remaining expected performance period under the arrangement. All such recognized revenues are included in collaborative licensing and development revenue in the Company's statements of operations.

Milestones are considered substantive if all of the following conditions are met: (1) the milestone is nonrefundable; (2) achievement of the milestone was not reasonably assured at the inception of the arrangement; (3) substantive effort is involved to achieve the milestone; and (4) the amount of the milestone appears reasonable in relation to the effort expended, and the other milestones in the arrangement and the related risk associated with the achievement of the milestone and any ongoing research and development or other services are priced at fair value.

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.

Deferred revenue represents the portion of payments received for which the earnings process has not been completed. Deferred revenue expected to be recognized within the next 12 months is classified as a current liability.

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.

#### *Stock Based Compensation*

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

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

Stock-based compensation for employees, executives and directors is measured based on the fair value of the shares issued on the date of grant and is to be recognized over the requisite service period in both research and development expenses and general and administrative expenses on the statement of operations. For non-employees, the fair value of the award is generally measured based on contractual terms.

#### *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 AXAL, 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, 2013.

## **New Accounting Pronouncements**

See Note 2 to our financial statements that discusses new accounting pronouncements.

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

At October 31, 2016, the Company had approximately \$152.1 million in cash, cash equivalents and investments, which consisted primarily of bank deposits, money market funds and short term investments such as certificates of deposit, domestic governmental agency loans and U.S treasury notes. The Company's investment policy and strategy are focused on preservation of capital and supporting the Company's liquidity requirements. The Company uses a combination of internal and external management to execute its investment strategy and achieve its investment objectives. The Company typically invests in highly-rated securities, and its investment policy generally limits the amount of credit exposure to any one issuer. The policy requires investments generally to be investment grade, with the primary objective of minimizing the potential risk of principal loss. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations of interest income have not been significant.

We have not been exposed nor do we anticipate being exposed to material risks due to changes in interest rates. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

## **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.**

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

Under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework published in 2013. Based on its evaluation, our management concluded that our internal control over financial reporting was effective as of the end of the period covered by this Annual Report on Form 10-K.

**(a) Evaluation of Disclosure Controls and Procedures**

An evaluation was performed under the supervision and with the participation of our management, including our chief executive officer and our chief financial officer as to the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of the end of the period covered by this report. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Based on that evaluation, the chief executive officer and the chief financial officer of the Company have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are effective.

**(b) Management's Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. Internal control over financial reporting includes those policies and procedures that:

- (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- (ii) provide reasonable assurance that the transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with the authorization of management and/or our Board of Directors; and
- (iii) provide reasonable assurance regarding the prevention or timely detection of any unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate due to changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Marcum LLP, an independent registered public accounting firm, has audited the Consolidated Financial Statements included in this Annual Report on Form 10-K and, as part of the audit, has issued an attestation report, included herein, on the effectiveness of our internal control over financial reporting. See “Reports of Independent Registered Public Accounting Firm” included in this filing.

**(c) Changes in Internal Control over Financial Reporting**

During the quarter ended October 31, 2016, there were no 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.

*Limitations on the Effectiveness of Controls* . Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON INTERNAL CONTROL OVER FINANCIAL REPORTING

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

We have audited Advaxis Inc.'s (the "Company") internal control over financial reporting as of October 31, 2016, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013. The Company's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Management Annual Report on Internal Control over Financial Reporting". Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that degree of compliance with the policies or procedures may deteriorate.

In our opinion, Advaxis, Inc. maintained, in all material aspects, effective internal control over financial reporting as of October 31, 2016, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets as of October 31, 2016, and the related statements of operations, shareholders' equity, and cash flows for the years ended October 31, 2016, 2015 and 2014 of the Company and our report dated January 9, 2017 expressed an unqualified opinion on those financial statements.

New York, NY  
January 9, 2017



**Item 9B: Other Information.**

None.

## **PART III**

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

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2017 Annual Meeting of Stockholders.

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

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2017 Annual Meeting of Stockholders.

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

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2017 Annual Meeting of Stockholders.

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

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2017 Annual Meeting of Stockholders.

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

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2017 Annual Meeting of Stockholders.



## 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.

Exhibit Number	Description of Exhibits
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 (reverse stock split). Incorporated by reference to 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	Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on March 10, 2016. Incorporated by reference to Exhibit 3.1 to Current Report on

Edgar Filing: Advaxis, Inc. - Form 10-K

Form 8-K filed with the SEC on March 11, 2016.

- 3.9 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 Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K filed with the SEC on November 12, 2010.
- 4.3 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.
- 4.4 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.

44

<b>Exhibit Number</b>	<b>Description of Exhibits</b>
4.5	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.
4.6	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.
4.7	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.
4.8	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.
4.9	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.
4.10	Form of Warrant to Purchase 30,154 Shares of Common Stock issued September 17, 2013 pursuant to an engagement letter termination agreement. Incorporated by reference to Exhibit 4.20 to Registration Statement on Form S-1/A (File No. 333-188637) filed with the SEC on September 27, 2013.
4.11	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.
4.12	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.
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.

<b>Exhibit Number</b>	<b>Description of Exhibits</b>
10.4	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.
10.5	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.
10.6	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.
10.7	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.
10.8	2011 Employee Stock Purchase Plan. Incorporated by reference to Annex B to DEF 14A Proxy Statement filed with the SEC on August 29, 2011.
10.9	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.
10.10	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.
10.11	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.
10.12	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.
10.13	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.
10.14	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.
10.15	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 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.

- 10.16 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.
- 10.17 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.



<b>Exhibit Number</b>	<b>Description of Exhibits</b>
10.18 ‡	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.
10.19	Indemnification Agreement. Incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed with the SEC on August 20, 2013.
10.20 ‡	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.
10.21 ‡	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.
10.22 ‡	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.
10.23	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.
10.24 ‡	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.
10.25 ‡	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.
10.26 ‡	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.
10.27 ‡	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.
10.28	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.
10.29	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.

10.30‡ 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.

10.31‡ 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.

10.32‡ 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.

10.33‡ 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.

<b>Exhibit Number</b>	<b>Description of Exhibits</b>
10.34‡	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.
10.35‡	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.
10.36‡	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
10.37‡	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.
10.38	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.
10.39	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.
10.40	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.
10.41	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.
10.42	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.
10.43	Clinical Trial Collaboration and Supply Agreement by and between Advaxis, Inc. and Merck & Co. dated August 22, 2014. Incorporated by reference to Exhibit 10.101 to Annual Report on Form 10-K filed with the SEC on January 6, 2015
10.44‡	Amendment No. 1, dated as of April 17, 2015, to the Employment Agreement by and between Advaxis, Inc and David J. Mauro. Incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed with the SEC on June 15, 2015.
10.45‡	Amendment No. 2, dated as of April 17, 2015, to the Employment Agreement by and between Advaxis, Inc and Sara M. Bonstein. Incorporated by reference to Exhibit 10.3 to Quarterly Report on Form 10-Q

Edgar Filing: Advaxis, Inc. - Form 10-K

filed with the SEC on June 15, 2015.

- 10.46‡ Amendment No. 3, dated as of April 17, 2015, 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 15, 2015.
- 10.47‡ Amendment No. 3, dated as of April 17, 2015, 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 15, 2015.
- 10.48‡ Amendment No. 3, dated as of April 17, 2015, 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 15, 2015.
- 10.49 Exclusive License Agreement, dated August 25, 2015, by and between Advaxis, Inc. and Knight Therapeutics, Inc. Incorporated by reference to Exhibit 10.57 to Annual Report on Form 10-K filed with the SEC on January 8, 2016.
- 10.50 Securities Purchase Agreement, dated as of August 25, 2015, between Advaxis, Inc., Knight Therapeutics Inc., and Sectoral Asset Management. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on August 28, 2015.
- 10.51 ‡ Amendment No. 4, dated as of December 31, 2015, to the Employment Agreement by and between Advaxis, Inc and Robert G. Petit. Incorporated by reference to Exhibit 10.58 to Annual Report on Form 10-K filed with the SEC on January 8, 2016.
- 10.52 ‡ Amendment No. 3, dated as of December 31, 2015, to the Employment Agreement by and between Advaxis, Inc and Sara M. Bonstein. Incorporated by reference to Exhibit 10.59 to Annual Report on Form 10-K filed with the SEC on January 8, 2016.
- 10.53 ‡ Amendment No. 4, dated as of December 31, 2015, to the Employment Agreement by and between Advaxis, Inc and Daniel J. O'Connor. Incorporated by reference to Exhibit 10.60 to Annual Report on Form 10-K filed with the SEC on January 8, 2016.
- 10.54 ‡ Amendment No. 4, dated as of December 31, 2015, to the Employment Agreement by and between Advaxis, Inc and Gregory T. Mayes. Incorporated by reference to Exhibit 10.61 to Annual Report on Form 10-K filed with the SEC on January 8, 2016.
- 10.55 Co-Development and Commercialization Agreement between Advaxis, Inc. and Especificos Stendhal SA de CV dated February 3, 2016. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on February 26, 2016.
- 10.56 Change of Control Plan dated February 24, 2016. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on February 26, 2016.
- 10.57 \*\*\* License and Collaboration Agreement, dated August 2, 2016, by and between Advaxis, Inc. and Amgen Inc.
- 10.58 Securities Purchase Agreement, dated as of August 1, 2016, between Advaxis, Inc. and Amgen, Inc. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on August 2, 2016.

10.59 Placement Agency Agreement, dated as of August 16, 2016, between Advaxis, Inc. Jefferies LLC and Barclay's Capital Inc., as representatives. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on August 16, 2016.

<b>Exhibit Number</b>	<b>Description of Exhibits</b>
14.1	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.
23.1	Consent of Independent Registered Public Accounting Firm.
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 9<sup>th</sup> day of January 2017.

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> Daniel J. O'Connor	President, Chief Executive Officer and Director (Principal Executive Officer)	January 9, 2017
<i>/s/ Sara Bonstein</i> Sara Bonstein	Chief Financial Officer, Executive Vice President and Secretary (Principal Financial and Accounting Officer)	January 9, 2017
<i>/s/ David Sidransky</i> David Sidransky	Chairman of the Board	January 9, 2017
<i>/s/ James Patton</i> James Patton	Vice Chairman of the Board	January 9, 2017

<i>/s/ Richard Berman</i> Richard Berman	Director	January 9, 2017
<i>/s/ Thomas McKearn</i> Thomas McKearn	Director	January 9, 2017
<i>/s/ Samir Khleif</i> Samir Khleif	Director	January 9, 2017
<i>/s/ Roni Appel</i> Roni Appel	Director	January 9, 2017
<i>/s/ Thomas Ridge</i> Thomas Ridge	Director	January 9, 2017
<i>/s/ Gregory T. Mayes</i> Gregory Mayes	Director	January 9, 2017



**ADVAXIS, INC.**

**FINANCIAL STATEMENTS**

**INDEX**

	Page
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Balance Sheets</u>	F-3
<u>Statements of Operations</u>	F-4
<u>Statements of Shareholders' Equity</u>	F-5
<u>Statements of Cash Flows</u>	F-6
<u>Notes to the Financial Statements</u>	F-8

F-1

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, 2016 and 2015, and the related statements of operations, shareholders’ equity and cash flows for the years ended October 31, 2016, 2015 and 2014. 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. 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, 2016 and 2015, and the results of its operations and its cash flows for the years ended October 31, 2016, 2015 and 2014, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Advaxis, Inc.’s internal control over financial reporting as of October 31, 2016, based on the criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013 and our report dated January 9, 2017 expressed an unqualified opinion on the effectiveness of the Company’s internal control over financial reporting.

*/s/ Marcum llp*  
Marcum llp  
New York, NY  
January 9, 2017



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

	October 31, 2016	2015
<b>ASSETS</b>		
Current Assets:		
Cash and Cash Equivalents	\$112,750,980	\$66,561,683
Investments – Held-to-Maturity	39,336,548	45,594,495
Interest Receivable	80,142	145,299
Prepaid Expenses	812,830	338,841
Income Tax Receivable	2,549,862	1,609,349
Deferred Expenses	4,291,385	749,790
Other Current Assets	53,451	15,116
Total Current Assets	159,875,198	115,014,573
Property and Equipment (net of accumulated depreciation)	4,389,074	1,087,244
Intangible Assets (net of accumulated amortization)	4,329,121	3,355,033
Other Assets	450,667	148,843
<b>TOTAL ASSETS</b>	<b>\$169,044,060</b>	<b>\$119,605,693</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts Payable	\$1,720,428	\$696,117
Accrued Expenses	10,905,003	3,191,941
Deferred Revenue	15,020,576	-
Lease Incentive Obligation	40,226	-
Short-term Convertible Notes and Fair Value of Embedded Derivative	-	29,549
Common Stock Warrant Liability	20,156	-
Total Current Liabilities	27,706,389	3,917,607
Deferred Rent	475,749	-
Deferred Revenue	21,234,568	-
Lease Incentive Obligation- net of current portion	325,160	-
Common Stock Warrant Liability	-	89,211
Total Liabilities	49,741,866	4,006,818
Commitments and Contingencies – Note 11		
Shareholders' Equity:		
Preferred Stock, \$0.001 par value; 5,000,000 shares authorized; Series B Preferred Stock; 0 shares issued and outstanding at October 31, 2016 and 2015. Liquidation preference of \$0 at October 31, 2016 and 2015.	-	-

Edgar Filing: Advaxis, Inc. - Form 10-K

Common Stock - \$0.001 par value; 65,000,000 shares authorized, 40,057,067 shares issued and 40,041,047 shares outstanding at October 31, 2016 and 33,591,882 shares issued and 33,574,963 shares outstanding at October 31, 2015.	40,057	33,592
Additional Paid-In Capital	327,098,749	249,807,303
Treasury Stock, at cost, 16,020 shares at October 31, 2016 and 16,919 shares October 31, 2015	(129,787 )	(187,761 )
Accumulated Deficit	(207,706,825)	(134,054,259)
Total Shareholders' Equity	119,302,194	115,598,875
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>\$169,044,060</b>	<b>\$119,605,693</b>

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

F-3

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

	Year Ended October 31,		
	2016	2015	2014
Revenue	\$3,994,856	\$-	\$1,000,000
Operating Expenses:			
Research and Development Expenses	48,774,589	24,426,967	8,862,854
General and Administrative Expenses	31,712,505	24,243,690	11,675,724
Total Operating Expenses	80,487,094	48,670,657	20,538,578
Loss from Operations	(76,492,238)	(48,670,657)	(19,538,578)
Other Income (Expense):			
Interest Income	331,529	114,219	36,305
Net Changes in Fair Value of Derivative Liabilities	69,055	(48,950)	619,089
Other Income (Expense), Net	(201)	(35,079)	990
Net Loss Before Income Tax Benefit	(76,091,855)	(48,640,467)	(18,882,194)
Income Tax Benefit	2,535,625	1,609,349	2,356,880
Net Loss	\$(73,556,230)	\$(47,031,118)	\$(16,525,314)
Net Loss per Common Share, Basic and Diluted	\$(2.08)	\$(1.68)	\$(0.97)
Weighted Average Number of Common Shares Outstanding, Basic and Diluted	35,400,980	28,026,197	17,106,577

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

**ADVAXIS, INC.****STATEMENTS OF SHAREHOLDERS' EQUITY**

	Preferred Stock Shares	Common Stock Amount Shares	Common Stock Amount	Additional Paid-In Capital	Treasury Stock Shares	Treasury Stock Amount	Accumulated Deficit	Shareholders' Equity
Balance at October 31, 2013	-	\$-	13,719,861	\$13,720	\$88,454,245	-	\$-	\$(70,465,823 ) \$18,002,142
Stock compensation to employees, directors and consultants		501,651	502	3,839,202				3,839,704
Tax withholdings paid related to net share settlement of equity awards				(959,425 )				(959,425 )
Common Stock issued upon exercise of warrants		50	-	250				250
Common Stock issued to consultants		247,218	247	1,551,186				1,551,433
Issuance of shares to employees under ESPP Plan		2,110	2	6,249				6,251
Issuance of shares to investors under stock purchase agreements		467,249	467	2,033,670				2,034,137
Advaxis Public Offering		4,692,000	4,692	12,676,116				12,680,808
Net Loss							(16,525,314 )	(16,525,314 )
Balance at October 31, 2014	-	\$-	19,630,139	\$19,630	\$107,601,493	-	\$-	\$(86,991,137 ) \$20,629,986

Edgar Filing: Advaxis, Inc. - Form 10-K

Stock compensation to employees, directors and consultants	789,438	790	16,667,800					16,668,590
Tax withholdings paid related to net share settlement of equity awards			(1,375,979 )					(1,375,979 )
Treasury stock purchased to pay employee withholdings on equity awards				(114,445 )	(1,388,086)			(1,388,086 )
Treasury shares sold to pay for employee tax withholdings on equity awards			16,273	97,526	1,200,325	(32,004 )		1,184,594
Common Stock issued upon exercise of options	65,167	65	58,335					58,400
Common Stock issued upon exercise of warrants	691,268	691	2,341,758					2,342,449
Common Stock issued to consultants	378,538	379	4,707,061					4,707,440
Conversion of notes payable into common stock	4,104	4	39,928					39,932
Issuance of shares to employees under ESPP	7,063	7	28,784					28,791
Plan								
Advaxis registered direct offerings	8,806,165	8,806	63,046,722					63,055,528
Advaxis Public	3,220,000	3,220	56,675,128					56,678,348



Edgar Filing: Advaxis, Inc. - Form 10-K

Offering									
Net Loss							(47,031,118 )	(47,031,118 )	
Balance at									
October 31, 2015	- \$-	33,591,882	\$33,592	\$249,807,303	(16,919 )	\$(187,761 )	\$(134,054,259)	\$115,598,875	
Stock compensation to employees and directors		873,642	874	21,886,185				21,887,059	
Tax withholdings paid related to net share settlement of equity awards				(61,350 )				(61,350 )	
Treasury stock purchased to pay employee withholdings on equity awards					(332,537)	(2,729,230)		(2,729,230 )	
Treasury shares sold to pay for employee tax withholdings on equity awards				64,110	333,436	2,787,204	(96,336 )	2,754,978	
Common stock issued upon exercise of warrants		122,661	123	614,245				614,368	
Common stock issued to consultants		168,885	169	1,565,719				1,565,888	
Conversion of notes payable into common stock		1,481	1	29,548				29,549	
Issuance of shares to employees under ESPP		6,627	7	73,237				73,244	
Plan									
Advaxis registered direct offerings		2,244,443	2,244	28,154,163				28,156,407	
Sale of common		3,047,446	3,047	24,965,589				24,968,636	

shares to

Amgen

Net Loss

(73,556,230 ) (73,556,230 )

Balance at

October 31, - \$- 40,057,067 \$40,057 \$327,098,749 (16,020 ) \$(129,787 ) \$(207,706,825) \$119,302,194  
2016

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

F-5

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

	Year ended October 31,		
	2016	2015	2014
<b>OPERATING ACTIVITIES</b>			
Net Loss	\$(73,556,230 )	\$(47,031,118 )	\$(16,525,314)
Adjustments to reconcile Net Loss to net cash used in operating activities:			
Stock compensation	23,472,947	21,431,030	5,365,610
Non-cash interest expense	-	-	51
Loss (gain) on change in value of warrants and embedded derivative	(69,055 )	48,950	(619,089 )
Warrant expense	-	8,170	4,446
Gain on disposal of property and equipment	-	(10,000 )	-
Loss on write-off of intangible assets	-	28,480	-
Settlement expense	-	-	34,125
Employee stock purchase plan	73,244	28,791	6,251
Depreciation of property and equipment	283,538	59,033	27,611
Amortization of intangible assets	252,654	206,357	175,686
Lease incentive obligation	365,386	-	-
Amortization of premium on held-to-maturity investments	252,730	60,608	-
Debt conversion expense	-	6,599	-
Gain on note retirement	-	-	(6,243 )
Change in operating assets and liabilities:			
Interest receivable	65,157	(145,299 )	-
Prepaid expenses	(473,989 )	(155,863 )	(151,723 )
Income taxes receivable	(940,513 )	121,968	(1,731,317 )
Other current assets	(38,335 )	8,066	-
Deferred expenses	(3,541,595 )	214,934	(617,676 )
Other assets	(301,824 )	(110,405 )	-
Accounts payable and accrued expenses	8,354,447	1,094,155	(1,948,987 )
Deferred revenue	36,255,144	-	-
Deferred rent	475,749	-	-
Interest payable	-	-	(98,192 )
Net cash used in operating activities	(9,070,545 )	(24,135,544 )	(16,084,761)
<b>INVESTING ACTIVITIES</b>			
Investments in held to maturity investments	(44,524,783 )	(45,655,103 )	-
Proceeds from maturities and redemptions on held-to-maturity investments	50,530,000	-	-
Purchase of property and equipment	(3,222,442 )	(972,859 )	(24,595 )
Cost of intangible assets	(1,226,742 )	(821,925 )	(415,080 )
Net cash provided by (used in) investing activities	1,556,033	(47,449,887 )	(439,675 )
<b>FINANCING ACTIVITIES</b>			

Edgar Filing: Advaxis, Inc. - Form 10-K

Repayment of officer loan	-	-	(64,926 )
Proceeds from exercise of options	-	58,400	-
Proceeds from the exercise of warrants	614,368	2,342,449	250
Net proceeds of issuance of common stock	53,125,043	119,733,876	14,580,808
Tax withholdings paid related to net share settlement of equity awards	(61,350 )	(1,375,979 )	(936,898 )
Treasury stock purchased to pay employee withholdings on equity awards	(2,729,230 )	(1,388,086 )	-
Treasury shares sold to pay for employee tax withholdings on equity awards	2,754,978	1,169,594	-
Net cash provided by financing activities	53,703,809	120,540,254	13,579,234
Net increase (decrease) in cash and cash equivalents	46,189,297	48,954,823	(2,945,202 )
Cash and cash equivalents at beginning of year	66,561,683	17,606,860	20,552,062
Cash and cash equivalents at end of year	\$ 112,750,980	\$ 66,561,683	\$ 17,606,860

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

**Supplemental Disclosures of Cash Flow Information**

	Year Ended October 31,		
	2016	2015	2014
Cash paid for Interest	\$-	\$ -	\$ 103,445
Cash paid for Taxes	\$50,000	\$ -	\$-

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

	Year Ended October 31,		
	2016	2015	2014
Accounts payable and accrued Expenses settled with Common Stock	\$55,000	\$-	\$103,012
Conversion of notes payable into Common Stock	\$29,549	\$39,932	\$-
Sale of treasury shares pending settlement	\$-	\$15,000	\$-
Property and equipment included in accounts payable and accrued expenses	\$362,926	\$-	\$-

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*” or “*Lm* Technology™”) 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.

Axalimogene filolisbac (“AXAL”) is our lead *Lm*-LLO immunotherapy product candidate for the treatment of Human Papilloma Virus (“HPV”) - associated cancers. The Company completed a randomized Phase 2 study in 110 patients with recurrent cervical cancer that was shown to have a manageable safety profile, apparent improved survival and objective tumor responses. In addition, the Gynecologic Oncology Group (“GOG”) Foundation, Inc., now part of NRG Oncology, conducted a cooperative group / Company sponsored Phase 2 open-label clinical study of AXAL in patients with persistent or recurrent cervical cancer with documented disease progression. The study, known as GOG-0265, has successfully completed the first and second stages in its Simon 2-stage design. The results from both stages combined demonstrate a 38% 12-month overall survival. Upon early closure of this study, a total of 50 patients were dosed resulting in a 12-month survival rate of 38.0% with a manageable safety profile. The Company has initiated a registrational Phase 3 clinical trial for the adjuvant treatment of women with high-risk locally advanced cervical cancer and is planning to initiate a registrational Phase 3 clinical trial in 2017 in the metastatic cervical cancer setting. The Company also plans to pursue registrational opportunities in Europe in 2017 for the metastatic cervical cancer setting.

AXAL 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 has received European Medicines Agency (“EMA”) orphan drug designation for anal cancer. AXAL has been designated by the FDA as a Fast Track product for adjuvant therapy for high-risk locally advanced cervical cancer patients. It has also been classified as an advanced-therapy medicinal product (“ATMP”) for the treatment of cervical cancer by the European Medicines Agency’s Committee for Advanced Therapies (“CAT”). AXAL is subject to an agreement with the FDA, under the Special Protocol Assessment (“SPA”) process, for the Phase 3 AIM2CERV trial in patients with high-risk, locally advanced cervical cancer. It is also being evaluated in Company-sponsored trials executed under an Investigational New Drug (“IND”) which include the following: (i) a Phase 1/2 clinical trial alone and in combination with MedImmune, LLC’s

(“MedImmune”) investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab (MEDI4736), in patients with previously treated metastatic cervical cancer or patients with HPV-associated head and neck cancer; and (ii) a single arm Phase 2 monotherapy study in patients with metastatic anal cancer. In addition to the Company-sponsored trials, AXAL is also being evaluated in two investigator-initiated clinical trials as follows: neoadjuvant treatment of HPV-positive head and neck cancer (Mount Sinai & Baylor College of Medicine), and locally advanced high risk anal cancer (Brown University).

ADXS-PSA is the Company’s *Lm*-LLO immunotherapy product candidate designed to target the Prostate Specific Antigen (“PSA”) associated with prostate cancer which is being evaluated in a Phase 1/2 clinical trial alone and in combination with KEYTRUDA® (pembrolizumab), Merck & Co.’s (“Merck”) humanized monoclonal antibody against PD-1, in patients with previously treated metastatic castration-resistant prostate cancer.

ADXS-HER2 is the Company’s *Lm*-LLO immunotherapy product candidate designed for the treatment of Human Epidermal Growth Factor Receptor 2 (“HER2”) expressing cancers, including human and canine osteosarcoma. ADXS-HER2 is being evaluated in a Phase 1b clinical trial in patients with metastatic HER2 expressing solid tumors. The Company received orphan drug designation from both the FDA and EMA for ADXS-HER2 in osteosarcoma and have received Fast Track designation from the FDA for patients with newly-diagnosed, non-metastatic, surgically-resectable osteosarcoma. Clinical research with ADXS-HER2 in canine osteosarcoma is being developed by the Company’s pet therapeutic partner, Aratana Therapeutics Inc. (“Aratana”), who holds exclusive rights to develop and commercialize ADXS-HER2 and three other *Lm* -LLO immunotherapies for pet health applications. Aratana has announced that a product license application for use of ADXS-HER2 in the treatment of canine osteosarcoma has been filed with the United States Department of Agriculture (“USDA”). Aratana received communication from the USDA in March 2015 stating that the previously submitted efficacy data for product licensure for AT-014 (ADXS-HER2), the cancer immunotherapy for canine osteosarcoma, was accepted and that it provides a reasonable expectation of efficacy that supports conditional licensure. While additional steps need to be completed, including in the areas of manufacturing and safety, Aratana anticipates that AT-014 could receive conditional licensure from the USDA in 2017.

In October of 2015, the Company received notification from the FDA that the INDs for AXAL were put on clinical hold in response to its submission of a safety report to the FDA. The clinical hold also included the INDs for ADXS-PSA and ADXS-HER2. Following discussions with the FDA and in accordance with their recommendations, the Company agreed to implement certain risk mitigation measures, including revised study protocol inclusion / exclusion criteria, post-administration antibiotic treatment and patient surveillance and monitoring measures. In December 2015, the FDA notified the Company that the hold had been lifted with respect to its INDs.

The Company has focused its development efforts on establishing a drug development pipeline that incorporates this technology into therapeutic cancer immunotherapies, with clinical trials currently targeting HPV-associated cancers (cervical cancer, head and neck cancer, and anal cancer), prostate cancer, and osteosarcoma. Although no immunotherapies have been commercialized to date, the Company continues to invest in research and development to advance the technology and make it available to patients with many different types of cancer. 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 it continues conducting and expanding its clinical development programs. In addition to its existing single antigen vectors that target one tumor associated antigen, the Company is actively engaged in the development of new constructs that will address multiple targets that are common to tumor types, as well as mutation-associated epitopes that are specific to an individual patient's tumor. The Company is also leveraging its *Lm* Technology™ to target common (public or shared) mutations (hotspots) in tumor driver genes. The Company is exploring a preclinical infectious disease program as well to examine potential applications of its *Lm* Technology™. Lastly, the Company is continuing to build-out its manufacturing capabilities at the state-of-the-art manufacturing facility in Princeton, NJ, to produce supplies for its neoepitope and other development programs.

#### *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. During fiscal 2015, the Company raised gross proceeds of approximately \$125.9 million in equity offerings. On August 1, 2016, the Company entered into a collaboration agreement with Amgen Inc. ("Amgen"). In exchange for receiving an exclusive worldwide license to develop and commercialize ADXS-NEO, Amgen made an upfront payment of \$40 million and purchased directly from the Company 3,047,446 shares of common stock for gross proceeds of approximately \$25 million. On August 19, 2016, the Company sold 2,244,443 shares of common stock in a registered direct offering for gross proceeds of approximately \$30.3 million to certain health care specialist investors. The net proceeds to the Company were approximately \$28.2 million. As of October 31, 2016, the Company had approximately \$152.1 million in cash, cash equivalents and investments on its balance sheet.

The Company believes its current cash position is sufficient to fund its business plan approximately through the second quarter of fiscal 2019. The estimate is based on assumptions that may prove to be wrong, and the Company could use available capital resources sooner than currently expected. Because of the numerous risks and uncertainties associated with the development and commercialization of its product candidates, the Company is unable to estimate the amount of increased capital outlays and operating expenses associated with completing the development of its current product candidates.

The Company recognizes it may need to raise additional capital 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 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.



## 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 property and equipment intangible assets (patents and licenses), the fair value of investments, 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 is expected to derive the majority of its revenue from patent licensing and research and development services associated with 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.

Revenue associated with nonrefundable upfront license fees under arrangements where the license fees and research and development activities cannot be accounted for as separate units of accounting is deferred and recognized as revenue on a straight-line basis over the expected period of performance.



Revenues from the achievement of research and development milestones, if deemed substantive, are recognized as revenue when the milestones are achieved and the milestone payments are due and collectible. If not deemed substantive, the Company recognizes such milestones as revenue on a straight-line basis over the remaining expected performance period under the arrangement. All such recognized revenues are included in collaborative licensing and development revenue in the Company's statements of operations.

Milestones are considered substantive if all of the following conditions are met: (1) the milestone is nonrefundable; (2) achievement of the milestone was not reasonably assured at the inception of the arrangement; (3) substantive effort is involved to achieve the milestone; and (4) the amount of the milestone appears reasonable in relation to the effort expended, and the other milestones in the arrangement and the related risk associated with the achievement of the milestone and any ongoing research and development or other services are priced at fair value.

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.

Deferred revenue represents the portion of payments received for which the earnings process has not been completed. Deferred revenue expected to be recognized within the next 12 months is classified as a current liability.

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.

#### *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, 2016 and October 31, 2015, the Company had approximately \$106.7 million and \$62.8 million in cash equivalents.

#### *Concentration of Credit Risk*

The Company maintains its cash in bank deposit accounts (checking) that at times exceed federally insured limits. Approximately \$112.4 million is subject to credit risk at October 31, 2016. 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.

### *Investments*

Investment securities consist of certificates of deposit, domestic governmental agency loans, and U.S. treasury notes. The Company classifies these securities as held-to-maturity. Held-to-maturity securities are those securities in which the Company has the ability and intent to hold the security until maturity. Held-to-maturity securities are recorded at amortized cost, adjusted for the amortization or accretion of premiums or discounts. Premiums and discounts are amortized or accreted over the life of the related held-to-maturity security as an adjustment to yield using the effective interest method.

A decline in the market value of any investment security below cost, that is deemed to be other than temporary, results in a reduction in the carrying amount to fair value. The impairment is charged to operations and a new cost basis for the security is established. Other-than-temporary impairment charges are included in Other Income (Expense), net. The Company did not recognize any impairment charges during the years ended October 31, 2016, 2015 or 2014. Interest income is recognized when earned.

### *Deferred Expenses*

Deferred expenses consist of advanced payments made on research and development projects. Expense is recognized as the research and development activity is performed, which generally ranges from six months to two years, and is charged to Research and Development Expense in the Statement of Operations.

### *Property and Equipment*

Property and equipment consists of computer equipment, laboratory equipment, furniture and fixtures and leasehold improvements and is stated at cost. Depreciation and amortization is provided for on the straight-line basis over the estimated useful lives of the respective assets ranging from three to ten years. Leasehold Improvements are amortized over the lesser of the asset's economic life or the lease term. 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.

F-10

*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 20 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. Intangible assets also consist of software, which is amortized over three years.

*Impairment of Long-Lived Assets.*

Management has reviewed its long-lived assets, including property and equipment and intangible 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 AXAL, 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 Advaxis 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.

*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 outstanding during the period. In the case of a net loss the impact of the potential Common Stock resulting from warrants, outstanding stock options and convertible debt are 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 are 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,		
	2016	2015	2014
Warrants	3,110,575	3,241,466	4,158,092
Stock Options	3,351,795	1,981,939	467,968
Convertible Debt (using the if-converted method)	-	1,576	3,354
Total	6,462,370	5,224,981	4,629,414

### *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.

### *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 records forfeitures as they occur. As such, the Company recognizes stock-based compensation cost only for those stock-based awards that vest over their requisite service period, based on the vesting provisions of the individual grants.

### *Treasury Stock*

The Company accounts for repurchases of common stock and shares withheld in lieu of taxes when restricted stock vests using the cost method with common stock in treasury classified in the balance sheet as a reduction in shareholders' equity.

### *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.

### *Recent Accounting Pronouncements*

In May 2014, as part of its ongoing efforts to assist in the convergence of GAAP and International Financial Reporting Standards, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers, which is a new standard related to revenue recognition. Under the new standard, recognition of revenue occurs when a customer obtains control of promised services or goods in an amount that reflects the consideration to which the entity expects to receive in exchange for those goods or



services. In addition, the standard requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from customer contracts. The standard must be adopted using either a full retrospective approach for all periods presented in the period of adoption or a modified retrospective approach. In July 2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers - Deferral of the Effective Date, which defers the implementation of this new standard to be effective for fiscal years beginning after December 15, 2017. Early adoption is permitted effective January 1, 2017. In March 2016, the FASB issued ASU 2016-08, Principal versus Agent Considerations, which clarifies the implementation guidance on principal versus agent considerations in the new revenue recognition standard pursuant to ASU 2014-09. In April 2016, the FASB issued ASU 2016-10, Identifying Performance Obligations and Licensing, and in May 2016, the FASB issued ASU 2016-12, Narrow-Scope Improvements and Practical Expedients, which amend certain aspects of the new revenue recognition standard pursuant to ASU 2014-09. We are currently evaluating which transition approach we will utilize and the impact of adopting this accounting standard on the Company's financial statements.

In August 2014, the FASB issued ASU 2014-15, *Disclosures of Uncertainties About an Entity's Ability to Continue as a Going Concern*. The new standard provides guidance around management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early adoption is permitted. The Company does not expect that this guidance will have a material impact on its financial position, results of operations or cash flows.

In January 2015, the FASB issued ASU 2015-01, Income Statement—Extraordinary and Unusual Items. The objective of this Update is to simplify the income statement presentation requirements in Subtopic 225-20 by eliminating the concept of extraordinary items. Extraordinary items are events and transactions that are distinguished by their unusual nature and by the infrequency of their occurrence. Eliminating the extraordinary classification simplifies income statement presentation by altogether removing the concept of extraordinary items from consideration. This Accounting Standards Update is the final version of Proposed Accounting Standards Update 2014-220—Income Statement—Extraordinary Items (Subtopic 225-20), which has been deleted. The amendments in this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. This Update is not expected to have a material impact on the Company's financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases ("ASU 2016-02"). The standard amends the existing accounting standards for lease accounting, including requiring lessees to recognize most leases on their balance sheets and making targeted changes to lessor accounting. ASU 2016-02 will be effective beginning in the first quarter of 2019. Early adoption of ASU 2016-02 is permitted. The new leases standard requires a modified retrospective transition approach for all leases existing at, or entered into after, the date of initial application, with an option to use certain transition relief. The Company is currently evaluating the impact of adopting ASU 2016-02 on the Company's financial statements.

In March 2016, the FASB issued ASU 2016-09, Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. This ASU makes targeted amendments to the accounting for employee share-based payments. This guidance is to be applied using various transition methods such as full retrospective, modified retrospective, and prospective based on the criteria for the specific amendments as outlined in the guidance. The guidance is effective for annual periods, and interim periods within those annual periods, beginning after

December 15, 2016. Early adoption is permitted, as long as all of the amendments are adopted in the same period. The Company has evaluated this standard and has chosen early adoption effective March 30, 2016. This ASU has not had a material impact on the Company's financial statements.

F-12

In June 2016, the FASB issued Accounting Standards Update ASU 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. The standard significantly changes how entities will measure credit losses for most financial assets and certain other instruments that aren't measured at fair value through net income. The standard will replace today's "incurred loss" approach with an "expected loss" model for instruments measured at amortized cost. For available-for-sale debt securities, entities will be required to record allowances rather than reduce the carrying amount, as they do today under the other-than-temporary impairment model. It also simplifies the accounting model for purchased credit-impaired debt securities and loans. This ASU is effective for annual periods beginning after December 15, 2019, and interim periods therein. Early adoption is permitted for annual periods beginning after December 15, 2018, and interim periods therein. This ASU is not expected to have a material impact on the Company's financial statements.

In August 2016, the FASB issued Accounting Standards Update ASU 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. Stakeholders indicated that there is diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows under Topic 230, Statement of Cash Flows, and other Topics. This Accounting Standards Update addresses the following eight specific cash flow issues: Debt prepayment or debt extinguishment costs; settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing; contingent consideration payments made after a business combination; proceeds from the settlement of insurance claims; proceeds from the settlement of corporate-owned life insurance policies (COLIs) (including bank-owned life insurance policies (BOLIs)); distributions received from equity method investees; beneficial interests in securitization transactions; and separately identifiable cash flows and application of the predominance principle. The amendments in this Update apply to all entities, including both business entities and not-for-profit entities that are required to present a statement of cash flows under Topic 230. This Update is the final version of Proposed Accounting Standards Update EITF-15F—Statement of Cash Flows—Classification of Certain Cash Receipts and Cash Payments (Topic 230), which has been deleted. The amendments in this Update are effective for public business entities for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early adoption is permitted as all of the amendments are adopted in the same period. This ASU is not expected to have a material impact on the Company's 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. INVESTMENTS

The following table summarizes the Company's investment securities at amortized cost as of October 31, 2016 and 2015:

	October 31, 2016			
	Amortized cost, as adjusted	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term investments:				
Certificates of Deposit	\$ 10,737,563	-	-	10,737,563
Domestic Governmental Agency Loans	2,500,000	-	250	2,499,750
U.S Treasury Notes	26,098,985	2,404	7,556	26,093,833
Total short-term investment securities	\$ 39,336,548	2,404	7,806	39,331,146

	October 31, 2015			
	Amortized cost, as adjusted	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term investments:				
Certificates of Deposit	\$ 12,628,880	-	-	12,628,880
Domestic Governmental Agency Loans	27,951,633	5,827	5,979	27,951,481
U.S Treasury Notes	5,013,982	700	262	5,014,420
Total short-term investment securities	\$ 45,594,495	6,527	6,241	45,594,781

All of the Company's investments mature within the next 12 months.

#### 4. PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

	October 31,	
	2016	2015
Leasehold Improvements	\$ 1,835,602	\$ 237,209
Laboratory Equipment	2,038,704	532,249
Furniture and Fixtures	549,025	331,500
Computer Equipment	240,910	48,745
Construction in Progress	151,368	80,538
Total Property and Equipment	4,815,609	1,230,241
Accumulated Depreciation and Amortization	(426,535 )	(142,997 )
Net Property and Equipment	\$ 4,389,074	\$ 1,087,244

Depreciation expense for the years ended October 31, 2016, 2015 and 2014 was \$283,538, \$59,033 and 27,611, respectively.

#### 5. 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,	
	2016	2015
License	\$ 776,992	\$ 651,992
Patents	4,980,610	3,898,493
Software	19,625	-
Total intangibles	5,777,227	4,550,485
Accumulated Amortization	(1,448,106)	(1,195,452)
Net Intangible Assets	\$ 4,329,121	\$ 3,355,033

The expirations of the existing patents range from 2017 to 2037 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. Patent applications having a net book value of \$0, \$28,480 and \$0 were abandoned and were charged to Other Income (Expense) in the statement of operations for the years ended October 31, 2016, 2015 and 2014, respectively. Amortization expense for intangible assets is included in general and administrative expenses and aggregated \$252,654, \$206,357 and 175,686 for the years ended October 31, 2016, 2015 and 2014, respectively.

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

Year ending October 31,	
2017	\$279,000
2018	\$279,000
2019	\$276,000
2020	\$272,000
2021	\$272,000

**6. ACCRUED EXPENSES:**

The following table represents the major components of accrued expenses:

	October 31,	
	2016	2015
Salaries and other compensation	\$2,325,998	\$1,698,371
Vendors	2,098,792	833,032
Professional fees	6,338,561	439,605
Withholding taxes payable	141,652	220,933
Total Accrued Expenses	\$10,905,003	\$3,191,941

**7. 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 were convertible into shares of the Company’s Common Stock at a fixed exercise price. As of October 31, 2015, the Company had approximately \$30,000 in principal outstanding on its junior subordinated convertible promissory notes that were overdue and were recorded as current liabilities on the Company’s balance sheet at October 31, 2015. During April 2016, the last remaining promissory note of \$29,549 was converted into 1,481 shares of common stock at the \$18.75 conversion price per the promissory note agreement.

During February 2015, the Company induced certain noteholders to convert their convertible promissory notes into common shares by offering conversion prices at a \$1.61 discount from the market price of the common stock. In total, \$33,333 of promissory notes were converted into 4,104 shares of common stock. In connection with the note conversions, the Company recorded a debt conversion expense of \$6,599 in the accompanying statement of operations.

*Embedded Derivative Liability*

The Company had convertible features (known as “Embedded Derivatives”) in its outstanding convertible promissory note. The Embedded Derivatives were recorded as liabilities at issuance. These Embedded Derivatives were 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, 2016 and 2015, the fair value of the Embedded Derivative Liability was \$0 as the related notes were paid off, converted or reached maturity.

## 8. COMMON STOCK PURCHASE WARRANTS AND WARRANT LIABILITY

### *Warrants*

As of October 31, 2016, there were outstanding warrants to purchase 3,110,575 shares of the Company’s Common Stock with exercise prices ranging from \$3.75 to \$18.75 per share.

As of October 31, 2015, there were outstanding warrants to purchase 3,241,466 shares of the Company’s Common Stock with exercise prices ranging from \$2.76 to \$18.75 per share.

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.

A summary of warrant activity was as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life In Years	Aggregate Intrinsic Value
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	\$ 5.43	3.94	\$9,518
Issued	2,361	7.20		



Edgar Filing: Advaxis, Inc. - Form 10-K

Exercised *	(769,349 )	5.12		
Expired	(149,638 )	14.61		
Outstanding and Exercisable Warrants at October 31, 2015	3,241,466	\$ 5.07	2.90	\$19,588,099
Issued	-			
Exercised	(122,661 )	5.01		
Expired	(8,230 )	18.75		
Outstanding and Exercisable Warrants at October 31, 2016	3,110,575	\$ 5.04	1.91	\$9,558,159

F-15

\* Includes the cashless exercise of 300,376 warrants that resulted in the issuance of 222,295 shares of common stock.

At October 31, 2016, the Company had approximately 3.09 million of its total 3.11 million outstanding warrants classified as equity (equity warrants). At October 31, 2015, the Company had approximately 3.22 million of its total 3.24 million outstanding warrants classified as equity (equity warrants). At October 31, 2014, the Company had approximately 4.04 million of its total 4.16 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.

#### *Warrant Liability*

At October 31, 2016, the Company had approximately 18,000 of its total 3.11 million outstanding warrants classified as liabilities (liability warrants). At October 31, 2015, the Company had approximately 18,000 of its total 3.24 million outstanding warrants classified as liabilities (liability warrants). At October 31, 2014, the Company had approximately 123,000 of its total 4.16 million outstanding warrants classified as liability warrants. 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. As of October 31, 2015, all of the liability warrants that were subject to weighted-average anti-dilution provisions had expired. The remaining 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, 2016 and October 31, 2015, the fair value of the warrant liability was \$20,156 and \$89,211, respectively. For the years ended October 31, 2016, 2015 and 2014, the Company reported income of \$69,054, a loss of \$48,950 and income of \$619,089, respectively, due to changes in the fair value of the warrant liability.

In fair valuing the warrant liability, at October 31, 2016, 2015 and 2014, the Company used the following inputs in its BSM:

	10/31/2016	10/31/2015	10/31/2014
Exercise Price	\$ 10.63-18.75	\$ 10.63-18.75	\$ 2.76-21.25

Stock Price	\$8.09	\$11.09	\$3.18
Expected Term	0.55-0.75 years	1.52-1.76 years	0.01-2.76 years
Volatility %	81.84%-87.09 %	93.87%-95.00 %	55.41%-129.38 %
Risk Free Rate	0.51%-0.66 %	.075 %	.01-1.62 %

### *Exercise of Warrants*

During the year ended October 31, 2016, accredited investors exercised 122,661 warrants at a weighted average exercise price of \$5.01, resulting in net proceeds to the Company of \$614,368.

During the year ended October 31, 2015, accredited investors exercised 769,349 warrants at a weighted average exercise price of \$5.12, resulting in net proceeds to the Company of \$2,342,449.

During the year 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.

### *Expiration of Warrants*

During the year ended October 31, 2016, the Company had 8,230 warrants, all with no anti-dilution provisions, expired unexercised.

During the year ended October 31, 2015, the Company had 62,430 warrants with anti-dilution provisions, and 87,208 warrants, with no such anti-dilution provisions, expired unexercised.

During the year ended October 31, 2014, the Company had 179,666 warrants with anti-dilution provisions, and 340,147 warrants, with no such anti-dilution provisions, expired unexercised.

*Warrants with anti-dilution provisions*

Some of the Company's warrants contained anti-dilution provisions originally set at an exercise price of \$25.00 with a term of five years. As of October 31, 2015, all of these warrants had expired. As of October 31, 2014, these warrants had an exercise price of approximately \$7.71. If the Company had issued 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 have been adjusted to a new price and amount of shares per the "weighted average" formula included in the warrant agreement. For the year ended October 31, 2015, this anti-dilution provision required the Company to issue approximately 2,400 additional warrant shares, and the exercise price to be lowered to \$7.20.

For those warrants with exercise price reset features (anti-dilution provisions), the Company computed 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 \$7.20 and \$6.00, weighting the possibility of warrants being exercised at \$7.20 between 40% and 50% and warrants being exercised at \$6.00 between 50% and 60%.

## **9. SHARE BASED COMPENSATION**

*Amendments*

On March 30, 2015, the Board of Directors adopted, subject to stockholder approval at the Annual Meeting, the Advaxis, Inc. 2015 Incentive Plan (the "2015 Plan"). The 2015 Plan became effective on May 27, 2015 when it was approved by the Company's stockholders at the 2015 Annual Meeting. The 2015 Plan serves as the successor to the Advaxis, Inc. 2011 Omnibus Incentive Plan (the "Prior Plan"). Effective May 27, 2015, all future equity awards were made from the 2015 Plan, and no additional awards will be granted under the Prior Plan. Subject to proportionate adjustment in the event of stock splits and similar events, the aggregate number of shares of Common Stock that may be issued under the 2015 Plan is 3,600,000 shares, plus a number of additional shares (not to exceed 650,000) underlying awards outstanding as of the effective date of the 2015 Plan under the Prior Plan that thereafter terminate or expire unexercised, or are cancelled, forfeited or lapse for any reason.

At the Annual Meeting of Stockholders of the Company held on March 10, 2016, the stockholders ratified and approved an amendment to the Company's 2015 Incentive Plan to increase the aggregate number of shares of common stock authorized for issuance under such plan from 3,600,000 shares to 4,600,000 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 45,000,000 shares of common stock to 65,000,000 shares of common stock. As of October 31, 2016, there were 1,145,264 shares available for issuance under the 2015 Plan.

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 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.

### *Employment Agreements*

Management voluntarily purchased restricted stock directly from the Company at market price. The respective stock purchases occur on the last trading day of each month. This voluntary election is outlined in the employment agreement of Daniel J. O'Connor, Chief Executive Officer and President, Gregory T. Mayes, Executive Vice President, Chief Business Officer, Robert G. Petit, Executive Vice President, Chief Scientific Officer and Sara M. Bonstein, Executive Vice President, Chief Financial Officer and Secretary, (each an "Executive"). The table below reflects the purchases of each Executive:

Executive	For the Year Ended October 31, 2016			
	Gross Purchase		Net Purchase	
	\$	# of shares	\$	# of shares
Daniel J. O'Connor	\$99,404	12,001	\$65,882	7,838
Gregory T. Mayes	\$27,794	3,259	\$21,335	2,498
Robert G. Petit	\$28,704	3,370	\$21,162	2,456
Sara M. Bonstein	\$25,420	2,991	\$19,527	2,293

For the year ended October 31, 2016, the Company recorded stock compensation expense of \$225,647 for the portion of management salaries paid in stock, representing 26,764 shares of its Common Stock (19,260 shares on a net basis after employee payroll taxes).

From 2013 to present, in addition to the purchases of Common Stock set forth in the above table, Mr. O'Connor has also purchased an additional 164,909 shares of Common Stock out of his personal funds at the then market price for an aggregate consideration of \$689,004. These purchases consisted of the conversion of amounts due to Mr. O'Connor under a promissory note given by Mr. O'Connor to the Company in 2012 of approximately \$66,500 for 21,091 shares, 2013 base salary which he elected to receive in Common Stock of approximately \$186,555 for 34,752 shares (21,489 on a net basis after employee payroll taxes), 2013 and 2014 cash bonuses voluntarily requested to receive in equity of \$214,359 for 62,064 shares (57,990 on a net basis after employee payroll taxes), fiscal 2014 voluntary request to purchase stock directly from the Company at market price purchases of \$68,750 for 21,687 shares (15,950 on a net basis after employee payroll taxes), fiscal 2015 voluntary request to purchase stock directly from the Company at market price purchases of \$88,840 for 8,482 shares (7,556 on a net basis after employee payroll taxes), 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.

For the year ended October 31, 2015, executive officers received a portion of their year-end performance bonus (with a total fair value of approximately \$418,000) in the aggregate amount of 125,411 shares of the Company's Common Stock (98,603 on a net basis after employee payroll taxes).

For the year ended October 31, 2014, 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 31,845 shares of the Company's Common Stock (21,389 on a net basis after taxes).

#### *Restricted Stock Units (RSUs)*

A summary of the Company's RSU activity and related information for the twelve months ended October 31, 2016, 2015 and 2014 is as follows:

	Number of RSUs	Weighted-Average Grant Date Fair Value
Balance at October 31, 2013:	112,500	\$ 3.57
Granted	1,268,580	3.88
Vested	(547,030 )	3.91

Edgar Filing: Advaxis, Inc. - Form 10-K

Cancelled	(42,171 )	4.14
Balance at October 31, 2014:	791,879	\$ 3.81
Granted	864,192	15.14
Vested	(583,403 )	7.58
Cancelled	(3,333 )	11.76
Balance at October 31, 2015:	1,069,335	\$ 10.89
Granted	695,040	9.31
Vested	(824,317 )	8.35
Cancelled	(220,610 )	15.81
Balance at October 31, 2016	719,448	\$ 10.77

The fair value as of the respective vesting dates of RSUs was approximately \$6,643,000, \$7,771,000 and \$1,944,000 for the years ended October 31, 2016, 2015 and 2014, respectively.

As of October 31, 2016, there was approximately \$6,583,000 of unrecognized compensation cost related to non-vested RSUs, which is expected to be recognized over a remaining weighted average vesting period of approximately 2.19 years.

As of October 31, 2016, the aggregate intrinsic value of non-vested RSUs was approximately \$221,000.

#### *Employee Stock Awards*

Common Stock issued to executives and employees related to vested incentive retention awards, employment inducements and employee excellence awards totaled 692,846 shares, 487,591 shares (406,691 shares on a net basis after employee taxes) and 489,287 shares (280,848 shares on a net basis after employee taxes) during the years ended October 31, 2016, 2015 and 2014, respectively. Total stock compensation expense associated with these awards for the years ended October 31, 2016, 2015 and 2014 was \$5,233,176, \$5,226,302 and \$1,836,143, respectively.

Furthermore, non-executive employees were entitled to receive a performance-based year-end cash bonus. Several non-executive employees voluntarily requested to be paid all or a portion of their cash bonus in the Company's Common Stock instead of cash. During the year ended October 31, 2016, the total fair value of these equity purchases were \$102,022, or 9,150 shares of the Company's Common Stock. During the year ended October 31, 2015, the total fair value of these equity purchases were \$67,671, or 20,322 shares of the Company's Common Stock (14,300 on a net basis after employee payroll taxes).

#### *Director Stock Awards*

During the years ended October 31, 2016, 2015 and 2014, common stock issued to the Directors for compensation related to board and committee membership was 152,386 shares, 267,186 shares and 146,899 shares for compensation related to board and committee membership. During the years ended October 31, 2016, 2015 and 2014, total stock compensation expense to the Directors was \$1,184,780, \$1,223,118 and \$614,750, respectively.

#### *Stock Options*

A summary of changes in the stock option plan for the years ended October 31, 2016, 2015 and 2014 is as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life In Years	Aggregate Intrinsic Value
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	\$-
Granted	1,668,995	13.41	9.42	
Exercised *	(137,667 )	12.29		
Cancelled or Expired	(17,357 )	36.24		
Outstanding as of October 31, 2015	1,981,939	\$ 13.78	8.72	\$ 285,330
Granted	1,385,000	12.81	8.12	
Cancelled or Expired	(15,144 )	29.69		
Outstanding as of October 31, 2016	3,351,795	\$ 13.31	7.82	\$ 61,980
Vested and Exercisable at October 31, 2016	1,403,109	\$ 13.68	6.48	\$ 61,980



\* Includes the cashless exercise of 117,667 options that resulted in the issuance of 45,167 shares of common stock.

The following table summarizes information about the outstanding and exercisable options at October 31, 2016.

Exercise Price Range	Options Outstanding			Intrinsic Value	Options Exercisable			Intrinsic Value
	Number Outstanding	Weighted Average Remaining Contractual	Weighted Average Exercise Price		Number Exercisable	Weighted Average Remaining Contractual	Weighted Average Exercise Price	
\$3.00 - \$9.99	119,720	5.79	\$ 8.71	\$61,980	119,720	5.79	\$ 8.71	\$61,980
\$10.00 - \$14.99	3,006,606	8.12	\$ 13.14	\$-	1,057,920	6.87	\$ 13.31	\$-
\$15.01 - \$19.99	224,669	5.03	\$ 18.06	\$-	224,669	5.03	\$ 18.06	\$-
\$20.00 - \$25.00	800	3.60	\$ 21.25	\$-	800	3.60	\$ 21.25	\$-

The fair value of each option granted from the Company's stock option plans during the years ended October 31, 2016 and 2015 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 expected lives of the options. The Company used their own historical volatility in determining the volatility to be used. The expected term of the stock option grants was calculated using the "simplified" method in accordance with the SEC Staff Accounting Bulletin 107. The "simplified" method was used since the Company believes its historical data does not provide a reasonable basis upon which to estimate expected term and the Company does not have enough option exercise data from its grants issued to support its own estimate as a result of vesting terms and changes in the stock price. 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.

In determining the fair value of the stock options granted during the years ended October 31, 2016, 2015 and 2014, the Company used the following inputs in its BSM:

	Year Ended		
	October 31, 2016	October 31, 2015	October 31, 2014
Expected Term	5.51-6.51 years	5-10 years	5 years
Expected Volatility	109.23%-115.25 %	109.26%-154.54 %	151.38-171.12 %
Expected Dividends	0 %	0 %	0 %
Risk Free Interest Rate	1.65-2.00 %	1.41%-2.27 %	1.39%-1.72 %

Total compensation cost related to the Company's outstanding stock options, recognized in the statement of operations for the years ended October 31, 2016, 2015 and 2014 was approximately \$15,223,000, \$9,521,000 and \$920,000, respectively.

During the year ended October 31, 2016, 1,385,000 options were granted with a total grant date fair value of approximately \$14,838,000. During the year ended October 31, 2015, 1,668,995 options were granted with a total grant date fair value of approximately \$29,014,000. During the year ended October 31, 2014, 36,000 options were granted with a total grant date fair value of approximately \$145,000.

During the year ended October 31, 2015, options to purchase 137,667 shares of common stock were exercised, which resulted in cash proceeds of \$58,400.

As of October 31, 2016, there was approximately \$19,329,000 of unrecognized compensation cost related to non-vested stock option awards, which is expected to be recognized over a remaining weighted average vesting period of approximately 1.68 years.

#### *Shares Issued to Consultants*

During the year ended October 31, 2016, 168,885 shares of Common Stock valued at \$1,565,888 were issued to consultants for services. The Company recorded a liability on its balance sheet for \$75,000 for shares earned pursuant to consulting agreements but not delivered. The common stock share values were based on the dates the shares vested.

During the year ended October 31, 2015, 378,538 shares of Common Stock valued at \$4,707,440 were issued to consultants for services. The Company recorded a liability on its balance sheet for \$55,000 for shares earned pursuant to consulting agreements but not delivered. The common stock share values were based on the dates the shares vested.

During the year ended October 31, 2014, 405,603 shares of Common Stock valued at \$1,551,591 were issued to consultants for services. The common stock share values were based on the dates the shares vested.

The following table summarizes share-based compensation expense included in the Statement of Operations by expense category for the years ended October 31, 2016, 2015 and 2014, respectively:

	Year Ended October 31,		
	2016	2015	2014
Research and development	\$7,985,651	\$6,293,791	\$1,250,747
General and administrative	15,487,296	15,137,239	4,114,863
Total	\$23,472,947	\$21,431,030	\$5,365,610

### 2011 Employee Stock Purchase Plan

The Company's Board of Directors adopted the Advaxis, Inc. 2011 Employee Stock Purchase Plan, which the Company's 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 year ended October 31, 2016, 6,627 shares were purchased under the ESPP, and the Company recorded an expense of \$73,244. During the year ended October 31, 2015, 2,110 shares were purchased under the ESPP, and the Company recorded an expense of \$28,791. During the year ended October 31, 2014, 2,110 shares were purchased under the ESPP, and the Company recorded an expense of \$6,251. As of October 31, 2016, 16,200 shares of Company's Common Stock remain available for issuance under the ESPP.

## 10. COLLABORATION AND LICENSING AGREEMENTS

### *Amgen*

On August 1, 2016, the Company entered into a global agreement (the “Amgen Agreement”) with Amgen for the development and commercialization of the Company’s ADXS-NEO, a novel, preclinical investigational immunotherapy, using the Company’s proprietary *Listeria monocytogenes* attenuated bacterial vector which activates a patient’s immune system to respond against unique mutations, or neoepitopes, contained in and identified from an individual patient’s tumor. Under the terms of the Amgen Agreement, Amgen receives an exclusive worldwide license to develop and commercialize ADXS-NEO. Amgen made an upfront payment to Advaxis of \$40 million and purchased \$25 million of Advaxis common stock. Advaxis and Amgen will collaborate through a joint steering committee for the development and commercialization of ADXS-NEO. Under the Amgen Agreement, Amgen will fund the clinical development and commercialization of ADXS-NEO and Advaxis will retain manufacturing responsibilities. Advaxis will also receive development, regulatory and sales milestone payments of up to \$475 million and high single digit to double digit royalty payments based on worldwide sales.

In connection with the Amgen Agreement, Amgen purchased directly from Advaxis 3,047,446 shares of the Company’s Common Stock, at approximately \$8.20 per share (representing a purchase at market using a 20 day VWAP methodology). The gross proceeds to Advaxis from the sale of the shares was approximately \$25 million.

The Company identified the following performance deliverables under the agreement: 1) the license, 2) the obligation to provide research activities, 3) the obligation to provide clinical supplies, 4) the obligation to perform regulatory functions and 5) the obligation to participate on a Joint Research Committee.

The Company considered the provisions of the multiple-element arrangement guidance in determining how to recognize the total consideration of the agreement. The Company determined that none of the deliverables have standalone value; all of these obligations will be delivered throughout the estimated period of performance and therefore are accounted for as a single unit of accounting. Accordingly, the Company recorded the \$40 million upfront payment as deferred revenue on the balance sheet and will recognize revenue on a straight-line basis over the estimated period of performance under the Amgen Agreement. Changes in the estimated period of performance will be accounted for prospectively as a change in estimate. During the year ended October 31, 2016, the Company recognized revenue from the Amgen Agreement of approximately \$3,745,000 related to amortization of the upfront fees.

### *Específicos Stendhal SA de CV*

On February 3, 2016, the Company entered into a Co-Development and Commercialization Agreement (the “Stendhal Agreement”) with Especificos Stendhal SA de CV (“Stendhal”), for Advaxis’ lead *Lm* Technology™ immunotherapy, AXAL, in HPV-associated cancers. Under the terms of the Stendhal Agreement, Stendhal will pay \$10 million (“Support Payments”) towards the expense of AIM2CERV. The Support Payments will be made over the duration of the trial. Stendhal will also work with the Company to complete the clinical trial of AXAL in Mexico, Brazil, Colombia and other investigational sites in Latin American countries. Stendhal will manage and is responsible for the costs associated with the regulatory approval process, promotion, commercialization and market access for AXAL in these markets. Upon approval and commercialization of AXAL, Advaxis and Stendhal will share profits on a pre-determined basis.

The Company considered the provisions of the research and development and collaboration guidance in determining how to recognize the Support Payments to be received from Stendhal. The Company determined the Stendhal Agreement should be accounted for within the scope of collaboration arrangement accounting guidance. Furthermore, the Company determined that Advaxis is the principal in the Stendhal Agreement. As a result, the Company will account for the support payments as a reduction of research and development expenses in the statement of operations.

#### *Knight Therapeutics*

On August 26, 2015, the Company entered into a licensing agreement with Knight Therapeutics Inc. (“Knight”), a Canadian-based specialty pharmaceutical company focused on acquiring, in-licensing, selling and marketing innovative prescription and over-the-counter pharmaceutical products, to commercialize in Canada the Company’s product candidates. Under the terms of the licensing agreement, Knight will be responsible to conduct and fund all regulatory and commercial activities in Canada. The Company is eligible to receive royalty and sales. In connection with the licensing agreement, the Company sold directly to Knight 359,454 shares of the common stock at \$13.91 per share. In addition, the Company sold directly to Sectoral Asset Management, a leading Canadian-based global healthcare investment advisor, 1,437,815 shares of common stock at \$13.91 per share. The combined net proceeds to the Company from these direct investments was approximately \$25 million. The sale of the shares closed on August 28, 2015.

*Merck & Co., Inc.*

On August 22, 2014, the Company 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, ADXS-PSA (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 the Company will be responsible for all third party costs of conducting the study. Merck will be responsible for manufacturing and supplying the Merck Compound. The Company will be responsible for manufacturing and supplying the Advaxis Compound. The Company 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.

During the years ended October 31, 2016, 2015 and 2014, the Company incurred approximately \$1,587,000, \$1,723,000 and \$72,000, respectively, in expenses pertaining to the Merck agreement, and such expenses were a component of research and development expenses in the statement of operations.

*MedImmune/AstraZeneca*

On July 21, 2014, the Company 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, AXAL, 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. The Company 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 AXAL 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 AXAL 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.

During the years ended October 31 2016, 2015 and 2014, the Company incurred approximately \$1,978,000, \$1,888,000 and \$50,000, respectively, in expenses pertaining to the MedImmune agreement, and such expenses were a component of research and development expenses in the statement of operations.

#### *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 during the 12 months ended October 31, 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’ 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’ 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.

#### *Global BioPharma Inc.*

On December 9, 2013, the Company entered into an exclusive licensing agreement for the development and commercialization of AXAL with Global BioPharma, Inc. (“GBP”), a Taiwanese based biotech company funded by a



group of investors led by Taiwan Biotech Co., Ltd (TBC).

GBP is planning to conduct a randomized Phase 2, open-label, controlled study in HPV-associated NSCLC in patients following first-line induction chemotherapy. GBP has obtained Taiwanese regulatory approval for this study and plans to initiate this study in 2017. This trial will be fully funded exclusively by GBP. GBP will continue to explore the use of our lead product candidate in several other indications including head and neck, and anal cancer. GBP also plans to conduct registration trials with AXAL for the treatment of advanced cervical cancer.

GBP will pay Advaxis event-based financial milestones, an annual license 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.

GBP will be responsible for all clinical development and commercialization costs in the GBP territory. GBP will also reimburse us \$2.25 million toward AIM2CERV. GBP is committed to establishing manufacturing capabilities for its own. Under the terms of the agreement, we will exclusively license the rights of AXAL 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 AXAL for the rest of the world.

During the year ended October 31, 2016, the Company received the first annual license fee and recorded licensing revenue of \$250,000.

## 11. COMMITMENTS AND CONTINGENCIES

### *Legal Proceedings*

#### *Iliad Research and Trading*

On March 24, 2014, Iliad Research and Trading, L.P. (“Iliad”) filed a Complaint against the Company in the Third Judicial District Court of Salt Lake County, Utah. On June 30, 2014, after Iliad had filed an Amended Complaint, the Company removed the action to the United States District Court for the District of Utah. On August 1, 2014, Iliad filed a Second Amended Complaint (the “SAC”). Iliad alleged that the Company granted a participation right to Tonaquint, Inc. (“Tonaquint”) in a securities purchase agreement between Tonaquint and the Company (the “Purchase Agreement”), pursuant to which Tonaquint was entitled to participate in transactions that the Company structured in accordance with Section 3(a)(10) of the Securities Act of 1933, as amended. Iliad further alleged that the Company’s settlement 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. The SAC purports to assert claims for breach of contract (express and implied), fraud (federal securities, state securities and common law) and conversion.

On November 24, 2014, in response to the Company’s motion to dismiss, the Court dismissed the conversion claim but denied the remainder of the motion. On December 8, 2014, Advaxis filed its answer to the SAC and a counterclaim (the “Counterclaim”), alleging that Iliad – by purporting to have surreptitiously preserved its claim for breach of Tonaquint’s alleged right to participate in the Ironridge transaction – had fraudulently induced Advaxis to enter into the parties’ post-assignment Exchange and Settlement Agreement and, in the alternative, had breached the covenant of good faith and fair dealing implied therein. On January 23, 2015, Iliad filed its Reply to Counterclaim. On May 4, 2015, in response to Iliad’s motion for partial summary judgment concerning liability on the express contract claim and Advaxis’ Rule 56(d) motion to deny that motion and allow discovery, the Court found that Advaxis had materially breached the Purchase Agreement.

On September 10, 2015, the parties entered into a definitive confidential settlement agreement and the case was dismissed.

*KCM*

On August 21, 2015, Knoll Capital Management L.P. (“KCM”) filed a complaint against the Company in the Delaware Court of Chancery. The complaint alleges the existence of an oral agreement for the purchase by Knoll from the Company of 1,666,666.67 shares of Company stock at a price of \$3.00 per share. KCM alleges that the Company breached this alleged agreement and seeks specific performance or, alternatively, money damages for breach of contract. KCM served the Company with the complaint on August 31, 2015, and then served an amended complaint on October 16, 2015. The Company moved to dismiss the amended complaint on October 26, 2015 and that motion was denied on January 29, 2016. The Company filed an answer to the amended complaint on February 12, 2016. The Company intends to defend itself vigorously.

*Larkin and Bono*

On July 27, 2015, a derivative complaint was filed by a purported Company shareholder in the Court of Chancery of the State of Delaware against certain of the Company’s officers and directors styled Timothy Larkin v. O’Connor, et al., Case No. 11338-CB (Del. Ch. July 27, 2015) (the “Larkin Action”). The Larkin Action was brought derivatively on behalf of the Company, which is also named as a nominal defendant. On August 20, 2015, a related derivative complaint was filed by a purported Company shareholder in the United States District Court for the District of New Jersey against the same defendants styled David Bono v. O’Connor, et al., Case No. 3:15-CV-006326-FLW-DEA (D.N.J. Aug. 20, 2015) (the “Bono Action”). Both complaints are based on general allegations related to certain stock options granted to the individual defendants and generally allege counts for breaches of fiduciary duty and unjust enrichment. The Bono complaint alleges additional claims for violation of Section 14(a) of the Securities Exchange Act of 1934 and for waste of corporate assets. Both complaints seek damages and costs of an unspecified amount, disgorgement of compensation obtained by the individual defendants, and injunctive relief.

Defendants filed motions to dismiss in both actions. On March 22, 2016, the Delaware Court of Chancery issued a partial ruling on the motion to dismiss in the Larkin Action. The court denied the motion to dismiss as to the breach of fiduciary duty and unjust enrichment claim against the three members of the Compensation Committee, but expressly reserved ruling on the disclosure claim against all defendants and the breach of fiduciary duty and unjust enrichment claims against the other eight individual defendants. On September 12, 2016, the court dismissed the complaint in its entirety without prejudice.

On May 23, 2016, the United States District Court for the District of New Jersey issued an opinion and order granting in part and denying in part defendants' motion to dismiss. The court denied the motion to dismiss as to the breach of fiduciary duty claim and unjust enrichment claim against the three members of the Compensation Committee, but dismissed without prejudice the breach of fiduciary duty and unjust enrichment claims against the other eight individual defendants. The court dismissed without prejudice the Section 14(a) disclosure claim and waste claims against all defendants. On October 5, 2016, the court denied plaintiff's motion for reconsideration of its May 23 order.

At this stage of the Bono proceeding, the Company does not express any opinion as to likely outcome, but the Company intends to defend the action vigorously.

#### *Office & Laboratory Lease*

The Company's corporate offices are currently located at 305 College Road East, Princeton, New Jersey 08540. On April 1, 2011, the Company entered into a sublease agreement for such office, and the agreement expired on November 29, 2015. In May 2015, the Company signed a direct lease for an expansion area, as well as a direct lease for the existing office, lab and vivarium space upon the expiration of the sublease agreement, which is approximately 20,000 square foot of space in total in Princeton, NJ. The lease term was seven years and scheduled to expire on November 30, 2022. The Company paid a security deposit of \$82,426. The lease required base annual rent of approximately \$442,000 with annual increases in increments between 2% and 4% throughout the remainder of the lease. The lease contains two options to renew for five years each.

Effective February 1, 2016, the Company entered into an amendment to its office lease. On August 29, 2016, the Company entered into a second amendment to its office lease that will become effective January 1, 2017. The first and second amendments increased the leased space by approximately 25,000 and 4,000 square feet respectively, to a total of approximately 48,500 square feet. The additional space will allow the Company to expand manufacturing, testing, and product development capabilities, accelerate execution of pipeline related projects, strengthen the supply chain, and continue to ensure reliable and cost competitive supply of product. The lease term was extended by three years and is now scheduled to expire on November 30, 2025. The Company paid an additional security deposit of \$100,061. The amended lease requires an annual rent of approximately \$962,000 with annual increases in increments between 2% and 11% throughout the remainder of the lease. The lease amendment contained a six month rent abatement period that ran from February 2016 to July 2016, and a reduced lease rate for four months that started in August 2016.

Rent expense will be recognized on a straight-line basis over the term of the lease. After the second amendment, the Company is entitled to a \$439,575 tenant improvement allowance for leasehold improvements. As of October 31, 2016, the tenant improvement allowance used was \$378,795 and was recorded both as a leasehold improvement and a lease incentive obligation on the Company's balance sheet.

Rent expense for the years ended October 31, 2016, 2015 and 2014 was \$945,054, \$150,000 and \$330,000, respectively.

Future minimum payments under the Company's operating leases are as follows:

Year ended October 31,

2017	\$961,796
2018	1,041,895
2019	1,107,385
2020	1,232,907
2021	1,317,640
Thereafter	5,747,340
Total	\$ 11,408,963

The Company plans to continue to rent necessary offices and laboratories to support its business.

#### *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 November 2016, the Company received a net cash amount of \$2,549,862 from the sale of its state NOLs and research and development tax credits for the period ended October 31, 2015. In December 2015, the Company received a net cash amount of \$1,609,349 from the sale of its state NOLs and research and development tax credits for the period ended October 31, 2014. 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.

**12. INCOME TAXES:**

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

	October 31, 2016	October 31, 2015	October 31, 2014
Federal			
Current	\$-	\$-	\$-
Deferred	(18,152,484)	(14,513,684)	(5,777,937)
State and Local			
Current	(2,535,625 )	(1,609,349 )	(2,356,880)
Deferred	(3,698,506 )	(1,840,276 )	1,008,338
Change in valuation allowance	21,850,990	16,353,960	4,769,599
Income tax provision (benefit)	\$(2,535,625 )	\$(1,609,349 )	\$(2,356,880)

The Company has U.S. federal net operating loss carryovers (NOLs) of approximately \$140,527,000, \$100,662,000 and \$75,348,000 at October 31, 2016, 2015 and 2014, 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. In fiscal 2016, the Company performed a detailed analysis of any historical and/or current Section 382 ownership changes that may limit the utilization of the net operating loss carryovers. From the entire federal NOL of \$140,527,000, as of October 31, 2016, approximately \$101,523,000 is available for immediate use based on Internal Revenue Code Section 382 analysis. The NOL and the deferred tax asset table below does not include approximately \$24,824,000 of NOL's that may expire unused. The Company also has New Jersey State Net Operating Loss carryovers of approximately \$66,029,000, \$26,245,000 and \$18,078,000 as of October 31, 2016, 2015 and 2014, respectively, available to offset future taxable income through 2035.

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 years ended October 31, 2016, 2015 and 2014, the change in the valuation allowance was approximately \$21,851,000, \$16,354,000 and \$4,770,000, respectively.

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 Income (Expense)” in the statement of operations. Penalties would be recognized as a component of “General and Administrative Expenses” in the statement of operations.

No interest or penalties on unpaid tax were recorded during the years ended October 31, 2016, 2015 and 2014, respectively. As of October 31, 2016 and 2015, 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, 2013.

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

	Years Ended	
	October 31, 2016	October 31, 2015
<b>Deferred Tax Assets</b>		
Net operating loss carryovers	\$51,701,000	\$34,366,000
Stock-based compensation	15,239,000	10,282,000
Other deferred tax assets	5,672,000	4,878,000
Total deferred tax assets	\$72,612,000	\$49,526,000
Valuation allowance	(69,317,000)	(47,466,000)
Deferred tax asset, net of valuation allowance	\$3,295,000	\$2,060,000
<b>Deferred Tax Liabilities</b>		
Other deferred tax liabilities	(3,295,000 )	(2,060,000 )
Total deferred tax liabilities	\$(3,295,000 )	\$(2,060,000 )
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 31, 2016	October 31, 2015	October 31, 2014			
US Federal statutory rate	34.0 %	34.0 %	34.0 %			
State income tax, net of federal benefit	5.9	5.9	5.9			
Deferred tax adjustment	(13.1)	(2.2 )	(13.3 )			
Change in valuation allowance	(28.7)	(33.6 )	(25.3 )			
Income tax benefit from sale of New Jersey NOL carryovers	3.3	3.3	12.5			
Other permanent differences	1.9	(4.1 )	(1.3 )			
Income tax (provision) benefit	3.3 %	3.3 %	12.5 %			

### 13. SHAREHOLDERS' EQUITY:

#### *Registered Direct Offerings*



On August 19, 2016, the Company sold 2,244,443 shares of common stock in a registered direct offering at a per share price of \$13.50 for gross proceeds of approximately \$30.3 million. The net proceeds to the Company, after deducting the Placement Agents' fees and other estimated offering expenses payable by the Company, were approximately \$28.2 million.

On February 18, 2015, the Company priced a registered direct offering of 3,068,095 shares of its Common Stock at \$7.50 per share. The transaction closed on February 19, 2015, and the Company received gross proceeds of approximately \$23.0 million from the offering. After deducting offering expenses, the net proceeds from the offering were approximately \$22.3 million.

On December 19, 2014, the Company priced a registered direct offering of 3,940,801 shares of its Common Stock at \$4.25 per share. The transaction closed on December 22, 2014, and the Company received gross proceeds of approximately \$16.7 million from the offering. After deducting offering expenses, the net proceeds from the offering were approximately \$15.8 million.

#### *Public Offerings*

On May 5, 2015, the Company closed on an underwritten public offering of 2,800,000 shares of Common Stock at a public offering price of \$19.00 per share. On May 20, 2015, the Company closed the underwriters' overallotment option to purchase 420,000 shares of its Common Stock at a public offering price of \$19.00 per share. The Company received gross proceeds of approximately \$61.2 million from the May 2015 public offerings. After deducting offering expenses, the net proceeds from the May 2015 public offerings were approximately \$56.7 million.

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.

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.

#### **14. 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.

Edgar Filing: Advaxis, Inc. - Form 10-K

The following table provides the assets and liabilities carried at fair value measured on a recurring basis as of October 31, 2016 and October 31, 2015:

October 31, 2016	Level 1	Level 2	Level 3	Total
Common stock warrant liability, warrants exercisable at \$10.63- \$18.75 from November 2016 through August 2017	-	-	\$20,156	\$20,156

October 31, 2015	Level 1	Level 2	Level 3	Total
Common stock warrant liability, warrants exercisable at \$10.63- \$18.75 from November 2015 through August 2017	\$ -	\$ -	\$89,211	89,211

The following table sets forth a summary of the changes in the fair value of the Company's warrant liabilities:

	October 31,	
	2016	2015
Beginning balance	\$89,211	\$32,091
Issuance of additional warrants due to anti-dilution provisions	-	8,170
Change in fair value	(69,055)	48,950
Ending Balance	20,156	89,211

**15. EMPLOYEE BENEFIT PLAN**

The Company sponsors a 401(k) Plan. Employees become eligible for participation upon the start of employment. Participants may elect to have a portion of their salary deferred and contributed to the 401(k) plan up to the limit allowed under the Internal Revenue Code. The Company makes a matching contribution to the plan for each participant who has elected to make tax-deferred contributions for the plan year. The Company made matching contributions which amounted to \$172,276, \$51,403 and \$39,889 for the years ended October 31, 2016, 2015 and 2014, respectively. These amounts were charged to the Statement of Operations. The Employer contributions vest immediately.

**16. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)**

The following interim financial information presents the Company's 2016, 2015 and 2014 results of operations on a quarterly basis (in thousands, except per share amounts):

	Quarter Ended			
	January 31, 2016	April 30, 2016	July 31, 2016	October 31, 2016
Revenue	\$250,000	\$-	\$-	\$3,744,856
Net loss	(19,844,935)	(15,522,450)	(16,486,008)	(21,702,837)
Net loss income per common share, basic and diluted	(0.59 )	(0.45 )	(0.48 )	(0.55 )

	Quarter Ended			
	January 31, 2015	April 30, 2015	July 31, 2015	October 31, 2015
Revenue	\$-	\$-	\$-	\$-
Net loss	(7,033,870)	(13,855,259)	(13,562,026)	(12,579,963)
Net loss income per common share, basic and diluted	(0.33 )	(0.52 )	(0.44 )	(0.38 )

	Quarter Ended			
	January 31, 2014	April 30, 2014	July 31, 2014	October 31, 2014
Revenue	\$-	\$1,000,000	\$-	\$-
Net loss	(5,187,392)	(2,314,617)	(5,779,194)	(3,244,111)
Net loss income per common share, basic and diluted	(0.37 )	(0.15 )	(0.30 )	(0.17 )

**17. SUBSEQUENT EVENTS**

On November 3, 2016, the Company granted to executives 376,952 options with an exercise price of \$7.71 and 145,751 PRSU's. The options and PRSU's vest annually in equal installments such that 100% of the awards granted will vest by the third anniversary of the grant date, and the vesting of the PRSU's are subject to performance conditions. The awards granted vest one-third after the one year anniversary, one-third after the two year anniversary and one-third after the three year anniversary.

On November 3, 2016, the Company granted to Directors 180,000 options with an exercise price of \$7.71. The options vest annually in equal installments such that 100% of the options granted will vest by the third anniversary of the grant date. The options granted vest one-third after the one year anniversary, one-third after the two year anniversary and one-third after the three year anniversary.

On December 30, 2016, the Company granted Sara M. Bonstein, Executive Vice President and Chief Financial Officer, a promotion award of 50,000 RSUs. The award vests one-fourth immediately, one-fourth after the one year anniversary, one-fourth after the two year anniversary and one-fourth after the three year anniversary.

