# 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)

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 [X]

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

Yes [ ] No [X]

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

Yes [X] No [ ]

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

Yes [X] No [ ]

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

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

Large accelerated filer [ ]	Accelerated filer [X]
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 [X]

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). [X]

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.

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#### 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," "will," "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 TM") 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).

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<sup>TM</sup> 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<sup>TM</sup>. 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 1x10<sup>9</sup> 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 ≥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 Stated 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 Tcell 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, TNFa, 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 sixmonth 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 " $\underline{F}$ ighting  $\underline{A}$ nal-Cancer  $\underline{w}$ ith  $\underline{C}$ TL  $\underline{E}$ nhancing  $\underline{T}$ umor  $\underline{T}$ herapy"), 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  $5x10^9$  CFU and  $1x10^{10}$  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  $1x10^9$  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 x 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<sup>TM</sup>" (My Immunotherapy Neo-Epitopes).

The goal of MINE<sup>TM</sup> is to use our *Lm* Technology<sup>TM</sup> to develop patient specific neo-epitope targeted immunotherapies based on mutations found in an individual patient's tumor ("ADXS-NEO"). MINE<sup>TM</sup> 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  $^{\mathbb{R}}$  (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  $5x10^9$  CFU and  $1x10^{10}$  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  $1x10^{-9}$  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<sup>TM</sup> including, but not limited to, the use of Lm Technology<sup>TM</sup> 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 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.

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<sup>TM</sup> 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 bioengineered 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 <sup>®</sup> (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 necepitope 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-approvable, commercially competitive products on a timely basis. Failure can occur at any stage of the process. If such programs are not successful, we may invest substantial amounts of time and money without developing revenue-producing products. As we enter a more extensive clinical program for our product candidates, the data generated in these studies may not be as compelling as the earlier results.

The proposed development schedules for our immunotherapies may be affected by a variety of factors, including technological difficulties, clinical trial failures, regulatory hurdles, 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

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, keyperson 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
	31		

#### **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

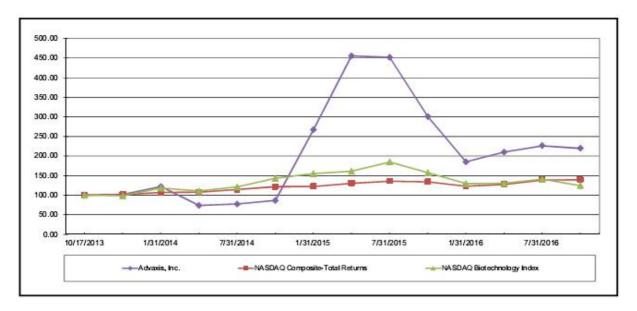
(1) Consists of shares repurchased by the Company for certain employees' restricted stock units that vested to satisfy minimum tax withholding obligations that arose on the vesting of the restricted stock units.

#### **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



<sup>\* \$100</sup> 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)		
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	<del>-</del>	<del>-</del>		(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		
	32						

			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 preclinically. 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 preclinically. 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**

		Payments Due by Period								
		Less than			More than					
Contractual Obligations	Total		1 year		1-3 years		3-5 years		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 filling.

## (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

Marcun LLP



## 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 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.

Exhibit Number	Description of Exhibits
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.
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Exhibit Number	Description of Exhibits
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.

Exhibit Number	Description of Exhibits
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.

Exhibit Number	Description of Exhibits
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 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

10.55

- 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.
- 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.
- 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.

Exhibit Number	Description of Exhibits
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
* F11.1	L

- \* 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				
/s/ Daniel J. O'Connor Daniel J. O'Connor	President, Chief Executive Officer and Director (Principal Executive Officer)	January 9, 2017				
/s/ Sara Bonstein Sara Bonstein	Chief Financial Officer, Executive Vice President and Secretary (Principal Financial and Accounting Officer)	January 9, 2017				
/s/ David Sidransky David Sidransky	Chairman of the Board	January 9, 2017				
/s/ James Patton James Patton	Vice Chairman of the Board	January 9, 2017				
/s/ Richard Berman Richard Berman	Director	January 9, 2017				
/s/ Thomas McKearn Thomas McKearn	Director	January 9, 2017				
/s/ Samir Khleif Samir Khleif	Director	January 9, 2017				
/s/ Roni Appel Roni Appel	Director	January 9, 2017				
/s/ Thomas Ridge Thomas Ridge	Director	January 9, 2017				
/s/ Gregory T. Mayes Gregory Mayes	Director	January 9, 2017				
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## ADVAXIS, INC.

## FINANCIAL STATEMENTS

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#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheets of Advaxis, Inc. (the "Company") as of October 31, 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.

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

## ADVAXIS, INC. BALANCE SHEETS

SSETS		October 31,				
Current Assetts         S 112,750,980         5 66,561,86           Cash and Cash Equivalents         39,365,48         45,594,95           Investments - Held-to-Maturity         39,365,48         45,594,95           Interest Receivable         80,142         1145,299           Deferred Expenses         42,491,385         749,790           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         1,082,533           Other Assets         369,044,060         \$119,605,693           TOTAL ASSETS         \$169,044,060         \$119,605,693           LABILITIES AND SHAREHOLDERS' EQUITY         ***         ***           Current Liabilities:         \$1,720,428         66,611           Accounts Payable         \$1,202,576         \$19,605,693           Accounts Payable         \$1,202,576         \$2,924           Accounts Payable         \$1,202,576         \$2,924           Accounts Payable         \$1,202,576         \$2,924           Common Stock Warrant Liability         \$2,915         \$2,924           Deferred			2016		2015	
Cash and Cash Equivalents         \$ 112,750,980         \$ 6,561,683           Investments Held-to-Maturity         393,36,548         \$ 45,594,495           Interest Receivable         80,142         1 145,299           Prepaid Expenses         812,830         33,8481           Income Tax Receivable         2,249,862         1,609,349           Deferred Expenses         4,291,385         749,790           Other Current Assets         159,875,188         115,101,573           Property and Equipment (net of accumulated depreciation)         4,389,074         1,007,244           Intangible Assets (net of accumulated amortization)         4,389,074         1,007,244           Offer Assets         450,667         148,843           TOTAL ASSETS         169,044,000         \$ 119,605,693           LIABILITIES AND SHAREHOLDERS' EQUITY         2         1,500,503           LIABILITIES AND SHAREHOLDERS' EQUITY         15,000,503         3,191,941           Deferred Revenue         15,000,503         3,191,941           Deferred Revenue         2         2,249           Cesus Incentive Obligation         40,226         -           Common Stock Warrant Liability         2         2,156           Total Current Liabilities         22,156         -	ASSETS					
Interest Receivable Interest Receivable Interest Receivable Interest Receivable (145.29)         80,142 (145.29)           Prepaid Expenses (160,348)         812.830 (338.841)           Income Tax Receivable (160,349)         2,549,862 (160,349)           Deferred Expenses (160,349)         4,291,335 (160,349)           Other Current Assets (153,451)         153,161           Total Current Assets (160,349)         4,389,074 (160,349)           Property and Equipment (net of accumulated depreciation) (164,349,121)         4,389,074 (168,348)           Property and Equipment (net of accumulated amortization) (164,349,349)         43,890,74 (168,348)           TOTAL ASSETS (164,348)         169,044,060 (178,348)           TOTAL ASSETS (164,348)         169,044,060 (178,348)           LABBILITIES AND SHAREHOLDERS' EQUITY         11,720,428 (179,428)           Current Liabilities: (164,349)         11,720,428 (179,428)           Accounts Payable (164,349)         11,720,428 (179,428)           Accounts Payable (164,349)         11,720,428 (179,428)           Deferred Revenue (150,500,57)         12,243,58 (179,428)           Deferred Revenue (174,544)         12,243,58 (179,428)           Lease Incentive Obligation - net of current portion (174,409,57)         325,16 (179,47)           Deferred Revenue (174,544)         145,17 (179,47)           Lease Incentive Obligation - n	Current Assets:					
Interest Receivable	Cash and Cash Equivalents	\$	112,750,980	\$	66,561,683	
Prepaid Expenses         812,80         338,841           Income Tax Receivable         2,549,862         1,609,349           Deferred Expenses         4,291,335         749,790           Other Current Assets         53,451         15,116           Total Current Assets         159,875,198         15,014,573           Property and Equipment (net of accumulated depreciation)         4,389,074         1,087,244           Intangible Assets (net of accumulated amortization)         4,389,074         1,087,244           Other Assets         \$ 169,044,060         \$ 119,605,693           LIABILITIES AND SHAREHOLDERS' EQUITY           Current Liabilities:         \$ 1,720,428         \$ 669,117           Accounts Payable         \$ 1,720,428         \$ 669,117           Accounts Payable         \$ 1,720,428         \$ 669,117           Accurued Expenses         10,905,003         3,191,941           Deferred Revenue         5,020,576         -           Cass Incentive Obligation         40,226         -           Short-term Convertible Notes and Fair Value of Embedded Derivative         21,526,58         -           Common Stock Warrant Liability         20,156         -           Deferred Rent         475,749         -           De	Investments – Held-to-Maturity		39,336,548		45,594,495	
Deferred Expenses	Interest Receivable		80,142		145,299	
Deferred Expenses         4,29,1,385         749,790           Other Current Assets         53,451         15,116,16           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           OTAL ASSETS         \$169,044,060         \$118,883           TOTAL ASSETS         \$1,720,428         \$6,961,17           Accounts Payable         \$1,200,256         -           Lease Incentive Obligation         \$0,950,03         3,191,941           Deferred Revenue         \$1,500,576         -           Common Stock Warrant Liability         \$2,156         -           Total Current Liabilities         \$27,706,389         3,917,607           Deferred Revenue         \$21,234,586         -           Common Stock Warrant Liability         \$25,166         -           Total L	Prepaid Expenses		812,830		338,841	
Property and Equipment (net of accumulated depreciation)	Income Tax Receivable		2,549,862		1,609,349	
Property and Equipment (net of accumulated depreciation)	Deferred Expenses		4,291,385		749,790	
Total Current Assets					15,116	
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           TOTAL ASSETS         \$ 169,044,060         \$ 119,605,693           LIABILITIES AND SHAREHOLDERS' EQUITY           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         29,549           Common Stock Warrant Liability         20,156         -           Total Current Liabilities         27,766,389         3,917,607           Deferred Rent         475,749         -           Deferred Revenue         21,234,586         -           Lease Incentive Obligation- net of current portion         325,160         -           Common Stock Warrant Liability         4,757,49         -           Lease Incentive Obligation- net of current portion         325,160         -           Common Stock Warrant Liability         49,741,866         4,006,81           Common Stock W	Total Current Assets					
Intangible Assets (net of accumulated amortization)         4,329,121         3,355,033           Other Assets         450,667         148,843           TOTAL ASSETS         \$ 169,044,060         \$ 119,605,693           LIABILITIES AND SHAREHOLDERS' EQUITY           Current Liabilities:           Accounts Payable         \$ 1,720,428         \$ 666,117           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         2,7506,389         3,917,607           Deferred Rent         475,749         -           Deferred Revenue         21,234,568         -           Deferred Revenue         325,160         -           Lease Incentive Obligation- net of current portion         325,160         -           Common Stock Warrant Liability         2         -           Common Stock Warrant Liabilities         49,741,866         4,006,818           Common Stock Warrant Liability         -         89,211           Total Liabilities         49,741,866         4,006,818           Common Stock Warrant Liability	Total Callette Hoods		133,073,130		110,011,075	
Intangible Assets (net of accumulated amortization)         4,329,121         3,355,033           Other Assets         450,667         148,843           TOTAL ASSETS         \$ 169,044,060         \$ 119,605,693           LIABILITIES AND SHAREHOLDERS' EQUITY           Current Liabilities:           Accounts Payable         \$ 1,720,428         \$ 666,117           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         2,7506,389         3,917,607           Deferred Rent         475,749         -           Deferred Revenue         21,234,568         -           Deferred Revenue         325,160         -           Lease Incentive Obligation- net of current portion         325,160         -           Common Stock Warrant Liability         2         -           Common Stock Warrant Liabilities         49,741,866         4,006,818           Common Stock Warrant Liability         -         89,211           Total Liabilities         49,741,866         4,006,818           Common Stock Warrant Liability	Property and Equipment (net of accumulated depreciation)		4.389.074		1.087.244	
Other Assets         450,667         148,843           TOTAL ASSETS         \$ 169,044,060         \$ 119,605,693           LIABILITIES AND SHAREHOLDERS' EQUITY         Current Liabilities:           Accounts Payable         \$ 1,720,428         \$ 696,117           Accounts Payable         \$ 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         2,0156         -           Common Stock Warrant Liability         227,706,389         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           Common Stock Warrant Liability         -         -         89,211           Total Liabilities         -         89,211           Common Stock Warrant Liability         -         -         89,211           Total Liabilities         -         -						
TOTAL ASSETS						
LIABILITIES AND SHAREHOLDERS' EQUITY   Current Liabilities:		_	130,007		1 10,0 15	
LIABILITIES AND SHAREHOLDERS' EQUITY   Current Liabilities:	TOTAL ASSETS	¢	160 044 060	¢	110 605 602	
Current Liabilities:         \$ 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         20,156            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         449,741,866  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.           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 3,574,963 shares outstanding at October 31, 2015 and 33,591,882 shares issued and 3,574,963 shares outstanding at October 31, 2016 and 33,591,882 shares issued and 3,574,963 shares outstanding at October 31, 2016 and 31,591,882 shares issued and 3,574,963 shares ou	TOTAL ADDLITS	Ф	109,044,000	Þ	119,003,093	
Current Liabilities:         \$ 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         20,156            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         449,741,866  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.           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 3,574,963 shares outstanding at October 31, 2015 and 33,591,882 shares issued and 3,574,963 shares outstanding at October 31, 2016 and 33,591,882 shares issued and 3,574,963 shares outstanding at October 31, 2016 and 31,591,882 shares issued and 3,574,963 shares ou	ALLEN VENEZ AND COLLEGE DEPOSIT FOR VENEZ POR PORTER OF THE PORTER OF TH					
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 40,041,047 shares outstanding at October 31, 2016 and 2015. Liquidation preference of \$0 at October 31, 2016 and 2015.         -         -           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         40,057<						
Accrued Expenses         10,005,003         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:         -         89,211           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. 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         40,057         33,592           Additional Paid-In Capital         327,098,749         249,807,303         37,908,749         249,807,303 </td <td></td> <td></td> <td></td> <td></td> <td></td>						
Deferred Revenue		\$		\$		
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.         -         -         -           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         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)         <					3,191,941	
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 sissued and outstanding at October 31, 2016 and 2015. Liquidation preference of \$0 at October 31, 2016 and 2015.         -         -           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 40,041,047 shares outstanding at October 31, 2016 and 33,591,882 shares issued and 33,574,963         40,057         33,592           Additional Paid-In Capital         327,098,749         249,807,303         37 (187,761)           Accumulated Deficit         (207,706,825)         (134,054,259)           Total Shareholders' Equity </td <td></td> <td></td> <td></td> <td></td> <td>-</td>					-	
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.         -         -           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 40,041,047 shares outstanding at October 31, 2016 and 33,591,882 shares issued and 33,574,963         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' E			40,226		-	
Deferred Rent			-		29,549	
Deferred Rent	Common Stock Warrant Liability		20,156		-	
Deferred Revenue	Total Current Liabilities		27,706,389		3,917,607	
Deferred Revenue						
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 susued and outstanding at October 31, 2016 and 2015. Liquidation preference of \$0 at October 31, 2016 and 2015.         -         -         -           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 40,041,047 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	Deferred Rent		,		-	
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.           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         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			21,234,568		-	
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.  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.  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	Lease Incentive Obligation- net of current portion		325,160		-	
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.  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.  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	Common Stock Warrant Liability		-		89,211	
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.  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.  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	Total Liabilities		49,741,866		4,006,818	
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.  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.  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					, ,	
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.  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.  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	Commitments and Contingencies – Note 11					
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.  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.  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	e de la companya de					
issued and outstanding at October 31, 2016 and 2015. Liquidation preference of \$0 at October 31, 2016 and 2015.  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.  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	Shareholders' Equity:					
issued and outstanding at October 31, 2016 and 2015. Liquidation preference of \$0 at October 31, 2016 and 2015.  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.  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	Preferred Stock, \$0.001 par value: 5,000,000 shares authorized: Series B Preferred Stock: 0 shares					
2016 and 2015.  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.  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						
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 49,807,303         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	· · · · · · · · · · · · · · · · · · ·		_		_	
40,041,047 shares outstanding at October 31, 2016 and 33,591,882 shares issued and 33,574,963       40,057       33,592         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						
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						
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			40.057		33 592	
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						
Accumulated Deficit         (207,706,825)         (134,054,259)           Total Shareholders' Equity         119,302,194         115,598,875						
Total Shareholders' Equity 119,302,194 115,598,875	·					
TOTAL VILLEY INVESTIGATION OF THE STATE OF T				_		
101AL LIADILITIES AND SHAKEHOLDERS EQUITI \$ 169,044,060 \$ 119,605,693	* *	Φ.		¢.		
	TOTAL LIADILITIES AND SHAKEHULDEKS EQUITY	\$	169,044,060	\$	119,605,693	

# ADVAXIS, INC. Statements of Operations

	Year Ended October 31,							
		2016		2015	2	2014		
Revenue	\$	3,994,856	\$	<u>-</u> \$	S	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) \$	S (	16,525,314)		
Net Loss per Common Share, Basic and Diluted	\$	(2.08)	\$	(1.68) \$	3	(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 conj	unction	with the financia	ıl stat	ements.				

# ADVAXIS, INC. STATEMENTS OF SHAREHOLDERS' EQUITY

					Additional				
		ed Stock	Common		Paid-In		ry Stock	Accumulated	Shareholders'
Balance at October 31,	Shares	Amount	Shares	Amount	Capital	Shares	Amount	Deficit	Equity
2013 Stock compensation to	-	\$ -	13,719,861	\$13,720	\$ 88,454,245	-	\$ -	\$ (70,465,823)	\$ 18,002,142
employees, directors and consultants			501 651	502	2 920 202				2 920 704
Tax withholdings paid			501,651	302	3,839,202				3,839,704
related to net share settlement of equity									
awards					(959,425)				(959,425)
Common Stock issued upon exercise of									
warrants Common Stock issued			50	-	250				250
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			2,110	2	0,249				0,231
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 Balance at October 31,								(16,525,314)	(16,525,314)
2014		<u>\$ -</u>	19,630,139	\$19,630	\$107,601,493		\$ -	\$ (86,991,137)	\$ 20,629,986
Stock compensation to employees, directors and			700 420	700	16 667 900				16 669 500
consultants Tax withholdings paid			789,438	790	16,667,800				16,668,590
related to net share settlement of equity									
awards Treasury stock					(1,375,979)				(1,375,979)
purchased to pay employee withholdings									
on equity awards Treasury shares sold to						(114,445)	(1,388,086)		(1,388,086)
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 Common Stock issued			691,268	691	2,341,758				2,342,449
to consultants			378,538	379	4,707,061				4,707,440
Conversion of notes payable into common			4 10 4	4	20.020				20.022
stock Issuance of shares to			4,104	4	39,928				39,932
employees under ESPP Plan			7,063	7	28,784				28,791
Advaxis registered direct offerings			8,806,165	8,806	63,046,722				63,055,528
Advaxis Public Offering Net Loss			3,220,000	3,220	56,675,128			(47,031,118)	56,678,348 (47,031,118)
Balance at October 31, 2015		\$ -	33,591,882	\$33,592	\$249,807,303	(16,919)	\$ (187,761)	\$(134,054,259)	
Stock compensation to employees and directors			873,642	874	21,886,185				21,887,059
Tax withholdings paid related to net share			073,072	37 <del>4</del>	21,000,103				21,007,007
settlement of equity									

Trenslary stock purchased to pay employee withholdings				(61,350)				(61,350)
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 Plan		6,627	7	73,237				73,244
Advaxis registered direct offerings		·		·				
		2,244,443	2,244	28,154,163				28,156,407
Sale of common shares to Amgen		3,047,446	3,047	24,965,589				24,968,636
Net Loss							(73,556,230)	(73,556,230)
Balance at October 31, 2016	- \$	- 40,057,067	\$40,057	\$327,098,749	(16,020)	\$ (129,787)	\$(207,706,825)	\$119,302,194

# ADVAXIS, INC. Statement of Cash Flows

Year ended October 31, 2014 2016 2015 OPERATING ACTIVITIES 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 (619,089)48,950 (69.055)8,170 Warrant expense 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 60,608 252,730 6,599 Debt conversion expense 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 8,066 (38,335)214,934 (617,676)Deferred expenses (3,541,595)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)**INVESTING ACTIVITIES** 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 (3,222,442)Purchase of property and equipment (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)FINANCING ACTIVITIES 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 14,580,808 53,125,043 119,733,876 Tax withholdings paid related to net share settlement of equity awards (61,350)(936,898)(1,375,979)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 (2,945,202)46,189,297 48,954,823 Cash and cash equivalents at beginning of year 20,552,062 66,561,683 17,606,860 Cash and cash equivalents at end of year 112,750,980 66,561,683 17,606,860

## **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	\$	-	\$	-			

# 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 TM") 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<sup>TM</sup> 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<sup>TM</sup>. 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.

#### 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.

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 bankowned 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 3	1, 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
	Amortized cost, as adjusted	October 3 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
	F-13			

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	<u>-</u>	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,				
	201	6	2015			
License	\$	776,992 \$	651,992			
Patents	4	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
	F-14	

#### 6. ACCRUED EXPENSES:

The following table represents the major components of accrued expenses:

		October 31,				
	2016		2015			
Salaries and other compensation	\$ 2,32	5,998 \$	1,698,371			
Vendors	2,09	8,792	833,032			
Professional fees	6,33	8,561	439,605			
Withholding taxes payable	14	1,652	220,933			
Total Accrued Expenses	\$ 10,90	5,003 \$	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.

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A summary of warrant activity was as follows:

		Weighted				
		Weighted Remaining				
		Average	Contractual Life	A	ggregate	
	Shares	Exercise Price	In Years	Intri	nsic 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				
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

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\* 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:

		For the Year Ended October 31, 2016									
		Gross P	urchase		Net Purchase						
Executive		\$	# 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					
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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		
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:

		Weighted Average							
		Weighted	Remaining						
		Average	Contractual Life	Aggregate					
	Shares	Exercise Price	In Years	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					

<sup>\*</sup> 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.

		Options Outstanding					Options Exercisable						
		Weighted Average		Veighted Average				Weighted Average		eighted verage			
Exercise	Number	Remaining	F	Exercise	Iı	ntrinsic	Number	Remaining	E	excise	Iı	ntrinsic	
Price Range	Outstanding	Contractual		Price		Value	Exercisable	Contractual		Price		Value	
\$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.

# 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<sup>TM</sup> 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.

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'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		Octo	October 31, 2015		ober 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				
	Octo	ber 31, 2016	October 31, 2015		
<u>Deferred Tax Assets</u>					
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	
<u>Deferred Tax Liabilities</u>					
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.

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
E_28				_

#### 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)		
diffuted	(0.39	) (0.43)	(0.40)	(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	(0.27	(0.15)	(0.20)	(0.17)		
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.

Exhibit No. 10.57

CONFIDENTIAL EXECUTION COPY

#### LICENSE AND COLLABORATION AGREEMENT

THIS LICENSE AND COLLABORATION AGREEMENT (the "Agreement") is entered into as of August 1, 2016 (the "Effective Date"), by and between ADVAXIS, INC., a corporation organized under the laws of the State of Delaware ("Advaxis"), having an address of 305 College Road East, Princeton, New Jersey 08540, and AMGEN INC., a corporation organized under the laws of the State of Delaware ("Amgen"), having an address of One Amgen Center Drive, Thousand Oaks, California 91320.

#### Recitals

Whereas, Advaxis has developed the Program and possesses rights to certain patents and other intellectual property related thereto;

Whereas, the parties hereto intend to enter into a collaboration for the development, manufacture and commercialization of Products, subject to the terms and conditions of this Agreement;

Whereas, Amgen desires to obtain from Advaxis, and Advaxis desires to grant to Amgen, an exclusive license to research, develop and commercialize Products, subject to the terms and conditions of this Agreement; and

Whereas, concurrently with the execution and delivery of this Agreement, the parties hereto are entering into a stock purchase agreement, dated as of the date of this Agreement, providing for the purchase by Amgen of common stock of Advaxis.

# Agreement

**Now, Therefore**, in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Advaxis and Amgen hereby agree as follows:

# 1. **DEFINITIONS**

- 1.1 "Advaxis Background Patents" means any and all Patents that Advaxis or any of its Affiliates Controls that Covers Advaxis Know-How, excluding Advaxis Invention Patents. Advaxis Background Patents include such patents as identified on Schedule 1.1.
- 1.2 "Advaxis Invention" means any Invention invented solely by Advaxis or its Affiliates or by any of their employees or contractors.

- 1.3 "Advaxis Invention Patent" means a Patent Controlled by Advaxis or its Affiliates that arises from the performance of the activities under this Agreement and Covers an Advaxis Invention.
- **1.4 "Advaxis Know-How"** means all Know-How that Advaxis or any of its Affiliates Controls as of the Effective Date or during the Early Development Term and that (x) is reasonably necessary or useful to research, develop, make, have made, use, export, sell and offer for sale or otherwise exploit Products in the Field in the Territory, (y) was used by Advaxis and its Affiliates in its research and development of the Program prior to the Effective Date, or (z) that is used by Advaxis or its Affiliates to perform the Early Development Plan on or after the Effective Date, excluding Advaxis Inventions.
  - 1.5 "Advaxis Patents" means all Advaxis Invention Patents and Advaxis Background Patents, as applicable.
  - 1.6 "Advaxis Technology" means the Advaxis Know-How, Advaxis Inventions and Advaxis Patents.
- 1.7 "Affiliate" means, with respect to a given Person, any Person that, directly or indirectly, through one or more intermediaries, is controlled by, controls, or is under common control with such party, as the case may be, but for only so long as such control exists. As used in this Section 1.7, "control" shall mean direct or indirect beneficial ownership of more than 50% (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital or other equity or economic interest of a Person, or the power, whether pursuant to a contract, ownership of securities or otherwise, to direct the management and policies of a Person.
- 1.8 "Amgen Background Patents" means any and all Patents that Amgen or any of its Affiliates Controls as of the Effective Date or during the Early Development Term that (i) claim or Cover Amgen Know-How, or (ii) would be infringed by the performance of Advaxis' obligations hereunder, excluding Amgen Invention Patents.
- 1.9 "Amgen Invention" means any Invention invented solely by Amgen or its Affiliates or Sublicensees or by any of their employees or contractors.
- **1.10 "Amgen Invention Patent"** means a Patent Controlled by Amgen or its Affiliates that arises from the performance of the activities under this Agreement and Covers an Amgen Invention.
- 1.11 "Amgen Know-How" means all Know-How that Amgen or any of its Affiliates Controls as of the Effective Date or during the Early Development Term (subject to Section 14.6), excluding Amgen Inventions, which Know-How (i) is disclosed by Amgen to Advaxis, in Amgen's sole discretion and is reasonably necessary or useful for Advaxis to perform the obligations and other activities set forth in the Early Development Plan, or (ii) is used by Amgen or its Affiliates, in research and development of the Program on or after the Effective Date.
  - 1.12 "Amgen Patents" means all Amgen Background Patents and Amgen Invention Patents.

- 1.13 "Amgen Senior Executive" means an executive of Amgen with a title of Senior Vice President or Executive Vice President.
- 1.14 "Amgen Technology" means the Amgen Know-How, Amgen Inventions and the Amgen Patents.
- 1.15 "Ancillary Agreement" means any Supply Agreement, Quality Agreement or Pharmacovigilance Agreement.
- **1.16 "BLA Filing Date"** means the date of the filing of a Biologic Licensing Application, including all supplements and amendments thereto, for the approval to market a Product by the FDA.
- 1.17 "Blocking Patents" means as to a Product, any Patent rights of a Third Party that claim, in a particular country, the composition or use of such Product, and which such Patent rights would be infringed by the manufacture, use, offer for sale, sale, import or export of such Product in such country.
- **1.18 "Calendar Quarter"** means each respective period of three consecutive months ending on March 31, June 30, September 30, and December 31.
  - 1.19 "Calendar Year" means each respective period of 12 consecutive months ending on December 31.
- 1.20 "Change of Control" means with respect to a specified party: (a) the acquisition, directly or indirectly, by a Person or "group" (whether in a single transaction or multiple transactions) of more than 50% of the voting power of such party or of beneficial ownership of (or the right to acquire such beneficial ownership) of more than 50% of the outstanding equity or convertible securities of such party (including by tender offer or exchange offer); (b) any merger, consolidation, share exchange, business combination, recapitalization, the sale of substantially all assets of, or similar corporate transaction involving such party (whether or not including one or more wholly owned subsidiaries of such party), other than: (i) transactions involving solely such party and one of more Affiliates, on the one hand, and one or more of such party's Affiliates, on the other hand, and/or (ii) transactions in which the stockholders of such party immediately prior to such transaction hold at least 50% of the voting power of the surviving company or ultimate parent company of the surviving company; or (c) the adoption of a plan relating to the liquidation or dissolution of such party. For purposes of this definition, the terms "group" and "beneficial ownership" shall have the meaning accorded in the U.S. Securities Exchange Act of 1934 and the regulations promulgated thereunder in effect as of the Effective Date.
  - 1.21 "Combination Product" means a Product sold in combination with other pharmaceutical products.
- 1.22 "Commercially Reasonable Efforts" means, with respect to a party and an obligation to conduct a particular activity pertaining to the research, development or commercialization obligations hereunder, that level of efforts and resources reasonably required to carry out such obligation consistent with the efforts commonly used by a similarly situated company in the biopharmaceutical industry with respect to a biopharmaceutical product which is of similar market potential and at a similar stage in its development or product life, and other relevant factors such as efficacy, safety, approved labeling, the competitiveness of alternative products in the marketplace, the patent and other proprietary position of the product, the likelihood of Regulatory Approval given the regulatory structure involved, profitability and other technical, legal, scientific or medical factors. Without limiting the foregoing, Commercially Reasonable Efforts requires, with respect to such obligations, that the party: promptly assign responsibility for such obligation to specific employee(s) or management team, which employees or team are responsible for progress and monitor such progress on an on-going basis, set annual objectives for carrying out such obligations, and allocate resources designed to advance progress with respect to such objectives. Notwithstanding the foregoing, to the extent that the performance of a party's obligations hereunder is impaired by the other party's failure to perform its obligations hereunder, the determination of whether such first party has used Commercially Reasonable Efforts in performing a given obligation will be determined in the context of such other party's failure.

- **1.23 "Confidential Information**", of a party, means confidential or proprietary information, whether written, oral or in any other form, disclosed by such party to the other party, including any of the foregoing of Third Parties. "Confidential Information" shall also include information exchanged prior to the date hereof by either party pursuant to the Nondisclosure Agreement. "Confidential Information" includes the following, which are transferred, disclosed or made available by the disclosing party:
  - (a) confidential and proprietary technical and commercial information, Know-How, drawings, specifications, models and/or designs relating to development, manufacture, production, registration, promotion, distribution, marketing, performance or sale(s);
  - (b) experimental, manufacturing, process, analytical, packaging, product, warehousing, quality control and quality assurance and marketing specifications, standards, procedures, processes, methods, instructions and techniques, samples, prototypes, formulae, writings of any kind, opinions or otherwise unwritten data or in the form of computer software or computer programs;
  - (c) biological, chemical or physical materials provided under this Agreement;
  - (d) reports provided under this Agreement; and
  - (e) subject to Section 11.5, the terms of this Agreement, including correspondence and notices provided under this Agreement.

1.24 "Control" or "Controlled" means, with respect to any Know-How, Patent or other intellectual property right, the legal authority or right (whether by ownership, license or otherwise but without taking into account any rights granted by one party to the other party under the terms of this Agreement) of a party or its Affiliates to grant access, a license or a sublicense of or under such Know-How, Patent or other intellectual property rights to another party hereto, or to otherwise disclose proprietary or trade secret information to such other party, without (i) breaching the terms of any agreement with a Third Party, or misappropriating the proprietary or trade secret information of a Third Party, in each case in existence as of the time such party or its Affiliates would first be required hereunder to grant the other party such access, license or sublicense, or (ii) requiring any payment (whether or not then due and payable) with respect to the grant or exercise of such access, license or sublicense under any agreement with any Third Party in place as of the time such party would first be required hereunder to grant such access and license or sublicense (unless the other party agrees in writing to be responsible for such payments).

- 1.25 "Cover" means, with respect to a product and a Patent, that, in the absence of a (sub)license under, or ownership of, such Patent, the making, using, importing, offering for sale, selling or exporting of such product with respect to a given country would infringe a Valid Claim of such Patent, or with respect to a patent application, any claim of such patent application as if it were contained in an issued patent. Cognates of the word "Cover" or "cover" shall have correlative meanings.
- 1.26 "Early Development Plan" means the development plan to be conducted by the parties during the Early Development Term, which shall include the development budget during the Early Development Term, as promptly approved by the JSC following the Effective Date, and as such plan may be periodically reviewed by the JSC (as may be requested by any party) and amended by the JSC pursuant to Section 2.3.
- **1.27 "Early Development Term"** means the period from the Effective Date until the POC Date, unless this Agreement is terminated earlier in accordance with Article 11.
  - 1.28 "FDA" means the U.S. Food and Drug Administration, or any successor agency thereto.
  - 1.29 "Field" means any and all uses.
- **1.30 "First Commercial Sale"** means, on a Product-by-Product and country-by-country basis, the first sale of such Product by Amgen or any of its Affiliates or Sublicensees to a Third Party for end use or consumption in such country after Regulatory Approval has been granted with respect to such Product in such country; provided, that "First Commercial Sale" shall not include any sale (i) by Amgen to an Affiliate or Sublicensee, or (ii) sale, disposal or use of a Product for marketing, regulatory, development or charitable purposes, such as clinical trials, pre-clinical trials, compassionate use, named patient use, or indigent patient programs, without consideration.
- **1.31 "GAAP"** means the then current generally accepted accounting principles in the United States as established by the Financial Accounting Standards Board or any successor entity or other entity generally recognized as having the right to establish such principles in the United States, in each case consistently applied.
- **1.32 "GCP"** means the then-current good clinical practices officially published by the FDA and under the ICH, and comparable regulatory standards in jurisdictions outside the U.S., that may be in effect from time to time.

- **1.33 "GLP"** means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, and comparable regulatory standards in jurisdictions outside the U.S., that may be in effect from time to time.
- 1.34 "GMP" means then-current good manufacturing practices required by the FDA, as set forth in the U.S. Federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated thereunder, for the manufacture and testing of biopharmaceutical materials, and comparable laws or regulations applicable to the manufacture and testing of biopharmaceutical materials in jurisdictions outside the U.S., that may be in effect from time to time. For clarity, GMP shall include applicable quality guidelines promulgated under the ICH.
- **1.35 "ICH"** means the International Conference on Harmonization (of Technical Requirements for Registration of Pharmaceuticals for Human Use).
- **1.36 "IND**" means an investigational new drug application filed with the applicable Regulatory Authority, which application is required to commence human clinical trials in the applicable country.
  - 1.37 "Initiation", with respect to a clinical trial, means the first dosing of a subject in such clinical trial.
- 1.38 "Inventions" means all inventions, whether or not patentable, that are invented in the course of performing activities under this Agreement.
- **1.39 "Joint Invention"** means any Invention invented, jointly by, on the one hand, Amgen or its Affiliates or Sublicensees or by any of their employees or contractors, and, on the other hand, Advaxis or its Affiliates or by any of their employees or contractors, in the course of performing activities under this Agreement.
- **1.40 "Joint Invention Patent"** means any Patent for a Joint Invention, which Patent arises from the performance of the activities under this Agreement and Covers such Joint Invention.
- 1.41 "Know-How" means all techniques, technology, trade secrets, inventions (whether patentable or not), methods, processes, know-how, data and results (including all research data, clinical pharmacology data, chemistry-manufacture-controls data (including analytical and quality control data and stability data), pre-clinical data and clinical data), regulatory documents and filings, and all other scientific, clinical, regulatory, manufacturing, marketing, financial and commercial information.
- **1.42 "Lm-LLO Technology"** means technology utilizing live attenuated Listeria monocytogenes bioengineered to secrete antigen/adjuvant fusion proteins.
- **1.43 "Materials"** means any materials that are required for, or as an input to, the production or administration of a Product, including any active and inactive components thereto.
- **1.44 "MSKCC Agreement"** means the Collaborative Research Agreement, dated as of October 5, 2015, by and between Memorial Sloan Kettering Cancer Center and Advaxis.

1.45 "Net Sales" means, with respect to the sale of a unit of Product, the gross amounts invoiced by Amgen or any of its Affiliates or Sublicensees to Third Parties for sales of such Product, less the following deductions actually incurred, allowed, paid, accrued or otherwise specifically allocated to the sale of such unit of Product by Amgen or any of its Affiliates or Sublicensees using GAAP applied on a consistent basis:

- (a) credits or allowances actually granted for defective or damaged Product, returns or rejections of Product (including allowances for spoiled, outdated, or withdrawn Product), price adjustments and billing errors;
- (b) governmental and other rebates, refunds and chargebacks (or equivalents thereof) granted to managed health care organizations, pharmacy benefit managers (or equivalents thereof), federal, state, provincial, local and other governments, their agencies and purchasers and reimbursers or to trade customers;
- (c) normal and customary trade, cash, prompt payment and/or and quantity discounts, allowances and credits actually allowed or paid and mandated discounts;
- (d) sales taxes, VAT taxes, excise taxes, use taxes and other taxes and duties paid in relation to such Product and any other equivalent governmental charges imposed upon the importation, use or sale of Product;
- (e) reasonable fees paid to wholesalers, distributors, selling agents (excluding any sales representatives of Amgen or any of its Affiliates or Sublicensees), group purchasing organizations, Third Party payors, other contractees and managed care entities, in each case with respect to such Product;
- (f) 2% of gross sales to cover items such as bad debt, freight or other transportation charges, insurance charges, additional special packaging and other governmental charges; and
- (g) retroactive price reductions actually granted to the Third Party applicable to sales of such Product.

Net Sales shall not include sales to Affiliates, Sublicensees or contractors engaged by Amgen to develop, promote, co-promote, market, sell or otherwise distribute Product, solely to the extent that such Affiliate, Sublicensees or contractor purchasing the Product will resell such Product to a Third Party. However, subsequent sales of Product by such Amgen Affiliates, Sublicensees or contractors to a Third Party shall be included in the Net Sales when sold in the market for end-user use. For the avoidance of doubt, sales of a Product at or below Amgen's actual cost of goods for such Product for use in conducting clinical trials of such Product in a country in order to obtain the Regulatory Approval of such Product in such country shall be excluded from Net Sales calculations for all purposes. Also, notwithstanding anything to the contrary above, sales of a Product at or below Amgen's actual cost of goods for such Product for any compassionate use or named patient sales shall be excluded from Net Sales calculations.

In no event shall any particular amount identified above be deducted more than once in calculating Net Sales (i.e., no "double counting" of reductions).

In the event that Product is sold as part of a financial bundle with other products or included in financial package deals to customers and in such case, the price of Product relevant for the calculation of Net Sales will be the average invoiced sales price of Product in the preceding Calendar Quarter sold separately less the average discount of all products sold as part of such bundle or package.

For Net Sales of a Combination Product, the Net Sales applicable to such Combination Product in a country will be determined by multiplying the total Net Sales of such combined product by the fraction A/(A+B), where A is the actual price of the Product that is included in such Combination Product in the same dosage amount or quantities in the applicable country during the applicable quarter if sold separately, and B is the sum of the actual prices of all other products with which such Product is combined in such Combination Product, in the same dosage amount or quantities in the applicable country during the applicable quarter if sold separately. If A or B cannot be determined because values for such Product or such other products with which such Product is combined are not available separately in a particular country, then the parties shall discuss an appropriate allocation for the fair market value of such Product and such other products with which such Product is combined to mutually determine Net Sales for the relevant transactions based on an equitable method of determining the same that takes into account, in the Territory, variations in potency, the relative contribution of each therapeutically active ingredient, and relative value to the end user of each therapeutically active ingredient.

- **1.46 "Nondisclosure Agreement"** means the confidential disclosure agreement between the parties dated as of April 27, 2015, as amended and including all subsequent addendums.
- 1.47 "Patents" means (i) all patents, priority patent filings and patent applications, and (ii) any renewal, divisional, continuation (in whole or in part), or request for continued examination of any of such patents, and patent applications, and any and all patents or certificates of invention issuing thereon, and any and all reissues, reviews, reexaminations, extensions, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.
- **1.48 "Person"** means any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, any other entity or body, or an individual.
- 1.49 "Phase 1 Clinical Trial" means a study in humans, conducted in normal volunteers or patients to generate information on product safety, tolerability, pharmacological activity or pharmacokinetics, as more fully defined in 21 CFR §312.21(a) or comparable regulations in any country or jurisdiction outside the U.S., and any amended or successor regulations.
- **1.50 "Phase 2 Clinical Trial"** means a study in humans for which a primary endpoint is a preliminary determination of efficacy in patients with the disease being studied, as more fully defined in 21 CFR §312.21(b) or comparable regulations in any country or jurisdiction outside the U.S., and any amended or successor regulations.

- 1.51 "Phase 2 Package" means, with respect to any Phase 2 Clinical Trial, (a) the final study report from such Phase 2 Clinical Trial, including completed case report forms, as and to the extent available, for all patients who participated in the Phase 2 Clinical Trial, and (b) the status of and reasonable access to available results and data of all ongoing studies (including preclinical and clinical) with respect to the Product. For purposes of this definition, the study report shall be deemed "final" at such time as such report is in the form that will be filed with the FDA.
- 1.52 "Phase 3 Clinical Trial" means a controlled study in humans that is performed after preliminary evidence suggesting effectiveness of a product has been obtained, and is intended to demonstrate or confirm the therapeutic benefit of such product and to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of such product and to provide support for filing for Regulatory Approval and for such product's labeling and summary of product characteristics, as more fully defined in 21 CFR §312.21(c) or comparable regulations in any country or jurisdiction outside the U.S., and any amended or successor regulations.
- **1.53 "Program"** means the ADXS-NEO immunotherapy technology platform, as further described in Schedule 1.53 and as may be further developed in accordance with the terms hereof.
- **1.54 "Product"** means any product, treatment or therapy that was produced through the Program, or any modified or optimized version thereof, in any dosage form or formulation, to treat a specific indication.
- **1.55 "Prosecution and Maintenance"** (including variations such as "Prosecute and Maintain") means, with respect to a Patent, the preparing, filing, prosecuting and maintenance of such Patent, in any jurisdiction, as well as re-examinations, reviews, reissues and the like with respect to such Patent, together with the conduct of interferences, the defense of oppositions, post-grant reviews, inter partes reviews and other similar proceedings with respect to a Patent.
- **1.56 "Public Official or Entity"** means (i) any officer, employee (including physicians, hospital administrators, or other healthcare professionals), agent, representative, department, agency, de facto official, representative, corporate entity, instrumentality or subdivision of any government, military or international organization, including any ministry or department of health or any state-owned or affiliated company or hospital, or (ii) any candidate for political office, any political party or any official of a political party.
- 1.57 "Regulatory Approval" means any and all approvals, licenses, registrations, or authorizations of any country, federal, supranational, state or local regulatory agency, department, bureau or other government entity that are necessary for the development, manufacture, use, storage, import, transport, distribution, commercialization and sale of a Product in a given jurisdiction, including any pricing approvals deemed necessary by Amgen.

- **1.58 "Regulatory Authority**" means any international, national, provincial, local or, in respect of any other political subdivision, regulatory agency, department, bureau, court or other government entity or instrumentality, that has responsibility in its applicable jurisdiction over the research, development, manufacture, distribution, and commercialization of Products.
- **1.59 "Regulatory Filing"** means any all (a) submissions, material correspondence, notifications, registrations, licenses, authorizations, applications and other filings with any Regulatory Authority with respect to the research, development, manufacture, distribution, pricing, reimbursement, marketing or sale of the Products, and (b) Regulatory Approvals for the Products.
- **1.60 "RACI Document"** means the document jointly developed and agreed in writing by the parties on the Effective Date setting forth certain operational responsibilities of each Party with respect to Development, Manufacturing, Commercialization and other Product-related activities, as the same may updated by the JSC from time to time.
- **1.61 "Royalty Term"** means, on a Product-by-Product and country-by-country basis, the period of time commencing on the First Commercial Sale of such Product in such country and ending at the later of (i) \* after the date of the First Commercial Sale of such Product in such country and (ii) the date on which the manufacture, use or sale of such Product is no longer covered by a Valid Claim of an Advaxis Patent or Joint Invention Patent in such country.
  - **1.62 "Safety Databases"** means the global safety databases related to the Regulatory Filings.
  - 1.63 "SEC" means the U.S. Securities and Exchange Commission or any successor entity.
- 1.64 "Sublicensee" means a Third Party that is granted a license or sublicense to develop, make, have made, use, market, import, offer for sale or sell any Product, beyond the mere right to purchase Product from Amgen and its Affiliates, and shall not include Amgen's Affiliates or Third Party subcontractors acting solely for Amgen or its Affiliates in the supply chain or that perform discrete services (as opposed to being granted or delegated broad rights or responsibilities) on behalf of Amgen or its Affiliates. In no event shall Advaxis or any of its Affiliates be deemed a Sublicensee.
- **1.65 "Substitute Product"** means, with respect to a given Product in a given country, any other product, treatment or therapy designated for human use that contains or utilizes the Lm-LLO Technology for neoepitope-based personalized immunotherapy for an indication in which such Product has received Regulatory Approval.
  - **1.66 "Territory"** means the entire world.
  - 1.67 "Third Party" means a Person other than Advaxis or Amgen, or an Affiliate of Advaxis or Amgen.

<sup>\*</sup> Confidential material redacted and filed separately with the Commission.

1.68 "U.S." means the United States of America, including its territories and the District of Columbia.

1.69 "Valid Claim" means a claim of any issued and unexpired patent or patent application within the Advaxis Patents or Joint Invention Patents, as applicable, that has not been held invalid or unenforceable by a final decision of a court or governmental agency of competent jurisdiction, which decision can no longer be appealed or was not appealed within the time allowed; provided, however, that if a claim of a pending patent application within the Advaxis Patents or Joint Invention Patents shall not have issued within seven years after the earliest filing date from which such claim takes priority, such claim shall not constitute a Valid Claim for the purposes of this Agreement unless and until a Patent right issues with such claim (from and after which time the same would be deemed a Valid Claim).

1.70 Additional Definitions. The following terms have the meanings set forth in the corresponding Sections of this Agreement:

Term	Section
Advaxis	Preamble
Advaxis Indemnitee	13.2
Agreement	Preamble
Alliance Manager	2.1(b)
Amgen	Preamble
Amgen Indemnitee	13.1
Annual Cap	4.1(a)
DCSI	4.2(b)
Dispute Claim	14.1
DSUR	4.2(b)
Effective Date	Preamble
Infringement	9.4(a)
JSC	2.1(a)
Losses	13.1
Milestone	7.2(a)
Milestone Payment	7.2(a)
Non-Publishing Party	11.4
Pharmacovigilance Agreement	4.2(f)
POC Date	3.2
POC Notice	3.2
Publishing Party	11.4
Quality Agreement	4.2(f)
Quality Agreement Term Sheet	4.2(f)
Regulatory Filing Transfer Date	4.2(a)
Regulatory Lead	4.2(c)
Sale Transaction	14.5(a)
Supply Agreement	4.3(c)
Supply Agreement Term Sheet	4.3(c)
Technology Transfer	4.3(c)
Term	12.1
Third Party Patent	7.3(b)
VAT	8.3(c)

#### 2. GOVERNANCE

#### 2.1 Committee Formation.

- (a) Promptly after the Effective Date, the parties will establish a joint steering committee (the "JSC") to oversee the collaboration as described herein. The JSC will be comprised of six total representatives, three of which shall be appointed by each of Advaxis and Amgen, respectively, and each of whom shall be employees of the applicable appointing party. Each party will notify the other party of its initial JSC members within 30 days after the Effective Date. The parties, through the mutual agreement of their representatives to the JSC, may change the number of JSC representatives as long as there are an equal number of representatives of each of Advaxis and Amgen respectively on the JSC. Each party may change its JSC representatives at any time by written notice to the other party. Any representative of the JSC may designate a substitute to attend and perform the functions of that representative at any meeting of the JSC. Amgen shall appoint one of its JSC representatives as chairperson of the JSC, whose sole role as chairperson shall be to convene and preside at meetings of the JSC. Each party may invite a reasonable number of non-voting representatives of such party to attend meetings of the JSC. The JSC in its discretion may create functional subcommittees or working teams. Neither party shall invite a Third Party to attend without the prior consent of the other party, which consent shall not be unreasonably withheld, conditioned, or delayed.
- (b) Within 30 days of the Effective Date, each party shall appoint a representative ("Alliance Manager") who possesses a general understanding of development, regulatory, manufacturing and commercialization matters to facilitate communications between the parties and to act as a liaison between the parties. Each party may replace its Alliance Manager at any time upon notice to the other party. Each Alliance Manager shall be charged with (i) creating and maintaining a collaborative work environment within and among the JSC and subcommittees thereof, (ii) providing a single point of communication for seeking consensus both within the respective parties' organizations and together regarding key strategy and plan issues and (iii) planning and coordinating internal and external communications in accordance with the terms of this Agreement. The Alliance Managers shall be entitled to attend all JSC meetings and each Alliance Manager may bring any matter to the attention of the JSC where such Alliance Manager reasonably believes that such matter requires the attention of the JSC.
- **2.2 Committee Meetings.** The JSC will hold meetings once each Calendar Quarter, or as otherwise agreed to by the parties. Such meetings may be conducted by videoconference, teleconference or in person, as agreed to by the parties; provided, that no less than one meeting of the JSC each Calendar Year shall be in person (alternating between meeting at Advaxis' facilities and at Amgen's facilities), unless otherwise agreed to by the parties. Minutes will be kept of all JSC meetings and will reflect material decisions made at such meetings. Meeting minutes will be prepared by the parties on a rotating basis and sent to each member of the JSC for review and approval promptly following each meeting. Minutes will be deemed approved unless a member of the JSC objects to the accuracy of such minutes within 30 days of receipt. Any costs and expenses incurred by a party or its representatives related to a JSC meeting, including, if applicable, travel or telecommunication expenses, shall be borne by such party.

- 2.3 Committee Authority. The JSC shall be responsible for review and oversight of the parties' collaboration activities, as further described herein. Without limiting the foregoing, the JSC shall (1) be a forum for the parties' review and discussion of, and facilitate the exchange of information and analysis relating to, collaboration activities described herein, (2) attempt to resolve issues presented to it by, and disputes within, any functional subcommittees or working teams, and (3) monitor the parties' activities under this Agreement pursuant to any plans or strategies approved by the JSC and the RACI Document, (4) review and approve any amendment to the RACI Document, and (5) have such other responsibilities as expressly delegated to it under the Agreement or as mutually agreed upon by the parties in writing on a case-by-case basis. In addition, the JSC shall:
  - (a) During the Early Development Term:
- (i) review and approve the Early Development Plan, all clinical research plans (including any protocols therein), all biomarker plans and all regulatory plans, in each case, including any amendments thereto;
  - (ii) facilitate the sharing of expertise regarding CMC and process development;
- (iii) review and approve any PR, global medical communication, marketing or commercial strategies or other long range strategic plans; and
  - (iv) review and approve selection of manufacturing sites and contract manufacturers.
  - (b) Following the Early Development Term:
    - (i) review and approve the commercial supply price for Materials and any supply forecast for Materials; and
- (ii) facilitate any discussion of a potential transfer of Material manufacturing to Amgen or a Third Party

The JSC shall only have such powers as are specifically assigned to it in this Agreement, and such powers shall be subject to the terms and conditions set forth herein. Without limiting the generality of the foregoing, the JSC shall have no power to amend this Agreement, and no decision of the JSC shall be in contravention of any terms and conditions of this Agreement.

2.4 Committee Decision-Making. Decisions of the JSC with respect to matters within the decision-making authority of the JSC shall be made by unanimous vote, with Advaxis' representatives on the JSC collectively having one vote and Amgen's representatives on the JSC collectively having one vote. At each JSC meeting, at least one member appointed by each party present at the meeting shall constitute a quorum. If the JSC fails to reach unanimous agreement on a matter before it for decision for a period in excess of 30 days, then either party may refer the matter to the appropriate Amgen Senior Executive and the Chief Executive Officer, for Advaxis. Such executives shall endeavor to meet promptly to discuss the matter. In the event that such executives are unable to reach agreement regarding any matter referred to them within 30 days of such referral, and provided that Amgen's executive has used good faith efforts to reach a mutually satisfactory resolution, then Amgen shall decide such matter; provided, however, that Amgen shall not have the power to resolve such a matter (a) in a manner that would require Advaxis to perform additional activities or incur material expenses not contemplated by this Agreement or the Early Development Plan (as the Early Development Plan is initially agreed to by both parties pursuant to Section 4.7 below or as it was last amended with Advaxis' consent); or (b) with the effect of reducing or delaying payments to Advaxis in contravention of Article 7 of this Agreement.

**2.5 Dissolution.** The JSC shall dissolve and cease to exist upon the fifth anniversary of the date of Regulatory Approval of a Product in the U.S. or as otherwise agreed by the parties.

#### 3. PROOF OF CONCEPT

- **3.1 Diligence.** As promptly as practicable but no later than sixty (60) days following database lock of the first Phase 2 Clinical Trial of a Product, Advaxis shall provide to Amgen a top-line summary of data and results from such Phase 2 Clinical Trial. In addition, as promptly as practicable following completion of such Phase 2 Clinical Trial and, in any event, no later than one hundred twenty (120) days following database lock of such Phase 2 Clinical Trial, Advaxis shall prepare and deliver to Amgen the Phase 2 Package and, for a period of ninety (90) days after delivery of the Phase 2 Package, respond in good faith to Amgen's reasonable questions related to (a) the data and results delivered in the Phase 2 Package, and (b) any other aspects of the Products or the Program (including CMC or other matters relating to the manufacturing of Products).
- 3.2 Proof of Concept. At any time following Advaxis' delivery to Amgen of the Phase 2 Package as described in Section 3.1, Amgen may elect, in its sole discretion, to deliver to Advaxis written notice stating that proof-of-concept has been established (such written notice, the "POC Notice" and the date of such written notice, the "POC Date"). Promptly following the POC Date, the parties (through their respective members on the JSC) shall meet, develop a plan for and manage the orderly transition of roles and responsibilities and other activities as contemplated in this Agreement and, to the extent necessary or useful (as determined by the JSC), the transfer to Amgen of Advaxis Know-How ("Technology Transfer").
- **3.3** Advaxis Negotiation Right. In the event that, following Advaxis' delivery to Amgen of the Phase 2 Package as described in Section 3.1, either (a) Amgen delivers a written notice to Advaxis confirming its view that proof-of-concept has not been established, or (b) Amgen fails to deliver to Advaxis the POC Notice within three (3) months following the date of Advaxis' delivery to Amgen of the Phase 2 Package, in each such case, Advaxis shall be entitled to deliver to Amgen a notice of its intention to negotiate a prompt termination of this Agreement. Following delivery of such notice, Advaxis and Amgen shall promptly negotiate in good faith an agreement \*, which agreement shall provide for \*.

**3.4 MSKCC Agreement.** If and when requested by Amgen, Advaxis shall use best efforts to \* of the MSKCC Agreement, and to obtain from \*.

# 4. DEVELOPMENT, REGULATORY, MANUFACTURING AND COMMERCIALIZATION MATTERS

# 4.1 Development Matters.

- (a) Advaxis Responsibilities during the Early Development Term.
- (i) During the Early Development Term, subject to the authority of the JSC as described in Section 2.3, Advaxis shall have primary responsibility for overseeing all development activities for the Products (including sponsorship and conduct of any Phase 1 Clinical Trial or Phase 2 Clinical Trial of Products). Notwithstanding the foregoing, Advaxis shall consult with, and consider in good faith any input provided by, Amgen regarding any material plans or decisions regarding the development of Products during the Early Development Term.
- (ii) Furthermore, for each of Calendar Years 2017 and 2018, Advaxis shall be responsible for all out-of-pocket costs incurred by Advaxis for the sponsorship and conduct of any Phase 1 Clinical Trial or Phase 2 Clinical Trial of Products, solely to the extent that such costs exceed the Annual Cap (as defined below) during any Calendar Year, unless otherwise agreed in writing by the parties. During the Early Development Term, Advaxis shall monitor such out-of-pocket costs no less frequently than on a quarterly basis and shall promptly notify Amgen if such out-of-pocket costs for a given fiscal year are reasonably expected to be greater than the lesser of either (x) \*% or (y) \$\* more than as set forth in the development budget contained in the then-current Early Development Plan (such lesser amount, the "Annual Cap"); and Amgen shall not have any obligation to pay for any additional costs in excess of the lesser of the amount referenced in clause (x) or (y). Within 60 days following the end of each Calendar Quarter during the Early Development Term, Advaxis shall invoice Amgen for the amount due pursuant to Section 4.1(b) (subject to this clause (ii) of Section 4.1(a)) and, if requested by Amgen, shall provide to Amgen reasonable documentation evidencing such incurred costs.
  - (b) Amgen Responsibilities during the Early Development Term.
- (i) During the Early Development Term, Amgen shall provide Advaxis with strategic input for the development of such Products and operational support with respect to such development as expressly set forth in the Early Development Plan or as otherwise contemplated hereunder.
- (ii) During the Early Development Term, Amgen shall be responsible for all out-of-pocket costs incurred by Advaxis for the sponsorship and conduct of any Phase 1 Clinical Trial or Phase 2 Clinical Trial of Products; provided, however, that Amgen shall not be responsible for any such costs in an aggregate amount in excess of the Annual Cap during any Calendar Year.

<sup>\*</sup> Confidential material redacted and filed separately with the Commission.

- (c) Advaxis Responsibilities following the Early Development Term. Following the Early Development Term, Advaxis shall provide Amgen with strategic input for the development of such Products and operational support with respect to such development as may be agreed upon in writing by the parties or as otherwise contemplated hereunder.
- (d) Amgen Responsibilities following the Early Development Term. Following the Early Development Term, Amgen shall have primary responsibility for overseeing all development activities for the Products (including sponsorship and conduct of any Phase 3 Clinical Trial of Products). Notwithstanding the foregoing, Amgen shall consult with, and consider in good faith any input provided by, Advaxis regarding any material plans or decisions regarding the development of Products following the Early Development Term. Following the Early Development Term, Amgen shall bear all costs associated with development activities relating to Products.

### 4.2 Regulatory Matters.

- (a) Transfer of Regulatory Filing and Safety Databases. As promptly as practicable, but no later than ninety (90) days, after the POC Date, or as otherwise agreed by the parties, Advaxis shall transfer and assign to Amgen any Regulatory Filings controlled by Advaxis for the Products and the Safety Databases (such date of transfer and assignment, the "Regulatory Filing Transfer Date"). From and after the Regulatory Filing Transfer Date, Amgen (or its designee) shall file and hold title to Regulatory Filings relating to the Products. From and after the Regulatory Filing Transfer Date, as between the parties, Amgen will be responsible for preparing, filing and maintaining, and will own, all Regulatory Filings and related submissions with respect to the Products and will bear the cost of such preparation, filing, maintenance and ownership, provided, however, that, if requested by Amgen, Advaxis shall provide reasonable assistance with the foregoing.
- (b) Safety Matters. At all times prior to the POC Date, Advaxis shall retain responsibility for maintaining the Safety Databases, developmental core safety information ("DCSI"), and core data sheet (if any). Advaxis also shall retain all expedited and periodic regulatory reporting responsibilities for the Products, including but not limited to producing and submitting the Products' Development Safety Update Reports and any regional equivalents, according to applicable law (each, a "DSUR"). Advaxis shall provide Amgen with the opportunity to review and comment on each new version of the DCSI, core data sheet, and DSUR prior to finalization and/or submission to a Regulatory Authority, and shall consider Amgen's comments in good faith. Following the POC Date, the parties shall work in good faith to agree on a reasonable and orderly transition of such responsibilities from Advaxis to Amgen until such time as they have executed the Pharmacovigilance Agreement described in Section 3.1(f).
- (c) Advaxis Responsibilities. From the Effective Date until the Regulatory Filing Transfer Date, subject to the authority of the JSC as described in Section 2.3, Advaxis shall have primary responsibility for overseeing the preparation, submission and maintenance of, and shall own, all Regulatory Filings with respect to the Products (such role, the "Regulatory Lead"). Notwithstanding the foregoing, during such period, Advaxis shall consult with, and consider in good faith any input provided by, Amgen regarding any material decisions regarding Regulatory Filings of Products.

- (d) Amgen Responsibilities. Following the Regulatory Filing Transfer Date, Amgen shall be the Regulatory Lead. Notwithstanding the foregoing, Amgen shall consult with, and consider in good faith any input provided by, Advaxis regarding any material plans or decisions regarding Regulatory Filings of Products.
- (e) Regulatory Meetings and Communications. From the Effective Date until the date of the receipt of Regulatory Approval for a Product in the U.S., the following provisions shall apply:
- (i) The applicable Regulatory Lead shall consult with the other party reasonably in advance of the date of any anticipated meeting with a Regulatory Authority and shall consider any timely recommendations made by such other party in preparation for such meeting. Up to three (3) representatives of such other party, in each case, with appropriate subject matter expertise, may attend scheduled meetings between the Regulatory Lead and the applicable Regulatory Authority with respect to any Product, to the extent permissible by such Regulatory Authority. The Regulatory Lead shall (x) inform the other party of any unscheduled teleconferences and meetings (other than teleconferences and meetings that are solely administrative in nature) with Regulatory Authorities with respect to any Product reasonably promptly after they occur and (y) promptly notify the other party of, and provide a copy of (or, in the case of oral correspondence or communication, a reasonably detailed summary of), any material correspondence or other communication from any Regulatory Authority relating to any Product.
- (ii) Unless exigent action is required with respect to such Regulatory Filing or a material communication with a Regulatory Authority with respect to a given Product or unless otherwise determined by the JSC, the Regulatory Lead shall provide the other party with copies of all material Regulatory Filings (which, for clarity, shall not be required to include communications that are solely administrative in nature) prior to submission within a reasonable amount of time and reasonably consider comments of such other party (but in the event of a disagreement between the parties with respect to such comments and proposed revisions, such matter shall be escalated to the JSC for review). The Regulatory Lead shall consult with the other party regarding, and keep the other party informed of, the status of the preparation of all Regulatory Filings (which, for clarity, shall not be required to include communications that are solely administrative in nature) it submits, Regulatory Authority review of any such Regulatory Filings, and all Regulatory Approvals that it obtains with respect to the applicable Product. The Regulatory Lead shall provide to the other party copies of all final Regulatory Filings it submits promptly after the submission.
- (f) Pharmacovigilance Agreement. Promptly following the POC Date, or as otherwise required by applicable law, at the request of either party, the parties agree to negotiate in good faith a pharmacovigilance agreement governing the coordination of collection, investigation, reporting, and exchange of information concerning adverse events with respect to the applicable Product, sufficient to permit each party, its Affiliates and Sublicensees to comply with applicable law (the "Pharmacovigilance Agreement").

### 4.3 Manufacturing and Supply Matters.

- (a) Manufacturing Lead. Advaxis shall have primary responsibility (either by itself, or by the use of a Third Party contract manufacturer approved in writing by Amgen) for the manufacture and supply of Materials in accordance with the Supply Agreement and the Quality Agreement. Notwithstanding the foregoing, Advaxis shall regularly consult with, and consider in good faith any input provided by, Amgen regarding any material manufacturing or process development plans or decisions.
- (b) Clinical Supply. Notwithstanding anything in this Agreement to the contrary, Advaxis shall bear all costs associated with supplying any and all Materials that is required for all clinical trials contemplated in this Agreement.
- (c) Supply Agreement. Promptly following the POC Date, the parties shall negotiate in good faith a phase-appropriate clinical and commercial supply agreement (the "Supply Agreement") for the supply of Materials to Amgen following the POC Date consistent with the terms set forth on the supply agreement term sheet set forth on Schedule 4.3(c) (the "Supply Agreement Term Sheet"). The Supply Agreement shall provide for commercial supply of Materials by Advaxis, or a mutually agreed upon CMO (Contract Manufacturing Organization), on an at-cost basis (with such calculation to be determined pursuant to a reasonable, agreed-upon formula).
- (d) Quality Matters. Promptly following the POC Date, the parties shall negotiate in good faith a quality agreement (the "Quality Agreement"), with respect to the supply of Materials to Amgen as contemplated under the Supply Agreement, consistent with the terms set forth on the quality agreement term sheet set forth on Schedule 4.3(d) (the "Quality Agreement Term Sheet"). In the event that the JSC determines that Materials produced prior to the POC Date are reasonably likely to be supplied to Amgen for use after the POC Date, then, from the date of such determination until the earlier of (x) the execution of the Quality Agreement or (y) the termination of this Agreement in accordance with its terms, Amgen shall have the right to perform quality audits of Advaxis, or participate with Advaxis in its quality and/or facilities audit of its Third Parties utilized for sequencing, manufacturing, testing, disposition, storage, or transportation of Materials once per twelve (12) months period, or at any time in the event of a quality issue.
- (e) Process Development. During the Early Development Term, Advaxis shall be responsible for developing and maintaining, at its own expense, a commercially viable product and process as reflected in Module 3 and shall keep Amgen reasonably apprised of developments relating to the foregoing. Amgen, at its own expense, shall provide Advaxis with consulting support with respect to such process development matters as set forth in the Early Development Plan. During the Early Development Term, Advaxis shall provide Amgen reasonable access to Module 3 and its supporting documents. Following the POC Date, Amgen shall be responsible for decision making on process development matters and the costs relating to such process development. Following the POC Date, the JSC shall discuss and agree upon an allocation of responsibilities between the parties for post-POC Date process development activities.

#### 4.4 Commercialization Matters.

(a) Prior to the POC Date, the parties, though their representatives on the JSC, shall be jointly responsible for resolving any matter concerning the commercialization of Products, including patient biopsy, sequencing, manufacturing, testing, disposition, storage, distribution, transportation, import, export, marketing, promotion and sales activities. Following the POC Date, Amgen shall have the sole right to, and shall bear all costs associated with, commercialization of the Products. Notwithstanding the preceding sentence, following the POC Date, Amgen shall periodically consult with, and consider in good faith any input provided by, Advaxis regarding commercialization matters.

#### 4.5 Conduct of Activities.

- (a) From and after the Effective Date, each party shall use Commercially Reasonable Efforts (itself and with its Affiliates and Sublicensees, as applicable) to (i) develop the Products in accordance with, and as such activities are allocated to such Party under, this Agreement and, as applicable, the Early Development Plan; and (ii) conduct regulatory activities for each Product in accordance with, and as such activities are allocated to such Party under, this Agreement and, as applicable, the Early Development Plan. Amgen shall use Commercially Reasonable Efforts (itself or through its Affiliates or Sublicensees, as applicable) to develop, obtain and maintain Regulatory Approval of, and, if successful, commercialize a Product on a worldwide basis.
- (b) In performing all activities hereunder, each party shall (and shall cause its Affiliates and Sublicensees, as applicable, to) use relevant facilities and equipment in a good scientific manner and in compliance with applicable scientific standards, laboratory practices and legal and regulatory requirements, and retain adequately trained personnel and engage and control adequately qualified internal or external personnel and collect and develop all relevant Know-How for the research, development and commercialization of Products.
- (c) Each party (and its Affiliates and Sublicensees, as applicable) shall perform its activities with respect to Products in the Field in the Territory in good scientific manner and in compliance with all requirements of applicable laws, rules and regulations, including (as applicable): the U.S. Federal Food, Drug and Cosmetic Act, as amended (FFDCA), the U.S. Public Health Service Act (PHSA), the rules governing medicinal products in the European Union and further national legislation, regulatory provisions regarding protection of animal or human subjects, GCP, GLP, GMP, IND regulations, and any conditions imposed by a Regulatory Authority, and comparable statutes and regulatory requirements in other jurisdictions.
- (d) Each party shall be entitled to utilize the service of Third Parties to perform such development, regulatory, manufacturing and commercialization activities with respect to Products in the Territory; provided, that any such Third Party service provider relationship shall be in writing and shall be subject to, and consistent with, the terms and conditions of this Agreement and such party shall be responsible for compliance with the terms and conditions of this Agreement by any such Third Party service provider.

- **4.6 RACI Document.** The parties agree and acknowledge that the RACI Document is intended to provide guidance as to which party is responsible for conducting certain activities from an operational perspective with respect to the development, manufacturing and commercialization of a Product, provided that the RACI Documents shall not govern any decision making with respect to the development, manufacturing or commercialization of a Product, which decision making shall be determined in accordance with this Agreement. In the event of a conflict between the terms of this Agreement (or an Ancillary Agreement) and the RACI Document, the terms of this Agreement (or such Ancillary Agreement, as applicable) shall prevail.
- **4.7 Initial Early Development Plan.** Within 30 days of the Effective Date, the parties will meet to discuss and begin drafting the initial Early Development Plan. The parties will use reasonable best efforts to complete and agree to the initial Early Development Plan (which Early Development Plan shall contemplate Initiation of a Phase 1 Clinical Trial during the Calendar Quarter ended June 30, 2017) within 60 days of the Effective Date.

### 5. GRANT OF LICENSES

- **5.1 License Grant to Amgen.** Subject to the terms and conditions of this Agreement, during the Term, Advaxis hereby grants to Amgen:
- (a) an exclusive (even as to Advaxis and its Affiliates, except as expressly set forth herein and subject to Advaxis and its Affiliates retaining the non-exclusive rights reasonably necessary or useful to perform Advaxis' obligations under the Early Development Plan), worldwide, royalty-bearing license, with the right to grant sublicenses as provided in Section 5.3, under the Advaxis Technology and Advaxis' rights under the Joint Invention Patents, solely to research and develop, conduct clinical trials, obtain Regulatory Approval of, make, have made, use, import, offer for sale, sell, export or otherwise exploit, Products in the Field in the Territory; and
- (b) a non-exclusive, worldwide, royalty-free license, with the right to grant sublicenses as provided in Section 5.3, under the Advaxis Technology and Advaxis' rights under the Joint Invention Patents, solely to perform Amgen's obligations under the Early Development Plan during the Early Development Term.
- **5.2 License Grant to Advaxis.** Subject to the terms and conditions of this Agreement, during the Term, Amgen hereby grants to Advaxis a non-exclusive, worldwide, royalty-free license, with the right to grant sublicenses as provided in Section 5.3, under the Amgen Technology and Amgen's rights under the Joint Invention Patents, solely to perform Advaxis' obligations under the Early Development Plan during the Early Development Term.
- **5.3 Sublicenses.** Each party shall have the right to grant sublicenses under the licenses granted to it under Section 5.1 or 5.2, as applicable, to any Affiliate or Third Party. Any and all sublicenses granted hereunder shall be in writing and shall be subject to, and consistent with, the terms and conditions of this Agreement and written approval by Advaxis, not to be unreasonably withheld. Each party shall be responsible for compliance with the terms and conditions of this Agreement by its Sublicensees and Affiliates to whom it grants any sublicense hereunder and will continue to be responsible for the full performance of all of such party's obligations under the Agreement. Within 30 days after execution, each party shall provide the other party with a full and complete copy of each agreement granting a sublicense to any Sublicensee (provided that a party may redact any confidential information contained therein that is not necessary or useful to confirm compliance with this Agreement). For clarity, the obligation to provide a copy of each sublicense agreement includes the agreements granted through multiple tiers of sublicensing.

- **5.4 Reserved Rights.** Subject only to the rights expressly granted to Amgen under Section 5.1 and the obligations set forth in Articles 5 and 6, Advaxis hereby expressly reserves all rights to practice, and to grant licenses under, the Advaxis Technology for any and all purposes, including to conduct all activities to be conducted by Advaxis pursuant to the Early Development Plan.
- **5.5 No Implied License.** No right or license under any Patents or other intellectual property rights of a party is granted or shall be granted by implication to the other party, and each party covenants not to practice or use any Patents or other intellectual property rights of the other party except pursuant to the licenses expressly granted in this Agreement or any other written agreement between the parties. All such rights or licenses are or shall be granted only as expressly provided in the terms of this Agreement. Each party further covenants and agrees that it shall not (and shall cause its Affiliates and Sublicensees not to), either directly or indirectly, use the Advaxis Technology(in the case of Amgen), or the Amgen Technology (in the case of Advaxis), in any manner not expressly set forth in Sections 5.1 or Section 5.2, as applicable.

# 6. EXCLUSIVITY.

**6.1 Exclusivity.** During the Term, Advaxis and its Affiliates will not conduct or participate in, or knowingly advise, assist or enable any Third Party to conduct or participate in, the development, manufacture or commercialization of any product, treatment or therapy that contains or utilizes the Lm-LLO Technology for neoepitope-based, personalized immunotherapy, as described in Schedule 1.53.

### 7. FEES AND PAYMENTS

- **7.1 Initial Payment.** Amgen shall make a one-time, non-refundable, non-creditable payment to Advaxis of \$40,000,000 within 30 days after the Effective Date.
- **7.2 Milestone Payments.**(a) Within ten (10) business days after the first achievement of each of the events set forth below (each, a "**Milestone**") Amgen shall notify Advaxis in writing of such occurrence. Thereafter, Advaxis shall invoice Amgen for the corresponding payment amount (each, a "**Milestone Payment**") and Amgen will pay each such invoice within forty five (45) days of its receipt thereof:

	Milestone		Milestone Payment	
1.	Development Milestones			
	(a) *	\$	*	
	(b) *	\$	*	
	(c) *	\$	**	
2.	Sales Milestones			
	(a) *	\$	*	
	(b) *	\$	*	
	(c) *	\$	*	
3.	<b>Total Milestone Payments</b>	\$	475,000,000	

(b) All Milestones Payments are non-creditable and non-refundable and shall be due and payable upon the occurrence of the corresponding Milestone regardless of any failure by Amgen to provide the notice required by Section 7.2(a). For clarity, each Milestone Payment is payable only once. No Milestone Payment shall be payable for subsequent or repeated achievements of such Milestone Event with one or more of the same or different Products in the Program.

(c) In the event that the development or commercialization of a Product would trigger a Milestone Payment that skips any of the preceding Milestones, then at the time such Milestone Payment is made, all skipped Milestone Payments shall become immediately due and payable (e.g., in the event that a Product moves directly from \* to \*, then upon achievement of \*, both the Milestone Payment associated with such \* and the Milestone Payment associated with \* shall become due and payable).

# 7.3 Royalty Payments.

(a) On an aggregate basis across all Products under this Agreement and during the Royalty Term, Amgen shall pay to Advaxis royalties on Net Sales of Products at the applicable rate set forth below with respect to all Net Sales in a given Calendar Year:

Worldwide Net Sales of Products in any Calendar Year	Royalty Due to Advaxis (as a percentage of Net Sales)
That portion of Net Sales in any given Calendar Year that is less than or equal to \$*	*0/0
That portion of Net Sales in any given Calendar Year that is greater than \$*, but less than or	
equal to \$*	*0/0
That portion of Net Sales in any given Calendar Year that exceeds \$*	*0/0

<sup>\*</sup> Confidential material redacted and filed separately with the Commission.

- (b) Amgen shall have the right (but not the obligation), at its own expense (subject to the reduction provided for by this Section 7.3(c)), for obtaining any licenses from any Third Parties (that are not Sublicensees of Amgen with respect to a Product in such country) to Patents that cover Advaxis Technology or a Product that Amgen determines may be reasonably necessary or useful to allow Amgen and its Sublicensees to research, develop, conduct clinical trials, obtain Regulatory Approval of, make, have made, use, import, offer for sale, sell, export or otherwise exploit, a given Product in a particular country (each such Patent, a "Third Party Patent"). If Amgen obtains such a license to a Third Party Patent, Amgen shall be entitled to credit \*% of the royalties, milestones or other payments paid to such Third Party during a Calendar Quarter from the royalty payment otherwise payable by Amgen to Advaxis pursuant to this Section 7.3 with respect to such Product and such country in such Calendar Quarter, subject to Section 7.3(b). If there are any excess amounts that are not deducted and would have been deductible from the royalty payments in a given Calendar Quarter but for the application of the \*% limitation, such excess amounts may be deducted by Amgen in succeeding Calendar Quarter(s) as necessary, still subject to the limitation in Section 7.3(d) below, until such excess amounts are credited in full.
- (c) Notwithstanding the foregoing, if a Substitute Product with respect to a Product obtains regulatory approval to market the Substitute Product in a given country, then the royalty rates set forth in this Section 7.3 with respect to Net Sales for such Product in such country shall be reduced by \*%.
- (d) In no event shall any royalty payment for Products in any country in any Calendar Quarter be reduced to less than \*% of the royalty payment otherwise payable by Amgen to Advaxis pursuant to Section 7.3(a) (before taking into account any adjustment pursuant to Section 7.3(b) or 7.3(c)) as a result of the adjustments under Section 7.3(b) or Section 7.3(c).

# 8. PAYMENT; RECORDS; AUDITS

**8.1 Payment; Reports.** The royalty payments due by Amgen to Advaxis under Section 7.3 shall be calculated, reported and paid for each Calendar Quarter within 60 days after the end of each Calendar Quarter during which the applicable Net Sales occurred and shall be accompanied by a report setting forth Net Sales of Products by Amgen and its Affiliates and Sublicensees in reasonably sufficient detail to permit confirmation of the accuracy of the royalty payment made, including the gross sales and Net Sales of each Product, on a country-by-country basis, and the exchange rates used in accordance with Section 8.2.

<sup>\*</sup> Confidential material redacted and filed separately with the Commission.

**8.2 Manner and Place of Payment.** All references to dollars and "\$" herein shall refer to U.S. dollars. When conversion of payments from any currency other than U.S. dollars is required, such conversion shall be calculated using the average rate of exchange over the applicable Calendar Quarter to which the sales relate, in accordance with GAAP and the then current standard methods of Amgen or the applicable Sublicensee, to the extent reasonable and consistently applied; provided, however, that if, at such time, Amgen or the applicable Sublicensee does not use a rate for converting into U.S. dollar equivalents that is maintained in accordance with GAAP, then such party shall use an exchange rate equal to the rate of exchange for the currency of the country from which such payments are payable as published by *The Wall Street Journal*, Western U.S. Edition, as of the last day of the applicable Calendar Quarter in which the applicable sales were made (or, if unavailable on such date, the first date thereafter on which such rate is available). All payments hereunder shall be payable in U.S. dollars. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by the receiving party, unless otherwise specified in writing by such party.

### 8.3 Taxes.

- (a) The parties acknowledge and agree that it is their mutual objective and intent to minimize, to the extent feasible, taxes payable with respect to their collaborative efforts under this Agreement and that they shall use their commercially reasonable efforts to cooperate and coordinate with each other to achieve such objective. For the avoidance of doubt, as between the parties, Amgen shall be responsible for any Branded Prescription Drug Fees that may be levied under section 9008 of the Affordable Care Act with respect to any Product sold.
- (b) Subject to this Section 8.3(b), Advaxis will pay any and all taxes levied on account of any payments made to it under this Agreement. If any taxes are paid or required to be withheld by Amgen for the benefit of Advaxis on account of any payments payable to Advaxis under this Agreement, Amgen will (i) deduct such taxes from the amount of payments otherwise due to Advaxis, (ii) timely pay the taxes to the proper taxing authority, (iii) send proof of payment to Advaxis as promptly as practicable following such payment and (iv) cooperate with Advaxis in any way reasonably required by Advaxis to obtain available reductions, credits or refunds of such taxes.
- (c) All remuneration amounts payable by Amgen to Advaxis are net amounts. Amgen shall be responsible for all Value Added Taxes ("VAT"), if any, attributable to transactions contemplated by this Agreement upon receipt of a valid VAT invoice and without any offset or reimbursement from Advaxis. Advaxis shall cooperate with Amgen in any way reasonably requested by Amgen to obtain available reductions, credits or refunds of any VAT amounts attributable to transactions contemplated by this Agreement. For clarity, this Section 8.3(c) is not intended to limit Amgen's right to deduct value-added taxes in determining Net Sales.
- (d) In the event that any tax is owing as a result of any action by Amgen, including any assignment or sublicense (including assignment to, or payment hereunder by, another Amgen-related entity or Affiliate), or any failure on the part of Amgen or its Affiliates to comply with applicable tax laws or filing or record retention requirements, that has the effect of modifying the tax treatment of Advaxis hereto, then the payment in respect of which such tax is owing shall be made without deduction for or on account of such tax to ensure that Advaxis receives a sum equal to the sum which it would have received had such tax not been due or otherwise, and any such payment shall be made after deduction of such tax. Each party shall cooperate with the other party in any way reasonably requested by the other party to minimize the tax implications of any such action.
- (e) As between the parties and with respect to Products in the U.S., Amgen shall be solely responsible for the annual fee on branded prescription pharmaceutical manufacturers and importers, imposed on Amgen, or its Affiliates or Sublicensees, pursuant to Section 9008 of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as may be amended).

8.4 Records; Audit. During the Term and for three years thereafter, Amgen shall keep, and shall cause its Affiliates and Sublicensees to keep, complete and accurate records pertaining to the sale or other disposition of Product in sufficient detail to permit Advaxis to confirm the accuracy of payments due hereunder. Advaxis shall have the right, upon 30 days' prior written notice to Amgen, to cause an independent, certified international public accounting firm reasonably acceptable to Amgen to audit such records during Amgen's normal business hours with the purpose of confirming the number of Product units sold, the gross sales and Net Sales of Product, the royalties payable, the method used to calculate the royalties payable, and the exchange rates used in accordance with Section 8.2. The audit shall be limited to pertinent records kept by Amgen and its Affiliates and Sublicensees for any year ending not more than 24 months prior to the date of the written notice. An audit under this Section 8.4 shall not occur more than once in any Calendar Year, except in the case of any subsequent "for cause" audit. The accounting firm shall disclose to Advaxis only whether the reports are correct or incorrect and the specific details concerning any discrepancies. No other information shall be provided to Advaxis. The accounting firm shall provide Amgen with a copy of any disclosures or reports made to Advaxis and Amgen shall have an opportunity to discuss such disclosures or reports with Advaxis and the accounting firm. Information, disclosures, or reports arising from any such examination shall be Confidential Information of Amgen subject to the confidentiality and other obligations of Article 11. Prompt adjustments shall be made by the parties to reflect the results of such audit (but in no event later than 45 days thereafter). Advaxis shall bear the full cost of such audit unless such audit discloses a variance of more than the greater of (x) \*% of the payments due under this Agreement or (y) \$\*, in which case, Amgen shall bear the full cost of such audit.

**8.5 Late Payments.** In the event that any payment due under this Agreement is not sent to Advaxis when due in accordance with the applicable provisions of Sections 7.1, 7.2, or 8.1, the payment shall accrue interest from the date due at the prime rate as reported by Citibank N.A., plus \*% per year calculated on the number of days such payment is delinquent, compounded annually and computed on the basis of a 365-day year; provided, however, that in no event shall such rate exceed the maximum legal annual interest rate. The payment of such interest shall not limit Advaxis from exercising any other rights it may have as a consequence of the lateness of any payment.

### 9. INTELLECTUAL PROPERTY

### 9.1 Ownership of Inventions.

(a) Inventorship, and ownership, of any Inventions will be determined in accordance with the standards of inventorship and conception under U.S. patent laws (without reference to any conflict of law principles).

(b) Without modifying or limiting the ownership and rights as provided for in Section 9.1(a), each party shall, prior to any public disclosure or filing of a Patent application, disclose to the other party each Invention, and shall allow reasonably sufficient time (at least 30 days from the date of receipt by the other party) for comment and review by the other party as to whether such other party would recommend for a Patent to be filed (but only by the party or parties who is or are entitled to do so in accordance with Section 9.2). The parties will work together to resolve any issues regarding inventorship or ownership of Inventions; provided, that the final decision on whether to file a Patent on an Invention shall be in the sole discretion of the party owning the Invention.

<sup>\*</sup> Confidential material redacted and filed separately with the Commission.

- (c) Each party shall perform its activities under this Agreement through personnel who are subject to written obligations to assign intellectual property created in the course of their employment to such party or its Affiliate.
- (d) Except as expressly provided in this Agreement, it is understood that neither party will have any obligation to obtain any approval or consent of, nor pay a share of the proceeds to or account to, the other party to practice, enforce, license, assign or otherwise exploit inventions or intellectual property owned jointly by the parties hereunder, including any Joint Inventions or Joint Invention Patents, and each party hereby waives any right it may have under the laws of any jurisdiction to require such approval, consent or accounting. Each party agrees to cooperate with the other party, as reasonably requested and at the requesting party's reasonable expense, and to take such actions, at the requesting party's reasonable expense, as may be required to give effect to this Section 9.1(d) in a particular country in the Territory.

### 9.2 Patent Prosecution and Maintenance.

(a) Coordination. Each party shall undertake Prosecution and Maintenance of Joint Invention Patents, Amgen Invention Patents and Advaxis Invention Patents in accordance with this Section 9.2, and subject to discussion by the parties. Furthermore, with respect to the Prosecution and Maintenance of each such Patent each party agrees to: (i) keep the other party reasonably informed with respect to such activities; (ii) consult with the other party regarding such matters, including the final abandonment of any such Patent claims; and (iii) reasonably consider the other party's comments. For clarity, the parties understand that some Inventions may require coordination of Patent filings, including timing and coordination of genus and species filings as appropriate, to preserve and maximize intellectual property rights, prolong exclusivities and minimize the creation of prior art against such Patent filings of either party. If a party controls Prosecution and Maintenance of an Invention Patent pursuant to this Section 9.2, and the other party in good faith reasonably believes that Advaxis Technology (in the case of Advaxis) or the Amgen Technology (in the case of Amgen) would be adversely affected by such controlling party's Prosecution and Maintenance activities, the parties shall use reasonable best efforts to work together to develop a mutually agreeable solution. If the parties are unable to agree on such solution within a reasonable period of time, the issue will be escalated to the chief patent counsels of each of Advaxis and Amgen, as applicable, for resolution. If the chief patent counsels cannot reach a mutually agreeable solution, then the controlling party shall have the right to make the decision taking into account the other party's interest.

(b) **Joint Invention Patents.** Amgen shall have the first right, at its expense, to control the Prosecution and Maintenance of Joint Invention Patents. Amgen shall consult with Advaxis as to the Prosecution and Maintenance of the Joint Invention Patents reasonably prior to any deadline or action with the applicable patent office and shall furnish to Advaxis copies of all relevant documents reasonably in advance of such consultation; provided, that if Amgen determines not to continue the Prosecution and Maintenance of any Joint Invention Patents, then Amgen shall provide reasonable prior written notice to Advaxis of such determination (which notice shall, in any event, be given no later than 60 days prior to the next deadline for any action that may be taken with respect to such Joint Invention Patent with the applicable patent office), and Advaxis shall have the right to undertake such Prosecution and Maintenance at its own expense.

- (c) Amgen Invention Patents. Amgen shall have the sole right, at its expense, to control the Prosecution and Maintenance of Amgen Invention Patents. Amgen shall consult with Advaxis as to the Prosecution and Maintenance of the Amgen Invention Patents that claim or Cover Products, or the manufacture or use thereof, reasonably prior to any deadline or action with the applicable patent office and shall furnish to Advaxis copies of all relevant documents reasonably in advance of such consultation.
- (d) Advaxis Invention Patents. Advaxis shall have the sole right, at its expense, to control the Prosecution and Maintenance of Advaxis Invention Patents. Advaxis shall consult with Amgen as to the Prosecution and Maintenance of the Advaxis Invention Patents that claim or Cover Products or the manufacture or use thereof, reasonably prior to any deadline or action with the applicable patent office and shall furnish to Amgen copies of all relevant documents reasonably in advance of such consultation; provided, that if Advaxis determines not to continue the Prosecution and Maintenance of any Advaxis Invention Patent that solely Covers a Product then Amgen shall have the right to undertake such Prosecution and Maintenance at its own expense.
- (e) **Background Patents.** Advaxis shall have the sole right, but not the obligation, at its expense, to control the Prosecution and Maintenance of the Advaxis Background Patents and Amgen shall have the sole right, but not the obligation, at its expense, to control the Prosecution and Maintenance of the Amgen Background Patents.

9.3 Cooperation of the Parties. Each party shall cooperate with the other party in connection with all activities relating to the Prosecution and Maintenance of the Advaxis Invention Patents, Amgen Invention Patents and Joint Invention Patents undertaken by such other party pursuant to Section 9.2, including: (i) making available in a timely manner any documents or information such other party reasonably requests to facilitate such other party's Prosecution and Maintenance of the Advaxis Invention Patents, Amgen Invention Patents or Joint Invention Patents pursuant to Section 9.2; and (ii) if and as appropriate, signing (or causing to have signed) all documents relating to the Prosecution and Maintenance of any Advaxis Invention Patents, Amgen Invention Patents or Joint Invention Patents by such other party. Each party shall, if requested, permit such other party to participate at its own expense in any opposition, interference, appeal, inter partes review, post-grant review or similar proceeding with respect to any Advaxis Invention Patent, Amgen Invention Patents or Joint Invention Patent to the extent the same are directed to any Product, or manufacturing or use thereof.

# 9.4 Infringement or Misappropriation by Third Parties.

- (a) **Notice.** In the event that Advaxis or Amgen becomes aware of actual or threatened infringement or misappropriation of any Advaxis Patent, Amgen Patent, Joint Invention Patent, Advaxis Know-How, Amgen Know-How or Joint Invention by the manufacture, sale, use or importation of a Product or Substitute Product, including the filing of any certification pursuant to the Biologics Price Competition and Innovation Act of 2009 (or any amendment or successor statute thereto) or any equivalent thereof (any of the foregoing, an "**Infringement**"), that party shall promptly notify the other party in writing.
- (b) **Joint Invention Patents.** Amgen shall have the first right, but not the obligation, to initiate and control any infringement proceedings or take other appropriate actions against an Infringement of the Joint Invention Patents or to defend a challenge of such Joint Invention Patent in a declaratory judgment action, at its own expense and by counsel of its own choice, and Advaxis shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. If Amgen fails to bring any such action or proceeding with respect to an Infringement by the sooner of (a) 30 days following a request by Advaxis to do so, or (b) 30 days before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, then Advaxis shall have the right to bring and control any such action at its own expense and by counsel of its own choice, and Amgen shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. It is understood that Amgen may exercise its rights under this Section 9.4(b) through a Sublicensee or other designee, and actions of such a Sublicensee or designee under authority from Amgen shall be deemed actions of Amgen for purposes of this Section 9.4(b).
- (c) Advaxis Patents. Advaxis shall have the first right to initiate any infringement proceedings or take other appropriate enforcement actions against an Infringement of any Advaxis Patent or to defend against any challenge of a Advaxis Patent. If Advaxis elects not to so enforce or defend any Advaxis Patents, then it shall notify Amgen in writing within nine (9) months of receiving notice that an Infringement exists (or such shorter period as may be necessary to prevent exhaustion of a statute of limitations (or laches) applicable to such Infringement), and Amgen may, in its sole judgment, and at its own expense, take steps to enforce or defend any such patent and control, settle, and defend such suit in a manner consistent with the terms and provisions hereof, and recover any damages, awards or settlements resulting therefrom. Advaxis shall reasonably cooperate in any such litigation (including joining or being named a necessary party thereto) at Amgen's expense. Amgen shall not enter into any settlement of any claim described in this Section 49.4(c) that admits to the invalidity or unenforceability of any Advaxis Patent, incurs any financial liability on the part of Advaxis or requires an admission of liability, wrongdoing or fault on the part of Advaxis without Advaxis' prior written consent, such consent not to be unreasonably withheld.

- (d) **Amgen Patents.** Amgen shall have the sole right to initiate any infringement proceedings or take other appropriate actions against an Infringement of any Amgen Patent or to defend against any challenge of an Amgen Patent.
- (e) **Allocation of Recoveries.** Except as otherwise agreed to by the parties, any recovery realized as a result of any infringement proceeding or other action pursuant to this Section 9.4, after reimbursement of any litigation expenses of Advaxis and Amgen, shall be (i) provided to, or retained by, as applicable, Amgen and (ii) treated as Net Sales of a Product for purposes of royalty calculations in the period in which payment of such recovery was received, in each case, unless Amgen elects not to participate in such action and Advaxis pursues such action at its own risk, in which case Advaxis shall be entitled to retain the amount so contemplated to be provided to Amgen pursuant to clause (i) above.
- (f) Cooperation. In the event a party brings an infringement proceeding or other action in accordance with this Section 9.4, the other party shall reasonably cooperate with the party bringing the proceeding, including, if legally required to bring such action, being named as a party. The parties shall keep one another informed of the status of their respective activities regarding any proceeding or action undertaken with respect to (i) a Joint Invention Patent, or (ii) any Amgen Invention Patent or Advaxis Invention Patent that Cover Products, pursuant to this Section 9.4 or settlement thereof, and the parties shall assist one another and cooperate in any such action at the other's reasonable request. The party enforcing and/or defending a Joint Invention Patent or any Advaxis Invention Patent or Amgen Invention Patent that Cover Products, may enter into any settlement, consent judgment, or other voluntary final disposition of any action contemplated by this Section 9.4 without the other party's prior consent; provided, that (a) the other party receives a general release of any claims against it in such proceeding and is promptly provided thereafter a copy of such settlement, consent judgment or other voluntary disposition and (b) such settlement does not have an adverse impact on (1) (A) the rights granted by a party to the other party hereunder or (B) if Amgen is the settling party, any Advaxis Background Patent, or, if Advaxis is the settling party, any Amgen Background Patent, or (2) result in a payment or other liability by the other party to a Third Party. Any other settlement, consent judgment or voluntary final disposition of any proceeding under this Section 9.4 by the party enforcing an Amgen Invention Patent, Advaxis Invention Patent or Joint Invention Patent shall require the prior written consent of the other party, which consent such other party shall not unreasonably withhold.
- 9.5 Defense and Settlement of Third Party Claims. Each party shall promptly notify the other in writing of (a) any allegation by a Third Party that the activity of either of the parties pursuant to this Agreement infringes or may infringe the intellectual property rights of such Third Party or (b) any declaratory judgment action that is brought naming either party as a defendant and alleging invalidity of any of the Amgen Patents, Advaxis Patents or Joint Invention Patents. Advaxis shall have the sole right to control any defense of any such claim involving alleged infringement of Third Party rights by Advaxis' activities at its own expense and by counsel of its own choice, and Amgen shall have the right, at its own expense, to be represented in any such action by counsel of its own choice, and Advaxis shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Neither party shall have the right to settle any patent infringement litigation under this Section 9.5 in a manner that admits the invalidity or unenforceability of the other party's Patents or a Joint Invention Patent or imposes on the other party restrictions or obligations or other liabilities, without the written consent of such other party, which consent shall not be unreasonably withheld.

- 9.6 Patent Extension. The parties shall cooperate in determining which Patent claiming, covering, or that is directed to a given Product should be extended, and thereafter the parties shall cooperate in obtaining patent term restorations, supplemental protection certificates and/or their equivalents, and other forms of patent term extensions for a given Product with respect to any applicable Advaxis Patent, Amgen Patent or Joint Invention Patent in any country or region where applicable; provided that, Amgen shall have the final decision making authority with respect thereto; provided, further, that Amgen shall not have the right to seek any such restoration, supplemental protection certificate or other extension of any Advaxis Background Patent without Advaxis' prior written consent, which Advaxis may withhold in its sole discretion.
- **9.7 Trademarks.** As between the parties, Amgen shall own all right, title and interest in and to any trademarks adopted by Amgen for use with a Product, and shall be responsible for the registration, filing, maintenance and enforcement thereof.

# 10. REPRESENTATIONS, WARRANTIES AND COVENANTS

#### 10.1 Mutual Covenants.

- (a) **Employees, Consultants and Contractors.** Each party covenants that it has obtained or will obtain written agreements from each of its employees, consultants and contractors who perform research or development activities pursuant to this Agreement, which agreements will obligate such persons to obligations of confidentiality and non-use and to assign Inventions in a manner consistent with the provisions of this Agreement.
- (b) **Debarment.** Each party represents, warrants and covenants to the other party that it is not debarred or disqualified under the U.S. Federal Food, Drug and Cosmetic Act or comparable laws in any country or jurisdiction other than the U.S. and, to its knowledge, does not, and will not during the Term knowingly, employ or use, directly or indirectly, including through Affiliates or, in the case of Amgen, Sublicensees, the services of any person who is debarred or disqualification with activities relating any Product. In the event that either party becomes aware of the debarment or disqualification or threatened debarment or disqualification of any person providing services to such party, directly or indirectly, including through Affiliates or, in the case of Amgen, Sublicensees, which directly or indirectly relate to activities contemplated by this Agreement, such party shall promptly notify the other party in writing and such party shall cease employing, contracting with, or retaining any such person to perform any such services.

- (c) **Compliance.** Each party covenants to the other that:
- (i) In the performance of its obligations under this Agreement, such party shall comply with, and shall cause its and its Affiliates' employees and contractors to comply, with all applicable laws, rules and regulations.
- (ii) As of the Effective Date through the expiration and termination of this Agreement, such party and, to its knowledge, its and its Affiliates' employees and contractors, shall not, in connection with the performance of their respective obligations under this Agreement, directly or indirectly through Third Parties, pay, promise or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to a Public Official or Entity or other person for the purpose of obtaining or retaining business for or with, or directing business to, any Person, including either party (it being understood that, without any limitation to the foregoing, such party, and to its knowledge, its and its Affiliates' employees and contractors, has not directly or indirectly promised, offered or provided any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift or hospitality or other illegal or unethical benefit to a Public Official or any other Person in connection with the performance of such party's obligations under this Agreement, and shall not, directly or indirectly, engage in any of the foregoing).
- 10.2 Mutual Representations and Warranties. Each party represents and warrants to the other that, as of the Effective Date: (a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof, (b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action, (c) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material applicable law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it and (d) no consent, approval, authorization or order of any court or governmental agency or governmental body or Third Party is required for execution and delivery by such party of this Agreement.
- 10.3 Advaxis Representations and Warranties. Advaxis represents, warrants and covenants to Amgen that, as of the Effective Date:

- (a) Advaxis has full legal or beneficial title and ownership of, or an exclusive license to, the Advaxis Patents as is necessary to grant the licenses (or sublicenses) to Amgen to such Advaxis Patents that Advaxis purports to grant pursuant to this Agreement.
- (b) Advaxis has the rights necessary to grant the licenses to Amgen under Advaxis Know-How that Advaxis purports to grant pursuant to this Agreement.
- (c) The Advaxis Patents owned by Advaxis are not subject to, and to Advaxis' knowledge the Advaxis Patents licensed to Advaxis are not subject to, any liens or encumbrances, and Advaxis has not, and will not during the Term, grant any right to any Third Party under or with respect to the Advaxis Technology that would conflict with the rights granted to Amgen hereunder or terminate any rights granted by a Third Party to Advaxis or its Affiliates that are further granted to Amgen hereunder. None of the Advaxis Patents are inlicensed by Advaxis.
- (d) Advaxis has shared with Amgen complete and accurate copies of all Third Party licenses and agreements pursuant to which Advaxis or its Affiliates has obtained rights to Advaxis Patents and Advaxis Know-How.
- (e) No claim or action has been brought or, to Advaxis' knowledge, threatened by any Third Party alleging that (i) the Advaxis Patents are invalid or unenforceable or (ii) use of the Advaxis Technology infringes or misappropriates or would infringe or misappropriate any right of any Third Party, and no Advaxis Patent is the subject of any interference, opposition, cancellation or other protest proceeding.
- (f) There are no pending actions, claims, investigations, suits or proceedings against Advaxis or its Affiliates, at law or in equity, or before or by any Regulatory Authority, and neither Advaxis nor any Affiliate has received any written notice regarding any pending or threatened actions, claims, investigations, suits or proceedings against Advaxis or such Affiliate, at law or in equity, or before or by any Regulatory Authority, in either case with respect to the Advaxis Technology.
- (g) To Advaxis' knowledge, no Third Party, including any current or former employee or consultant of Advaxis, is infringing or misappropriating or has infringed or misappropriated the Advaxis Technology.

10.4 Disclaimer. Except as expressly set forth in this Agreement, THE TECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS, AND MATERIALS (IF ANY), PROVIDED BY EACH PARTY HEREUNDER ARE PROVIDED "AS IS" AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES, IN ALL CASES WITH RESPECT THERETO. Without limiting the generality of the foregoing, (i) neither party represents or warrants as to the success of any study or test conducted by such party pursuant to this Agreement or the safety or usefulness for any purpose of the technology, right or materials it provides hereunder, or that either party will be successful in obtaining any patents rights, or that any patents will issue based on a pending application; and (ii) each party specifically disclaims any guarantee that the Products will be successful, in whole or in part.

**10.5 Limitation of Liability.** EXCEPT FOR LIABILITY FOR BREACH OF ARTICLE 11, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, LOST PROFITS, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; provided, however, that this Section 10.5 shall not be construed to limit either party's indemnification obligations under Article 13.

#### 11. CONFIDENTIALITY

11.1 Confidential Information. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the parties, the parties agree that, during the Term and for \* (\*) years thereafter, the receiving party shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement any Confidential Information furnished to it by the other party pursuant to this Agreement or any Confidential Information developed by the other party hereunder, and both parties shall keep confidential and, subject to Section 11.5, shall not publish or otherwise disclose the terms of this Agreement. Each party may use the other party's Confidential Information only to the extent required to accomplish the purposes of this Agreement (including exercising rights and performing obligations). Each party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but no less than reasonable care) to ensure that its employees, agents, consultants, contractors and other representatives do not disclose or make any unauthorized use of the Confidential Information of the other party. Each party will promptly notify the other upon discovery of any unauthorized use or disclosure of the Confidential Information of the other party.

11.2 Exceptions. The obligations of confidentiality and restriction on use under this Article 11 shall not apply to any Confidential Information that: (a) is now, or hereafter becomes, through no act or failure to act on the part of the receiving party, generally known or available to the public; (b) is known by the receiving party or any of its Affiliates at the time of receiving such information, other than by previous disclosure of the disclosing party, or its Affiliates, employees, agents, consultants, or contractors; (c) is hereafter furnished to the receiving party or any of its Affiliates without restriction by a Third Party who is not known by the receiving party to be subject to an obligation of confidentiality or limitations on use with respect thereto, as a matter of right; or (d) is independently discovered or developed by the employees, subcontractors, consultants or agents of the receiving party or any of its Affiliates without the use of Confidential Information belonging to the disclosing party, which the receiving party can prove by competent written evidence.

<sup>\*</sup> Confidential material redacted and filed separately with the Commission.

- 11.3 Authorized Disclosure. Each party may disclose Confidential Information belonging to the other party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:
  - (a) filing, prosecuting, or maintaining Patents as permitted by this Agreement;
- (b) Regulatory Filings for Products that such party has a license or right to develop hereunder in a given country or jurisdiction;
  - (c) prosecuting or defending litigation as permitted by this Agreement;
- (d) complying with applicable law or governmental regulations (including any securities law or regulation or the rules of a securities exchange) or with a court order or legal or administrative proceeding; and
- (e) disclosure to Affiliates, Sublicensees, employees, consultants, contractors, agents or other Third Parties in connection with due diligence or similar investigations by such Third Parties (including potential Third Party acquirers (whether through asset or stock purchase or merger)), and disclosure to potential Third Party investors in confidential financing documents, provided, in each case, that any such Affiliate, Sublicensee, employee, consultant, contractor, agent or Third Party agrees to be bound by terms of confidentiality and non-use consistent with those set forth in this Article 11; and provided further, that no financial terms shall be disclosed to any such potential acquirer or investor if it has a competing product to any Product.

Notwithstanding the foregoing, in the event a party is required to make a disclosure of the other party's Confidential Information pursuant to Section 11.3(c) through (d), it will give reasonable advance notice to the other party of such disclosure and use Commercially Reasonable Efforts to secure confidential treatment of such Confidential Information and at least as diligently as such party would use to protect its own confidential information. In any event, the parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder. Any information disclosed pursuant to Section 11.3(c) through (d) shall still be deemed Confidential Information and subject to the restrictions set forth in this Agreement, including the foregoing provisions of Article 11.

# 11.4 Publications.

(a) If a party (the "Publishing Party") proposes to publish or present on any results or data on any Product, or use thereof, or, in the case of Amgen as the Publishing Party, any Advaxis Technology (excluding publications or presentations which include only a standard source reference to Advaxis Technology, consistent with scientific journal publication practices) or, in the case of Advaxis as the Publishing Party, any Amgen Technology (excluding publications or presentations which include only a standard source reference to Amgen Technology, consistent with scientific journal publication practices), the other party (the "Non-Publishing Party") shall, in accordance with and to the extent provided in the following clause (b), have the right to review and comment on any material proposed for such publication or presentation by the Publishing Party, such as by oral presentation at scientific conferences or seminars, scientific journal manuscripts or abstracts; provided, however, that Amgen will have the sole right (without Advaxis' consent but subject to the review and comment provisions in Section 11.4(b)) to publish and make scientific presentations with respect to Products or make other public disclosures regarding any such Products, and Advaxis will not do so without Amgen's prior written consent, except as required by law.

- (b) With respect to any such publications or presentation, before any such material is submitted for publication or presentation, the Publishing Party shall deliver a complete copy of such material to the Non-Publishing Party at least 30 days prior to the proposed submission for publication or presentation, and the Non-Publishing Party shall use reasonable efforts to give its comments to the Publishing Party as promptly as practicable following delivery of such material. The Publishing Party shall (a) give due consideration to any editorial comments received from the Non-Publishing Party, (b) comply with any request from the Non-Publishing Party to delete the Non-Publishing Party's Confidential Information (for this purpose, Pre-Clinical Development Data shall not be considered Advaxis Confidential Information) in any such material, and (c) delay any submission for publication or presentation for a period of up to an additional 60 days for the purpose of preparing and filing appropriate patent applications in accordance with the terms of Article 8 hereof.
- (c) Notwithstanding the foregoing, Advaxis will not publish any data revealing the sequence of patient-specific neo-epitopes or immune responses to such neo-epitopes, without Amgen's prior written consent (to be given or withheld in its sole discretion).

11.5 Publicity; Public Disclosures. A joint press release substantially in the form attached hereto as Schedule 11.5 shall be issued by the parties on or following the Effective Date (but in no event later than four business days following the Effective Date). It is understood that each party may desire or be required to issue subsequent press releases or other public statements relating to this Agreement or activities hereunder, and each party agrees not to issue any press release or other public statement disclosing information relating to this Agreement or the transactions contemplated hereby or the terms hereof without the prior return consent of such party, not to be unreasonably withheld, conditioned or delayed; provided, that, no such consent shall be required with respect to the publication of materials or information that have been previously disclosed. The parties agree to consult with each other reasonably and in good faith with respect to the text and timing of such press release or public statement; provided, however, that the issuing party will provide the reviewing party with a copy of the proposed press release or public statement within a reasonable time prior to issuance thereof (but in no event less than four business days) and the parties will consult and work in good faith to prepare a mutually acceptable press release. Notwithstanding the foregoing (but subject to the parties' rights to review and comment), either party may make such disclosures as required by law based on the advice of counsel (including with respect to the achievement of a Milestone and the amount of, and receipt of, any Milestone Payment). The parties will consult with each other on the provisions of this Agreement to be redacted in any filings made by a party with the SEC or as otherwise required by law. In addition, following the initial press release announcing this Agreement, either party shall be free to disclose, without the other party's prior written consent, the existence of this Agreement, the identity of the other party and those terms of the Agreement which have already been publicly disclosed in accordance herewith.

- 11.6 Prior Non-Disclosure Agreement. As of the Effective Date, the terms of this Article 11 shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the parties (or their Affiliates) dealing with the subject of this Agreement, including the Nondisclosure Agreement. Any information disclosed pursuant to any such prior agreement shall be deemed Confidential Information of the applicable party for purposes of this Agreement.
- 11.7 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that a party may suffer upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 11. In addition to all other remedies, a party shall be entitled to specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 11 without the need to post any bond.
- 11.8 Attorney-Client Privilege. Neither party is waiving, nor will be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges recognized under the applicable law of any jurisdiction as a result of disclosing information pursuant to this Agreement, or any of its Confidential Information (including Confidential Information related to pending or threatened litigation) to the receiving party, regardless of whether the disclosing party has asserted, or is or may be entitled to assert, such privileges and protections. The parties may become joint defendants in proceedings to which the information covered by such protections and privileges relates and may determine that they share a common legal interest in disclosure between them that is subject to such privileges and protections, and in such event, may enter into a joint defense agreement setting forth, among other things, the foregoing principles, but are not obligated to do so.

#### 12. TERM AND TERMINATION

- **12.1 Term.** This Agreement shall commence on the Effective Date, and unless terminated earlier as provided in this Article 12 or by mutual written agreement of the parties, shall continue, until the expiration of the Royalty Term with respect to any Product under this Agreement (the "**Term**").
- **12.2 Termination for Cause.** Each party shall have the right to terminate this Agreement upon 90 days' (30 days' for any payment default) prior written notice to the other party upon the occurrence of any of the following:

- (a) upon or after the bankruptcy, insolvency, dissolution or winding up of the other party (other than a dissolution or winding up for the purpose of reconstruction or amalgamation); or
- (b) after the material breach of this Agreement by the other party if the breaching party has not cured such breach within the 90-day period (30-day period for any payment default) following written notice of termination by the non-breaching party. Notwithstanding the foregoing, in the event of a good faith dispute as to any payment due under this Agreement, the foregoing cure period with respect thereto will be tolled pending resolution of such dispute in accordance with the terms of this Agreement; provided, that for any dispute over payment such tolling of the cure period will only apply with respect to payment of the disputed amounts and not with respect to any undisputed amounts.

### 12.3 Individual Party Termination Rights.

- (a) Amgen shall have the right to terminate this Agreement at any time and for any reason or for no reason upon delivery of at least (i) 60 days' prior written notice to \* if \*, and (ii) 90 days' prior written notice to \*.
- (b) Advaxis shall have the right to terminate this Agreement upon written notice to \* if (i) \* or any of its Affiliates directly, or indirectly through any Third Party, commences any opposition proceeding, post-grant review, inter partes review or ex parte reexamination or Third Party submissions or submits observations with respect to, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any or (ii) any Sublicensee directly, or indirectly through any Third Party, commences any opposition proceeding, post-grant review, inter partes review or ex parte reexamination or Third Party submissions or submits observations with respect to, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any \*, and (A) \* does not cause such Sublicensee to withdraw such action or (B) \* does not terminate the sublicense agreement with such Sublicensee, in each case, within 10 days of \* receiving from \* written notice of any such action being taken by such Sublicensee. Notwithstanding the foregoing, \* shall have no such right to terminate this Agreement in the case of (I) \* or any of its Affiliates' good faith assertion that (x) any Invention claimed by a Patent filed by or on behalf of \* as a \* was an \* or a Joint Invention; or (y) any Invention claimed by a Joint Invention Patent filed by or on behalf of \* as a Joint Invention Patent was an \*; (II) \* or any of its Affiliates' good faith assertion, in the context of whether a payment of royalties is due to \*, that no Valid Claim within the \* applies with respect to a Product; (III) any claim made by \* or any of its Affiliates or Sublicensees as a defense in any lawsuit or administrative proceeding brought by or on behalf of \* or its Affiliates, licensors or licensees; or (IV) any lawsuit, reexamination proceeding or opposition brought by \* or any of its Affiliates or Sublicensees challenging the validity or enforceability of any claim within an issued \* that does not claim the \* that is licensed to \* for use in the Program.

(c) Advaxis shall have the right to cause the parties to negotiate in good faith the termination of this Agreement pursuant to Section 3.3.

<sup>\*</sup> Confidential material redacted and filed separately with the Commission.

### 12.4 Effect of Expiration or Termination; Surviving Obligations.

- (a) **Effect of Expiration.** Upon expiration of this Agreement in accordance with Section 12.1, and provided that Amgen has paid all undisputed payments payable under this Agreement, the licenses granted by Advaxis to Amgen shall become non-exclusive and survive on a fully-paid, irrevocable, perpetual basis, and all other rights and obligations of the parties under this Agreement shall terminate, except as provided elsewhere in this Section 12.4.
- (b) **Effect of Termination.** Upon any termination of this Agreement, the following provisions shall apply (subject to Section 12.4(d)):
- (i) all licenses granted pursuant to Sections 5.1 and 5.2 shall automatically terminate and all other rights and obligations of the parties under this Agreement shall terminate, except as provided elsewhere in this Section 12.4, and following such termination, Amgen shall have no further obligation pursuant to Section 4.5(a) to develop and commercialize any Product; and
- (ii) upon Amgen's request and subject to Advaxis' consent, any sublicenses granted by Amgen pursuant to Section 5.2 with respect to any Product shall remain in effect and become direct licenses from Advaxis subject to the terms and conditions of the applicable sublicense agreement; provided, that the relevant Sublicensee is in good standing under this Agreement and the applicable sublicense agreement.
- (c) **Confidential Information and Material.** Upon expiration or termination of this Agreement in its entirety, except to the extent that a party retains a license from the other party as provided in this Section 12.4, each party shall promptly, upon request of the other party, delete or destroy, all Material and relevant records and materials in such party's possession or control containing Confidential Information of the other party; provided that such party may keep one copy of such records and materials for legal archival purposes only subject to continuing confidentiality obligations in accordance with Article 10.
- (d) **Survival.** Expiration or termination of this Agreement shall not relieve the parties of any liability accruing prior to such expiration or termination. In addition to any provisions expressly set forth herein, the provisions set forth below shall survive expiration or termination of this Agreement:
  - Article 1 Definitions
  - Section 8.3 Taxes (with respect to sales of Products made before such expiration or termination)
  - Section 8.4 Records; Audit (with respect to sales of Products made before such expiration or termination)
  - Section 8.5 Late Payments (with respect to sales made before such expiration or termination)
  - Section 9.1 Ownership of Intellectual Property
  - Section 9.2(a) and (b) Patent Prosecution and Maintenance

Sections 9.4 (a), (b), (e) and (f) – Infringement and Misappropriation by Third Parties (with respect to actions initiated prior to such expiration or termination)

Section 10.4 - Disclaimer

Section 10.5 – Limitation of Liability

Article 11 - Confidentiality

Section 12.4 – Effect of Termination; Surviving Obligations

Section 12.5 – Exercise of Right to Terminate

Section 12.6 - Damages; Relief

Section 12.7 - Rights in Bankruptcy

Article 13 – Indemnification

Article 14 – General Provisions

All other rights and obligations will terminate upon expiration or termination of this Agreement.

- 12.5 Exercise of Right to Terminate. The use by either party hereto of a termination right provided for under this Agreement shall not give rise to the payment of damages or any other form of compensation or relief to the other party solely with respect thereto; provided, however, that termination of this Agreement shall not preclude either party from claiming any other damages, compensation or relief at law or in equity that it may be entitled to upon such termination.
- **12.6 Damages; Relief.** Subject to Section 12.5, termination of this Agreement shall not preclude either party from claiming any other damages, compensation or relief at law or in equity that it may be entitled to upon such termination.
- 12.7 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by one party to the other party are, and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws, licenses of rights to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. The parties agree that a party that is a licensee of such rights under this Agreement will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. The parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a party to this Agreement under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws, the other party will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and the same will, if not already in its possession, be promptly delivered to it (a) upon any such commencement of a bankruptcy or insolvency proceeding upon its written request therefor, unless the bankrupt party elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under (a) above, following the rejection of this Agreement by or on behalf of the bankrupt party upon written request therefor by the other party.

### 13. INDEMNIFICATION

13.1 Indemnification by Advaxis. Advaxis hereby agrees to save, defend and hold Amgen and its Affiliates and its and their respective directors, officers, employees and agents (each, an "Amgen Indemnitee") harmless from and against any and all liabilities, expenses and losses, including reasonable legal expenses and attorneys' fees (collectively, "Losses"), to which any Amgen Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise directly or indirectly out of: (a) the development, manufacture, use, handling, storage, sale or other disposition of any Product by or on behalf of Advaxis or its Affiliates or Sublicensees (b) the gross negligence or willful misconduct of Advaxis or any of its Affiliates, Sublicensees or subcontractors in performing under this Agreement, or (c) the breach by Advaxis of any warranty, representation, covenant or agreement made by Advaxis in this Agreement; except, in each case, to the extent such Losses result from clause (a), (b) or (c) of Section 13.2.

13.2 Indemnification by Amgen. Amgen hereby agrees to save, defend and hold Advaxis, its Affiliates, its licensees and their respective directors, officers, employees and agents (each, an "Advaxis Indemnitee") harmless from and against any and all Losses to which any Advaxis Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise directly or indirectly out of: (a) the development, manufacture, use, handling, storage, sale or other disposition of any Product by or on behalf of Amgen or its Affiliates or Sublicensees, (b) the gross negligence or willful misconduct of Amgen or any of its Affiliates, Sublicensees or subcontractors in performing under this Agreement, or (c) the breach by Amgen of any warranty, representation, covenant or agreement made by Amgen in this Agreement; except, in each case, to the extent such Losses result from clause (a), (b) or (c) or Section 13.1.

13.3 Control of Defense. Any entity entitled to indemnification under this Article 13 shall give notice to the indemnifying party of any Losses that may be subject to indemnification, promptly after learning of such Losses (provided, however, that any failure or delay to notify shall not excuse any obligation of the indemnifying party except to the extent such party is actually prejudiced thereby), and the indemnifying party shall assume (and have control over) the defense of such Losses with counsel reasonably satisfactory to the indemnified party and the indemnified party shall reasonably cooperate (at the indemnifying party's reasonable expense). If such defense is assumed by the indemnifying party with counsel so selected, the indemnifying party will not settle any claim with respect to such Losses without the indemnified party's prior written consent (but such consent will not be unreasonably withheld or delayed), and will not be obligated to pay the fees and expenses of any separate counsel retained by the indemnified party with respect to such Losses. For clarity, the indemnified party may freely withhold its consent to a settlement of a claim with respect to Losses if (i) such settlement does not include a complete release from liability of the indemnified party or if such settlement would involve undertaking an obligation (including the payment of money by an indemnified party), (ii) would bind or impair the indemnified party or (iii) includes any admission of wrongdoing or that any intellectual property or proprietary right of the indemnified party or this Agreement is invalid, narrowed in scope or unenforceable. The Indemnified Party shall not settle or compromise any claim for which it is entitled to indemnification without the prior written consent of the Indemnifying Party, unless the Indemnifying Party is in breach of its obligation to defend hereunder.

13.4 Insurance. Each party, at its own expense, shall maintain product liability and other appropriate insurance (or self-insure sufficiently to provide materially the same level and type of protection) in an amount consistent with sound business practice and adequate in light of its obligations under this Agreement during the Term. Each party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other party upon request. Such insurance will not create a limit to either party's liability hereunder.

# 14. GENERAL PROVISIONS

14.1 Governing Law; Jurisdiction. This Agreement and its effect are subject to and shall be construed and enforced in accordance with the law of the State of New York, without regard to its conflicts of laws, except as to any issue which depends upon the validity, scope or enforceability of any Patent, which issue shall be determined in accordance with the laws of the country in which such patent was issued. Each of the parties hereto hereby irrevocably and unconditionally consents to submit to the exclusive jurisdiction of the courts of the State of New York for any matter arising out of or relating to this Agreement and the transactions contemplated hereby, and agrees not to commence any litigation relating thereto except in such courts. Each of the parties hereto hereby irrevocably and unconditionally waives any objection to the laying of venue of any matter arising out of this Agreement or the transactions contemplated hereby in the courts of the State of New York and hereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such matter brought in any such court has been brought in an inconvenient forum. The parties hereto agree that a final judgment in any such matter shall be conclusive and may be enforced in other jurisdictions by suits on the judgment or in any other manner provided by law. Any proceeding brought by either party hereto under this Agreement shall be exclusively conducted in the English language.

- **14.2 Entire Agreement; Modification.** This Agreement (including the Schedules attached hereto) constitutes a complete and exclusive statement with respect to all of its terms. This Agreement (including the Schedules attached hereto) supersedes all prior and contemporaneous agreements and communications, whether oral, written or otherwise, concerning any and all matters contained herein. This Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by the parties.
- 14.3 Relationship Between the Parties. The parties' relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship between the parties. Neither party is a legal representative of the other party, and neither party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other party for any purpose whatsoever. For clarity, the parties acknowledge and agree that their activities hereunder will not create a partnership for tax purposes.
- **14.4 Non-Waiver.** The failure of a party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such party.
- **14.5 Assignment.** Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either party without the prior written consent of the other party (which consent shall not be unreasonably withheld, conditioned or delayed); provided, however, that either party may assign or otherwise transfer this Agreement and its rights and obligations hereunder without the other party's consent:
- (a) in connection with the transfer or sale of all or substantially all of the business or assets of such party relating to the subject matter of this Agreement to a Third Party, whether by merger, consolidation, divesture, restructure, sale of stock, sale of assets or otherwise (a "Sale Transaction"); or

(b) to an Affiliate, provided that the assigning party shall remain liable and responsible to the non-assigning party hereto for the performance and observance of all such duties and obligations by such Affiliate.

The rights and obligations of the parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the parties specified above, and the name of a party appearing herein will be deemed to include the name of such party's successors and permitted assigns to the extent necessary to carry out the intent of this Section 14.5. Any assignment not in accordance with this Agreement shall be void.

# 14.6 Rights upon Change of Control or Material Breach by Advaxis.

- (a) Advaxis shall give Amgen written notice within five days after the first public announcement or disclosure of any Change of Control of Advaxis. Upon such notice, Amgen shall have the right to (i) transfer or have transferred, in an orderly process, some or all of the activities and decision-making as contemplated herein from Advaxis to Amgen, upon written notice by Amgen, and (ii) exclude Advaxis (following such Change of Control) from participation in whole or in part from the JSC or any other governance committees or working teams.
- (b) Upon the material breach of this Agreement by Advaxis and Advaxis' failure to cure such breach within the 90-day period following written notice by Amgen of such breach, Amgen shall have the right, upon the further written notice to Advaxis, to elect, in lieu of termination pursuant to Section 12.2(b), to (i) transfer or have transferred, in an orderly process, some or all of the activities and decision-making as contemplated herein from Advaxis to Amgen, and (ii) exclude Advaxis (following such election) from participation in whole or in part from the JSC or any other governance committees or working teams. Following such election, all milestone and royalty payments otherwise due to Advaxis hereunder shall be reduced by 50%.
- **14.7 No Third Party Beneficiaries.** This Agreement is neither expressly nor impliedly made for the benefit of any party other than the parties and their successors and permitted assigns, except for the persons expressly entitled to indemnification as provided in Article 13 and only in accordance with the terms of such Article 13.
- 14.8 Severability. If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable or illegal by a court of competent jurisdiction, such adjudication shall not, to the extent feasible, affect or impair, in whole or in part, the validity, enforceability, or legality of any remaining portions of this Agreement. All remaining portions shall remain in full force and effect as if the original Agreement had been executed without the invalidated, unenforceable or illegal part.
- 14.9 Notices. Any notice to be given under this Agreement must be in writing and delivered either in person, by (a) air mail (postage prepaid) requiring return receipt, (b) overnight courier, or (c) email or facsimile confirmed thereafter by any of the foregoing, to the party to be notified at its address(es) given below, or at any address such party may designate by prior written notice to the other in accordance with this Section 14.9. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (i) the date of actual receipt; (ii) if air mailed, five days after the date of postmark; (iii) if delivered by overnight courier, the next day the overnight courier regularly makes deliveries; or (iv) if emailed or sent by facsimile, the date of confirmation of receipt if during the recipient's normal business hours, otherwise the next day.

### If to Amgen, notices must be addressed to:

Amgen Inc.

One Amgen Center Drive Thousand Oaks, CA 91320 Attention: Corporate Secretary

Facsimile: \*

Advaxis, Inc.

305 College Road East

Attention: Corporate Secretary

Princeton, NJ 08540

Amgen Inc.

One Amgen Center Drive Thousand Oaks, CA 91320

Attention: Senior Vice President, Business

with a copy (which shall not constitute notice) to:

Development Facsimile: \*

If to Advaxis, notices must be addressed to:

with a copy (which shall not constitute notice) to:

Advaxis, Inc.

305 College Road East Princeton, NJ 08540

Attention: President/Chief Executive Officer

14.10 Force Majeure. Each party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement (other than failure to make payment when due) by reason of any event beyond such party's reasonable control including acts of God, fire, flood, explosion, earthquake, pandemic flu, or other natural forces, war, civil unrest, acts of terrorism, accident, destruction or other casualty or any other event similar to those enumerated above. Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the party has not caused such event(s) to occur. Notice of a party's failure or delay in performance due to force majeure must be given to the other party within 10 days after its occurrence. All delivery dates under this Agreement that have been affected by force majeure shall be tolled for the duration of such force majeure. In no event shall any party be required to prevent or settle any labor disturbance or dispute.

<sup>\*</sup> Confidential material redacted and filed separately with the Commission.

14.11 Interpretation. The headings of clauses contained in this Agreement preceding the text of the sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable. Unless otherwise specified, references in this Agreement to any Article shall include all Sections, subsections and paragraphs in such Article, references to any Section shall include all subsections and paragraphs in such Section, and references in this Agreement to any subsection shall include all paragraphs in such subsection. The word "including" and similar words means including without limitation. The word "or" means "and/or" unless the context dictates otherwise because the subject of the conjunction are mutually exclusive. The words "herein," "hereof" and "hereunder" and other words of similar import refer to this Agreement as a whole and not to any particular Section or other subdivision. All references to days in this Agreement shall mean calendar days, unless otherwise specified. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either party, irrespective of which party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the parties regarding this Agreement shall be in the English language.

**14.12 Counterparts; Electronic or Facsimile Signatures.** This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Agreement may be executed and delivered electronically or by facsimile and upon such delivery such electronic or facsimile signature will be deemed to have the same effect as if the original signature had been delivered to the other party.

14.13 Schedules. All schedules referred to in this Agreement are attached hereto and incorporated herein by this reference.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties hereto have caused this LICENSE AND COLLABORATION AGREEMENT to be executed and entered into by their duly authorized representatives as of the Effective Date.

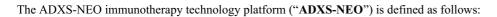
ADVAXIS, INC.	AMGEN INC.
By: /s/ Daniel J. O'Connor	By: /s/ Robert A. Bradway
Name: Daniel J. O'Connor	Name: Robert A. Bradway
Title: President & CEO	Title: Chairman of the Board, President & CEO
Signature Page to License ar	

Schedule 1.1 – Advaxis Background Patents

Country	Advaxis Patent Family Ref. No.	Prosecution Status	Patent Number		Application Number	Title	Abstract	Priority Date	Filing Date
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<sup>\*</sup> Confidential material redacted and filed separately with the Commission.

# Schedule 1.53 – The Program



a. \*;
b. \*;
c. \*;
d. \*;
e. \*;
f. \*;
g. \*;
h. \*;
i. \*;
j. \*; and
k. \*.

<sup>\*</sup> Confidential material redacted and filed separately with the Commission.

# Schedule 4.3(C) – Supply Agreement Term Sheet

- Approved clinical and commercial supply and quality agreements must be in place prior to (x) the first shipment of Product (such term, as used in this schedule, to be agreed upon by the parties) to Amgen or Amgen's designated clinical site and (y) the manufacture of the lot designated for commercial launch, respectively.
- Phase appropriate terms and descriptions outlined below, together with any terms contained or described in the Agreement, will serve as the basis for a definitive clinical and commercial supply agreement between the parties.

Term	Description
Stage Supplied	Advaxis will supply Amgen (or Amgen's clinical site) with Product in finished form (i.e., drug product that has been packaged, labeled and is ready for immediate use) and manage all Third Party suppliers (unless otherwise agreed to by the parties) contracted by Advaxis to perform the Services (such term, as used in this schedule, to be agreed upon by the parties) for Amgen. For clarity, the manufacture of Product in finished form includes the entire process from patient biopsy, sequencing, manufacturing, testing, disposition, storage, transportation from and transportation to the patient.
Reserved Capacity	Advaxis will reserve a mutually agreed upon capacity for the manufacturing of Product for Amgen.
Material Safety Stock	Advaxis will hold a mutually agreed upon safety stock of Materials (such term, as used in this schedule, to be agreed upon by the parties) needed to perform the Services and manufacture Product for Amgen.
Product Safety Stock	Advaxis will generate sufficient Product supply to ensure patients receive all required doses (including provisions for safety factors, reserves, testing, etc.)
IncoTerm	Product will be supplied to Amgen (or the clinical site) EXW (Incoterms 2010 ICC) if shipment is domestic or FCA (Incoterms 2010 ICC) if shipment is international.
Cost	Product will be supplied to Amgen at Advaxis' *. For clarity, if Advaxis is using a Third Party contract manufacturer, then the actual costs of the supplied product will be * for such Product.
Site of Manufacture	The JSC shall determine the manufacturing site. If Advaxis is manufacturing Product, or if Advaxis is manufacturing Product through the use of a Third Party contract manufacturer, then Amgen shall have the right to approve the site(s) utilized for manufacturing, such approval not to be unreasonably withheld.
Tech Transfer to Amgen or Third Party Manufacturer	If the JSC determines to transfer manufacturing of Products to Amgen (directly or through a Third Party contract manufacturer of its choice), Advaxis shall conduct a Technology Transfer to Amgen or its designee. The parties shall agree to the costs and manpower related to Technology Transfer.

<sup>\*</sup> Confidential material redacted and filed separately with the Commission.

Term	Description
Rejected batches	The parties shall agree to a process for replacing and/or reimbursement related to nonconforming Product.
Process Changes	Advaxis shall implement all mandatory (i.e. Regulatory mandated) changes and changes reasonably requested by Amgen. Amgen will have the right to approve all Process and Product changes requested by Advaxis used in the sequencing, manufacturing, testing, disposition, storage and transportation of Product. The Parties shall discuss the timing, cost and implementation of Process Changes so as to ensure continued supply of Product to patients.
Audit Right	Amgen shall have the right to perform financial audits of Advaxis solely as it relates to the Product and/or Services provided to Amgen once per twelve (12) months period.
Records	Advaxis shall be responsible for maintaining accurate records related to cold chain transportation, chain of custody, customs clearance and all associated costs. Amgen has the right to request and review such records at a mutually agreed to frequency.
Forecasting	The clinical and commercial supply agreement will contain phase appropriate forecasting provisions for the purchase of Product. Such forecasting provisions shall include: frequency of forecast submission (i.e. monthly, quarterly, etc.), length of forecast including binding and nonbinding portions of the forecast, min/max order quantity and forecast variance.
Additional terms	The supply agreement will contain customary terms including but not limited to: Representations, Warranties, Covenants, Indemnification, Limits of Liability, Dispute Resolution, Termination, IP Rights, Governing Law etc.
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## Schedule 4.3(D) - Quality Agreement Term Sheet

- Approved clinical and commercial supply and quality agreements must be in place prior to (x) the first shipment of Product (such term, as used in this schedule, to be agreed upon by the parties) to Amgen or Amgen's designated clinical site, and (y) the manufacture of the lot designated for commercial launch, respectively.
- Phase appropriate terms and descriptions outlined below, together with any terms contained or described in the Agreement, will serve as the basis for a definitive clinical and commercial quality agreement between the parties.

Section	High Level Summary
Purpose	Including scope, parties involved, products and services involved.
Roles & Responsibilities	Defined responsibilities, including Guiding Principles, Organizational Structure, and Communication expectations of each party, including contact information for parties involved.
cGMP Compliance	All services performed by Advaxis under the Supply and Quality Agreements shall be performed in compliance with cGMP, US Pharmacopoeia ("USP"), European Pharmacopoeia ("PhEur"), and other regulatory jurisdictions, as may be agreed between the parties, Amgen specifications, Product license filings, and all relevant international, federal, state and local laws and regulations and, to the extent consistent with the foregoing requirements and regulations, in accordance with Advaxis procedures and guidelines. Advaxis must have appropriate Quality Systems in place.
Specifications	Advaxis will manufacture and release Product to Amgen per mutually agreed upon specifications and cGMP. Amgen may perform certain specified additional testing of the Product.
Audit Right	Amgen will have the right to perform quality and/or facilities audits of Advaxis, or participate with Advaxis in its quality and/or facilities audit of its Third Parties utilized for sequencing, manufacturing, testing, disposition, storage, transportation of Product on a frequency to be agreed upon by both parties , as well as more often in case of a quality issue.
Person In Plant (PIP)	Amgen shall have the right to elect to locate one person in the plant ("PIP") in the Advaxis facility to provide Product oversight during Phase III / commercial activities and any development and qualification activities, or as requested by Amgen.
Change Management including Change of Materials/ Change of Material Supplier	Defined requirements for changes proposed by Advaxis or Amgen. Amgen will have the right to approve all Material changes and/or changes of Material supplier used in the sequencing, manufacturing, testing, disposition, storage, transportation of Product.

Section	High Level Summary	
Exception Management	Defined terms to include the responsibilities during nonconformances/deviations and Out of Specification (OOS) investigations.	
Disposition Requirements and Batch Rejection	Advaxis shall review and perform the manufacturer's disposition for each Batch of Product. For each Batch of Product, Advaxis shall provide Amgen with predefined documentation prior to shipment of the Batch.	
Document Access	Advaxis shall make available to Amgen Advaxis standard operating procedures, manufacturing records, specifications, laboratory records, summary reports, validation protocols and reports, investigation reports, training records, equipment, utilities and facilities, cleaning, calibration and maintenance records associated with the manufacture of Amgen products, and other supportive records/reports if and as far as reasonably required and relating to Product.	
Regulatory Correspondence	Amgen and Advaxis shall establish a group consisting of one or more representatives from each party to coordinate the activities and the flow of information among the parties in support of regulatory filings and related regulatory matters. The purpose of this group is to provide timely and accurate submissions for Product and ensure all parties have the most current regulatory filings. Amgen shall lead the regulatory efforts in the Territories and is responsible for all Product regulatory filings and submissions with the relevant regulatory agencies. Advaxis shall supply specific information necessary for filings with regulatory agencies within timelines agreed to with Amgen for those filings for the Product.	
Regulatory Inspections / Notifications	Advaxis shall notify Amgen of regulatory inspections at an Advaxis facility or a Third Party contract manufacturer related to the Product. Advaxis will permit, and cause its Third Party contract manufacturer(s) to permit, officials of any Regulatory Authority to inspect the manufacturing facility utilized for manufacturing Product for Amgen, and will inform Amgen promptly of any planned or anticipated inspection. Advaxis will permit, or cause its Third Party contract manufacturer to permit, Amgen to accompany such official inspection. Advaxis will provide Amgen with copies of all reports and communications with the Regulatory Authority in connection therewith, will take into account Amgen's comments before responding to such communications and will remedy any deficiencies at its own expense.	
Third Party Suppliers / Subcontractors	Amgen will have the right to approve all suppliers used in the support of manufacturing Product, such approval not to be unreasonably withheld. An Annex will be included with Subcontractor name, address and type of service provided at a minimum.	
Dispute Resolution Parameters	Defined roles and responsibilities for dispute resolution unless covered in Supply Agreement.	
Additional Terms	The quality agreement will contain customary terms including but not limited to: Animal Derived Raw Material Program, Annual Product Review, Analytical Testing Roles and Responsibilities, Regulatory Health Authority Product Testing and Method Transfers, Biological Product Deviation Reporting, Complaint/Adverse Event Requirements, Data Integrity, Label Controls, Product Recall Responsibilities, Quality Metrics, Receiving/Storage/Shipment of Raw Materials, Components and Product, Reference / Retention Sample Requirements, Reprocessing / Rework Requirements, Product Recall Responsibilities, Risk Management, Stability Program, Training Program, and Validation Program.	
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## **Schedule 11.5 - Press Release**

[See attached.]





## News Release

## AMGEN AND ADVAXIS ENTER GLOBAL CANCER IMMUNOTHERAPIES COLLABORATION

## Collaboration Will Advance Highly Targeted, Patient-Specific Treatment Approach

### Advaxis Will Hold a Teleconference at 9:30 a.m. ET Today

THOUSAND OAKS, Calif., and PRINCETON, N.J., (Aug. 2, 2016) – Amgen (NASDAQ:AMGN) and Advaxis, Inc. (NASDAQ:ADXS) today announced a global agreement for the development and commercialization of Advaxis' ADXS-NEO, a novel, preclinical investigational cancer immunotherapy treatment that is designed to activate a patient's immune system to respond against the unique mutations, or neoepitopes, contained in and identified from each individual patient's tumor. This collaboration brings together Amgen's development expertise in immuno-oncology with Advaxis' MINE™ (My Immunotherapy NeoEpitopes) program, which is uniquely positioned to develop a customized approach to cancer treatment.

Under the terms of the agreement, Amgen receives exclusive worldwide rights to develop and commercialize ADXS-NEO. Amgen will make an upfront payment to Advaxis of \$40 million and purchase \$25 million of Advaxis common stock. Amgen will be fully responsible for funding clinical and commercial activities. Advaxis will lead the clinical development of ADXS-NEO through proof-of-concept, retain manufacturing responsibilities, and receive development, regulatory and sales milestone payments of up to \$475 million and potential high single digit to mid-double digit royalty payments based on worldwide sales.

"Amgen's collaboration with Advaxis leverages and enhances our development and commercialization expertise in novel immuno-oncology treatments," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "We look forward to partnering with Advaxis to advance this highly targeted and patient-specific treatment option for patients."

"Amgen is a pioneer in the science of using living cells to develop biologic medicines, making them an incredibly strong partner to develop and commercialize Advaxis' MINE," said Daniel J. O'Connor, president and chief executive officer at Advaxis. "With Amgen's resources, worldwide reach and a culture that embraces science and innovation, we are positioned to accelerate the clinical development program for ADXS-NEO to improve the lives of those who suffer from cancer."

The Advaxis Lm Technology™ utilizes live attenuated Listeria monocytogenes (Lm) bioengineered to produce and deliver tumor antigen/adjuvant fusion proteins within antigen presenting cells with the goal of generating strong, T-cell-mediated immunity. For ADXS-NEO, DNA from each patient's primary tumor and/or metastases as well as normal cells, is sequenced and compared to identify mutations in genes coding for potential neo-antigens in the cancer. Advaxis then engineers and manufactures patient-specific Lm-LLO (listeriolysin O) vectors capable of immunizing them against neoepitopes exclusive to their cancer. After the ADXS-NEO infusion, neoepitope peptides corresponding to each patient's cancer-associated mutations are delivered directly into their antigen presenting cells by Lm-LLO, where they can stimulate cellular immune responses against multiple neoepitopes simultaneously. Clinical trials for ADXS-NEO are expected to begin in 2017.

### About MINE™ (My Immunotherapy Neo-Epitopes) / ADXS-NEO

MINE<sup>TM</sup> (My Immunotherapy Neo-Épitopes) and ADXS-NEO are designed to activate a patient's immune system to respond against the unique mutations, or neoepitopes, contained in each individual patient's tumor. This strategy, using massive parallel sequencing, eliminates the need for predictive algorithms and enables the development of truly personalized immunotherapies that can be manufactured in a manner that is cost-effective and timely for patients.

MINE<sup>TM</sup> will evaluate the immunologic and anti-tumor activity of this patient tumor-specific, necepitope-based immunotherapy. Advaxis and Amgen will use learnings from MINE to identify and target necepitopes using Lm Technology<sup>TM</sup> and later develop patient specific immunotherapy constructs that incorporate the necepitope sequences identified in the patient's tumor cells. Clinical studies using ADXS-NEO are in development.

#### Conference Call and Webcast

Advaxis will host a conference call today, Aug. 2, 2016, beginning at 9:30 a.m. ET. Please see below for details.

Conference call numbers: Domestic/Canada: 888-466-4442 International: 719-325-2480 Conference ID: 2246109

Webcast: http://public.viavid.com/index.php?id=120644

Accessible via the Investor Relations section of Advaxis' website; http://ir.advaxis.com/

A replay of the conference call and webcast will be available beginning approximately one hour after the completion of the call. Access numbers for this replay are 1 (877) 870-5176 (U.S./Canada) and 1 (858) 384-5517 (international); conference ID: 2246109.

### About Amgen

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading

independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

### About Advaxis, Inc.

Located in Princeton, N.J., Advaxis, Inc. is a clinical-stage biotechnology company developing multiple cancer immunotherapies based on its proprietary Lm Technology™. The Lm Technology™, using bioengineered live attenuated Listeria monocytogenes (Lm) bacteria, is the only known cancer immunotherapy agent shown in preclinical studies to both generate cancerfighting T cells directed against cancer antigens and neutralize Tregs and myeloid-derived suppressor cells (MDSCs) that protect the tumor microenvironment from immunologic attack and contribute to tumor growth. Advaxis' lead Lm Technology™ immunotherapy, axalimogene filolisbac (AXAL), targets human papillomavirus (HPV)-associated cancers and is in clinical trials for three potential indications: Phase 2 in invasive cervical cancer, Phase 1/2 in head and neck cancer, and Phase 1/2 in anal cancer. The U.S. Food and Drug Administration (FDA) has granted AXAL orphan drug designation for each of these three clinical settings, as well as a Special Protocol Assessment for the Phase 3 AIM2CERV trial in patients with high risk, locally advanced cervical cancer. AXAL has also been classified as an advanced therapy medicinal product for the treatment of cervical cancer by the European Medicines Agency's Committee for Advanced Therapies. Advaxis has two additional immunotherapy products in human clinical development: ADXS-PSA in prostate cancer and ADXS-HER2 in HER2-expressing solid tumors. Advaxis has received Fast Track Designation for ADXS-HER2 for the treatment of patients with newly-diagnosed, non-metastatic, surgically-resectable osteosarcoma and for AXAL for the treatment of high-risk locally advanced cervical cancer.

For additional information on Advaxis, visit <a href="www.advaxis.com">www.advaxis.com</a> and connect on <a href="www.advaxis.com">Twitter</a>, <a href="LinkedIn">LinkedIn</a>, <a href="Facebook">Facebook</a>, <a href="YouTube">YouTube</a> and <a href="Google+">Google+</a>.

### **Amgen Forward-Looking Statements**

This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including its most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those Amgen projects. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, preclinical results do not guarantee safe and effective

performance of product candidates in humans. The complexity of the human body cannot be perfectly, or sometimes, even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for Amgen to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints Amgen has selected. Amgen develops product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify safety, side effects or manufacturing problems with its products after they are on the market.

Amgen's results may be affected by its ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing its products and global economic conditions. In addition, sales of Amgen's products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment. Furthermore, Amgen's research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Amgen or others could identify safety, side effects or manufacturing problems with its products after they are on the market. Amgen's business may be impacted by government investigations, litigation and product liability claims. In addition, Amgen's business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If Amgen fails to meet the compliance obligations in the corporate integrity agreement between it and the U.S. government, Amgen could become subject to significant sanctions. Further, while Amgen routinely obtains patents for its products and technology, the protection offered by its patents and patent applications may be challenged, invalidated or circumvented by its competitors, or Amgen may fail to prevail in present and future intellectual property litigation. Amgen performs a substantial amount of its commercial manufacturing activities at a few key manufacturing facilities and also depends on third parties for a portion of its manufacturing activities, and limits on supply may constrain sales of certain of its current products and product candidate development. In addition, Amgen competes with other companies with respect to many of its marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for Amgen's products are supplied by sole third-party suppliers. The discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on its business and results of operations. Amgen's efforts to acquire other companies or products and to integrate the operations of companies Amgen has acquired may not be successful. Amgen may not be able to access the capital and credit markets on terms that are favorable to it, or at all. Amgen is increasingly dependent on information technology systems, infrastructure and data security. Amgen's stock price may be volatile and may be affected by a number of events. Amgen's business performance could affect or limit the ability of the Amgen Board of Directors to declare a dividend or its ability to pay a dividend or repurchase its common stock.

The scientific information discussed in this news release related to Amgen's product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates.

## **Advaxis Forward-Looking Statement**

This media statement contains forward-looking statements, including, but not limited to: statements regarding Advaxis' ability to develop the next generation of cancer immunotherapies; and the safety and efficacy of Advaxis' proprietary immunotherapies. These forward-looking statements are subject to a number of risks, including the risk factors set forth from time to time in Advaxis' SEC fillings, including but not limited to its report on Form 10-K for the fiscal year ended October 31, 2015, which is available at <a href="http://www.sec.gov">http://www.sec.gov</a>. Advaxis undertakes no obligation to publicly release the result of any revision to these forward-looking statements, which may be made to reflect the events or circumstances after the date hereof or to reflect the occurrence of unanticipated events, except as required by law. You are cautioned not to place undue reliance on any forward-looking statements.

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### CONTACTS:

### Amgen, Thousand Oaks

Kristen Neese, 805-313-8267 (media) Trish Hawkins, 805-447-5631 (media) Arvind Sood, 805-447-1060 (investors)

### Advaxis, Inc.

Greg Mayes, Executive Vice President and COO mayes@advaxis.com 609-250-7515

JPA Health Communications (media) David Connolly dconnolly@jpa.com 617-543-3915

## INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of Advaxis, Inc. on Form S-8 [File Nos. 333-130080 and 333-210285] and Form S-3 [File Nos. 333-194009 and File No. 333-203497] of our report dated January 9, 2017, with respect to our audits of the financial statements of Advaxis, Inc. as of October 31, 2016 and 2015 and for the years ended October 31, 2016, 2015 and 2014 and our report dated January 9, 2017 with respect to our audit of the effectiveness of internal control over financial reporting of Advaxis, Inc. as of October 31, 2016, which reports are included in this Annual Report on Form 10-K of Advaxis, Inc. for the year ended October 31, 2016.

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

# CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO 18.U.S.C. 7350 (SECTION 302 OF THE SARBANES OXLEY ACT OF 2002)

### I, Daniel J. O'Connor, certify that:

- 1. I have reviewed this annual report on Form 10-K for the year ended October 31, 2016 of Advaxis, Inc.;
- Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to
  make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the
  period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

January 9, 2017

By: /s/Daniel J. O'Connor

Name: Daniel J. O'Connor

Title: Chief Executive Officer and President

### CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18. U.S.C. 7350 (SECTION 302 OF THE SARBANES OXLEY ACT OF 2002)

### I, Sara M. Bonstein, certify that:

- 1. I have reviewed this annual report on Form 10-K for the year ended October 31, 2016 of Advaxis, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

January 9, 2017

By: /s/ Sara M. Bonstein

Name: Sara M. Bonstein

Title: Chief Financial Officer, Executive Vice President

# CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Advaxis, Inc., a Delaware corporation (the "Company"), on Form 10-K for the year ended October 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, the Chief Executive Officer, hereby certifies pursuant to 18 U.S.C. Sec. 1350 as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002 that, to the undersigned's knowledge:

- (1) the Report of the Company filed today fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Date: January 9, 2017 By: /s/Daniel J. O'Connor

Name: Daniel J. O'Connor

Title: Chief Executive Officer and President

# CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Advaxis, Inc., a Delaware corporation (the "Company"), on Form 10-K for the year ended October 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, the Chief Financial Officer, hereby certifies pursuant to 18 U.S.C. Sec. 1350 as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002 that, to the undersigned's knowledge:

- (1) the Report of the Company filed today fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Date: January 9, 2017 By: /s/ Sara M. Bonstein

Name: Sara M. Bonstein

Title: Chief Financial Officer, Executive Vice President