

Advaxis, Inc.  
Form 10-K  
December 21, 2017

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-K**

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

**OF THE SECURITIES EXCHANGE ACT OF 1934**

**FOR THE FISCAL YEAR ENDED - OCTOBER 31, 2017**

**OR**

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

**OF THE SECURITIES EXCHANGE ACT OF 1934**

**FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_**

**COMMISSION FILE NUMBER 000-28489**

**ADVAXIS, INC.**

*(Name of Registrant in Its Charter)*

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

Delaware 02-0563870  
(State or Other Jurisdiction of (I.R.S. Employer  
Incorporation or Organization) Identification No.)

305 College Road East  
Princeton, New Jersey 08540  
(Address of Principal Executive Offices) (Zip Code)

(609) 452-9813  
(Issuer's Telephone Number)

Securities registered under Section 12(b) of the Exchange Act: Common Stock - \$.001 par value  
NASDAQ Capital Market

Securities registered under Section 12(g) of the Exchange Act: [None]

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes [ ] No [X]

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

Yes [ ] No [X]

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

Yes [X] No [ ]

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

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

Yes  No

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

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

Large Accelerated Filer  Accelerated Filer   
Non-accelerated Filer  (Do not check if smaller reporting company) Smaller Reporting Company   
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

As of April 30, 2017, the aggregate market value of the voting common equity held by non-affiliates was approximately \$336,054,000 based on the closing bid price of the registrant's Common Stock on the NASDAQ Capital Market. (For purposes of determining this amount, only directors, executive officers, and 10% or greater shareholders and their respective affiliates have been deemed affiliates).

The registrant had 41,303,988 shares of Common Stock, par value \$0.001 per share, outstanding as of December 15, 2017.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Proxy Statement for the registrant's 2018 Annual Meeting of Stockholders (the "Proxy Statement") to be filed within 120 days of the end of the fiscal year ended October 31, 2017 are incorporated by reference in Part III hereof. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as a part hereof.

Table of Contents

**Form 10-K Index**

**PART 1**

Item 1:	<u>Business</u>	4
Item 1A:	<u>Risk Factors</u>	16
Item 1B:	<u>Unresolved Staff Comments</u>	28
Item 2:	<u>Properties</u>	28
Item 3:	<u>Legal Proceedings</u>	28
Item 4:	<u>Mine Safety Disclosures</u>	28

**PART II**

Item 5:	<u>Market for Registrant’s Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities</u>	28
Item 6:	<u>Selected Financial Data</u>	30
Item 7:	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	31
Item 7A:	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	39
Item 8:	<u>Financial Statements and Supplementary Data</u>	39
Item 9:	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosures</u>	39
Item 9A:	<u>Controls and Procedures</u>	39
Item 9B:	<u>Other Information</u>	42

**PART III**

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

**Part IV**

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

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

## PART 1

### FORWARD LOOKING STATEMENTS

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

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

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

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

*the successful development and implementation of our sales and marketing campaigns;*  
*the change 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 late-stage biotechnology Company focused on the discovery, development and commercialization of proprietary *Lm* Technology antigen delivery products based on a platform technology that utilizes live attenuated *Listeria monocytogenes* (“*Lm*”) bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm*-based strains are believed to be a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy by accessing and directing 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 (“TME”) to enable the T cells to eliminate tumors. The Company believes that *Lm* Technology immunotherapies can complement and address significant unmet needs in the current oncology treatment landscape. Specifically, their product candidates have the potential to optimize checkpoint performance, while having a generally well-tolerated safety profile, and most of their product candidates are immediately available for treatment with a low cost of goods. The Company’s passion for the clinical potential of *Lm* Technology is balanced by focus and fiscal discipline and driven towards increasing shareholder value.

Advaxis is focused on four franchises in various stages of clinical and pre-clinical development, which they believe will provide the greatest opportunity to have a significant impact on patients and their families:

- Human Papilloma Virus (“HPV”)-associated cancers
- Neoantigen therapy
- Disease focused hotspot / cancer antigen therapies
- Prostate cancer

All four clinical franchises are anchored in the Company’s *Lm* Technology™, a unique platform designed for its ability to safely and effectively target various cancers in multiple ways. As an intracellular bacterium, *Lm* is an effective vector for the presentation of antigens through both the Major Histocompatibility Complex (“MHC”) I and II pathways, due to its active phagocytosis by Antigen Presenting Cells (“APCs”). Within the APCs, *Lm* produces virulence factors which allow survival in the host cytosol and potentially stimulate the immune system.

Through a license from the University of Pennsylvania, Advaxis has exclusive access to a proprietary formulation of attenuated *Lm* called *Lm* Technology. *Lm* Technology optimizes this natural system, and one of the keys to the enhanced immunogenicity of *Lm* Technology is the *tLLO* – fusion protein, which is made up of tumor associated



antigen (“TAA”) fused to a highly immunogenic bacterial protein that triggers potent cellular immunity. The *tLLO*-fusion protein also helps to reduce immune tolerance in the TME and promotes antigen spreading, thereby improving activity in the TME. Multiple copies of the *tLLO*-fusion protein within each construct may increase antigen presentation and TME impact.

As the field of immunotherapy continues to evolve, the flexibility of the *Lm* Technology platform has allowed Advaxis to develop highly innovative products. To date, *Lm* Technology has demonstrated preclinical synergy with multiple checkpoint inhibitors, co-stimulatory agents and radiation therapy, with clinical trials currently underway or planned in combination with Merck & Co., Inc. (“Merck”), AstraZeneca PLC (“AstraZeneca”), and Bristol-Myers Squibb Company’s (“BMS”) PD-1/PDL-1 inhibitors. The safety profile of all *Lm* Technology constructs seen to date has been predictable and manageable, consisting mostly of mild to moderate flu-like symptoms that have been transient and associated with infusion.

### **The Advaxis Corporate Strategy**

The Advaxis corporate strategy is to advance the *Lm* Technology platform and leverage its unique capabilities to design and develop an array of cancer treatments. The Company and its collaborators are currently conducting or planning clinical studies of *Lm* Technology immunotherapies in HPV-associated cancers (including cervical and head and neck), prostate cancer, non-small cell lung cancers, and microsatellite stable colorectal cancer. Advaxis’ partners and collaborators include Amgen, Inc. (“Amgen”), BMS, Merck, AstraZeneca, the Gynecological Oncology Group (“GOG”) Foundation, Inc. (now a member of NRG Oncology), the European Network for Gynaecological Oncological Trial groups (“ENGOT”), the Parker Institute for Cancer Immunotherapy, Baylor College of Medicine and the Prostate Cancer Foundation.

Moving forward, the Company will continue to invest in its core clinical franchises and will also remain opportunistic in evaluating Investigator Sponsored Trials (“ISTs”) as well as licensing opportunities. The *Lm* Technology platform is protected by a range of patents, covering both product and process, some of which the Company believes can be maintained into 2037.

## ***Lm* Technology and the Immunotherapy Landscape**

The challenge of cancer immunotherapy has been to find the best overall balance between efficacy and side effects when mobilizing the body's immune system to fight against cancer. The development of immune checkpoint inhibitors was a significant step forward, and brought with it impressive clinical activity in many different types of cancers, including melanoma and lung cancer. However, a literature review published in *Pharmacy and Therapeutics* in 2016 noted that checkpoint inhibitor monotherapy response rates are only in the 15-20% range, and rise to around 50% higher only in selected groups of patients with melanoma or lung cancer. Therefore, for most cancer patients, there is room for improvement. Checkpoint inhibitors can expand existing cancer fighting cells that may already be present in low numbers and support their activity against cancer cells, but if the right cancer-fighting cells are not present, checkpoint inhibitors may not provide clinical benefit. Similarly, there are many mechanisms of immune tolerance that are distinct from the checkpoints which, may also be blocking the immune system from fighting cancer. Based on both pre-clinical and early clinical data, Advaxis believes that checkpoint inhibitors, when combined with treatments such as *Lm* Technology, can have an amplified anti-tumor effect. *Lm* Technology incorporates several complementary elements that include innate immune stimulation, potent generation of cancer-targeted T cells, ability to boost immunity through multiple treatments, enhancing lymphocyte infiltration into tumors, reduction of non-checkpoint mediated immune tolerance within the tumor microenvironment, and promotion of antigen spreading which may amplify the effects of treatment. These results provide rationale for further testing of *Lm* Technology agents in combination with checkpoint inhibitors.

Traditional cancer vaccines were another development within immunotherapy and have a history beginning over 30 years ago. Unfortunately, these vaccines have largely been unsuccessful for a variety of potential reasons. These include poor selection of targets, imbalanced antigen presentation by inclusion of certain immune enhancing agents (adjuvants), failure to consider the blocking actions of immune tolerance, and choice of vaccine vectors. In some cases, patients may develop neutralizing antibodies, preventing further treatments. In contrast to traditional cancer vaccines, *Lm* Technology takes advantage of a natural pathway in the immune system that evolved to protect us against *Listeria* infections, that also happens to generate the same type of immunity that is required when fighting cancer. The live but weakened (attenuated) bacteria stimulate a balanced concert of innate immune triggers and present the tumor antigen target precisely where it needs to be to generate potent cancer fighting cells from within the immune system itself. The multitude of accompanying signals serves to broadly mobilize most of the immune system in support of fighting what seems to be a *Listeria* infection, and is then "re-directed" against cancer cell targets. Additionally, the unique intracellular lifecycle of *Listeria* avoids the creation of neutralizing antibodies, thereby allowing for repeat administration as a chronic therapy with a sustained enhancing of tumor antigen-specific T cell immunity.

More recently, a new category of immunotherapies called Adoptive Cell Transfer ("CAR-Ts", "TCRs", "TILs") has provided further evidence of the benefits of providing an enhanced T cell presence to fight cancer. As published in the *Journal of the American Medical Association* in November 2017, CAR-T has achieved dramatic results in liquid tumors, and can provoke clinical responses when other treatments stop working. These cells are artificially engineered outside the body and early versions have suffered from unanticipated side effects. The therapies are also limited in activity against a specific target, and have a limited persistence within the patient. To date, CAR-Ts activity has been

limited to liquid tumors and have shown potentially meaningful toxicity concerns. Moreover, CAR-Ts are complex therapeutic products that are primarily manufactured and released for each patient, leading to costly manufacturing and a number of treatments.

Looking back on the last two decades, there have been promising technology advancements to harness and activate killer T cells against cancers and every day more is learned about the interplay between immunity and cancer that can lead to improved treatments. However there are still significant unmet needs in the immunotherapy landscape that Advaxis feels *Lm* Technology can address and complement. Specifically, *Lm* Technology has the potential to optimize and expand checkpoint inhibitor activity in combination. It also avoids many of the limitations of previous cancer vaccine attempts by tapping into the pathway reserved for defense against *Listeria* infection while incorporating the best cancer-targets science can identify, including neoantigens that result from mutations in the cancer. To date, *Lm* Technology products have a generally well-tolerated safety profile, do not generate neutralizing antibodies lending themselves to retreatments, and most of the products are immediately available for treatment without the complication and expense of modifying a patient's own cells in a laboratory.

### ***Lm* Technology: An optimized *Listeria*-based antigen delivery system**

Advaxis' *Listeria*-based immunotherapies are optimized for antigen delivery through a process of insertion of multiple copies of the proprietary *tLLO*-fusion protein into each extrachromosomal protein expression and secretion plasmid that makes and secretes the target protein right inside the patient's antigen presenting cells to initiate and/or boost their immune response. The *tLLO*-fusion protein approach was developed at the University of Pennsylvania as an improvement over insertion of a single copy of the target gene, as an ACT-A (or other *Lm* peptide) fusion, within the bacterial genome for four key reasons:

1. Multiple copies of the DNA in the plasmids per bacteria can result in larger amounts of *tLLO*- fusion protein being expressed simultaneously, versus a single copy. This can improve antigen presentation and immunologic priming and increases the number of T cells generated for a particular treatment.
2. *tLLO* expressed on plasmids (with or without a tumor target protein attached) has been shown to reduce numbers and immune suppressive function of Tregs and MDSCs in the tumor microenvironment. Recently presented data demonstrates that Tregs are being destroyed as soon as 5 days after the first *Lm* Technology treatment in animal models.
3. The extrachromosomal DNA plasmids themselves also contain CPG sequence patterns that trigger TLR-9, which confers additional innate immune stimulation beyond a listeria without the plasmids.
4. The multiple copies of bacterial DNA plasmids (up to 80-100 per bacteria) confers additional stimulation of the STING receptor within APC's which has been associated with enhancing anti-cancer immunity in patients.

Through a license from the University of Pennsylvania, Advaxis has exclusive access to this proprietary formulation of attenuated *Lm* which further enhances this nearly ideal natural system. Clinical application in the Company's four franchise areas is the core focus of current development efforts.



## **Clinical Pipeline**

Advaxis is focused on the discovery, development and commercialization of proprietary *Lm* Technology antigen delivery products, with the lead program for cervical cancer in Phase 3 development. The Company and its collaborators are currently conducting or planning clinical studies of *Lm* Technology immunotherapies in four franchises:

- Human Papilloma Virus (“HPV”)-associate cancers
- Neoantigen therapy
- Disease focused hotspot / cancer antigen therapies
- Prostate cancer

As a late stage biotechnology company with no commercial products, Advaxis is aware of the need for fiscal responsibility, and is focusing our investment into the four franchises listed above. Additionally, the company will continue to be opportunistic by exploring ISTs, licensing and other external opportunities.

In October of 2015, the Company received notification from the FDA that the INDs for axalimogene filolisbac 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 trial 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.

## **Advaxis Pipeline of Product Candidates**

### ***HPV Related Cancers: Proof of Concept of Lm Technology***

The Company is developing a franchise in HPV-related cancers including both axalimogene filolisbac and ADXS-DUAL. Axalimogene filolisbac is an *Lm*-based antigen delivery product directed against HPV and designed to target cells expressing HPV. ADXS-DUAL, the Company's second immunotherapy targeting HPV-associated cancers, builds on the learnings from the clinical development of axalimogene filolisbac and incorporates an additional HPV target antigen into the *Lm* Technology vector. The company's HPV-related products are currently under investigation in two HPV-associated cancers: cervical cancer and head and neck cancer, either as a monotherapy or in combination. Advaxis has also completed treatment in two Phase 2 studies of axalimogene filolisbac for the treatment of anal cancer, and is evaluating the potential for collaborative external opportunities to further develop this program.

*Cervical Cancer: axalimogene filolisbac and ADXS-DUAL*

HPV is the most common viral infection of the reproductive tract and is the cause of a range of conditions in both females and males. In women, persistent infection with specific oncogenic types of HPV (most frequently alpha7 and alpha9 families) may lead to precancerous lesions which, if untreated, may progress to cervical cancer. There are approximately 527,000 new cases of cervical cancer caused by HPV worldwide every year, and 12,000 new cases in the U.S. alone, according to the World Health Organization ("WHO") Human Papillomavirus and Related Cancers in the World Summary Report 2017. There are approximately 4,250 deaths from cervical cancer each year according to the National Institutes of Health. Current preventative HPV vaccines such as Gardasil® and Cervarix® cannot treat or protect the large population of adults already infected with the virus, leaving several generations of women vulnerable. Furthermore, challenges with acceptance, accessibility, and compliance have resulted in suboptimal vaccination rates, with approximately 50% of young women and 38% of young men being fully vaccinated in the United States, according to statistics published by the Centers for Disease Control in 2017. Vaccination rates are even lower in other countries around the world.

Current treatments for metastatic cervical cancer can only extend life for about 6-8 months. Axalimogene filolisbac and ADXS-DUAL are *Lm* Technology immunotherapies designed to secrete the *tLLO-E7* fusion protein to target HPV-positive tumors.

Axalimogene filolisbac has received FDA orphan drug designation for invasive International Federation of Gynecology and Obstetrics (“FIGO”) Stage II-IV cervical cancer, and has received Fast Track designation from the FDA for the treatment of high-risk locally advanced cervical cancer. Axalimogene filolisbac has also been classified as an advanced-therapy medicinal product (“ATMP”) for the treatment of cervical cancer by the European Medicines Agency’s (“EMA”) 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 completed the CAT certification procedure and the CAT has certified that the preclinical and quality information have met the scientific and technical standards for a MAA.

### *Phase 2 Trial Results – axalimogene filolisbac*

In 2014, the company completed a randomized Phase 2 clinical trial (*Lm-LLO-E7-15*) in 109 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 trial, 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 Eastern Cooperative Oncology Group (“ECOG”) performance status of 2, a patient population that is often 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 axalimogene filolisbac in this trial did not significantly improve overall survival or objective tumor response ( $p = 0.9981$ ).

In this trial, 109 patients received 254 doses of axalimogene filolisbac. Axalimogene filolisbac 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.

Based on these results, the Gynecological Oncology Group (“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 trial of axalimogene filolisbac 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 trial was a Simon 2-stage design, with the primary efficacy endpoint being 12-month survival, with the objective of the secondary efficacy endpoints to evaluate progression-free survival, overall survival and objective tumor response. The primary safety endpoints were to evaluate the number of patients with dose-limiting toxicities and the frequency and severity of adverse effects.

To evaluate the trial's primary endpoint of 12-month overall survival rate, the GOG's protocol featured a prospectively-defined logistic model-based calculation of the expected 12-month survival rate using key predictive factors significantly related to survival and derived from 17 serially conducted GOG/NRG 2-stage studies of inactive agents in persistent/recurrent metastatic cervical cancer ("PRmCC") involving approximately 500 patients. This accumulated data by GOG used a consistent protocol design and a similar data collection methodology resulting in a robust and homogeneous patient dataset for the per protocol analysis of the primary endpoint. Per the trial protocol, this logistic model-based calculation was then used as a comparator for evaluating the 12-month survival rate of axalimogene filolisbac observed in GOG-0265.

The first stage of enrollment in GOG-0265 was successfully completed with 26 patients treated and met the predetermined safety and efficacy criteria required to proceed into the second stage of patient enrollment. Clinical data from the first stage of GOG-0265 was presented at the American Gynecological & Obstetrical Society ("AGOS") annual meeting on September 17, 2015. Overall survival at 12 months was 38.5% (10/26) (the predefined criteria for 12-month survival in order to progress to Stage 2 was  $\geq 20\%$ ), and, among patients who had received the full treatment regimen of 3 doses of axalimogene filolisbac, the 12-month survival rate was 55.6% (10/18). The adverse events observed in the first stage of the trial have been consistent with those reported in other clinical studies with axalimogene filolisbac.

Stage 2 of the trial 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 a clinical hold in October 2015 that resolved in mid-December 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 rate and safety data obtained from the 24 patients who had previously enrolled in Stage 2. The Stage 2 population demonstrated that treatment with axalimogene filolisbac resulted in a 37.5% (9/24) 12-month survival rate. This data was consistent with the findings in Stage 1 that showed a 38.5% 12-month survival rate, 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 in 50 subjects with a 12 month survival rate of 38% (19/50). The protocol defined logistic model-based calculation of the expected 12-month milestone survival rate was calculated to be 24.5% using the key predictors from the patients enrolled in the trial. The 12 month survival rate of 38% for patients receiving axalimogene filolisbac in the trial represented a 52% improvement over the expected 12-month milestone survival rate of 24.5%.

Overall, 28 out of 50 (56%) patients experienced a Grade 1 or Grade 2 TRAE associated with axalimogene filolisbac infusion. The most common (>30%) Grade 1 or Grade 2 TRAEs were fatigue, chills, anemia, nausea and fever. Eighteen (36%) patients experienced a Grade 3 TRAE and two patients experienced a Grade 4 AE, including a Klebsiella lung infection in one patient, and hypotension/cytokine related symptoms in another patient, which were considered possibly related to treatment.

In October 2016, upon review of these encouraging findings, the Company announced early closure of GOG-0265. Results from the GOG-0265 trial were presented as an oral late-breaker presentation at the Society of Gynecologic Oncology ("SGO") annual meeting on March 14, 2017. Based on these data, the Company has made a strategic decision



to submit for conditional Marketing Authorization (“MA”) in Europe.

Advaxis is also conducting an ongoing clinical trial with axalimogene filolisbac through a collaboration agreement with MedImmune, the global biologics research and development arm of AstraZeneca. This is a Phase 1/2, open-label, multicenter, dose determination and expansion cohort trial to determine the recommended Phase 2 dose (“RP2D”) and evaluate the safety and efficacy of axalimogene filolisbac, in combination with MedImmune’s investigational anti-PD-L1 immune checkpoint inhibitor, IMFINZI™ (“durvalumab”), as a 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”). The dose determination phase of the trial is complete. Two dose cohorts were enrolled. Cohort 1 enrolled 5 patients with metastatic cervical cancer who received  $1 \times 10^9$  cfu of axalimogene filolisbac + 3 mg/mg durvalumab. Cohort 2 enrolled 3 patients with metastatic cervical cancer and 2 patients with SCCHN who received  $1 \times 10^9$  cfu of axalimogene filolisbac + 10 mg/mg of durvalumab. No dose-limiting toxicities were observed in either cohort. The RP2D was determined to be  $1 \times 10^9$  cfu for axalimogene filolisbac + 10 mg/mg for durvalumab. Preliminary data showed that two patients with metastatic cervical cancer achieved a durable complete response (with confirmation) and a partial response (without confirmation), respectively.

Treatment-related adverse events (“TRAE”) were reported in 91% of patients; the majority were either Grade 1 (64%) or Grade 2 (55%) events. The most commonly reported TRAEs were chills, fever, nausea and hypotension. Three patients reported Grade 3 TRAEs ( $1 \times 10^9$  + 3 mg/kg rigor/chills;  $1 \times 10^9$  + 10 mg/kg - rigor/chills; and  $1 \times 10^9$  + 10 mg/kg - diarrhea and shortness of breath). One patient experienced a grade 4 TRAE of hypotension. The safety profile of the combination of axalimogene filolisbac + durvalumab was consistent with previous reported findings for both axalimogene filolisbac and durvalumab administered as monotherapy.

Enrollment in the Part A expansion phase (N = 20 patients with SCCHN) and Part B expansion phase (N=90 patients with metastatic cervical cancer) are open to enrollment. As of the latest data cut-off date of October 18, 2017, 7 patients receiving  $1 \times 10^9$  axalimogene filolisbac + 10 mg/kg durvalumab have been enrolled. In the Part B expansion, a total of 32 patients with metastatic cervical cancer were randomized to receive either 10 mg/kg durvalumab alone (N=16 patients) or  $1 \times 10^9$  axalimogene filolisbac + 10 mg/kg durvalumab (N = 16 patients) expansion phases. The Company expects an interim readout of the safety and efficacy data from the Part B expansion in 2019.

#### *Ongoing Registrational and Phase 3 Studies: ADXS-DUAL and axalimogene filolisbac*

In evaluating the data from GOG-0265, Advaxis observed that there was a significantly higher representation of alpha7 family viruses in the PRmCC patient population than are typically seen at an initial diagnosis of cervical cancer. Although axalimogene filolisbac had already been shown to improve survival in both alpha7 and alpha9 family cancers, the Company made the decision that late stage, metastatic patients need a potent therapy that presents antigens to both families, in order to give them the best chance to impede their disease progression. As a result, ADXS-DUAL was developed to have the potential to be even more potent against the alpha7 family strains found in metastatic cervical cancer. ADXS-DUAL incorporates additional peptides to increase potency against these alpha7 strains. ADXS-DUAL may give patients the best chance of benefit in the PRmCC setting, especially if combined with a checkpoint inhibitor.

To this end, the Company has entered into a clinical development collaboration agreement with BMS to evaluate their PD-1 immune checkpoint inhibitor, OPDIVO® (“nivolumab”), in combination with ADXS-DUAL as a potential treatment option for women with PRmCC. Advaxis plans to file an IND application for ADXS-DUAL in early 2018. Pending FDA feedback, we plan to initiate a global, randomized, registrational quality trial in 1H 2018 and will evaluate this combination regimen in women with persistent, recurrent or metastatic (squamous or non-squamous cell) carcinoma of the cervix who have failed at least one prior line of systemic chemotherapy (“ADVANCE” or “ADVAxis Immunotherapy with Nivolumab to Treat Recurrent or Metastatic Cervical Cancer”). Under the terms of the agreement, each party will bear its own internal costs and provide its immunotherapy agents. Advaxis will sponsor the trial and pay third-party costs. Subject to the positive outcome of this trial, the Company plans to file a Biologics License Application (“BLA”) for approval of ADXS-DUAL for metastatic cervical cancer in combination treatment.

Women who are diagnosed with high risk, locally advanced carcinoma of the cervix (“HRLACC”) face a higher chance that their cancer may recur following initial treatment when compared to earlier stages of the disease. When cervical cancer recurs, there are very few treatment options and the prognosis is dire. To address this unmet need, in 2016 the Company reached an agreement with the FDA, under the Special Protocol Assessment (“SPA”) process, for a Phase 3 trial evaluating axalimogene filolisbac in patients with HRLACC (“AIM2CERV” or “Advaxis Immunotherapy 2 Prevent Cervical Recurrence”) to be conducted in collaboration with the GOG/NRG Oncology.

AIM2CERV is a double-blind, randomized, placebo-controlled, Phase 3 trial of adjuvant axalimogene filolisbac following primary chemoradiation treatment of women with HRLACC. The primary objective of AIM2CERV is to compare the disease free survival of axalimogene filolisbac 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. The company’s 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. The AIM2CERV trial is expected to enroll 450 patients globally and, subject to the positive outcome, is designed to support a BLA submission in the U.S. and in other territories around the world.

The trial is active in ten countries and is currently enrolling.

#### *Axalimogene filolisbac EU conditional approval Filing*

Based on scientific advice provided by the Paul Ehrlich Institute in Germany and the Medical Products Agency in Sweden, the Company has made a strategic decision to submit for conditional Marketing Authorization (“MA”) in Europe. The company plans to file for conditional MA under the requirements in the EMA’s Commission Regulation and Committee for Medicinal Products for Human Use (“CHMP”) Guideline on MAs, which includes criteria such as a positive risk/benefit balance, unmet medical needs being fulfilled, benefits to public health outweighing the additional data required, and a high likelihood that comprehensive clinical data will be provided in the future.

Progress to date towards submission of the filing includes axalimogene filolisbac's designation as an ATMP, certification of quality and non-clinical data by the CAT, CHMP confirmation of eligibility for Union Marketing Authorization, assignment of EU rapporteurs, and pre-submission meetings held with the rapporteurs. Feedback from the rapporteurs advising the provision of additional clinical information in the submission package led to a delay of the filing which is now planned for Q1 2018. Once the package is submitted, the CHMP review process is expected to take approximately 13 months, and the Company plans to provide an update at the end of the review.

### *HPV Franchise Licensing Agreements*

Biocon Limited (“Biocon”), our co-development and commercialization partner for axalimogene filolisbac in India and key emerging markets, filed a Marketing Authorization Application (“MAA”) for licensure of this immunotherapy in India. The companies are currently evaluating next steps.

Especificos Stendhal SA de CV (“Stendhal”), the Company’s co-development and commercialization partner for axalimogene filolisbac in Mexico, Brazil, Colombia and other Latin American countries, will pay \$10 million in support payments towards the expense of AIM2CERV over the duration of the trial, contingent upon Advaxis achieving annual project milestones.

Knight Therapeutics Inc. (“Knight”), holds an exclusive license to commercialize axalimogene filolisbac in Canada, as well as our other product candidates.

Advaxis granted Global BioPharma (“GBP”) an exclusive license for the development and commercialization of axalimogene filolisbac for the treatment of cervical cancer in Asia. GBP is responsible for all development and commercial costs and activities associated with the development in their territories.

### Head and Neck Cancer

Squamous Cell Carcinoma of the Head and Neck (“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. According to the American Cancer Society, head and neck cancer accounts for about 3% of all cancers in the United States. But while the Pap smear and other HPV tests have reduced rates of cervical cancer, rates of oral cancer are growing, with 12,000 new cases projected to be diagnosed in the United States in 2016 according to the Surveillance, Epidemiology, and End Results (“SEER”) database.

A study published in the Annals of Internal Medicine found that 11.5% percent of U.S. men and 3% of women were actively infected with oral HPV between 2011 and 2014. That adds up to 11 million men and 3 million women who are at risk for developing SCCHN. SCCHN is typically asymptomatic until it has metastasized, and screening options do not exist. The only way to prevent infection is the HPV vaccine, but compliance has been low to date. Another challenge is that preventative vaccines cannot protect those already infected or older than 26, leaving several

generations of Americans vulnerable to SCCHN with no way of knowing if cancer is silently growing.

The safety and immunogenicity of axalimogene filolisbac is being evaluated in a Phase 2 IST 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 to evaluate the immunologic and pathologic effects of axalimogene filolisbac in patients at the time of initial diagnosis of HPV-associated head and neck cancer. The trial is designed to show that axalimogene filolisbac 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 axalimogene filolisbac confirmed that the trial met the target for the overall rate of vaccine-induced T-cell response. The results demonstrated that HPV E7- and/or E6-specific T cell responses increased in the peripheral blood in five of the trial patients. Increased infiltration of both CD4+ and CD8+ T cells were observed in the TME of four patients, with a reduction of FOXP3+ regulatory T cells within the tumors of 3/6 patients. Increased T cell responses to HPV E6 supports enhanced immune activity against additional tumor targets. Changes to the TME included cytotoxic T cell infiltration into the post-resection tumor, increased immune activation, a reduction of regulatory T cells, infiltration of cytotoxic T cells, and increased expression of inflammatory activation markers. In addition, fluctuations of circulating serum cytokine (IL-15, IL-9, TNF $\alpha$ , IL-2 and MIP-1b) levels were observed potentially suggesting consumption by activated T cells and migration of T cells to the TME. These results confirmed that the trial met its Stage 1 primary objective which allowed accrual to proceed in the second stage of the trial which is intended. The Stage 2 objective is consistent with Stage 1 and enrollment is ongoing.

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 trial to evaluate safety and efficacy of axalimogene filolisbac, in combination with durvalumab (MEDI4736), for patients with metastatic squamous or non-squamous carcinoma of the cervix and metastatic HPV-associated SCCHN. Part 1 of this trial is complete, and the Company has commenced enrollment in the Part A (20 patients with SCCHN) and B (90 patients with cervical cancer) expansion phases.

We will continue to be opportunistic towards alternative funding approaches for continued development in HPV-positive head and neck cancer, and plan to announce an IST with a prestigious academic institution in 2018. Axalimogene filolisbac 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 axalimogene filolisbac is being evaluated in a Phase 2 IST by Brown University in patients with high-risk locally advanced anal cancer. As of December 2017, no further enrollment in this trial is planned. 10 patients were treated including one with N2 and four with N3 disease. Two patients had grade 3 acute toxicities following the initial dose of axalimogene filolisbac including chills/rigors (n = 2), back pain (n = 1), and hyponatremia (n = 1). All toxicities occurred within 24 hours of administration. There was no apparent increase in chemoradiation toxicities or myelosuppression. One patient had a Grade 5 cardiopulmonary event shortly after beginning 5-FU treatment. This patient did not receive a dose of axalimogene filolisbac. All 9 assessable patients had complete clinical responses by sigmoidoscopy. Eight of the 9 patients (89%) are progression-free at a median follow-up of 42 months. These data were accepted and published in the International Journal of Radiation Oncology.

We conducted a Phase 2 multi-center, open-label, Simon two-stage trial (“FAWCETT” or “Fighting Anal-Cancer with CTL Enhancing Tumor Therapy”), testing axalimogene filolisbac in patients with persistent or recurrent metastatic anal cancer. FAWCETT is designed to evaluate the efficacy and safety of axalimogene filolisbac as a monotherapy in patients with HPV-associated metastatic anal cancer who have received at least one prior treatment regimen for the advanced disease. Patients will receive intravenous axalimogene filolisbac monotherapy ( $1 \times 10^9$  CFU) every 3 weeks for  $\leq 2$  years or until a discontinuation criterion is met. Stage 1 of the trial targeted enrollment of 36 patients with anal cancer whose disease recurred after receiving treatment, with an interim analysis planned on enrollment of 31 evaluable pts ( $\geq 1$  post-baseline scan) and met the predetermined safety and efficacy criteria required to proceed into the second stage of patient enrollment.

Preliminary Stage 1 results from 29 of the planned evaluable patients showed 1 (3.5%) patient had a durable partial response lasting  $> 6$  months (after progression on prior anti-PD-1 therapy) and 7 had stable disease (24%). Disease control rate was 28%. The current Kaplan Meier 6-month PFS estimate is 22%, indicating the trial met the criteria to proceed to Stage 2 of enrollment. Common ( $\geq 30\%$ ) TRAEs were grade 1-2 chills/rigors, fever, hypotension and vomiting. Grade 3 TRAEs of cytokine related symptoms (n=1; SAE), infusion related reactions (n=2; 1 SAE) and hypotension (n=2; 1 SAE) were reported. These results were reported at the annual meeting of the European Society for Medical Oncology (“ESMO”) in September 2017.

The Company has decided not to initiate the Stage 2 portion of the trial in order to focus its resources on other clinical priorities at this time. We will continue to evaluate alternative funding sources and collaborations to further develop this program. Axalimogene filolisbac has received FDA and EMA orphan drug designation for anal cancer.

*Neoantigen Therapy (ADXS-NEO)*

*Lm* Technology is an effective vector for immunotherapy, and the Company made the decision to branch into the growing field of individualized cancer treatments with ADXS-NEO. ADXS-NEO is designed to create individualized therapies by activating the patient's immune system to respond against multiple mutations, or neoantigens, identified from an individual patient's tumor through DNA sequencing. In August 2016, Advaxis entered into a global agreement with Amgen Inc. ("Amgen") for the development and commercialization of ADXS-NEO.

ADXS-NEO is an individualized *Lm* Technology antigen delivery product developed using whole-exome sequencing of a patient's tumor to identify neoantigens. ADXS-NEO is designed to work by presenting a large payload of neoantigens directly into dendritic cells within the patient's immune system and stimulating a T cell response against cancerous cells.

The FDA has cleared the initial IND application of ADXS-NEO and we will file an IND amendment in early 2018. This amendment is largely driven by enhancements to the manufacturing and antigen selection processes. We do not expect this to impact our project timelines, and we plan to initiate a Phase 1 trial in first half of 2018. The initial tumor types for the Phase 1 are non-small cell lung cancer, microsatellite stable colorectal cancer, and head and neck cancer. The Company has entered into various research collaborations, including the Parker Institute for Cancer Immunotherapy, to advance the trial of neoepitope-based, personalized cancer therapy as part of the Tumor neoantigen Selection Alliance ("TESLA") initiative.

*Disease focused hotspot / cancer antigen therapies (ADXS-HOT)*

Advaxis is creating a new group of immunotherapy constructs for major cancers that combines our optimized *Lm* Technology vector with promising targets to generate potent anti-cancer immunity. The ADXS-HOT franchise is a series of novel cancer immunotherapies that will target somatic mutations ("hotspots"), cancer testis antigens ("CTAs") and oncofetal antigens ("OFAs"). These three types of targets form the basis of the ADXS-HOT program because they are more capable of generating potent, tumor specific, and high strength killer T cells, versus more traditional over-expressed native sequence TAAs. Most hotspot mutations and OFA/CTA proteins play critical roles in oncogenesis; targeting both at once could significantly impair cancer proliferation. The ADXS-HOT products will combine many of the potential high avidity targets that are expressed in all patients with the target disease into one "off-the-shelf", ready to administer treatment. The ADXS-HOT technology has a strong Intellectual Property ("IP") position, with potential protection into 2037, and an IP filing strategy providing for broad coverage opportunities across multiple disease platforms and combination therapies.

The Company is currently prioritizing product development in the most prevalent cancers, with the first indication planned to be Non Small Cell Lung Cancer ("NSCLC"). Advaxis plans to file multiple ADXS-HOT INDs in 2018,



including NSCLC, with our first in human trial in one of the ADXS-HOT products to commence in 2018.

*Prostate Cancer (ADXS-PSA)*

According to the American Cancer Society, prostate cancer is the second most common type of cancer found in American men, and is the second leading cause of cancer death in men, behind only lung cancer. More than 161,000 men are estimated to be diagnosed with prostate cancer in 2017, with over 26,000 deaths each year. Unfortunately, in about 10 – 20% of cases, men with prostate cancer will go on to develop castration-resistant prostate cancer (“CRPC”), which refers to prostate cancer that progresses despite androgen deprivation therapy. Metastatic CRPC (“mCRPC”) occurs when the cancer spreads to other parts of the body and there is a rising prostate-specific antigen (“PSA”) level. This stage of prostate cancer has an average survival of 9-13 months, is associated with deterioration in quality of life, and has few therapeutic options available.

According to a data review published by MD Anderson Cancer Center in 2016, checkpoint inhibitor monotherapy has not shown significant activity in mCRPC to date. The authors hypothesize that may be due to the inability of the checkpoint inhibitor to infiltrate the tumor microenvironment, and that combination therapy with agents that induce T cell infiltration within the tumor may improve performance of checkpoints in prostate cancer.

*Lm* Technology constructs have been shown by multiple labs to reduce number and suppressive function of Tregs and MDSCs in the tumor microenvironment and cause the destruction of Tregs in the TME as soon as 5 days after dosing in models. This reduction of immune suppression in the tumors has been attributed to our proprietary *tLLO*-fusion peptides expressed by multiple copies of the plasmids in each bacteria. Advaxis feels that the combination of ADXS-PSA, our immunotherapy designed to target the PSA antigen, with a checkpoint inhibitor may provide an alternative treatment option for patients with mCRPC. Clinical benefit in prostate cancer could be a significant value creator to expand the *Lm* Technology platform into the prostate cancer market.

Advaxis has entered into a clinical trial collaboration and supply agreement with Merck to evaluate the safety and efficacy of ADXS-PSA as monotherapy and in combination with KEYTRUDA® (“pembrolizumab”), Merck’s anti PD-1 antibody, in a Phase 1/2, open-label, multicenter, dose determination and expansion trial in patients with previously treated metastatic, castration-resistant prostate cancer (Keynote-046). For the ADXS-PSA monotherapy dose escalation and determination portion of the trial, cohorts were started at a dose of  $1 \times 10^9$  cfu (n=7) and successfully escalated to higher dose levels of  $5 \times 10^9$  cfu (n=3) and  $1 \times 10^{10}$  cfu (n=3) without achieving a maximum tolerated dose. Treatment emergent adverse events noted at these higher dose levels were generally consistent with those observed at the lower dose level ( $1 \times 10^9$  cfu) other than a higher occurrence rate of Grade 2/3 hypotension. The ADXS-PSA monotherapy dose-determination phase of the trial has been completed. The RP2D of ADXS-PSA monotherapy was determined to be  $1 \times 10^9$  cfu based on a review of the totality of the clinical data. This dose was used in combination with 200 mg of pembrolizumab in a cohort of 6 patients to evaluate the safety of the combination before moving into an expanded cohort of patients (N=30 patients). The safety of the combination was confirmed and enrollment in the expansion cohort phase was initiated. Enrollment in this phase of the trial was completed in January 2017.

Preliminary data correlating clinical observations with immune data in mCRPC patients treated with ADXS-PSA monotherapy were presented at the third annual CRI-CIMT-EATI-AACR International Cancer Immunotherapy Conference in September 2017. By profiling and quantifying immune-related gene expression in patients before and after ADXS-PSA monotherapy, differences were noted between the pre- and post-treatment immune status of stable disease (“SD”) and non-stable disease patients. 100% of the patients who achieved SD (31%; 4/13) showed expansion of pre-existing, as well as generation of new T cells. There were significantly higher expression levels of genes indicative of CD4+ and CD8+ T cell activation and genes supporting M1 macrophages, and lower expression levels of immunosuppressive (protumor) genes. Patients with non-stable disease (69%; 9/13) exhibited gene expression profiles suggesting a more immunosuppressive myeloid profile with asynchronous and unsustained clonal T cell expansions, and increased expression of prostate cancer tumor markers in peripheral circulation. Together, these findings suggest that SD patients treated with ADXS-PSA may have a more pro-inflammatory immunologic picture, fewer circulating tumor cells, and potentially less tumor burden.

In November 2017 at the Society for Immunotherapy of Cancer (“SITC”), the Company presented additional preliminary data from this monotherapy arm that shows that after administration of ADXS-PSA, all 9 patients who received all three doses saw increasing numbers and strength of T cells targeting PSA, using an ELISpot data analysis. In 56% (5/9) patients, this increase was 3-fold. This data shows, for the first time clinically, that an *Lm* Technology construct has shown specific T cell generation against a specific target. In addition, the Company evaluated four other markers expressed by prostate cancers and 100% (9/9) patients had an increased frequency of T cells to at least one of these targets, demonstrating that antigen spreading after administration of ADXS-PSA does occur in the clinic and can expand activity.

Preliminary safety data shows the most common side effects include chills, fever, rigors, hypertension, fatigue, hypotension and vomiting which are consistent with cytokine release in response to ADXS-PSA administration.

Viewed collectively, the data presented at CRI-CIMT-EATI-AACR 2017 and SITC 2017 is an encouraging signal that ADXS-PSA allows for generation of sustained, strengthened T cells against prostate cancer, while weakening the TME and allowing T cells access to the tumor. The Company looks forward to providing additional data in 2018 from the combination arm of this trial with pembrolizumab.

In addition, the Company is actively developing an additional product candidate for prostate cancer, currently in preclinical testing, which could complement ADXS-PSA.

### ***Other Lm Technology Products***

#### ***HER2 Expressing Solid Tumors***



HER2 is overexpressed in a percentage of solid tumors including osteosarcoma. According to published literature, up to 60% of osteosarcomas are HER2 positive, and this overexpression is associated with poor outcomes for patients.

ADXS-HER2 is an *Lm* Technology antigen delivery product candidate designed to target HER2 expressing solid tumors including human and canine 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.

The dose finding phase of a Phase 1b trial in HER2 expressing tumors has been completed. Based on priorities and focus, the Company has decided not to proceed to the expansion phase of the trial. The Company remains open to investigator-initiated research or licensing proposals for ADXS-HER2.

#### Canine Osteosarcoma

On March 19, 2014, we entered into a definitive Exclusive License Agreement (the “Aratana 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 was filed by Aratana for ADXS-HER2 (also known as AT-014 by Aratana) for the treatment of canine osteosarcoma with the United States Department of Agriculture (“USDA”). Aratana received communication in December 2017 that the USDA granted Aratana conditional licensure for AT-014 for the treatment of dogs diagnosed with osteosarcoma, one year of age or older. Aratana plans to conduct an extended field study in a clinical setting and anticipates initiating the study in early 2018, which will be fully funded by Aratana. Initially, Aratana plans to make the therapeutic available for purchase at approximately two dozen veterinary oncology practice groups across the United States who participate in the study.

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.

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 for use in non-human animal health applications (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.

## 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 and manufacturing facility is located at 305 College Road East, Princeton, New Jersey 08540 and our telephone number is (609) 452-9813. We maintain a corporate website at [www.advaxis.com](http://www.advaxis.com) which contains descriptions of our technology, our product candidates and the development status of each drug. We make available free of charge through our Internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to these reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the SEC. We are not including the information on our website as a part of, nor incorporating it by reference into, this report. You may read and copy any materials we file at the SEC’s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 on official business days during the hours of 10:00 a.m. to 3:00 p.m. Please call the SEC at 1-800-SEC-0330 for information on the Public Reference Room. Additionally, the SEC maintains a website that contains annual, quarterly, and current reports, proxy statements, and other information that issuers (including us) file electronically with the SEC. The SEC’s website address is <http://www.sec.gov>.

## Intellectual Property

Protection of our intellectual property is important to our business. We have a robust and extensive patent portfolio that protects our product candidates and *Lm*-based immunotherapy technology. Currently, we own or have rights to approximately 433 patents and applications, which are owned, licensed from, or co-owned with University of

Pennsylvania (“Penn”), Merck, National Institute of Health (“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 axalimogene filolisbac, ADXS-DUAL, ADXS-PSA, ADXS-NEO, ADXS-HOT, ADXS-HER2.

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.

Issued patents which are directed to axalimogene filolisbac, ADXS-PSA, and ADXS-HER2 in the United States, will expire between 2017 and 2032. Issued patents directed to our product candidates axalimogene filolisbac, 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 pending patent applications directed to our product candidates axalimogene filolisbac, ADXS-PSA, ADXS-HER2, ADXS-NEO, ADXS-DUAL 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 axalimogene filolisbac, ADXS-DUAL, ADXS-PSA, ADXS-NEO, ADXS-HOT, ADXS-HER2 directed to the following indications and others: HPV-related cervical cancer, prostate cancer and her2/neu-expressing 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 treatment, of a specific type of cancer. There are many difficulties and uncertainties inherent in research and development of new products, resulting in high costs and variable success rates. Bringing a drug from discovery 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 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.

## **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 drugs. In the United States, the FDA subjects drugs 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 axalimogene filolisbac 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 axalimogene filolisbac 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**

Collaborations, partnerships and agreements are a key component of Advaxis' corporate strategy. As a late stage biotechnology company without sales revenue, partnerships are an essential part of the ongoing strategy. Additionally, the evolution of the field of immunotherapy has resulted in combination treatments becoming ubiquitous; ongoing clinical studies and agreements with many of the leading, large oncology pharmaceutical companies and teaching institutions ensures that *Lm* Technology will be a key component of the cancer treatment protocols of the future.

Our collaborators and partners include Amgen, Aratana, AstraZeneca, BMS, Biocon, GBP, Knight, Merck, Sellas Life Science Group, Stendhal, and others. For more information, see Footnote 9. Collaboration and Licensing Agreements with this Form 10-K and is incorporated herein by reference.

We entered into an exclusive worldwide license agreement with Penn, on July 1, 2002 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.

## **Manufacturing**

Current Good Manufacturing Practices ("cGMPs") are the standards identified 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 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.

Each of Advaxis' wholly owned product candidates is manufactured using a platform process, with uniform methods and testing procedures. This allows for an accelerated pathway from construct discovery to clinical product delivery, while keeping cost of goods low. The Company intends to add new constructs to this standardized manufacturing process as their pipeline evolves.



Advaxis has entered into agreements with multiple third-party organizations (“CMOs”) to handle the manufacturing, testing, and distribution of product candidates. These organizations have extensive experience within the biologics space and with the production of clinical and commercial GMP supplies. In 2017, the Company expanded and standardized their external clinical manufacturing network in order to access additional manufacture capacity as needed, and reduce their external manufacturing cost structure.

In parallel, the Company has also continued to invest in internal process/analytical development, quality systems, manufacturing, and quality control infrastructure with the goal of accelerating and advancing our pipeline. Advaxis has constructed a state-of-the-art manufacturing facility and laboratory to develop and manufacture clinical-grade products, supporting the clinical trials and future commercialization of the Company’s therapeutics. Increased manufacturing capability and capacity allows Advaxis to manufacture its own material and reduce reliance on CMOs, and improve supply flexibility, scalability, lead times, and costs of goods. The Company’s long-term manufacturing strategy is to leverage both their partners’ capabilities and their internal capabilities in order to build a supply chain that is reliable, flexible, and cost competitive.

In support of future conditional regulatory filing and future launch of axalimogene filolisbac in Europe, the Company has completed a full mapping of supply chain requirements and has established and validated a commercial process and testing in Europe. The Company plans to continue to refine end-to-end product delivery during the ongoing regulatory review process.

## **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. While we believe that our product candidates, technology, knowledge and experience provide us with competitive advantages, we face competition from established and emerging pharmaceutical and biotechnology companies, among others. 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., BMS, Celldex Therapeutics, Inovio Pharmaceutical Inc., ISA Pharmaceuticals, AstraZeneca, Merck, 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 October 31, 2017, we had 108 employees, all of which were full time employees, 87 of whom were engaged in research and development activities and 21 of whom were engaged in finance, business development, facilities, human resources and administrative support. Of our full-time employees, 28 hold Ph.D. degrees. None of our employees are represented by a labor union, and we consider our relationship with our employees to be good.

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, 2017, we had an accumulated deficit of \$301,142,227 and shareholders' equity of \$54,260,167. 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-approved, 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 Statute and the federal False Claims Act, and privacy laws. Noncompliance with applicable laws and requirements can result in various adverse consequences, including delay in approving or refusal to approve product licenses or other applications, suspension or termination of clinical investigations, revocation of approvals previously granted, fines, criminal prosecution, civil and criminal penalties, recall or seizure of products, exclusion from having our products reimbursed by federal health care programs, the curtailment or restructuring of our operations, injunctions against shipping products and total or partial suspension of production and/or refusal to allow a company to enter into governmental supply contracts.

The process of obtaining requisite FDA approval has historically been costly and time-consuming. Current FDA requirements for a new human biological product to be marketed in the United States include: (1) the successful conclusion of preclinical laboratory and animal tests, if appropriate, to gain preliminary information on the product’s safety; (2) filing with the FDA of an IND to conduct human clinical trials for drugs or biologics; (3) the successful

completion of adequate and well-controlled human clinical trials to establish the safety and efficacy of the investigational new drug for its recommended use; and (4) filing by a company and acceptance and approval by the FDA of a BLA for 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 axalimogene filolisbac 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 axalimogene filolisbac 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 433 patents and applications, which are owned, licensed from, or co-owned with Penn, Merck, NIH, and/or Augusta University. We have obtained the rights to all future patent applications in this field originating in the laboratories of Dr. Yvonne Paterson and Dr. Fred Frankel, at the University of Pennsylvania.

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

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

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

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



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

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

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

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

the patentability of our inventions relating to our product candidates; and/or

the enforceability, validity or scope of protection offered by our patents relating to our product candidates.

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

incur substantial monetary damages;

encounter significant delays in bringing our product candidates to market; and/or

be precluded from participating in the manufacture, use or sale of our product candidates or methods of treatment requiring licenses.

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

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

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

Pursuant to the terms of our license agreement with Penn, which has been amended from time to time, we have acquired exclusive worldwide licenses for patents and patent applications related to our proprietary Listeria vaccine technology. The license provides us with the exclusive commercial rights to the patent portfolio developed at Penn as of the effective date of the license, in connection with Dr. Paterson and requires us to pay various milestone, legal, filing and licensing payments to commercialize the technology. As of October 31, 2017, 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 many of our immunotherapies for research and development and testing purposes. While we have built our own manufacturing facility onsite in Princeton to manufacture clinical materials for some of our products, included ADXS-NEO, we depend on third-party manufacturers to supply most of our preclinical and clinical materials and will be reliant on a third-party manufacturer to produce axalimogene filolisbac on a commercial scale, should that product receive regulatory approval. Third-party manufacturers must be able to meet our deadlines as well as adhere to quality standards and specifications. Our predominant 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 our own manufacturing operation or any contracted manufacturing operation 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 own manufacturing operation or any third-party manufacturers will be able to meet commercialized scale production requirements in a timely manner or in accordance with applicable standards or current GMP.

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

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

Management of our relationships with our collaborators will require:

significant time and effort from our management team;

financial funding to support said collaboration;

coordination of our research and development programs with the research and development priorities of our collaborators; and

effective allocation of our resources to multiple projects.

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

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

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

Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for our immunotherapies;

damage to our reputation;

withdrawal of clinical trial participants;

costs of related litigation;

substantial monetary awards to patients or other claimants;

loss of revenues;

the inability to commercialize immunotherapies; and

increased difficulty in raising required additional funds in the private and public capital markets.

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

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

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

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

Our research and development activities involve the use of biological and hazardous materials. Although we believe our safety procedures for handling and disposing of these materials complies with federal, state and local laws and regulations, we cannot entirely eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of these materials. We do not carry specific biological waste or pollution liability or remediation insurance coverage, nor do our workers' compensation, general liability, and property and casualty insurance policies provide coverage for damages and fines/penalties arising from biological exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended or terminated.

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

As of December 15, 2017, we had 108 employees, all of which were full time employees. Our ability to attract and retain highly skilled personnel is critical to our operations and expansion. We face competition for these types of personnel from other technology companies and more established organizations, many of which have significantly larger operations and greater financial, technical, human and other resources than we have. We may not be successful in attracting and retaining qualified personnel on a timely basis, on competitive terms, or at all. If we are not

successful in attracting and retaining these personnel, or integrating them into our operations, our business, prospects, financial condition and results of operations will be materially adversely affected. In such circumstances we may be unable to conduct certain research and development programs, unable to adequately manage our clinical trials and other products, unable to commercialize any products, and unable to adequately address our management needs.

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

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

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

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

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

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

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

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

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

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

We are not currently marketing our product candidates, however we are seeking commercial opportunities for axalimogene filolisbac. We cannot assure you that we will be able to commercialize it or any other candidate 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 predominantly relies on a network of suppliers and vendors to manufacture its products. Should a regulatory authority make any significant findings on an inspection of Advaxis' own operations or the operations of those companies, the ability of Advaxis to continue producing its products could be adversely impacted and further production could cease. Regulatory GMP requirements are extensive and can present a risk of injury or recall, among other risks, if not manufactured or labeled properly under GMPs.

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 December 15, 2017, we had 41,303,988 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 December 15, 2017, we had outstanding options to purchase 4,380,557 shares of our Common Stock at a weighted average exercise price of approximately \$11.47 per share and outstanding warrants to purchase 3,092,395 shares of our Common Stock (including the above warrants subject to weighted-average anti-dilution protection); and zero 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 and manufacturing facility are located in approximately 48,500 square feet of office space at 305 College Road East, Princeton, New Jersey 08540 which is occupied pursuant to a lease which expires on November 30, 2025.

**Item 3. Legal Proceedings.**

The information required under this item is set forth in Footnote 10. 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 “ADX”. 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 2017	High	Low
Fourth Quarter	\$7.41	\$3.09
Third Quarter	\$9.16	\$5.94
Second Quarter	\$9.60	\$7.70
First Quarter	\$10.30	\$7.13

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

As of December 15, 2017, there were approximately 98 shareholders of record. Because shares of our Common Stock are held by depositaries, brokers and other nominees, the number of beneficial holders of our shares is substantially larger than the number of shareholders of record. On December 15, 2017, the last reported sale price per share for our Common Stock as reported by NASDAQ was \$3.14.

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.

**Recent Sales of Unregistered Securities**

On September 29, 2017, the registrant issued 1,439 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.





On October 24, 2017, the registrant issued 10,000 shares of Common Stock to accredited investors as payment for consulting services.

On October 31, 2017 the registrant issued 1,322 shares of Common Stock to its Executive Officers, pursuant to their Employment Agreements.

On November 30, 2017 the registrant issued 2,919 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, 2017:

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				
Options	3,893,558	\$ 12.51	N/A	
Restricted stock	1,363,119	N/A	N/A	
Equity compensation plans not approved by security holders	-	-	-	
Total	5,256,677	N/A	710,853	*

\* Number of securities remaining can be utilized for either options or restricted stock.

### Treasury Share Repurchases

The following table represents treasury share repurchases during the year ended October 31, 2017:

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
February 1, 2017 – February 29, 2017	9,485	\$ 8.74	N/A	N/A
July 1, 2017 – July 31, 2017	119,128	6.70	N/A	N/A
Total	128,613	\$ 6.85	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, 2017, with the cumulative total return over such period on (i) the U.S. Index of The NASDAQ Stock Market and (ii) the Biotechnology Index of The NASDAQ Stock Market. The graph assumes an investment of \$100 on October 17, 2013, in our common stock (at the closing market price) and in each of the indices listed above, and assumes the reinvestment of dividends.

### COMPARISON OF CUMULATIVE TOTAL RETURN\*

Among Advaxis, Inc., the NASDAQ Composite Index

and the NASDAQ Biotechnology Index

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

Fiscal year ending October 31.

### ITEM 6. Selected Financial Data.

The selected financial data included in this section are not intended to replace the consolidated financial statements included elsewhere in this Annual Report on Form 10-K. We derived the selected statements of operations data for the years ended October 31, 2017, 2016 and 2015 and the selected balance sheet data at October 31, 2017 and 2016 from our audited financial statements included elsewhere in this report. We derived the selected statements of operations data for the years ended October 31, 2014 and 2013 and the selected balance sheet data at October 31, 2015, 2014 and 2013 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.

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

	Year Ended October 31,				
	2017	2016	2015	2014	2013
Statements of Operations Data:					
Revenue	\$12,031,050	\$3,994,856	\$-	\$1,000,000	\$-
Operating Expenses:					
Research and Development Expenses	71,900,462	48,774,589	24,455,447	8,862,854	5,621,989
General and Administrative Expenses	38,658,464	31,712,505	24,243,690	11,675,724	9,071,613
Total Operating Expenses	110,558,926	80,487,094	48,699,137	20,538,578	14,693,602
Loss from Operations	(98,527,876 )	(76,492,238 )	(48,699,137 )	(19,538,578 )	(14,693,602 )
Other Income (Expense):					
Interest Income	669,759	331,529	114,219	36,305	(987,746 )
Net Changes in Fair Value of Derivative Liabilities	20,156	69,055	(48,950 )	619,089	(1,504,465 )
(Loss) on Note Retirement	-	-	-	-	(3,455,327 )
Other Income (Expense), Net	(123 )	(201 )	(6,599 )	990	(70,876 )
Net Loss Before Income Tax Benefit	(97,838,084 )	(76,091,855 )	(48,640,467 )	(18,882,194 )	(20,712,016 )
Income Tax Benefit	4,402,682	2,535,625	1,609,349	2,356,880	725,190
Dividends Attributable to Preferred Shares	-	-	-	-	(555,000 )
Net Loss Applicable to Common Stock	\$(93,435,402 )	\$(73,556,230 )	\$(47,031,118 )	\$(16,525,314 )	\$(20,541,826 )
Net Loss	\$(93,435,402 )	\$(73,556,230 )	\$(47,031,118 )	\$(16,525,314 )	\$(19,986,826 )
Net Loss per Common Share, Basic and Diluted	\$(2.31 )	\$(2.08 )	\$(1.68 )	\$(0.97 )	\$(4.10 )
Weighted Average Number of Common Shares Outstanding, Basic and Diluted	40,527,844	35,400,980	28,026,197	17,106,577	5,012,105

	October 31, 2017	2016	2015	2014	2013
Balance Sheet Data:					
Cash and Cash Equivalents and Investments <sup>(a)</sup>	\$70,885,113	\$152,087,528	\$112,156,178	\$17,606,860	\$20,552,062
Working capital	60,378,526	132,168,809	111,096,966	17,778,325	15,872,461
Total Assets	93,641,778	169,044,060	119,605,693	23,377,813	23,585,921
Common Stock Warrant Liability	-	20,156	89,211	32,091	646,734
Accumulated Deficit	(301,142,227)	(207,706,825)	(134,054,259)	(86,991,137)	(70,465,823)
Total Shareholders' Equity	54,260,167	119,302,194	115,598,875	20,629,986	18,002,142

(a) Includes restricted cash of \$587,000 at October 31, 2017. See Note 2. Summary of Significant Accounting Policies with this Form 10-K.

## 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

Advaxis, Inc. ("Advaxis" or the "Company") is a late-stage biotechnology Company focused on the discovery, development and commercialization of proprietary *Lm* Technology antigen delivery products based on a platform technology that utilizes live attenuated *Listeria monocytogenes* ("*Lm*") bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm*-based strains are believed to be a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy by accessing and directing 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 ("TME") to enable the T cells to eliminate tumors. The Company believes that *Lm* Technology immunotherapies can complement and address significant unmet needs in the current oncology treatment landscape. Specifically, their product candidates have the potential to optimize checkpoint performance, while having a generally well-tolerated safety profile, and most of their product candidates are immediately available for treatment with a low cost of goods. The Company's passion for the clinical potential of *Lm* Technology is balanced by focus and fiscal discipline and driven towards increasing shareholder

value.

Advaxis is focused on four franchises in various stages of clinical and pre-clinical development, which they believe will provide the greatest opportunity to have a significant impact on patients and their families:

- Human Papilloma Virus (“HPV”)-associated cancers
- Neoantigen therapy
- Disease focused hotspot / cancer antigen therapies
- Prostate cancer

31

All four clinical franchises are anchored in the Company's *Lm* Technology™, a unique platform designed for its ability to safely and effectively target various cancers in multiple ways. As an intracellular bacterium, *Lm* is an effective vector for the presentation of antigens through both the Major Histocompatibility Complex ("MHC") I and II pathways, due to its active phagocytosis by Antigen Presenting Cells ("APCs"). Within the APCs, *Lm* produces virulence factors which allow survival in the host cytosol and potently stimulate the immune system.

## Results of Operations

### Fiscal Year 2017 Compared to Fiscal Year 2016

#### *Revenue*

Revenue increased \$8,036,194 to \$12,031,050 for the year ended October 31, 2017 compared to \$3,994,856 for the year ended October 31, 2016. The increase was primarily due to a full year recognition of upfront fees received from Amgen in conjunction with the collaboration agreement signed in August 2016.

#### *Research and Development Expenses*

We make significant investments in research and development to support our pre-clinical and clinical development programs. Research and development expenses for the years ended October 31, 2017 and 2016 were categorized as follows:

	Year ended October 31,	
	2017	2016
HPV-associated cancers	\$26,650,340	\$12,875,876
Prostate cancer	3,879,894	2,293,549
Neoantigen therapy	2,286,701	1,812,086
Personnel expenses	22,113,902	18,584,165
Professional fees	14,453,151	7,800,517
Laboratory costs	8,610,682	2,751,557
Other clinical trial expenses	1,771,549	1,795,355
Other expenses	2,634,243	861,484

Partner reimbursements	(10,500,000)	-
Total research & development expense	\$71,900,462	\$48,774,589

*HPV-Associated Cancer Therapy*

HPV-associated expenses increased \$13,774,464 to \$26,650,340 for the year ended October 31, 2017 compared to \$12,875,876 for the year ended October 31, 2016. The increase resulted primarily from startup activities for additional countries in the Phase 3 AIM2CERV trial, as well as pre-clinical support on ADXS-DUAL.

*Prostate Cancer*

Prostate cancer expenses increased \$1,586,345 to \$3,879,894 for the year ended October 31, 2017 compared to \$2,293,549 for the year ended October 31, 2016. The increase resulted primarily from higher costs incurred due to the active enrollment of the expansion cohort on the Phase 1/2 trial in combination with Merck's KEYTRUDA® (pembrolizumab).

*Neoantigen Therapy*

Neoantigen therapy expenses increased \$474,615 to \$2,286,701 for the year ended October 31, 2017 compared to \$1,812,086 for the year ended October 31, 2016. The increase was a result of Phase 1 startup costs incurred during the year ended October 31, 2017.

*Personnel Expenses*

Personnel expenses increased \$3,529,737 to \$22,113,902 for the year ended October 31, 2017 compared to \$18,584,165 for the year ended October 31, 2016. The increase relates primarily to a 33% increase in R&D headcount.



*Professional Fees*

Professional fees increased \$6,652,634 to \$14,453,151 for the year ended October 31, 2017 compared to \$7,800,517 for the year ended October 31, 2016. The increase is primarily attributable to an increase in drug manufacturing process validation costs and drug stability studies in support of the MAA.

*Laboratory Costs*

Laboratory costs increased \$5,859,125 to \$8,610,682 for the year ended October 31, 2017 compared to \$2,751,557 for the year ended October 31, 2016. The increase is primarily attributable to an increase in headcount and laboratory space, as well as support of the MAA.

*Other Clinical Trial Expenses*

Clinical trial expenses decreased \$23,806 to \$1,771,549 for the year ended October 31, 2017 compared to \$1,795,355 for the year ended October 31, 2016 primarily as a result of the Company decision not to proceed to the expansion phase of the HER2 trial.

*Other Expenses*

Other expenses increased \$1,772,759 to \$2,634,243 for the year ended October 31, 2017 compared to \$861,484 for the year ended October 31, 2016. The increase was due to additional infrastructure costs incurred to support the increased headcount and laboratory expansion.

*Partner Reimbursements*

Partner reimbursements for the year ended October 31, 2017 were \$10,500,000. The Company received clinical development payments from Amgen for ADXS-NEO totaling \$7,500,000 and an additional payment of \$3,000,000 from Stendhal to support the AIM2CERV program.

*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 expenses increased \$6,945,960 to \$38,658,464 for the year ended October 31, 2017, compared with \$31,712,505 for the year ended October 31, 2016. The increase is primarily attributable to an increase in stock based compensation expense and severance associated with the resignation of the Company's Chief Executive Officer in July, 2017 and increased facility costs associated with the facility expansion. These increases were offset by a decrease in consulting fees resulting primarily from non-recurring costs associated with the collaboration agreement with Amgen which closed in August 2016.

We anticipate general and administrative expenses in the near term to remain comparable to current levels, exclusive of the impact of future stock awards, severance and facility expansion expenses.

*Interest Income*

Interest income was \$669,759 for the year ended October 31, 2017, compared with \$331,529 for the year ended October 31, 2016. The increase in interest income earned was driven primarily by an increase in interest rates as well as a higher investable balance resulting from cash received in fiscal 2016 from sales of the Company's common shares and an up-front cash payment received in conjunction with the collaboration agreement with Amgen.

*Changes in Fair Values*

For the year ended October 31, 2017, the Company recorded non-cash income from changes in the fair value of the warrant liability of \$20,156 due to the expiration of all the remaining the liability warrants.

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.

*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, 2017, the Company recorded Income Tax Receivable of \$4,452,682 from the sale of its state NOLs and research and development tax credits for the period ended October 31, 2016. 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, 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.

**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 axalimogene filolisbac.

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

*Research and Development Expenses*

We make significant investments in research and development in support of our development programs both clinically and pre-clinically. Research and development costs are expensed as incurred and primarily include salary and benefit costs, third-party grants, fees paid to clinical research organizations, and supply costs. Research and development expenses for the years ended October 31, 2016 and 2015 were categorized as follows:

	Year ended October 31,	
	2016	2015
HPV-associated cancers	\$12,875,876	\$7,358,020
Prostate cancer	2,293,549	1,826,978
Neoantigen therapy	1,812,086	172,541
Personnel expenses	18,584,165	8,492,511
Professional fees	7,800,517	3,464,321
Laboratory costs	2,751,557	508,002
Other clinical trial expenses	1,795,355	1,867,831
Other expenses	861,484	765,243
Total research & development expense	\$48,774,589	\$24,455,447

*HPV-Associated Cancer Therapy*

HPV-associated expenses increased \$5,517,856 to \$12,875,876 for the year ended October 31, 2016 compared to \$7,358,020 for the year ended October 31, 2015. The increase primarily resulted from the startup costs related to the initiation of the Phase 3 AIMZCERV trial.

*Prostate Cancer*

Prostate cancer expenses increased \$466,571 to \$2,293,549 for the year ended October 31, 2016 compared to \$1,826,978 for the year ended October 31, 2015. The increase primarily resulted from higher costs incurred due to an increase in enrollment and maintenance costs associated with the Phase 1/2 trial in combination with Merck's KEYTRUDA® (pembrolizumab).

*Neoantigen Therapy*

Neoantigen therapy expenses increased \$1,639,545 to \$1,812,086 for the year ended October 31, 2016 compared to \$172,541 for the year ended October 31, 2015. The increase was primarily a result of pre-IND activities and startup costs incurred during the year ended October 31, 2016.

*Personnel Expenses*

Personnel expenses increased \$10,091,654 to \$18,584,165 for the year ended October 31, 2016 compared to \$8,492,511 for the year ended October 31, 2015. The increase primarily relates to a 53% increase in headcount as well as non-cash stock based compensation for past employees.

*Professional Fees*

Professional fees increased \$4,336,196 to \$7,800,517 for the year ended October 31, 2016 compared to \$3,464,321 for the year ended October 31, 2015. The increase is primarily attributed to an increase in drug manufacturing process validation costs and drug stability studies.

*Laboratory Costs*

Laboratory costs increased \$2,243,555 to \$2,751,557 for the year ended October 31, 2016 compared to \$508,002 for the year ended October 31, 2015. The increase is primarily attributable to an increase in headcount as well as an expansion of laboratory space.

*Other Clinical Trial Expenses*

Clinical trial expenses decreased \$72,476 to \$1,795,355 for the year ended October 31, 2016 compared to \$1,867,831 for the year ended October 31, 2015. These expenses were related to the HER2 study and were consistent with the comparable prior period.

*Other Expenses*

Other expenses increased \$96,241 to \$861,484 for the year ended October 31, 2016 compared to \$765,243 for the year ended October 31, 2015. The increase was primarily due to additional infrastructure costs incurred to support the increased headcount and laboratory expansion.

*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 increased \$7,468,815 to \$31,712,505 for the year ended October 31, 2016, compared with \$24,243,690 for the year ended October 31, 2015. There was an increase of approximately \$6,925,600 in compensation related expense, including a non-cash increase in stock based compensation costs of approximately \$2,600,000, 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 \$1,564,900. Business development costs increased by approximately \$1,491,900. This was partially offset by a decrease in non-cash investor relations costs of approximately \$2,200,000.

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.

### **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 October 2017, we raised approximately \$222.5 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, 2017, the Company had approximately \$70.9 million in cash, restricted cash, cash equivalents and investments on its balance sheet. We believe our current cash position is sufficient to fund our business plan approximately into fiscal 2019. The actual amount of cash that we will need to operate is subject to many factors.

Since our inception through October 31, 2017, we reported accumulated net losses of approximately \$301.1 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, 2017 was approximately \$76.9 million (including proceeds from the sale of our state NOLs and Research and Development (R&D) tax credits of approximately \$2.5 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, 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.

### *Investing Activities*

Cash used in investing activities for the year ended October 31, 2017 was approximately \$12.5 million resulting from restricted cash established with letter of credit agreement, held-to-maturity investments, purchases of property and equipment, legal cost spending in support of our intangible assets (patents) and costs paid to Penn for patents.

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.

### *Financing Activities*

Cash provided by financing activities for the year ended October 31, 2017 was approximately \$528,000, resulting from the sale of 92,145 shares of our Common Stock in two at-the-market transactions resulting in net proceeds of approximately \$656,000 and proceed from the issuance of stock under an employee stock purchase plan of approximately \$251,000. This was partially offset by approximately \$357,000 of taxes paid related to the net share settlement of equity awards.

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.

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, 2017 and October 31, 2016, we had an accumulated deficit of \$301,142,227 and \$207,706,825, respectively, and shareholders' equity of \$54,260,167 and \$119,302,194, respectively.

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

The Company recognizes it may need to raise additional capital in order to continue to execute its business plan. There is no assurance that additional financing will be available when needed or that management will be able to

obtain financing on terms acceptable to the Company or whether the Company will become profitable and generate positive operating cash flow. If the Company is unable to raise sufficient additional funds, it will have to scale back its business plan, extend payables and reduce overhead until sufficient additional capital is raised to support further operations. There can be no assurance that such a plan will be successful.

**Tabular Disclosure of Contractual Obligations**

Contractual Obligations	Payments Due by Period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating Leases	\$10,447,167	\$1,041,895	\$2,340,292	\$2,686,459	\$4,378,521
Employment Agreements	\$1,978,225	\$1,978,225			
Consulting and other Services	\$2,173,388	\$1,877,492	\$262,896	\$33,000	

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, 2017, 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

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 axalimogene filolisbac, 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, 2017, the Company had approximately \$70.9 million in cash, restricted cash, cash equivalents and investments, which consisted primarily of bank deposits, restricted cash, 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-26.

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

Not applicable.

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

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

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

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

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

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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial

statements for external purposes in accordance with generally accepted accounting principles in the United States of America. Internal control over financial reporting includes those policies and procedures that:

(i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

(ii) provide reasonable assurance that the transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with the authorization of management and/or our Board of Directors; and

(iii) provide reasonable assurance regarding the prevention or timely detection of any unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

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

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

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

During the quarter ended October 31, 2017, 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, 2017, 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, 2017, 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, 2017 and 2016, and the related statements of operations, shareholders' equity, and cash flows for the years ended October 31, 2017, 2016 and 2015 of the Company and our report dated December 20, 2017 expressed an unqualified opinion on those financial statements.

Marcum llp  
New York, NY  
December 20, 2017



**Item 9B: Other Information.**

None.

42

## **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 2018 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 2018 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 2018 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 2018 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 2018 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	<u>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.</u>
3.2	<u>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.</u>
3.3	<u>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.</u>
3.4	<u>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.</u>
3.5	<u>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.</u>
3.6	<u>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.</u>
3.7	<u>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.</u>
3.8	

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

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 Purchase Warrant. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on August 31, 2011.

44

<b>Exhibit Number</b>	<b>Description of Exhibits</b>
4.8	<u>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.</u>
4.9	<u>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.</u>
4.11	<u>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.</u>
4.12	<u>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.</u>
10.1	<u>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.</u>
10.2	<u>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.</u>
10.3	<u>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.</u>
45	

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

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.

10.16 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.

46



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

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

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.

10.29‡ 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.

10.30‡ 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.

10.31‡ 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
10.32‡	<u>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.</u>
10.33‡	<u>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.</u>
10.34‡	<u>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</u>
10.35‡	<u>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.</u>
10.36	<u>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.</u>
10.37	<u>5<sup>th</sup> Amendment to the Amended &amp; 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.</u>
10.38	<u>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.</u>
10.39	<u>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.</u>
10.40	<u>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.</u>
10.41	<u>Clinical Trial Collaboration and Supply Agreement by and between Advaxis, Inc. and Merck &amp; 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</u>
10.42‡	<u>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.</u>
10.43‡	

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

- 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.
- 10.44‡ 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.
- 10.45‡ 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.
- 10.46‡ 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.
- 10.47 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.
- 10.48 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.
- 10.49‡ 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.
- 10.50‡ 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.
- 10.51‡ 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.
- 10.52‡ 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.
- 10.53 Co-Development and Commercialization Agreement between Advaxis, Inc. and Especificos Stendhal SA de CV dated February 3, 2016. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on February 26, 2016.
- 10.54 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.
- 10.55 License and Collaboration Agreement, dated August 2, 2016, by and between Advaxis, Inc. and Amgen Inc. Incorporated by reference to Exhibit 10.57 to Annual Report on Form 10-K filed with the SEC on January 9, 2017.

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

- 10.56 Securities Purchase Agreement, dated as of August 1, 2016, between Advaxis, Inc. and Amgen, Inc. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on August 2, 2016.
- 10.57 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.
- 10.58‡ Separation Agreement and General Release, dated July 6, 2017, between Advaxis, Inc. and Daniel J. O'Connor. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on July 7, 2017.
- 10.59‡ Employment Agreement, dated July 18, 2017, by and between Advaxis, Inc. and Anthony Lombardo. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on July 21, 2017.

Exhibit Number	Description of Exhibits
14.1	<u>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.</u>
23.1	<u>Consent of Independent Registered Public Accounting Firm.</u>
31.1*	<u>Certification of Chief Executive Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002</u>
31.2*	<u>Certification of Chief Financial Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002</u>
32.1*	<u>Certification of Chief Executive Officer pursuant to section 906 of the Sarbanes-Oxley Act of 2002</u>
32.2*	<u>Certification of Chief Financial Officer pursuant to section 906 of the Sarbanes-Oxley Act of 2002</u>
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definitions Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

\* Filed herewith.

\*\*Furnished herewith.

‡ 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 20<sup>th</sup> day of December 2017.

ADVAXIS, INC.

By: */s/ Anthony Lombardo*  
 Anthony Lombardo, Interim Chief Executive Officer

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

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

SIGNATURE	Title	DATE
<i>/s/ Anthony Lombardi</i> Daniel J. O'Connor	Interim Chief Executive Officer (Principal Executive Officer)	December 20, 2017
<i>/s/ Sara Bonstein</i> Sara Bonstein	Chief Financial Officer, Executive Vice President and Secretary (Principal Financial and Accounting Officer)	December 20, 2017
<i>/s/ David Sidransky</i> David Sidransky	Chairman of the Board	December 20, 2017
<i>/s/ James Patton</i>		

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

James Patton	Vice Chairman of the Board	December 20, 2017
<i>/s/ Richard Berman</i> Richard Berman	Director	December 20, 2017
<i>/s/ Thomas McKearn</i> Thomas McKearn	Director	December 20, 2017
<i>/s/ Samir Khleif</i> Samir Khleif	Director	December 20, 2017
<i>/s/ Roni Appel</i> Roni Appel	Director	December 20, 2017
<i>/s/ Thomas Ridge</i> Thomas Ridge	Director	December 20, 2017



**ADVAXIS, INC.**

**FINANCIAL STATEMENTS**

**INDEX**

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

F-1

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheets of Advaxis, Inc. (the “Company”) as of October 31, 2017 and 2016, and the related statements of operations, shareholders’ equity and cash flows for the years ended October 31, 2017, 2016, and 2015. 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 consolidated 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, 2017 and 2016, and the results of its operations and its cash flows for the years ended October 31, 2017, 2016, and 2015 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, 2017, based on the criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated December 20, 2017 expressed an unqualified opinion on the effectiveness of the Company’s internal control over financial reporting.

Marcum llp  
New York, NY  
December 20, 2017



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

	October 31, 2017	2016
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$23,899,809	\$112,750,980
Restricted cash	587,000	-
Investments	46,398,304	39,336,548
Income tax receivable	4,452,682	2,549,862
Deferred expenses	2,986,385	4,291,385
Prepaid expenses and other current assets	2,918,644	946,423
Total current assets	81,242,824	159,875,198
Property and equipment (net of accumulated depreciation)	7,111,081	4,389,074
Intangible assets (net of accumulated amortization)	4,856,775	4,329,121
Other assets	431,098	450,667
Total assets	\$93,641,778	\$169,044,060
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$5,121,406	\$1,720,428
Accrued expenses	8,700,036	10,905,003
Deferred revenue	6,995,336	15,020,576
Other current liabilities	47,520	60,382
Total current liabilities	20,864,298	27,706,389
Deferred revenue	17,478,758	21,234,568
Other liabilities	1,038,555	800,909
Total liabilities	39,381,611	49,741,866
Commitments and contingencies – Note 10		
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, 2017 and 2016. Liquidation preference of \$0 at October 31, 2017 and 2016.	-	-
Common stock - \$0.001 par value; 65,000,000 shares authorized, 41,206,538 shares issued and outstanding at October 31, 2017 and 40,057,067 shares issued and 40,041,047 shares outstanding at October 31, 2016.	41,207	40,057
Additional paid-in capital	355,361,187	327,098,749
	-	(129,787 )

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

Treasury stock, at cost, 0 shares at October 31, 2017 and 16,020 shares October 31, 2016

Accumulated deficit	(301,142,227)	(207,706,825)
Total shareholders' equity	54,260,167	119,302,194
Total liabilities and shareholders' equity	\$93,641,778	\$ 169,044,060

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

F-3

**ADVAXIS, INC.****STATEMENTS OF OPERATIONS**

	Year Ended October 31,		
	2017	2016	2015
Revenue	\$ 12,031,050	\$ 3,994,856	\$ -
Operating expenses:			
Research and development expenses	71,900,462	48,774,589	24,455,447
General and administrative expenses	38,658,464	31,712,505	24,243,690
Total operating expenses	110,558,926	80,487,094	48,699,137
Loss from operations	(98,527,876 )	(76,492,238 )	(48,699,137 )
Other income (expense):			
Interest income	669,759	331,529	114,219
Net changes in fair value of derivative liabilities	20,156	69,055	(48,950 )
Other income (expense), net	(123 )	(201 )	(6,599 )
Net loss before income tax benefit	(97,838,084 )	(76,091,855 )	(48,640,467 )
Income tax benefit	4,402,682	2,535,625	1,609,349
Net loss	\$(93,435,402 )	\$(73,556,230 )	\$(47,031,118 )
Net loss per common share, basic and diluted	\$(2.31 )	\$(2.08 )	\$(1.68 )
Weighted average number of common shares outstanding, basic and diluted	40,527,844	35,400,980	28,026,197

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

## ADVAXIS, INC.

## STATEMENTS OF SHAREHOLDERS' EQUITY

	Preferred	Common Stock		Additional	Treasury Stock		Accumulated	Total
	Stock	Shares	Amount	Paid-In	Shares	Amount	Deficit	Shareholders' Equity
Balance at October 31, 2014	- \$-	19,630,139	\$19,630	\$107,601,493	-	\$-	\$(86,991,137 )	\$20,629,986
Stock based compensation		1,167,976	1,169	21,374,861				21,376,030
Tax withholdings paid related to net share settlement of equity awards				(1,375,979 )				(1,375,979 )
Tax withholdings paid on equity awards					(114,445 )	(1,388,086)		(1,388,086 )
Tax shares sold to pay for tax withholdings on equity awards				16,273	97,526	1,200,325	(32,004 )	1,184,594
Common Stock issued upon exercise of options		65,167	65	58,335				58,400
Common Stock issued upon exercise of warrants		691,268	691	2,341,758				2,342,449
Conversion of notes payable into common stock		4,104	4	39,928				39,932
Issuance of shares to employees under ESPP		7,063	7	28,784				28,791

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

Plan Advaxis registered direct offerings	8,806,165	8,806	63,046,722					63,055,528
Advaxis Public Offering	3,220,000	3,220	56,675,128					56,678,348
Net Loss						(47,031,118 )		(47,031,118 )
Balance at October 31, 2015	- \$-	33,591,882	\$33,592	\$249,807,303	(16,919 )	\$(187,761 )	\$(134,054,259)	\$115,598,875
Stock based compensation Tax withholdings paid related to net share settlement of equity awards	1,042,527	1,043	23,451,904					23,452,947
Tax withholdings paid on equity awards					(332,537 )	(2,729,230)		(2,729,230 )
Tax shares sold to pay for 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
Conversion of notes payable into common stock	1,481	1	29,548					29,549
Issuance of shares to employees under ESPP	6,627	7	73,237					73,244
Plan Advaxis registered direct offerings	2,244,443	2,244	28,154,163					28,156,407
Sale of common shares to Amgen	3,047,446	3,047	24,965,589					24,968,636



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

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
Stock based compensation		1,030,507	1,031	27,864,642				27,865,673
Tax withholdings paid related to net share settlement of equity awards				(356,949 )				(356,949 )
Tax withholdings paid on equity awards				(997,029 )	(128,613)	(881,055 )		(1,878,084 )
Tax shares sold to pay for tax withholdings on equity awards				843,526	144,633	1,010,842		1,854,368
Common stock issued upon exercise of warrants		225		1,125				1,125
Issuance of shares to employees under ESPP Plan		26,594	27	251,347				251,374
Advaxis at-the-market sales		92,145	92	655,776				655,868
Net Loss							(93,435,402 )	(93,435,402 )
Balance at								
October 31, 2017	- \$-	41,206,538	\$41,207	\$355,361,187	-	\$-	\$(301,142,227)	\$54,260,167

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

**ADVAXIS, INC.****STATEMENT OF CASH FLOWS**

	Year ended October 31,		
	2017	2016	2015
<b>OPERATING ACTIVITIES</b>			
Net loss	\$ (93,435,402 ) \$ (73,556,230 ) \$ (47,031,118 )		
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock compensation	27,835,673	23,472,947	21,431,030
Loss (gain) on change in value of warrants and embedded derivative	(20,156 )	(69,055 )	48,950
Loss (gain) on disposal of property and equipment	3,187	-	(10,000 )
Warrant expense	-	-	8,170
Write-off of intangible assets	315,394	-	28,480
Depreciation expense	790,554	283,538	59,033
Amortization expense of intangible assets	329,866	252,654	206,357
Amortization of premium on held to maturity investments	183,947	252,730	60,608
Debt conversion expense	-	-	6,599
<u>Change in operating assets and liabilities:</u>			
Prepaid expenses and other current assets	(1,972,221 )	(447,167 )	(293,096 )
Income taxes receivable	(1,902,820 )	(940,513 )	121,968
Other assets	1,324,569	(3,843,419 )	104,529
Accounts payable and accrued expenses	1,159,534	8,354,447	1,094,155
Deferred revenue	(11,781,050 )	36,255,144	-
Other liabilities	244,940	841,135	-
Net cash used in operating activities	(76,923,985 )	(9,143,789 )	(24,164,335 )
<b>INVESTING ACTIVITIES</b>			
Restricted cash established with letter of credit agreement	(587,000 )	-	-
Purchases of investments	(71,175,703 )	(44,524,783 )	(45,655,103 )
Proceeds from maturities and redemptions of investments	63,930,000	50,530,000	-
Purchase of property and equipment	(3,449,271 )	(3,222,442 )	(972,859 )
Cost of intangible assets	(1,172,914 )	(1,226,742 )	(821,925 )
Net cash provided by (used in) investing activities	(12,454,888 )	1,556,033	(47,449,887 )
<b>FINANCING ACTIVITIES</b>			
Net proceeds of issuance of common stock	655,868	53,125,043	119,733,876
Proceeds from employee stock purchase plan	251,374	73,244	28,791
Proceeds from exercise of options	-	-	58,400
Proceeds from the exercise of warrants	1,125	614,368	2,342,449
Tax withholdings paid related to net share settlement of equity awards	(356,949 )	(61,350 )	(1,375,979 )
Employee tax withholdings paid on equity awards	(1,878,084 )	(2,729,230 )	(1,388,086 )
	1,854,368	2,754,978	1,169,594

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

Tax shares sold to pay for employee tax withholdings on equity awards

Net cash provided by financing activities	527,702	53,777,053	120,569,045
Net increase (decrease) in cash and cash equivalents	(88,851,171 )	46,189,297	48,954,823
Cash and cash equivalents at beginning of year	112,750,980	66,561,683	17,606,860
Cash and cash equivalents at end of year	\$23,899,809	\$112,750,980	\$66,561,683

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

F-6

**Supplemental Disclosures of Cash Flow Information**

	Year Ended October 31,		
	2017	2016	2015
Cash paid for interest	\$-	\$-	\$ -
Cash paid for taxes	\$50,000	\$50,000	\$ -

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

	Year Ended October 31,		
	2017	2016	2015
Accounts payable and accrued expenses settled with common stock	\$75,000	\$55,000	\$-
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	\$66,477	\$362,926	\$-

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

**ADVAXIS, INC.**

**NOTES TO FINANCIAL STATEMENTS**

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

Advaxis, Inc. (“Advaxis” or the “Company”) is a late-stage biotechnology Company focused on the discovery, development and commercialization of proprietary *Lm* Technology antigen delivery products based on a platform technology that utilizes live attenuated *Listeria monocytogenes* (“*Lm*”) bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm*-based strains are believed to be a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy by accessing and directing 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 (“TME”) to enable the T cells to eliminate tumors. The Company believes that *Lm* Technology immunotherapies can complement and address significant unmet needs in the current oncology treatment landscape. Specifically, their product candidates have the potential to optimize checkpoint performance, while having a generally well-tolerated safety profile, and most of their product candidates are immediately available for treatment with a low cost of goods. The Company’s passion for the clinical potential of *Lm* Technology is balanced by focus and fiscal discipline and driven towards increasing shareholder value.

Advaxis is focused on four franchises in various stages of clinical and pre-clinical development, which they believe will provide the greatest opportunity to have a significant impact on patients and their families:

- Human Papilloma Virus (“HPV”)-associated cancers
- Neoantigen therapy
- Disease focused hotspot / cancer antigen therapies
- Prostate cancer

All four clinical franchises are anchored in the Company’s *Lm* Technology™, a unique platform designed for its ability to safely and effectively target various cancers in multiple ways. As an intracellular bacterium, *Lm* is an effective vector for the presentation of antigens through both the Major Histocompatibility Complex (“MHC”) I and II pathways, due to its active phagocytosis by Antigen Presenting Cells (“APCs”). Within the APCs, *Lm* produces virulence factors which allow survival in the host cytosol and potentially stimulate the immune system.

*Liquidity and Financial Condition*

The Company's products that are being developed have not generated significant revenue. As a result, the Company has suffered recurring losses. These losses are expected to continue for an extended period of time. 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 October 2017, we raised approximately \$222.5 million in gross proceeds from various public and private offerings of our common stock.

As of October 31, 2017, the Company had approximately \$70.9 million in cash, restricted cash, cash equivalents and investments on its balance sheet. The Company plans to continue to be disciplined in regards to its utilization of its capital and anticipates its cash burn will decrease from fiscal 2017. This decrease will largely be due to several one-time items in fiscal 2017 related to the preparation of our MAA filing of axalimogene filolisbac and other one-time costs that the Company does not anticipate to recur. We believe our current cash position is sufficient to fund our business plan into fiscal 2019. The actual amount of cash that we will need to operate is subject to many factors.

The Company also 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 operations.

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

### *Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Estimates are used when accounting for such items as the fair value and recoverability of the carrying value of property and equipment and intangible assets (patents and licenses), the fair value of options, the fair value of embedded conversion features, warrants and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates, based on historical experience and on various other assumptions that it believes to be reasonable under the circumstances. Actual results may or may not 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.

F-8

### *Collaboration Agreements*

The Company evaluates whether an arrangement is a collaborative arrangement under the Financial Accounting Standards Board (the “FASB”) Accounting Standards Codification (“ASC”) Topic 808, Collaborative Arrangements, at its inception based on the facts and circumstances specific to the arrangement. The Company also reevaluates whether an arrangement qualifies or continues to qualify as a collaborative arrangement whenever there is a change in either the roles of the participants or the participants’ exposure to significant risks and rewards dependent on the ultimate commercial success of the endeavor. For those collaborative arrangements where it is determined that the Company is the principal participant, costs incurred and revenue generated from third parties are recorded on a gross basis in the financial statements.

From time to time, the Company enters into collaborative arrangements for the research and development, manufacture and/or commercialization of products and product candidates. These collaborations generally provide for non-refundable, upfront license fees, research and development and commercial performance milestone payments, cost sharing, royalty payments and/or profit sharing. The Company’s collaboration agreements with third parties are performed on a “best efforts” basis with no guarantee of either technological or commercial success.

### *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 from the date of purchase to be cash equivalents.

#### *Restricted Cash and Letter of Credit*

During 2017, the Company established a letter of credit with a financial institution as security for the purchase of custom equipment. The letter of credit is collateralized by cash which is unavailable for withdrawal or for usage for general obligations. No amount is outstanding under the letter of credit as of October 31, 2017.

F-9

### *Concentration of Credit Risk*

The Company maintains its cash in bank deposit accounts (checking) that at times exceed federally insured limits. Approximately \$23.1 million is subject to credit risk at October 31, 2017. 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 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, 2017, 2016 or 2015. Interest income is recognized when earned.

### *Deferred Expenses*

Deferred expenses consist of advanced payments made on research and development projects. Expense is recognized in the Statement of Operations as the research and development activity is performed.

### *Property and Equipment*

Property and equipment is stated at cost. Additions and improvements that extend the lives of the assets are capitalized, while expenditures for repairs and maintenance are expensed as incurred. Leasehold improvements are

amortized on a straight-line basis over the shorter of the asset's estimated useful life or the remaining lease term. Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets ranging from three to ten years.

When depreciable assets are retired or sold the cost and related accumulated depreciation are removed from the accounts and any resulting gain or loss is recognized in operations.

#### *Intangible Assets*

Intangible assets are recorded at cost and include patents and patent application costs, licenses and software. Intangible assets are amortized on a straight-line basis over their estimated useful lives ranging from 3 to 20 years. Patent application costs are written-off if the application is rejected, withdrawn or abandoned.

#### *Impairment of Long-Lived Assets*

The company reviews 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. Recoverability of assets held and used is measured by comparison of the carrying amount of an asset to the future undiscounted cash flows expected to be generated from the use of the asset and its eventual disposition. If the total of the undiscounted future cash flows is less than the carrying amount of those assets, an impairment loss is recognized in the Statement of Operations based on the excess of the carrying amount over the fair value of the asset.

#### *Net Income (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,		
2017	2016	2015

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

Warrants	3,092,935	3,110,575	3,241,466
Stock options	3,893,558	3,351,795	1,981,939
Restricted stock units	1,363,119	719,448	1,069,335
Convertible debt (using the if-converted method)	-	-	1,576
Total	8,349,612	7,181,818	6,294,316

F-10

### *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 value of financial instruments, including cash and cash equivalents, restricted cash and accounts payable approximated fair value as of the balance sheet date presented, due to their short maturities. The carrying amounts of 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.

#### *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.

*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. In December 2016, the FASB issued ASU 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers to clarify the codification or to correct unintended application of guidance. In September and November 2017, the FASB issued ASU 2017-13, Revenue Recognition (Topic 605), Revenue from Contracts with Customers (Topic 606), Leases (Topic 840), and Leases (Topic 842) and ASU 2017-14, Income Statement—Reporting Comprehensive Income (Topic 220), Revenue Recognition (Topic 605), and Revenue from Contracts with Customers (Topic 606) which amends certain aspects of the new revenue recognition standard. The Company is 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, ending after December 15, 2016. The Company has adopted this standard effective for the year ending October 31, 2017. There was no 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 fiscal 2020. 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. In September, the FASB issued ASU 2017-13, Revenue Recognition (Topic 605), Revenue from Contracts with Customers (Topic 606), Leases (Topic 840), and Leases (Topic 842) which amends certain aspects of the new lease standard. The Company is currently evaluating the impact of adopting ASU 2016-02 on the



Company's financial statements.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash. The new standard changes the presentation of restricted cash and cash equivalents on the statement of cash flows. Restricted cash and restricted cash equivalents will be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. Early adoption is permitted. This ASU is not expected to have a material impact on the Company's financial statements.

In January 2017, the FASB issued ASU No. 2017-01, "Business Combinations (Topic 805): Clarifying the Definition of a Business." The amendments in this Update clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of businesses. The amendments in this Update provide a screen to determine when a set is not a business. If the screen is not met, it (1) requires that to be considered a business, a set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output and (2) removes the evaluation of whether a market participant could replace the missing elements. This Update is the final version of Proposed ASU 2015-330 Business Combinations (Topic 805) – Clarifying The Definition of a Business, which has been deleted. The amendments in this Update are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted. This ASU is not expected to have a material impact on the Company's financial statements.

In May 2017, the FASB issued ASU 2017-09, "Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting" to provide clarity and reduce both (1) diversity in practice and (2) cost and complexity when applying the guidance in Topic 718, Compensation—Stock Compensation, to a change to the terms or conditions of a share-based payment award. The amendments in this Update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. This Update is the final version of Proposed ASU 2016-360—Compensation—Stock Compensation (Topic 718)—Scope of Modification Accounting, which has been deleted. The amendments in this Update are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted. 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.

### 3. INVESTMENTS

The following table summarizes the Company's investment securities at amortized cost as of October 31, 2017 and 2016:

	October 31, 2017			
	Amortized Cost, as Adjusted	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
Short-term investments:				
Certificates of Deposit	\$ 11,391,147	\$ -	\$ -	\$ 11,391,147
Domestic Governmental Agency Loans	499,957	-	162	499,795
U.S Treasury Notes	34,507,200	-	25,351	34,481,849
Total short-term investment securities	\$ 46,398,304	\$ -	\$ 25,513	\$ 46,372,791

	October 31, 2016			
	Amortized Cost, as Adjusted	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
Short-term investments:				
Certificates of Deposit	\$ 10,737,563	\$ -	\$ -	\$ 10,737,563
Domestic Governmental Agency Loans	2,500,000	-	250	2,499,750
U.S Treasury Notes	26,098,985	2,404	7,556	26,093,833
Total short-term investment securities	\$ 39,336,548	\$ 2,404	\$ 7,806	\$ 39,331,146

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,  
2017                      2016

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

Leasehold improvements	\$2,167,990	\$1,835,602
Laboratory equipment	4,381,428	2,038,704
Furniture and fixtures	728,725	549,025
Computer equipment	394,523	240,910
Construction in progress	645,000	151,368
Total property and equipment	8,317,666	4,815,609
Accumulated depreciation and amortization	(1,206,585)	(426,535 )
Net property and equipment	\$7,111,081	\$4,389,074

Depreciation expense for the years ended October 31, 2017, 2016 and 2015 was \$790,554, \$283,538 and \$59,033, respectively.

## 5. INTANGIBLE ASSETS

Intangible assets consist of the following:

	October 31,	
	2017	2016
Patents	\$5,727,298	\$4,980,610
License	776,992	776,992
Software	108,604	19,625
Total intangibles	6,612,894	5,777,227
Accumulated amortization	(1,756,119)	(1,448,106)
Net intangible assets	\$4,856,775	\$4,329,121

The expirations of the existing patents range from 2017 to 2038 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 \$315,394, \$0 and \$28,480 and were abandoned and were charged to research and development expenses in the Statement of Operations for the years ended October 31, 2017, 2016 and 2015, respectively. Amortization expense for intangible assets is included in general and administrative expenses and aggregated \$329,866, \$252,654 and \$206,357 for the years ended October 31, 2017, 2016 and 2015, respectively.

At October 31, 2017, the estimated amortization expense by fiscal year based on the current carrying value of intangible assets is as follows:

2018	\$365,848
2019	363,448
2020	346,593
2021	329,647
2022	329,647
Thereafter	3,121,592
Total	\$4,856,775

## 6. ACCRUED EXPENSES:

The following table represents the major components of accrued expenses:

	October 31,	
	2017	2016
Salaries and other compensation	\$2,652,583	\$2,467,650
Vendors	2,811,956	2,098,792
Professional fees	3,235,497	6,338,561
Total accrued expenses	\$8,700,036	\$10,905,003

## 7. COMMON STOCK PURCHASE WARRANTS AND WARRANT LIABILITY

### *Warrants*

A summary of warrant activity was as follows:

Shares	Weighted Average Exercise	Weighted Average Remaining	Aggregate Intrinsic Value
--------	---------------------------------	----------------------------------	---------------------------------

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

		Price	Contractual Life In Years	
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
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
Exercised	(225 )	5.00		
Expired	(17,955 )	11.43		
Outstanding and exercisable warrants at October 31, 2017	3,092,395	\$ 5.00	0.92	\$-

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

F-14

At October 31, 2017, the Company had all of its total 3.09 million outstanding warrants classified as equity (equity warrants). At October 31, 2016, the Company had approximately 3.09 million of its total 3.11 million outstanding warrants classified as equity. At October 31, 2015, the Company had approximately 3.22 million of its total 3.24 million outstanding warrants classified as equity. 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, 2017, the Company had no warrants classified as liabilities (liability warrants), as all of the liability warrants expired. At October 31, 2016, the Company had approximately 18,000 of its total 3.11 million outstanding warrants classified as liabilities. At October 31, 2015, the Company had approximately 18,000 of its total 3.24 million outstanding warrants classified as liabilities. 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, 2017 and October 31, 2016, the fair value of the warrant liability was \$0 and \$20,156, respectively and is reflected in other current liabilities in the Balance Sheet. For the years ended October 31, 2017, 2016 and 2015, the Company reported income of \$20,156, income of \$69,055 and a loss of \$48,950, respectively, due to changes in the fair value of the warrant liability.

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

	10/31/2016	10/31/2015
Exercise price	\$10.63-18.75	\$10.63-18.75
Stock price	\$8.09	\$11.09
Expected term	0.55-0.75 years	1.52-1.76 years
Volatility %	81.84%-87.09 %	93.87%-95.00 %
Risk free rate	0.51%-0.66 %	.075 %

*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. 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%.

**8. SHARE BASED COMPENSATION**

The following table summarizes share-based compensation expense included in the Statement of Operations by expense category for the years ended October 31, 2017, 2016 and 2015, respectively:

	Year Ended October 31,		
	2017	2016	2015
Research and development	\$5,647,913	\$7,985,651	\$6,293,791
General and administrative	22,187,760	15,487,296	15,137,239
Total	\$27,835,673	\$23,472,947	\$21,431,030

*Amendments*

The Advaxis, Inc. 2015 Incentive Plan (the "2015 Plan") was originally ratified and approved by the Company's stockholders on May 27, 2015. 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.

F-15



At the Annual Meeting of Stockholders of the Company held on March 10, 2016, the stockholders ratified and approved an amendment to the 2015 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.

At the Annual Meeting of Stockholders of the Company held on April 5, 2017, the stockholders ratified and approved an amendment to the 2015 Plan to increase the aggregate number of shares of common stock authorized for issuance under such plan from 4,600,000 shares to 6,100,000 shares. The amendment also included a provision that provides for pre-defined annual increases in the number of shares available for issuance under the Plan equal to the lesser of: (i) 5% of the total number of shares of Common Stock outstanding, (ii) 2,500,000, or (iii) a lesser number determined by the Board of Directors. As of October 31, 2017, there were 710,853 shares available for issuance under the 2015 Plan.

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

A summary of the Company's RSU activity and related information for the year ended October 31, 2017, 2016 and 2015 is as follows:

	Number of RSU's	Weighted-Average Grant Date Fair Value
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
Granted	1,632,134	7.90
Vested	(877,383 )	9.15
Cancelled	(111,080 )	8.74
Balance at October 31, 2017	1,363,119	\$ 8.54

The fair value as of the respective vesting dates of RSUs was approximately \$6,045,000, \$6,643,000 and \$7,771,000 for the years ended October 31, 2017, 2016 and 2015, respectively.

As of October 31, 2017, there was approximately \$9,434,000 of unrecognized compensation cost related to non-vested RSUs, which is expected to be recognized over a remaining weighted average vesting period of approximately 1.99 years.

As of October 31, 2017, the aggregate intrinsic value of non-vested RSUs was approximately \$4,635,000.

#### *Employee Stock Awards*

Common Stock issued to executives and employees related to vested incentive retention awards, employment inducements, management purchases and employee excellence awards totaled 878,948 shares (834,600 shares on a net basis after employee taxes), 719,610 shares (712,106 shares on a net basis after employee taxes), and 506,736 shares (422,781 shares on a net basis after employee taxes) during the years ended October 31, 2017, 2016 and 2015, respectively. Total stock compensation expense associated with these awards for the years ended October 31, 2017, 2016 and 2015 was \$8,883,123, \$5,458,823 and \$5,432,494, respectively.

Furthermore, during the year ended October 31, 2015, 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, 2015, the total fair value of these equity purchases were \$102,022, or 9,150 shares of the Company's Common Stock.

#### *Director Stock Awards*

During the years ended October 31, 2017, 2016 and 2015, common stock issued to the Directors for compensation related to board and committee membership was 30,000 shares, 152,386 shares and 267,186, respectively. During the years ended October 31, 2017, 2016 and 2015, total stock compensation expense to the Directors was \$403,200, \$1,184,780 and \$1,223,118, respectively.

*Stock Options*

A summary of changes in the stock option plan for the years ended October 31, 2017, 2016 and 2015 is as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life In Years	Aggregate Intrinsic Value
Outstanding as of October 31, 2014	467,968	\$ 15.51	6.34	\$ -
Granted	1,668,995	13.41		
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		
Cancelled or expired	(15,144 )	29.69		
Outstanding as of October 31, 2016	3,351,795	\$ 13.31	7.82	\$ 61,980
Granted	556,952	7.71		
Cancelled or expired	(15,189 )	14.07		
Outstanding as of October 31, 2017	3,893,558	\$ 12.51	5.72	\$ -
Vested and exercisable at October 31, 2017	2,795,826	\$ 13.05	4.80	\$ -

\* 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, 2017;

Exercise Price Range	Options Outstanding				Options Exercisable			
	Number Outstanding	Weighted Average Remaining Contractual	Weighted Average Exercise Price	Intrinsic Value	Number Exercisable	Weighted Average Remaining Contractual	Weighted Average Exercise Price	Intrinsic Value
\$3.63 - \$9.99	672,672	6.58	\$ 7.91	\$61,980	285,954	4.02	\$ 8.19	\$ -
\$10.00 - \$14.99	3,006,606	5.63	\$ 13.14	\$ -	2,295,592	4.95	\$ 13.18	\$ -
\$15.01 - \$19.99	213,480	4.29	\$ 18.07	\$ -	213,480	4.29	\$ 18.07	\$ -
\$20.00 - \$21.25	800	2.60	\$ 21.25	\$ -	800	2.60	\$ 21.25	\$ -

The fair value of each option granted from the Company's stock option plans during the years ended October 31, 2017, 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.

The following table provides the weighted average fair value of options granted to directors and employees and the related assumptions used in the Black-Scholes model:

	Year Ended		
	October 31, 2017	October 31, 2016	October 31, 2015
Weighted average fair value of options granted	\$6.36	\$10.71	\$17.38
Expected term	5.50-6.50 years	5.51-6.51 years	5-10 years
Expected volatility	107.07%-110.93%	109.23%-115.25%	109.26%-154.54%
Expected dividends	0%	0%	0%
Risk free interest rate	1.26%-1.58%	1.65-2.00%	1.41%-2.27%

Total compensation cost related to the Company's outstanding stock options, recognized in the statement of operations for the years ended October 31, 2017, 2016 and 2015 was approximately \$17,195,000, \$15,223,000 and \$9,521,000, respectively. Included in compensation expense is \$1,641,000 recognized as a result of the modification of certain option agreements associated with the resignation of the Company's Chief Executive Officer in July 2017. Pursuant to the separation agreement all the outstanding options vested immediately and the expiration date was extended until July 5, 2021.

During the year ended October 31, 2017, 556,952 options were granted with a total grant date fair value of approximately \$3,542,000. 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.

As of October 31, 2017, there was approximately \$4,680,000 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 1.11 years.

#### *Shares Issued to Consultants*

During the year ended October 31, 2017, 165,907 shares of Common Stock valued at \$1,384,350 were issued to consultants for services. The Company recorded a liability on its balance sheet for \$45,000 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, 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.

#### **2011 Employee Stock Purchase Plan**

The Advaxis, Inc. 2011 Employee Stock Purchase Plan (“ESPP”) was approved by the Company’s shareholders in September 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, 2017, 2016 and 2015 shares purchased under the ESPP were 26,594, 6,627 and 7,063 and the Company recorded expense of \$251,374, \$73,244 and \$28,791 respectively. As of October 31, 2017, 0 shares of Company's Common Stock remain available for issuance under the ESPP.

## 9. COLLABORATION AND LICENSING AGREEMENTS

### *BMS*

On May 30, 2017, the Company announced a clinical development collaboration with BMS to evaluate ADXS-DUAL, its second investigational immunotherapy targeting HPV-associated cancers, and BMS' PD-1 immune checkpoint inhibitor, Opdivo® (nivolumab), as a potential combination treatment option for women with metastatic cervical cancer.

Under the terms of the agreement, each party will bear their own internal costs and provide its immunotherapy agent. The Company will sponsor the trial and pay third-party costs.

### *Sellas Life Science Group*

On February 27, 2017, the Company entered into a license agreement with Sellas Life Science Group ("Sellas") to develop a novel cancer immunotherapy agent using Advaxis' proprietary *Lm*-based antigen delivery product with SELLAS' patented WT1 targeted heteroclitic peptide antigen mixture (galinpepimut-S)). Pursuant to the agreement, Advaxis will conduct all pre-clinical activities required for an IND filing and Sellas will be responsible for all clinical development and commercial activities. Advaxis will receive future payments of up to \$358 million from SELLAS if certain development, regulatory, and commercial milestones are met. SELLAS has agreed to pay Advaxis single-digit to low double-digit royalties based on worldwide net sales upon commercialization. If SELLAS sublicenses its rights, Advaxis will receive a percentage of applicable sublicense revenue paid.

*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. Amgen will fund the clinical development and commercialization of ADXS-NEO and Advaxis will retain manufacturing responsibilities. Advaxis and Amgen will collaborate through a joint steering committee for the development and commercialization of ADXS-NEO. 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.

The Company identified the following performance obligations 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 years ended October 31, 2017 and 2016, the Company recognized revenue from the Amgen Agreement of approximately \$11,781,000 and \$3,745,000 related to amortization of the upfront fees.

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 considered the provisions of the research and development and collaboration guidance in determining how to recognize the clinical development payments to be received from Amgen. The Company determined the clinical development payments should be accounted for within the scope of collaboration arrangement accounting guidance. As a result, the Company will account for the clinical development payments as a reduction of research and development expenses in the Statement of Operations. During the year ended October 31, 2017, the Company

received clinical development payments from Amgen totaling \$6,000,000. In addition, the Company recorded an expected clinical development payment of \$1,500,000 as prepaid expenses and other current assets on the balance sheet. In November 2017, the Company received the \$1,500,000 expected clinical development payment from Amgen.

#### *Especificos Stendhal SA de CV*

On February 3, 2016, the Company entered into a Co-Development and Commercialization Agreement (the “Stendhal Agreement”) with Especificos Stendhal SA de CV (“Stendhal”), for Advaxis’ lead *Lm* Technology™ immunotherapy, axalimogene filolisbac, 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 axalimogene filolisbac 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 axalimogene filolisbac in these markets. Upon approval and commercialization of axalimogene filolisbac, 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. As a result, the Company will account for the support payments as a reduction of research and development expenses in the Statement of Operations. During the year ended October 31, 2017, the Company reached the annual project milestones and received a \$3,000,000 Support Payment from Stendhal.

#### *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

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.





*Merck & Co., Inc.*

On August 22, 2014, the Company entered into a Clinical Trial Collaboration and Supply Agreement (the “Merck Agreement”) with Merck, pursuant to which the parties are collaborating on a Phase 1/2 dose-determination and safety trial. The Phase 1 portion of the trial evaluated 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”) and has determined a recommended Phase 2 combination dose. The Phase 2 portion is evaluating the safety and efficacy of the Advaxis Compound in combination with the Merck Compound. Both phases of the trial are 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 trial, while the Company will be responsible for all third party costs of conducting the trial. Merck is responsible for manufacturing and supplying the Merck Compound. The Company is responsible for manufacturing and supplying the Advaxis Compound. The Company is the sponsor of the trial and hold the IND related to the trial.

All data and results generated under the trial (“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, 2017, 2016 and 2015, the Company incurred approximately \$2,925,000, \$1,587,000 and \$1,723,000, 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 initiated a Phase 1/2 clinical trial 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, axalimogene filolisbac, 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 trial.

MedImmune is 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 is the sponsor of the trial and is responsible for the submission of all regulatory filings to support the trial, the negotiation and execution of the clinical trial agreements associated with each trial site, and the packaging and labelling of the Advaxis and MedImmune product candidates used in the trial and the costs associated therewith. For a period beginning upon the completion of the trial and the receipt by MedImmune of the last final report for the trial 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 axalimogene filolisbac 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 axalimogene filolisbac 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 2017, 2016 and 2015, the Company incurred approximately \$2,787,000, \$1,978,000 and \$1,888,000, 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.

#### *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 axalimogene filolisbac 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 axalimogene filolisbac .

*Global BioPharma Inc.*

On December 9, 2013, the Company entered into an exclusive licensing agreement for the development and commercialization of axalimogene filolisbac 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 trial in HPV-associated NSCLC in patients following first-line induction chemotherapy. GBP has obtained Taiwanese regulatory approval for this trial and plans to initiate this trial in 2018. 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 axalimogene filolisbac 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 Advaxis \$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 axalimogene filolisbac to GBP for the Asia, Africa, and former USSR territory, exclusive of India and certain other countries, for all HPV-associated indications. Advaxis will retain exclusive rights to axalimogene filolisbac for the rest of the world.

During each of the years ended October 31, 2017 and 2016, the Company recognized revenue of \$250,000 for annual license fees.

## 10. COMMITMENTS AND CONTINGENCIES

### *Legal Proceedings*

#### *Knoll*

On August 21, 2015, Knoll Capital Management L.P. (“KCM”) filed a complaint against the Company in the Delaware Court of Chancery. The complaint alleged 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 alleged that the Company breached this alleged agreement and sought 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.

In lieu of continuing to unnecessarily incur litigation expenses, on April 27, 2017, the Company settled the matter for a non-material amount, predominately reimbursed by the Company’s insurance, and the parties entered into a definitive confidential settlement agreement. The Company expressly denies any admission or wrongdoing and the settlement was entered into solely for the purpose of avoiding the burden, inconvenience, and expense of further litigation. On May 11, 2017, following resolution of the matter by the parties, the Court granted a Stipulation Of Dismissal With Prejudice.

#### *Bono*

On August 20, 2015, a derivative complaint was filed by a purported Company shareholder in the United States District Court for the District of New Jersey 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”). The complaint is based on general allegations related to certain stock options granted to the individual defendants and generally alleges counts for breaches of fiduciary duty and unjust enrichment. The complaint also alleges additional claims for violation of Section 14(a) of the Securities Exchange Act of 1934 and for waste of corporate assets. The complaint seeks damages and costs of an unspecified amount, disgorgement of compensation obtained by the individual defendants, and injunctive relief.

Defendants filed a motion to dismiss the Bono Action. On May 23, 2016, the Court issued an opinion and order granting in part and denying in part defendants’ motion to dismiss. On October 5, 2016, the Court denied plaintiff’s

motion for reconsideration of its May 23 order. On April 13, 2017, the parties advised the Court that they had reached a tentative agreement in principle to settle the action, subject to negotiating an award of attorneys' fees and expenses to plaintiff's counsel and a stipulation of settlement, and, ultimately, Court approval. The parties subsequently executed the stipulation of settlement on October 2, 2017. The Court entered an order preliminarily approving the settlement on November 7, 2017. The final fairness hearing with the Court is presently scheduled for January 29, 2018.

*Corporate Office & Manufacturing Facility Lease*

The Company leases its corporate office and manufacturing facility under an operating lease expiring in November, 2025.

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

Year ended October 31,

2018	\$ 1,041,895
2019	1,107,385
2020	1,232,907
2021	1,317,640
2022	1,368,819
Thereafter	4,378,521
Total	\$ 10,447,167

Rent expense for the years ended October 31, 2017, 2016 and 2015 was \$1,188,005, \$935,281 and \$150,000, respectively.



**11. INCOME TAXES:**

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

	October 31, 2017	October 31, 2016	October 31, 2015
Federal			
Current	\$-	\$-	\$-
Deferred	(34,296,121)	(18,152,484)	(14,513,684)
State and Local			
Current	(4,452,682 )	(2,535,625 )	(1,609,349 )
Deferred	(1,123,593 )	(3,698,506 )	(1,840,276 )
Change in valuation allowance	35,419,714	21,850,990	16,353,960
Income tax provision (benefit)	\$(4,452,682 )	\$(2,535,625 )	\$(1,609,349 )

The Company has U.S. federal net operating loss carryovers (“NOLs”) of approximately \$187,254,000, \$137,082,000 and \$100,662,000 at October 31, 2017, 2016 and 2015, 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 years 2017 and 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 \$187,254,000 as of October 31, 2017, approximately \$155,930,000 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 \$50,745,000, \$66,029,000 and \$26,245,000 as of October 31, 2017, 2016 and 2015, respectively, available to offset future taxable income through 2037.

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.

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, 2017, 2016 and 2015, respectively. As of October 31, 2017 and 2016, no liability for unrecognized tax benefits was required to be reported. The Company does not expect any significant changes in its unrecognized tax benefits in the next year.

The Company files tax returns in the U.S. federal and state jurisdictions and is subject to examination by tax authorities beginning with the year ended October 31, 2013.

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

	Years Ended	
	October 31, 2017	October 31, 2016
<b>Deferred Tax Assets</b>		
Net operating loss carryovers	\$66,681,000	\$51,701,000
Stock-based compensation	21,921,000	15,239,000
Research and development credits	7,293,000	5,672,000
Deferred revenue	9,775,000	-
Other deferred tax assets	1,515,000	-
Total deferred tax assets	\$107,185,000	\$72,612,000
Valuation allowance	(104,738,000)	(69,317,000)
Deferred tax asset, net of valuation allowance	\$2,447,000	\$3,295,000
<b>Deferred Tax Liabilities</b>		
Other deferred tax liabilities	(2,447,000 )	(3,295,000 )
Total deferred tax liabilities	\$(2,447,000 )	\$(3,295,000 )
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, 2017	October 31, 2016	October 31, 2015
US Federal statutory rate	34.00 %	34.00 %	34.00 %
State income tax, net of federal benefit	1.15	4.86	3.78
Permanent differences	(2.30 )	(2.00 )	(1.91 )
Research and development credits	2.36	2.16	2.06
Income tax benefit from sale of New Jersey NOL carryovers	4.55	3.33	3.31
Change in valuation allowance	(36.20)	(28.72 )	(33.62 )
Other	0.99	(10.30 )	(4.31 )
Income tax (provision) benefit	4.55 %	3.33 %	3.31 %

*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 fiscal 1Q 2018, the Company plans to receive a net cash amount of \$4,452,682 from the sale of its state NOLs and research and development tax credits for the period ended October 31, 2016. 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. Following the receipt of the NOL and research and development tax credit for the period ending October 31, 2016, the Company will have reached the limit under the NJ NOL program and will no longer be able to participate in future sales.

**12. 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.

**13. 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 \$449,086, \$172,276 and \$51,403 for the years ended October 31, 2017, 2016 and 2015, respectively. These amounts were charged to the Statement of Operations. The Employer contributions vest immediately.

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

The following interim financial information presents the Company's 2017, 2016 and 2015 results of operations on a quarterly basis (in thousands, except per share amounts):

	Quarter Ended			
	January 31, 2017	April 30, 2017	July 31, 2017	October 31, 2017
Revenue	\$3,790,842	\$3,425,380	\$3,051,620	\$1,763,208
Net loss	(17,081,003)	(20,467,655)	(32,625,595)	(23,261,249)
Net loss income per common share, basic and diluted	(0.43 )	(0.51 )	(0.80 )	(0.57 )

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

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



## 15. SUBSEQUENT EVENTS

On November 2, 2017, the Company granted to executives 300,000 options with an exercise price of \$3.19 and 84,000 performance-based RSU's ("PRSU's). The options and PRSU's vest annually in three equal installments beginning on the first anniversaries of the grant date.

On November 2, 2017, the Company granted to Directors 180,000 options with an exercise price of \$3.19. The options shall vest in one installment on the first anniversary of the grant date.

F-26



