Advaxis, Inc.
Form 10-K
January 11, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED - OCTOBER 31, 2018

OR

[ ] TRANSITION REPORT UNDER SECTION 13 OR 15 (d)

OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NUMBER 000-28489

ADVAXIS, INC.

(Name of Registrant in Its Charter)

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

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

(609) 452-9813

(Issuer's Telephone Number)

Securities registered under Section 12(b) of the Exchange Act:	Common stock - $0.001 par value NASDAQ Capital Market
Securities registered under Section 12(g) of the Exchange Act:	[None]

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

Yes [ ] No [X]

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

Yes [ ] No [X]

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

Yes [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files).

Yes [X] No [ ]

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	[X]
Non-accelerated Filer	[ ]	Smaller Reporting Company	[X]
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 [X]

As of April 30, 2018, the aggregate market value of the voting common equity held by non-affiliates was approximately $82,957,000, based on the closing bid price of the registrant's common stock on the NASDAQ Capital Market. (For purposes of determining this amount, only directors, executive officers, and 10% or greater shareholders and their respective affiliates have been deemed affiliates). [X]

The registrant had 69,703,219 shares of common stock, par value $0.001 per share, outstanding as of December 31, 2018.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the registrant's 2019 Annual Meeting of Stockholders (the "Proxy Statement") to be filed within 120 days of the end of the fiscal year ended October 31, 2018 are incorporated by reference into Part III hereof. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as a part hereof.

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PART 1

FORWARD LOOKING STATEMENTS

This annual report on Form 10-K ("Form 10-K") includes statements that are, or may be deemed to be, "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," "m "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 future 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;
our ability to continue as a going concern
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 and to resolve any clinical holds that may occur;
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;
our ability to identify license and collaboration partners and to maintain existing relationships;
the performance of our clinical research organizations, clinical trial sponsors and clinical trial investigators, and collaboration partners for any clinical trials we conduct; 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.

In this Form 10-K, unless otherwise stated or the context otherwise indicates, references to "Advaxis," "the Company," "we," "us," "our" and similar references refer to Advaxis, Inc., a Delaware corporation.

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 *Listeria monocytogenes* ("*Lm")* Technology antigen delivery products based on a platform technology that utilizes live attenuated *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 and are designed to access and direct antigen presenting cells to stimulate anti-tumor T cell immunity, activate the immune system with the equivalent of multiple adjuvants, and simultaneously reduce tumor protection in the Tumor Microenvironment ("TME") to enable 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, the Company's product candidates have the potential to optimize the clinical impact of checkpoint inhibitors while having a generally well-tolerated safety profile. The Company's passion for the clinical potential of *Lm* Technology is balanced by focus and fiscal discipline which is

directed towards improving treatment options for cancer patients and increasing shareholder value.

Advaxis is focused on four product-related areas 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
- Personalized neoantigen-directed therapies
- Disease focused hotspot/'off the shelf' neoantigen-directed therapies
- Prostate cancer

All four product areas are anchored in the Company's *Lm* Technology™, a unique platform designed for its ability to 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.

Through a license from the University of Pennsylvania, Advaxis has exclusive access to a proprietary formulation of attenuated *Lm* that we call *Lm* Technology. *Lm* Technology is designed to optimize 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 is also designed to help reduce immune tolerance in the TME and to promote 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 a clinical trial currently underway in combination with Merck & Co., Inc.'s ("Merck") PD-1 inhibitor. The safety profile of all *Lm* Technology constructs seen to date across over 470 patients has been generally 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 cancer and microsatellite stable colorectal cancer.

Moving forward, the Company expects that it will continue to invest in its core clinical program areas 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, particularly with anti-PD-1 therapies, and brought with it impressive clinical activity in many different types of cancers, including melanoma, lung, head and neck and urothelial cancers. However, a literature review published in *Science* in 2018 noted that anti-PD-1 monotherapy response rates are only in the 15-25% range, and rise to ≥ 50% only in selected groups of patients with desmoplastic melanoma, Merkel carcinoma or tumors with mismatch-repair deficiency. Development of secondary resistance with disease progression is yet another common limitation of these therapies. 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 alone and 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 able 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.

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 manageable safety profile, do not generate neutralizing antibodies lending themselves to retreatments, and most of the products are designed to be immediately available for treatment without the complication and expense of modifying a patient's own cells in a laboratory.

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

Advaxis' *Listeria*-based immunotherapies are designed 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 is designed to 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 preclinically to reduce numbers and immune suppressive function of Tregs and MDSCs in the tumor microenvironment. Presented preclinical data demonstrates that Tregs are destroyed as soon as five days after the first *Lm* Technology treatment and that suppressive M2 tumor-associated macrophages (TAMs) are replaced by M1 macrophages which support antigen presentation and adoptive immunity.
3. The extrachromosal 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 what we believe to be a nearly ideal natural system. Clinical application in the Company's four program 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 its latest stage 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 program areas:

Human Papilloma Virus ("HPV")-associated cancers
Personalized neoantigen-directed therapies
Disease focused hotspot/'off the shelf' neoantigen-directed therapies

Prostate cancer (ADXS-PSA)

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

Advaxis Pipeline of Product Candidates

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

The Company is developing therapies for HPV-related cancers using axalimogene filolisbac (AXAL). Axalimogene filolisbac is an *Lm*–based antigen delivery product directed against HPV and designed to target cells expressing HPV. The company's HPV-related products are currently under investigation, or being considered, 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 has decided to not pursue further studies in this cancer type at this time.

Cervical Cancer: axalimogene filolisbac

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.

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 completed the CAT certification procedure and the CAT certified that the preclinical and quality information have met the scientific and technical standards for a Marketing Authorization Application (MAA).

Phase 2 Trial Results – axalimogene filolisbac

In 2014, the company completed a randomized Phase 2 clinical trial (*Lm* -LLO-E7-15) with AXAL +/- chemotherapy in 109 women, conducted in India, 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 in September 2015. Overall survival at 12 months was 38.5% (10/26) (the predefined criteria for 12-month survival in order to progress to Stage 2 was ≥20%), and, among patients who had received the full treatment regimen of 3 doses of 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 previously taken and failed bevacizumab treatment prior to enrollment. 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 treatment-related adverse event (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 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 made a strategic decision to submit for conditional MAA in the European Union for axalimogene filolisbac to treat metastatic cervical cancer in patients who progress beyond first-line treatment in March 2018. However, Advaxis withdrew the application in July 2018 based on European Medicines Agency (EMA) feedback following its initial review indicating the application will likely need additional clinical data to support a conditional approval.

Advaxis also conducted a clinical trial with axalimogene filolisbac through a collaboration agreement with MedImmune, the global biologics research and development arm of AstraZeneca. This Phase 1/2, open-label, multicenter, dose determination and expansion cohort trial was designed 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 x 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 x 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 x 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.

TRAEs 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 x 10^9 + 3 mg/kg - rigor/chills; 1 x 10^9 + 10 mg/kg - rigor/chills; and 1 x 10^9 + 10 mg/kg - diarrhea and shortness of breath). One patient experienced a Grade 4 TRAE of hypotension. As of February 27, 2018, the safety profile of the combination of axalimogene filolisbac and durvalumab was consistent with previous reported findings for both axalimogene filolisbac and durvalumab administered as monotherapy. However, on March 9, 2018, a clinical hold was issued for this study following submission by the Company of a safety report to the FDA regarding a patient death that occurred on February 27, 2018, post-dosing, involving acute respiratory failure after receiving nine months of combination therapy in the trial. New guidelines for the early detection and treatment of such rare events were agreed to with the FDA and were implemented in this and all other studies evaluating our *Lm*-based drug candidates. The clinical hold was lifted by FDA on July 12, 2018. Enrollment and dosing in all other Advaxis and durvalumab clinical programs were not affected by the clinical hold.

In November 2018, the Company announced that enrollment in the Part A expansion phase (N = 20 patients with SCCHN) and planned Part B expansion phase (N=90 patients with metastatic cervical cancer) had ended in order to maximize the efficient use of its resources. As of the latest internal data cut-off date of October 10, 2018, 7 patients receiving 1 x 10^9 axalimogene filolisbac + 10 mg/kg durvalumab had 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 x 10^9 axalimogene filolisbac + 10 mg/kg durvalumab (N = 16 patients) expansion phases.

Ongoing Registrational and Phase 3 Study: Axalimogene filolisbac

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 its 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 current trial design has a planned sample size of 450 subjects to maintain adequate statistical power over a broader range of survival outcomes, as well as a pre-planned interim analysis (IA) of safety and efficacy. However, the Company has been evaluating the possibility of accelerating the IA timeline and establishing a more stringent futility boundary. The Company anticipates that in early 2019 it will finalize the redesign of the trial and review it with the FDA. During this time, the study is continuing to enroll patients under its current design, which is being conducted under a Special Protocol Assessment with the FDA.

HPV Program 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 will evaluate next steps regarding potential registration in India.

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, agreed to pay $10 million ("Support payment") towards the expense of AIM2CERV over the duration of the trial, contingent upon Advaxis achieving annual project milestones, pursuant to a Co-Development and Commercialization Agreement (the "Stendhal Agreement"). The Company is currently in arbitration proceedings with Stendhal, see Legal Proceedings in Note 10 to the financial statements.

Knight Therapeutics Inc. ("Knight"), holds an exclusive license to commercialize axalimogene filolisbac in Canada, as well as 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, Africa, and the former USSR territory, exclusive of India and certain other countries. 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 cavity and pharynx cancer are growing, with 51,540 new cases projected to be diagnosed in the United Stated in 2018 according to the Surveillance, Epidemiology, and End Results ("SEER") database.

A study published in the Annals of Internal Medicine found that approximately 12% of U.S. men and 3% of women were actively infected with oral HPV between 2011 and 2014. That totals 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.

We conducted a clinical trial in collaboration 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 results will be presented in 2019. The Company and MedImmune have decided to not continue further enrollment into the expansion phases of this study.

The Company plans to initiate an investigator-sponsored trial with a major research center in head and neck cancer in early 2019. Axalimogene filolisbac has received FDA orphan drug designation for HPV-associated head and neck cancer.

Personalized Neoantigen-directed Therapies (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 for the development and commercialization of ADXS-NEO. On December 10, 2018, Company received a written notice of termination of such agreement from Amgen. See Note 9 to our financial statements. The termination is effective as of February 8, 2019. The Company's ADXS-NEO study is currently enrolling patients and the Company will evaluate whether to re-partner the ADXS-NEO program.

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 allowed the IND application of ADXS-NEO. In June 2018, the Company announced the commencement of a Phase 1 trial with the dosing of the first patient with ADXS-NEO. ADXS-NEO is being evaluated in an open-label, dose-escalation, multicenter clinical trial in the United States. The study is open to patients with metastatic non-small cell lung cancer (NSCLC), metastatic microsatellite stable colon cancer and metastatic squamous head and neck cancer. The study had been in development in collaboration with Amgen until December 2018, when Amgen provided the Company with a notice of termination of their existing collaboration. Advaxis will evaluate whether to re-partner the ADXS-NEO program. Advaxis anticipates providing safety, tolerability and immune correlative data from the first two cohorts in the first half of 2019.

The Company has entered into various research collaborations, including with 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/'off the shelf' neoantigen 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 program 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 designed to be 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.

In July 2018, the Company announced that the U.S. Food and Drug Administration (FDA) allowed the Company's IND application for its ADXS-HOT drug candidate for non-small cell lung cancer (NSCLC). Advaxis plans to have the first subject enrolled in this Phase 1/2 study in early 2019 with an anticipated readout of safety, tolerability and immune correlative data from the first cohort in the first half of 2019. Advaxis plans to file additional ADXS-HOT INDs in 2019, in prostate and bladder cancers.

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 160,000 men are estimated to be diagnosed with prostate cancer in 2018, with approximately 30,000 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. Recent data from the Keynote-199 trial in bone predominant-mCRCP patients treated with KEYTRUDA® ("pembrolizumab") was presented at the 2018 ASCO Annual Meeting. In this trial, only 4 out of 60 patients (7%) had decrease PSA post-baseline, with only 1 case that was ≥50%. The total SD/disease stabilization rate was 37%.

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 five 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). ADXS-PSA was tested alone or in combination with KEYTRUDA in an advanced and heavily pretreated patient population who had progressed on androgen deprivation therapy. A total of 13 and 37 patients were evaluated on monotherapy and combination therapy, respectively. For the ADXS-PSA monotherapy dose escalation and determination portion of the trial, cohorts were started at a dose of 1 x 10^9 cfu (n=7) and successfully escalated to higher dose levels of 5x10^9 cfu (n=3) and 1x10^{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 x 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 Recommended Phase II Dose (RP2D) of ADXS-PSA monotherapy was determined to be 1x 10^9 cfu based on a review of the totality of the clinical data. This dose was used in combination with 200mg of pembrolizumab in a cohort of six patients to evaluate the safety of the combination before moving into an expanded cohort of patients. The safety of the combination was confirmed and enrollment in the expansion cohort phase was initiated. Enrollment in this phase of the trial (n = 37) was completed in January 2017.

Updated data of this study in mCRPC patients treated with ADXS-PSA monotherapy (Part A) and in combination with pembrolizumab (Part B) were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2018. At entry, Part A and Part B patients were similar in age (~70 yrs), Gleason score (~8.3), absence of visceral metastases (71% vs. 70%) and prior abiraterone use. Part B patients had higher median baseline PSA values (40.6 vs. 20.8 ng/ml), and more prior enzalutamide (53% vs. 26%) and chemotherapy (49% vs. 36%) use versus Part A patients. A total of 49 patients (98%) experienced treatment-related adverse events (TRAE), mainly chills, fever, nausea and hypotension. Five Part A and 13 Part B patients had grade 3-4 events: fatigue, hypotension, hypertension, anemia. Treatment-related adverse events (TRAEs) were mostly mild or moderate constitutional symptoms such as

fever, chills, rigors, hypotension, nausea and fatigue, consistent with immune activation and manageable with standard care. One patient in the monotherapy arm was discontinued from the study due to a grade 4 TRAE related to cytokine release, which resolved within 24 hours using medical management. Overall, two Part A (14%) v 16 Part B patients (43%) had a decreased PSA post-baseline. Of these, seven Part B (22%) versus 0 Part A patients achieved a PSA reduction ≥50% from baseline. Part B patients had higher rates (56.8%) of stable disease/disease stabilization than Part A patients (38.5%). Part B patients had higher rates (27%) of stable disease than monotherapy patients (7.7%). In all treated patients, an improvement in survival was observed in Part B patients with ≥ 50% PSA declines from baseline versus those with < 50% PSA declines. In conclusion, in this population of heavily pretreated mCRPC pts, ADXS-PSA + pembrolizumab had a manageable safety profile (mostly grade 1-2 TRAEs) and showed a greater level of activity compared to monotherapy. The Company anticipates providing an update on this study during the first quarter of 2019.

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.

In September 2018, the Company announced that it had granted a license to OS Therapies, LLC (“OS Therapies”) for the use of ADXS31-164, also known as ADXS-HER2, for evaluation in the treatment of osteosarcoma in humans. Under the terms of the license agreement, OS Therapies, in collaboration with the Children’s Oncology Group (COG), will be responsible for the conduct and funding of a clinical study evaluating ADXS-HER2 in recurrent, completely resected osteosarcoma. Pursuant to the agreement, Advaxis is to receive an upfront payment, reimbursement for product supply and other support, clinical, regulatory, and sales-based milestone payments, and royalties on future product sales. Additional details of the financial terms have not been disclosed.

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. 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 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 is currently conducting an extended field study which is a requirement for full USDA licensure. 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.

Under the terms of the Aratana Agreement, Aratana paid an upfront payment to Advaxis in the amount of $1,000,000 upon signing of the Aratana Agreement. Aratana will also pay Advaxis: (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. In fiscal year 2018, the Company received approximately $5,000 in royalty revenue from Aratana.

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 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 over 400 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-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 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 core 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. 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 helps validate

that *Lm* Technology may play a key role in the cancer treatment protocols of the future.

Our collaborators and partners include Merck, Aratana, OS Therapies, Biocon, Global BioPharma, Knight, and others. For more information, see Note 9 to our financial statements.

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 helping to keep cost of goods low. The Company intends to add new constructs to this standardized manufacturing process as its 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 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.

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, BioNtech, Moderna, Gritstone, BMS, 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, 2018, we had 58 employees, all of which were full time employees, 48 of whom were engaged in research and development activities and 10 of whom were engaged in finance, business development, facilities, human resources and administrative support. Of our full-time employees, 16 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 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, Industry and Strategy

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 foreseeable future due to our substantial investment in research and development. As of October 31, 2018, we had an accumulated deficit of approximately $367.7 million and stockholders' equity of approximately $24.1 million. 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.

The successful development of immunotherapies is highly uncertain.

Successful development of immunotherapies 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.

We are limited in our manufacturing, sales, marketing or distribution capability and we must rely upon third parties for such.

We currently have agreements with 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, New Jersey to manufacture clinical materials for some of our products, including 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, manage or maintain 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 and our collaborations may terminate at any time. 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 or terminate their collaborations with us, our preclinical or clinical development programs related to this collaboration could be delayed or terminated. For example, we had entered into a License and Collaboration Agreement, dated as of August 1, 2016 (the “Amgen Agreement”) pertaining to the development and commercialization of our ADXS-NEO program, whereby Amgen received an exclusive worldwide license to develop and commercialize the ADXS-NEO program and we and Amgen collaborated through a joint steering committee for the development and commercialization of ADXS-NEO and Amgen reimbursed us for certain research and development costs in support of the ADXS-NEO program. On December 10, 2018, we received a written termination notice from Amgen with respect to the Amgen Agreement. We will evaluate whether to re-partner the ADXS-NEO program, but the loss of the Amgen Agreement, could have an impact on our ability to timely complete our ADXS-NEO study and on our financial condition and results of operations.

Further, 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 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 October 31, 2018, we had 58 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: Gritstone, Moderna, Aduro Biotech, Agenus Inc., Inovio Pharmaceutical Inc., ISA Pharmaceuticals, BMS, Merck, Neon Therapeutics, Oncolytics Biotech Inc. and Oncothyreon Inc., among others, 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.

Risks Related to the Development and Regulatory Approval of Our Product Candidates

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 tour 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; and

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.

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 legal proceedings. Litigation and other legal proceedings are inherently uncertain, and adverse rulings could occur, including monetary damages, or an injunction stopping us from engaging in business practices, or requiring other remedies, such as compulsory licensing of patents.

The costs of litigation or any proceeding relating to our intellectual property or contractual rights could be substantial, even if resolved in our favor. Some of our competitors or financial funding sources have far greater resources than we do and may be better able to afford the costs of complex litigation. Also, a lawsuit, even if frivolous, will require considerable time commitments on the part of management, our attorneys and consultants. Defending these types of proceedings or legal actions involve considerable expense and could negatively affect our financial results.

We can provide no assurance of the successful and timely development of new products.

Our immunotherapies are at various stages of research and development. Further development and extensive testing will be required to determine their technical feasibility and commercial viability. We will need to complete significant additional clinical trials demonstrating that our product candidates are safe and effective to the satisfaction of the FDA and other non-U.S. regulatory authorities. The drug approval process is time-consuming, involves substantial expenditures of resources, and depends upon a number of factors, including the severity of the illness in question, the availability of alternative treatments, and the risks and benefits demonstrated in the clinical trials. Our success will depend on our ability to achieve scientific and technological advances and to translate such advances into licensable, FDA-approvable, commercially competitive products on a timely basis. Failure can occur at any stage of the process. If such programs are not successful, we may invest substantial amounts of time and money without developing revenue-producing products. As we enter a more extensive clinical program for our product candidates, the data generated in these studies may not be as compelling as the earlier results.

The proposed development schedules for our immunotherapies may be affected by a variety of factors, including technological difficulties, clinical trial failures, regulatory hurdles, clinical holds, competitive products, intellectual property challenges and/or changes in governmental regulation, many of which will not be within our control. Any delay in the development, introduction or marketing of our products could result either in such products being marketed at a time when their cost and performance characteristics would not be competitive in the marketplace or in the shortening of their commercial lives. In light of the long-term nature of our projects, the unproven technology involved and the other factors described elsewhere in this section, there can be no assurance that we will be able to successfully complete the development or marketing of any new products which could materially harm our business, results of operations and prospects.

Our research and development expenses are subject to uncertainty.

Factors affecting our research and development expenses include, but are not limited to:

- competition from companies that have substantially greater assets and financial resources than we have;

need for acceptance of our immunotherapies;

ability to anticipate and adapt to a competitive market and rapid technological developments;

ability to raise sufficient capital to fund our research and development activities;

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 may be required to suspend or discontinue clinical trials for a number of reasons, which could preclude approval of any of our product candidates.

Our clinical trials may be suspended at any time for a number of reasons. A clinical trial may be suspended or terminated by us, an IRB, the FDA or other regulatory authorities due to a failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, presentation or identification of unforeseen safety signals or issues, failure to demonstrate a benefit from using the investigational drug, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial, or for other business-related reasons. In addition, clinical trials for our product candidates could be suspended due to adverse side effects. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. We may also voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to patients or do not demonstrate clinical benefit. If we elect or are forced to suspend or terminate any clinical trial of any product candidates that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues from any of these product candidates will be delayed or eliminated. Any of these occurrences may significantly harm our business, financial condition, results of operations and prospects.

Preliminary or interim results of a clinical trial are not necessarily predictive of future or final results.

Interim or preliminary data from clinical trials that we may conduct may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Interim or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim or preliminary data. As a result, interim or preliminary data should be viewed with caution until the final data are available. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our proposed indications.

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.

We must comply with significant government regulations.

The research and development, manufacturing and marketing of human therapeutic and diagnostic products are subject to regulation, primarily by the FDA in the United States and by comparable authorities in other countries. These national agencies and other federal, state, local and foreign entities regulate, among other things, research and development activities (including testing in animals and in humans) and the testing, manufacturing, handling, labeling, storage, record keeping, approval, advertising and promotion of the products that we are developing. If we obtain approval for any of our product candidates, our operations will be directly or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statue and the federal False Claims Act, and privacy laws. Noncompliance with applicable laws and requirements can result in various adverse consequences, including delay in approving or refusal to approve product licenses or other applications, suspension or termination of clinical investigations, revocation of approvals previously granted, fines, criminal prosecution, civil and criminal penalties, recall or seizure of products, exclusion from having our products reimbursed by federal health care programs, the curtailment or restructuring of our operations, injunctions against shipping products and total or partial suspension of production and/or refusal to allow a company to enter into governmental supply contracts.

The process of obtaining requisite FDA approval has historically been costly and time-consuming. Current FDA requirements for a new human biological product to be marketed in the United States include: (1) the successful conclusion of preclinical laboratory and animal tests, if appropriate, to gain preliminary information on the product's safety; (2) filing with the FDA of an IND to conduct human clinical trials for drugs or biologics; (3) the successful completion of adequate and well-controlled human clinical trials to establish the safety and efficacy of the investigational new drug for its recommended use; and (4) filing by a company and acceptance and approval by the FDA of a BLA for marketing approval of a biologic, to allow commercial distribution of a biologic product. The FDA also requires that any drug or formulation to be tested in humans be manufactured in accordance with its cGMP regulations. This has been extended to include any drug that will be tested for safety in animals in support of human testing. The cGMPs set certain minimum requirements for procedures, record-keeping and the physical characteristics of the laboratories used in the production of these drugs. A delay in one or more of the procedural steps outlined above could be harmful to us in terms of getting our immunotherapies through clinical testing and to market.

We can provide no assurance that our clinical product candidates will obtain regulatory approval or that the results of clinical studies will be favorable.

We are currently evaluating the safety and efficacy of several of our candidates in a number of ongoing pre-clinical and clinical trials. However, even though the initiation and conduct of the clinical trials is in accordance with the governing regulatory authorities in each country, as with any investigational new drug (under an IND in the United States, or the equivalent in countries outside of the United States), we are at risk of a clinical hold at any time based on the evaluation of the data and information submitted to the governing regulatory authorities.

There can be delays in obtaining U.S FDA 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 BLA or 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 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 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, we predominantly rely on a network of suppliers and vendors to manufacture our products. Should a regulatory authority make any significant findings on an inspection of our own operations or the operations of those companies, the ability for us to continue producing our 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.

Even if we are successful in obtaining 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.

Risks Related to our Intellectual Property

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, 2018, we had $150,000 in outstanding payables 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.

Risks Related to Our Financial Position and Capital Needs

We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.

We are a clinical-stage biotechnology company. Investment in biotechnology product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. We have not generated any revenue from product sales to date, and we continue to incur significant development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception.

We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If any of our product candidates fails in clinical studies or do not gain regulatory approval, or if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' (deficit) equity and working capital.

We will require additional capital to fund our operations and if we fail to obtain necessary financing we will not be able to complete the development and commercialization of our product candidates.

The research and development of our products has consumed substantial amounts of cash since inception. We expect to continue to invest in advancing the clinical development of our product candidates and to commercialize any product candidates for which we receive regulatory approval. As of October 31, 2018, we had cash and cash equivalents of $45.1 million. We will require additional capital for the further development of our product candidates. We are pursuing various ways to support our development efforts including debt and/or equity financing as well as targeting potential collaborators of our products.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or product candidates or one or more of our other research and development initiatives. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

The progress, timing, costs and results of the clinical studies underway;

future clinical development plans we establish for our product candidates;

the number and characteristics of product candidates that we develop or may in-license;
the outcome, timing and cost of meeting regulatory requirements established by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect;
the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
the effect of competing technological and market developments;
the cost and timing of completion of commercial-scale outsourced manufacturing activities; and
the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

Our auditor's report includes a going concern paragraph.

Our auditor's report on our financial statements for the year ended October 31, 2018 includes a going concern paragraph. The Company's products that are being developed have not generated significant revenue. As a result, the Company has suffered recurring losses and requires significant cash resources to execute its business plans. These losses are expected to continue for an extended period of time. The aforementioned factors raise substantial doubt about the Company's ability to continue as a going concern within one year from the date of filing. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should the Company be unable to continue as a going concern within one year after the date the financial statements are issued.

Historically, the major source of our cash has been from proceeds from various public and private offerings of our common stock. Management's plans to mitigate an expected shortfall of capital, to support future operations, include raising additional funds. The actual amount of cash that it will need to operate is subject to many factors.

The Company also recognizes it will need to raise additional capital in order to continue to execute its business plan in the future. 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.

We have a material weakness in our internal control over financial reporting and our inability to remediate this weakness or otherwise implement and maintain effective internal control over financial reporting, or the inability of our independent registered public accounting firm to provide an unqualified report thereon, could have a

material adverse effect on us.

As a public company, we are required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, which require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of controls over financial reporting.

The annual assessment for fiscal year 2018 resulted in the identification of a material weakness that existed as of October 31, 2018, regarding the accounting for a derivative liability.

This material weakness could, among other things, adversely impact our ability to provide timely and accurate financial information or result in a misstatement of the account balances or disclosures that would result in a material misstatement to our annual or interim financial statements that would not be prevented or detected. The material weakness is described in greater detail in Item 9A, Disclosure Controls and Procedures.

A substantial majority of our authorized shares of common stock under our certificate of incorporation are either outstanding or reserved for issuance.

Our certificate of incorporation currently authorizes the issuance of 95,000,000 shares of common stock and 5,000,000 shares of preferred stock, par value $0.001 per share, for a total of 100,000,000 shares of capital stock. As of December 31, 2018, a total of 6,082,766 shares of common stock are reserved for issuance upon the exercise of outstanding stock options, a total of 340,467 shares of common stock are reserved for issuance for outstanding restricted stock units and a total of 500,937 shares of common stock are reserved for issuance in connection with future grants of stock options and/or future issuances of shares under our 2015 Stock Incentive Plan, as amended. In addition, as of December 31, 2018, we have 952,999 shares of our common stock are available for grant under the ESPP and we have outstanding warrants to purchase 14,169,542 shares of our common stock. After taking into account the total number of shares of common stock issued and outstanding, in addition to the aggregate number of shares of common stock reserved for future issuance as described above, approximately 3% of our authorized shares of common stock remain available to be issued as of December 31, 2018.

We currently intend to solicit the approval of our stockholders at our upcoming 2019 annual meeting of stockholders to increase the number of authorized shares. Absent the approval, we are left without sufficient authorized shares of common stock to pursue a variety of other business and financial objectives without further action of the stockholders (except when required by applicable law or regulation). As a result, a delay in securing, or a failure to secure, stockholder approval to amend our certificate of incorporation would seriously jeopardize the financial viability of the Company. Unless and until we attain the approval of our stockholders to increase the number of authorized shares, our ability to manage our capital needs is restricted which may have a material adverse effect on our business, results of operations and financial condition.

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Additional authorized shares of common stock available for issuance may adversely affect the market price of our securities.

We are currently authorized to issue 95,000,000 shares of our common stock. As of December 31, 2018, we had 69,703,219 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 2015 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 31, 2018 we had outstanding options to purchase 6,082,766 shares of our common stock at a weighted average exercise price of $6.74 per share and outstanding warrants to purchase 14,169,542 shares of our common stock (including the 14,166,666 warrants subject to anti-dilution protection); and 952,999 shares of our common stock are available for grant under the ESPP.

Risks Related to Ownership of our Securities

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.

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.

We are not currently in compliance with the continued listing requirements for NASDAQ. If the price of our common stock continues to trade below $1.00 per share for a sustained period or we do not meet other continued listing requirements, our common stock may be delisted from the NASDAQ Global Market, which could affect the market price and liquidity for our common stock and reduce our ability to raise additional capital.

Our common stock is listed on the NASDAQ Global Market. In order to maintain that listing, we must satisfy minimum financial and other requirements including, without limitation, a requirement that our closing bid price be at least $1.00 per share. On October 23, 2018, we received a written notice from NASDAQ indicating that we are not in compliance with the minimum bid price requirement for continued listing on the NASDAQ Global Market. We have until April 22, 2019 to regain compliance. We can regain compliance if at any time prior to April 22, 2019 the bid price of our common stock closes at or above $1.00 per share for a minimum of ten consecutive business days.

If we fail to regain compliance with the minimum bid price requirement by April 22, 2019, we may apply to transfer to The NASDAQ Capital Market where we should be afforded an additional 180-day period to regain compliance provided that (i) we meet the applicable market value of publicly held shares requirement for continued listing and all other applicable requirements for initial listing on the NASDAQ Capital Market (except for the bid price requirement) based on our most recent public filings and market information and (ii) we notify NASDAQ of our intent to cure the bid price requirement deficiency prior to the completion of the second 180-day compliance period by effecting a reverse stock split, if necessary. We anticipate that will seek stockholder approval at our next annual meeting, in 2019, to grant discretionary authority to our board of directors to amend our certificate of incorporation to effect a reverse split of our outstanding shares of common stock within a range of one share of common stock for every ten shares of common stock to one share of common stock for every twenty shares of common stock, with the exact reverse split ratio to be decided and publicly announced by the board of directors prior to the effective time of the amendment to our certificate of incorporation. We intend to monitor the closing bid price of our common stock and consider our available options to resolve our noncompliance with the minimum bid price requirement. There can be no assurance that we will be able to regain compliance with the minimum bid price requirement or we will otherwise be in compliance with other NASDAQ listing criteria. If we fail to regain compliance with the minimum bid requirement or to meet the other applicable continued listing requirements for the NASDAQ Global Market in the future and NASDAQ determines to delist our common stock, the delisting could adversely affect the market price and liquidity of our common stock and reduce our ability to raise additional capital. In addition, if our common stock is delisted from NASDAQ and the trading price remains below $5.00 per share, trading in our common stock might also become subject to the requirements of certain rules promulgated under the Exchange Act, which require additional disclosure by broker-dealers in connection with any trade involving a stock defined as a “penny stock” (generally, any equity security not listed on a national securities exchange or quoted on NASDAQ that has a market price of less than $5.00 per share, subject to certain exceptions).

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.

We may be at an increased risk of securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

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, and 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 Note 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 “ADXS”.

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

None.

Equity Compensation Plan Information

The following table provides information regarding the status of our existing equity compensation plans at October 31, 2018:

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	4,951,049	$ 8.19	N/A	
Restricted stock	489,270	N/A	N/A	
Equity compensation plans not approved by security holders	-	-	-	
Total	5,440,319	N/A	1,525,692	*

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

ITEM 6. Selected Financial Data .

Not applicable.

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 attack tumor cells. 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 program areas 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
- Personalized neoantigen-directed therapies
- Disease focused hotspot/‘off the shelf’ neoantigen-directed therapies
- Prostate cancer

All four clinical program areas 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 for the Year Ended October 31, 2018 Compared to the Year Ended October 31, 2017

Revenue

Revenue decreased $5.9 million to $6.1 million for the year ended October 31, 2018 compared to $12.0 million for the year ended October 31, 2017. The decrease was due to changes in the estimated performance period associated with upfront fees received from Amgen in conjunction with the collaboration agreement signed in August 2016.

Research and Development Expenses

We invest in research and development to advance our L*m* technology through our pre-clinical and clinical development programs. Research and development expenses for the years ended October 31, 2018 and 2017 were categorized as follows (in thousands):

	Years Ended October 31,		Increase (Decrease)	
	2018	2017	$	%
HPV-associated cancers	$24,272	$26,650	$(2,378)	(9)%
Personalized neoantigen-directed therapies	2,331	2,287	44	2
Hotspot mutation-based ‘off the shelf’ therapies	1,204	120	1,084	903
Prostate cancer	2,844	3,880	(1,036)	(27)
Other expenses	32,082	48,071	(15,989)	(33)
Partner reimbursements	(5,763)	(10,500)	4,737	(45)
Total research & development expense	$56,970	$70,508	$(13,538)	(19)%
Stock-based compensation expense included in research and development expense	$2,836	$5,648	$(2,812)	(50)%

HPV-associated cancers

The majority of the HPV-associated research and development costs include clinical trial and other related costs associated with our axalimogene filolisbac (AXAL) programs in cervical and head and neck cancers. HPV-associated costs for the year ended October 31, 2018 decreased approximately $2.4 million, or 9%, compared to the same period in 2017. The decrease resulted from the winding down of the GOG-0265 study, as well as the winding down of several studies that are transitioning into an *Lm* surveillance study (including our Fawcett study in anal cancer and our MEDI4736 study in combination with MedImmune's investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab). These decreases were partially offset by the expansion of the Phase 3 AIM2CERV trial into additional countries in early 2018.

Personalized neoantigen-directed therapies

Research and development costs associated with our personalized neoantigen-directed therapy (ADXS-NEO) of $2.3 million for the year ended October 31, 2018 were consistent with our costs associated with this program in fiscal year 2017. In June 2018, we announced the commencement of a Phase 1 trial with the dosing of the first patient with ADXS-NEO. ADXS-NEO is being evaluated in an open-label, dose-escalation, multicenter clinical trial in the United States. The study is open to patients with metastatic non-small cell lung cancer (NSCLC), metastatic microsatellite stable colon cancer and metastatic squamous head and neck cancer and is being developed in collaboration with Amgen, who provided reimbursement for certain research and development costs associated with conducting the clinical trial. In August 2016, we entered into a License and Collaboration Agreement, with Amgen ("Amgen Agreement") pertaining to the development and commercialization of our ADXS-NEO program, whereby Amgen received an exclusive worldwide license to develop and commercialize the ADXS-NEO program and we and Amgen collaborated through a joint steering committee for the development and commercialization of ADXS-NEO and Amgen reimbursed us for certain research and development costs in support of the ADXS-NEO program. On December 10, 2018, we received a written termination notice from Amgen with respect to the Amgen Agreement. We are continuing to advance the program and anticipate having early biomarker, immunological and correlative data from the first cohort of the study during the first half of 2019.

Hotspot mutation-based 'off the shelf' therapies

Research and development costs associated with our hotspot mutation-based therapies for the year ended October 31, 2018 increased approximately $1.1 million to $1.2 million compared to the same period in 2017. The increase is attributable to the filing of an IND application for our ADXS-HOT drug candidate for non-small cell lung cancer and the startup costs associated with the initiation of the Phase 1/2 clinical trial. This is the first study initiated using our ADXS-HOT construct which we believe is applicable across several tumor types. We anticipate having safety and immune response on the first cohort of our first clinical trial using ADXS-HOT, during the first half of 2019.

Prostate cancer

Research and development costs associated with our prostate cancer therapy for the year ended October 31, 2018 decreased approximately $1.0 million, or 27%, compared to the same period in 2017. The decrease is attributable to the winding down of the Phase 2 study of our ADXS-PSA compound in combination with KEYTRUDA® (pembrolizumab), Merck's humanized monoclonal antibody against PD-1. This study is transitioning into an *Lm* surveillance study and we anticipate providing an update on the clinical results of the Phase 2 portion of the study in the first half of 2019.

Other expenses

Other expenses include professional fees, laboratory costs and other internal and external costs associated with our research & development activities. Other expenses for the year ended October 31, 2018 decreased approximately $16.0 million, or 32%, compared to the same period in 2017. The decrease was primarily attributable to a decrease in laboratory costs, drug manufacturing process validation and drug stability studies supporting our Marketing Authorization Application ("MAA") in Europe in fiscal year 2018 as the majority of the costs were incurred in fiscal year 2017 in support of the filing which occurred in February 2018. In addition, there was a decrease in salary related expenses, including stock compensation, and travel expenses resulting from a reduction in headcount.

Partner reimbursements

Partner reimbursements decreased approximately $4.7 million, or 45%, for the year ended October 31, 2018 compared to the same period in 2017. The decrease partially relates to a reduction of $1.7 million in reimbursements from Amgen in support of the ADXS-NEO program. Amgen reimbursements were $5.8 million for the year ended October 31, 2018 compared to approximately $7.5 million for the year ended October 31, 2017 which covered one year of reimbursements during the year ended October 31, 2018 as compared to reimbursements covering 15 months during the same period in 2017. On December 10, 2018, the Company received a written notice of termination of the license and collaboration agreement with (see Note 9 to our financial statements). In addition, in fiscal year 2017 the Company received $3.0 million from Stendhal for partner reimbursements supporting the AIM2CERV study, but in fiscal year 2018, the Company did not receive its reimbursement of $3.0 million. We are currently in arbitration proceedings with Stendhal (see Note 9 to our financial statements).

General and Administrative Expenses

General and administrative expenses primarily include salary and benefit costs and stock-based compensation expense for employees included in our finance, legal and administrative organizations. Also included in general and administrative expenses are outside legal, professional services and facilities costs. General and administrative expenses for the years ended October 31, 2018 and 2017 were as follows (in thousands):

	Years Ended October 31,		Increase (Decrease)	
	2018	2017	$	%
General and administrative expense	$19,472	$39,969	$(20,497)	(51)%
Stock-based compensation expense included in general and administrative expense	$4,147	$22,188	$(18,041)	(81)%

General and administrative expenses for the year ended October 31, 2018 decreased approximately $20.5 million, or (51)%, compared to the same period in 2017. The decrease is primarily attributable to a decrease in stock-based compensation of approximately $18.0 million related to the resignation of our Chief Executive Officer in July 2017, two Board members who did not seek re-election in March 2018, the elimination of stock-based compensation paid to public relations consultants and a reduction in headcount. In addition, there was a decrease to legal costs on general corporate matters and litigation settlements. These decreases were partially offset by an increase in write-offs of abandoned patent applications.

Changes in Fair Values

For the year ended October 31, 2018, the Company recorded non-cash income from changes in the fair value of the warrant liability of approximately $3.4 million. The decrease in the fair value of liability warrants resulting from a decrease in our share price from $0.85 at September 11, 2018 (the date the liability warrants were issued) to $0.56 at October 31, 2018.

For the year ended October 31, 2017, the Company recorded non-cash income from changes in the fair value of the warrant liability of approximately $20,000 due to the expiration of all the remaining the liability warrants.

Income Tax Benefit

During the year ended October 31, 2017, we recorded an income tax receivable of approximately $4.5 million from the sale of its state NOLs and research and development tax credits for the year ended October 31, 2016. Following the receipt of the NOL and research and development tax credit for the year ending October 31, 2016, we reached the limit under the NJ NOL program.

Liquidity and Capital Resources

Going Concern and Managements Plans

Similar to other development stage biotechnology companies, our products that are being developed have not generated significant revenue. As a result, the Company has suffered recurring losses and requires significant cash resources to execute its business plans. These losses are expected to continue for an extended period of time. The aforementioned factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should the Company be unable to continue as a going concern within one year after the date the financial statements are issued.

Historically, our major sources of cash have comprised proceeds from various public and private offerings of our common stock, debt financings, option and warrant exercises, NOL tax sales, income earned on investments and grants, and interest income. From October 2013 through October 2018, we raised approximately $265 million in gross proceeds from various public and private offerings of our common stock. We have sustained losses from operations in each fiscal year since our inception, and we expect losses to continue for the indefinite future. As of October 31, 2018 and 2017, we had an accumulated deficit of approximately $367.7 million and $301.1 million, respectively, and stockholders' equity of approximately $24.1 million and $54.3 million, respectively.

As of December 31, 2018 and October 31, 2018, the Company had approximately $36.1 million and $45.1 million, respectively, in cash, restricted cash and cash equivalents. Management's plans to mitigate an expected shortfall of capital, to support future operations, include raising additional funds. It is the belief of the Company that it expects to have sufficient capital to fund its obligations, as they become due, in the ordinary course of business until September 2019. The actual amount of cash that it will need to operate is subject to many factors. 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.

We recognize that we will need to raise additional capital in order to continue to execute its business plan in the future. There is no assurance that additional financing will be available when needed or that we will be able to obtain financing on terms acceptable to us or whether we will become profitable and generate positive operating cash flow. If we are unable to raise sufficient additional funds, we will have to scale back our operations.

Cash Flows

Operating Activities

Net cash used in operating activities was approximately $62.1 million for the year ended October 31, 2018 compared to net cash used in operating activities of approximately $76.8 million for the year ended October 31, 2017. The decrease in the amount of cash used in operating activities was attributed to decreased spending associated with research and development and general and administrative activities, a reduction in headcount and an increase in proceeds received from the sale of our state NOLs and R&D tax credits of approximately $1.9 million.

Investing Activities

Net cash provided by investing activities was approximately $43.2 million for the year ended October 31, 2018 compared to net cash used in investing activities of approximately $12.5 million for the year ended October 31, 2017. During the year ended October 31, 2018, all of the Company's remaining short-term investment securities matured and a portion of the proceeds were used to fund operating activities, while in the prior year, a portion of the matured short-term investment securities were re-invested. In addition, there was a reduction in property and equipment purchases in fiscal year 2018 of approximately $2.0 million as compared to the prior year. During fiscal year 2018, there were $1.4 million in legal costs associated with supporting of our intellectual property as compared to $1.2 million in fiscal year 2017.

Financing Activities

Net cash provided by financing activities was approximately $39.2 million for the year ended October 31, 2018 as compared to approximately $0.4 million for the year ended October 31, 2017. The increase resulted primarily from net proceeds of approximately $36.6 million from sales of 26,666,666 shares of our common stock in public offerings and approximately $2.7 million from the sale of 881,629 shares of our common stock in at-the-market transactions.

Off-Balance Sheet Arrangements

As of October 31, 2018, we had no off-balance sheet arrangements.

Critical Accounting Estimates

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, account balances or disclosures: revenue recognition, stock compensation, impairment of intangibles and income tax disclosures.

Revenue Recognition

The Company derives 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

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 Monte Carlo valuation 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.

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 (AXAL), ADXS-NEO, ADXS-HOT, 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, 2014.

New Accounting Pronouncements

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

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

Not applicable.

Item 8: Financial Statements and Supplementary Data.

The information required by this Item 8 is incorporated by reference to our financial statements and the related notes and the report of our independent registered public accounting firm beginning at page F-1 of this report.

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

None.

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 not 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 not effective because of the material weakness discussed below under "Managements Report On Internal Control Over Financial Reporting.

(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.

A “material weakness” is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements would not be prevented or detected on a timely basis. We cannot assure you that we will adequately remediate the material weakness or that additional material weaknesses in our internal controls will not be identified in the future. Any failure to maintain or implement required new or improved controls or any difficulties we encounter in their implementation could result in additional material weaknesses or could result in material misstatements in our financial statements.

The material weakness in our internal control over financial reporting as of October 31, 2018 was:

Complex and Non-routine Transactions — We did not maintain effective controls over the accounting for complex and non-routine transactions. Specifically, we did not utilize sufficient technical accounting capabilities related to complex and non-routine transactions with respect to the accounting for a derivative liability.

This material weakness resulted from the need to record a significant adjustment at year end, whereby the Company was required to record a derivative liability for the fair value of warrants issued in a capital raise transaction. This issue arose, since the provisions of the warrant agreement may require the Company to net cash settle, such warrants, should the holder of the instrument elect to exercise their conversion option for shares of common stock and, at the time of the election, the Company has not maintained an effective registration statement. This capital raise transaction occurred in the fourth quarter of the fiscal year 2018. Accounting treatment under these circumstances require liability treatment for instruments of this nature.

Remediation Efforts

We are in the process of developing certain remediation steps to address the previously disclosed material weakness discussed above and to improve our internal control over financial reporting. We expect to complete our remediation process by the end of the first quarter of fiscal 2019. The Company and the Board take the control and integrity of the Company's financial statements seriously and believe that the remediation steps described below are essential to maintaining a strong internal control environment. The following remediation steps are among the measures that are being implemented by the Company:

Complex and Non-routine Transactions

Continued evaluation and enhancement of internal technical accounting capabilities augmented by the use of third-party advisors and consultants to assist with areas requiring specialized technical accounting expertise and reviewed by management.
Develop and implement technical accounting training, led by appropriate technical accounting experts, to enhance awareness and understanding of standards and principles related to relevant complex technical accounting topics.

We are committed to maintaining a strong internal control environment, and believe that these remediation actions will represent significant improvements in our controls. However, the identified material weakness in internal control over financial reporting will not be considered remediated until controls have been designed and/or controls are in operation for a sufficient period of time for our management to conclude that the material weakness has been

remediated. Additional remediation measures may be required, which may require additional implementation time. We will continue to assess the effectiveness of our remediation efforts in connection with our evaluations of internal control over financial reporting.

Marcum LLP, an independent registered public accounting firm, has audited the Financial Statements included in this Annual Report on Form l0-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, 2018, 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 Shareholders and Board of Directors of

Advaxis, Inc.

Opinion on Internal Control over Financial Reporting

We have audited Advaxis, Inc. 's (the "Company") internal control over financial reporting as of October 31, 2018, based on criteria established in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, because of the effect of the material weakness described below, the Company has not maintained, in all material respects, effective internal control over financial reporting as of October 31, 2018, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

A material weakness is deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on timely basis. The following material weaknesses have been identified and included in management's assessment. Management has identified a material weakness in controls related to the company's accounting for a derivative liability. This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2018 financial statements, and this report does not affect our reported dated January 11, 2019, on those financial statements.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the balance sheets as of October 31, 2018 and 2017 and the related statements of operations, shareholders' equity, and cash flows for the years then ended of the Company and our report dated January 11, 2019 includes an explanatory paragraph as to the Company's ability to continue as a going concern.

Basis for Opinion

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 are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. 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.

Definition and Limitations of Internal Control over Financial Reporting

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.

Marcum llp
New York, NY
January 11, 2019

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Item 9B: Other Information.

None.

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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 2019 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 2019 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 2019 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 2019 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 2019 Annual Meeting of Stockholders.

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PART IV

Item 15: Exhibits and Financial Statements Schedules.

(a) 1. **Financial Statements.**

For a list of the financial statements included herein, see Index to the Financial Statements on page F-1 of this Form 10-K.

2. Financial Statement Schedules.

No financial statement schedules have been submitted because they are not required or are not applicable or because the information required is included in the financial statements or the notes thereto.

3. List of Exhibits.

See the Exhibit Index in Item 15(b) below.

Exhibit Number	Description of Exhibits
3.1	Amended and Restated Certificate of Incorporation. Incorporated by reference to Annex C to DEF 14A Proxy Statement filed with the SEC on May 15, 2006.
3.2	Certificate of Designations of Preferences, Rights and Limitations of Series A Preferred Stock of the registrant, dated September 24, 2009. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on September 25, 2009.
3.3	Certificate of Designations of Preferences, Rights and Limitations of Series B Preferred Stock of the registrant, dated July 19, 2010. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on July 20, 2010.

3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on August 16, 2012. Incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the SEC on August 17, 2012.
3.5	Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on July 11, 2013 (reverse stock split). Incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the SEC on July 15, 2013.
3.6	Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on July 12, 2013 (reverse stock split). Incorporated by reference to Exhibit 3.2 to Current Report on Form 8-K filed with the SEC on July 15, 2013.
3.7	Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on July 9, 2014. Incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the SEC on July 10, 2014.
3.8	Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on March 10, 2016. Incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the SEC on March 11, 2016.
3.9	Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on March 21, 2018. Incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the SEC on March 21, 2018.

3.10	Amended and Restated Bylaws. Incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-QSB filed with the SEC on September 13, 2006.
4.1	Form of Common Stock certificate. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on October 23, 2007.
4.2	Form of Common stock Purchase Warrant. Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on August 31, 2011.
4.3	Form of Representative's Warrant. Incorporated by reference to Exhibit 4.19 to Registration Statement on Form S-1/A (File No. 333-188637) filed with the SEC on September 27, 2013.
4.4	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.
4.5	Form of Warrant Agency Agreement, dated as of September 11, 2018 between Advaxis, Inc. and Continental Stock Transfer and Trust Company (and Form of Warrant contained therein), Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on September 11, 2018.
4.6	Form of Common Stock Warrant dated September 11, 2018 (included in Exhibit 4.5)
10.1	2004 Stock Option Plan of the registrant. Incorporated by reference to Exhibit 4.1 to Report on Form S-8 filed with the SEC on December 1, 2005.
10.2	2005 Stock Option Plan of the registrant. Incorporated by reference to Annex A to DEF 14A Proxy Statement filed with the SEC on May 15, 2006.
10.3	License Agreement, between the Trustees of the University of Pennsylvania and the registrant dated as of June 17, 2002, as Amended and Restated on February 13, 2007. Incorporated by reference to Exhibit 10.11 to Annual Report on Form 10-KSB filed with the SEC on February 13, 2007.

10.4	Amended and Restated 2009 Stock Option Plan of the registrant. Incorporated by reference to Annex A to DEF 14A Proxy Statement filed with the SEC on April 30, 2010.
10.5	Second Amendment to the Amended and Restated Patent License Agreement between the registrant and the Trustees of the University of Pennsylvania dated as of May 10, 2010. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on June 3, 2010.
10.6	2011 Omnibus Incentive Plan of registrant. Incorporated by reference to Annex A to DEF 14A Proxy Statement filed with the SEC on August 29, 2011.
10.7	Amendment No. 1 to the Advaxis, Inc. 2011 Employee Stock Purchase Plan. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on December 20, 2011.
10.8	Amendment No. 1, dated as of March 26, 2007, to the License Agreement, between the Trustees of the University of Pennsylvania and Advaxis, Inc. dated as of June 17, 2002, as amended and restated on February 13, 2007. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on June 14, 2012.
10.9	Amendment No. 3, dated as of December 12, 2011, to the License Agreement, between the Trustees of the University of Pennsylvania and Advaxis, Inc. dated as of June 17, 2002, as amended and restated on February 13, 2007. Incorporated by reference to Exhibit 10.5 to Quarterly Report on Form 10-Q filed with the SEC on June 14, 2012.
10.10	Amendment No. 1 to 2011 Omnibus Incentive Plan of registrant. Incorporated by reference to Annex B to DEF 14A Proxy Statement filed with the SEC on July 19, 2012.

10.11	Indemnification Agreement. Incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed with the SEC on August 20, 2013.
10.12‡	Employment Agreement between Advaxis, Inc. and Robert Petit, dated September 26, 2013. Incorporated by reference to Exhibit 10.70 to Registration Statement on Form S-1/A (File No. 333-188637) filed with the SEC on September 27, 2013.
10.13	Exclusive License and Technology Transfer Agreement by and between Advaxis, Inc. and Global BioPharma, Inc., dated December 9, 2013. Incorporated by reference to Exhibit 10.79 to Annual Report on Form 10-K/A filed with the SEC on February 6, 2014.
10.14‡	Amendment No. 1, dated as of December 19, 2013, to the Employment Agreement by and between Advaxis, Inc. and Robert G. Petit. Incorporated by reference to Exhibit 10.82 to Annual Report on Form 10-K/A filed with the SEC on February 6, 2014.
10.15	Distribution and Supply Agreement, dated as of January 20, 2014, by and between Advaxis, Inc. and Biocon, Limited. Incorporated by reference to Exhibit 10.7 to Quarterly Report on Form 10-Q filed with the SEC on March 17, 2014.
10.16	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.
10.17‡	Amendment No. 2, dated as of June 5, 2014, to the Employment Agreement by and between Advaxis, Inc. and Robert G. Petit. Incorporated by reference to Exhibit 10.6 to Quarterly Report on Form 10-Q filed with the SEC on June 10, 2014.
10.18	Clinical Trial Collaboration Agreement, dated July 21, 2014, by and between Advaxis, Inc. and MedImmune, LLC. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on September 9, 2014.
10.19	5th Amendment to the Amended & Restated License Agreement, dated July 25, 2014, by and between Advaxis, Inc. and University of Pennsylvania. Incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed with the SEC on September 9, 2014.
10.20	Amendment No. 2 to the Advaxis, Inc. 2011 Omnibus Incentive Plan, effective July 9, 2014. Incorporated by reference to Annex A to Current Report on Schedule 14A filed with the SEC on May 20, 2014.
10.21	Amended and Restated 2011 Omnibus Incentive Plan, dated September 8, 2014. Incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-Q filed with the SEC on September 9, 2014.
10.22	Master Services Agreement for Technical Transfer and Clinical Supply, dated February 5, 2014, by and between Advaxis, Inc. and SynCo Bio Partners B.V. Incorporated by reference to Exhibit 10.1 to Current Report to Form 8-K filed with the SEC on February 11, 2014.
10.23	Clinical Trial Collaboration and Supply Agreement by and between Advaxis, Inc. and Merck & Co. dated August 22, 2014. Incorporated by reference to Exhibit 10.101 to Annual Report on Form 10-K filed with the

	SEC on January 6, 2015
10.24‡	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.
10.25	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.

10.26‡	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.
10.27	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.
10.28‡	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.
10.29	2015 Incentive Plan of registrant. Incorporated by reference to Annex A to DEF 14A Proxy Statement filed with the SEC on April 7, 2015.
10.30‡	Separation Agreement and General Release, dated April 23, 2018, 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 April 23, 2018.
10.31‡	Employment Agreement between Advaxis, Inc. and Molly Henderson, dated June 6,2018. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on June 6, 2018.
14.1	Code of Business Conduct and Ethics dated July 9, 2014. Incorporated by reference to Exhibit 14.1 to Current Report on Form 8-K filed with the SEC on July 10, 2014.
23.1	Consent of Independent Registered Public Accounting Firm.
31.1*	Certification of Chief Executive Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Chief Executive Officer pursuant to section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer pursuant to section 906 of the Sarbanes-Oxley Act of 2002
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definitions Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

** Furnished herewith.

‡ Denotes management contract or compensatory plan or arrangement.

ITEM 16. Form 10-K Summary

None.

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 11th day of January, 2019.

ADVAXIS, INC.

By:*/s/ Kenneth Berlin*
President and Chief Executive Officer

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

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

SIGNATURE	Title	DATE
/s/ Kenneth Berlin Kenneth Berlin	President, Chief Executive Officer and Director (Principal Executive Officer)	January 11, 2019
/s/ Molly Henderson Molly Henderson	Chief Financial Officer, Executive Vice President (Principal Financial and Accounting Officer)	January 11, 2019
/s/ David Sidransky David Sidransky	Chairman of the Board	January 11, 2019
/s/ James Patton		

James Patton	Vice Chairman of the Board	January 11, 2019
/s/ Richard Berman		
Richard Berman	Director	January 11, 2019
/s/ Samir Khleif		
Samir Khleif	Director	January 11, 2019
/s/ Roni Appel		
Roni Appel	Director	January 11, 2019

ADVAXIS, INC.

FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of

Advaxis, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Advaxis, Inc. (the "Company") as of October 31, 2018 and 2017, the related statements of operations, shareholders' equity and cash flows for each of the two years in the period ended October 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of October 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended October 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of October 31, 2018, based on the criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in 2013 and our report dated January 11, 2019, expressed an adverse opinion on the effectiveness of the Company's internal control over financial reporting because of the existence of a material weakness.

Explanatory Paragraph – Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Marcum llp

Marcum llp

We have served as the Company's auditor since 2012.

New York, NY

January 11, 2019

ADVAXIS, INC.

BALANCE SHEETS

(In thousands, except share and per share data)

	October 31, 2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	$44,141	$23,900
Restricted cash	977	587
Short-term investment securities	-	46,398
Income tax receivable	-	4,453
Deferred expenses	2,072	2,986
Prepaid expenses and other current assets	3,275	2,919
Total current assets	50,465	81,243
Property and equipment (net of accumulated depreciation)	6,684	7,111
Intangible assets (net of accumulated amortization)	4,838	4,857
Other assets	280	431
Total assets	$62,267	$93,642
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$5,646	$5,121
Accrued expenses	6,185	8,700
Deferred revenue	4,476	6,995
Common stock warrant liability	6,517	-
Other current liabilities	48	48
Total current liabilities	22,872	20,864
Deferred revenue	14,189	17,479
Other liabilities	1,155	1,039
Total liabilities	38,216	39,382
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, 2018 and 2017. Liquidation preference of $0 at October 31, 2018 and 2017.	-	-
Common stock - $0.001 par value; 95,000,000 shares authorized, 69,556,452 shares issued and outstanding at October 31, 2018 and 41,206,538 shares issued and outstanding at October 31, 2017.	70	41

Additional paid-in capital	391,638	355,361
Accumulated deficit	(367,657)	(301,142)
Total shareholders' equity	24,051	54,260
Total liabilities and shareholders' equity	$62,267	$93,642

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

ADVAXIS, INC.

STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)

	Year Ended October 31,	
	2018	2017
Revenue	$6,063	$12,031
Operating expenses:		
Research and development expenses	56,970	70,508
General and administrative expenses	19,472	39,969
Total operating expenses	76,442	110,477
Loss from operations	(70,379)	(98,446)
Other income (expense):		
Interest income	577	670
Net changes in fair value of derivative liabilities	3,400	20
Other expense	(63)	(82)
Net loss before income tax benefit	(66,465)	(97,838)
Income tax expense (benefit)	50	(4,403)
Net loss	$(66,515)	$(93,435)
Net loss per common share, basic and diluted	$(1.29)	$(2.31)
Weighted average number of common shares outstanding, basic and diluted	51,522,361	40,527,844

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

ADVAXIS, INC.

STATEMENTS OF SHAREHOLDERS' EQUITY

(In thousands, except share and per share data)

	Preferred Stock		Common Stock		Additional Paid-In Capital	Treasury Stock		Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount		Shares	Amount		
Balance at October 31, 2016	-	$ -	40,057,067	$ 40	$327,099	(16,020)	$(130)	$(207,707)	$119,302
Stock based compensation			1,030,507	1	27,865				27,866
Tax withholdings paid related to net share settlement of equity awards					(357)				(357)
Tax withholdings paid on equity awards					(997)	(128,613)	(881)		(1,878)
Tax shares sold to pay for tax withholdings on equity awards					843	144,633	1,011		1,854
Common stock issued upon exercise of warrants			225		1				1
Issuance of shares to employees under ESPP Plan			26,594		251				251
Advaxis at-the-market sales			92,145		656				656
Net Loss								(93,435)	(93,435)
Balance at October 31,	-	$-	41,206,538	$41	$355,361	-	$-	$(301,142)	$54,260

2017										
Stock based compensation			762,448	1	7,027					7,028
Tax withholdings paid related to net share settlement of equity awards					(87)					(87)
Tax withholdings paid on equity awards					(474)					(474)
Tax shares sold to pay for tax withholdings on equity awards					460					460
Issuance of shares to employees under ESPP Plan			39,171		50					50
Advaxis at-the-market sales			881,629	1	2,658					2,659
Advaxis public offerings			26,666,666	27	26,643					26,670
Net Loss								(66,515)		(66,515)
Balance at October 31, 2018	-	$-	69,556,452	$70	$391,638	-	$-	$(367,657)		$24,051

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

ADVAXIS, INC.

STATEMENT OF CASH FLOWS

(In thousands, except share and per share data)

	Year Ended October 31,	
	2018	2017
OPERATING ACTIVITIES		
Net loss	$(66,515)	$(93,435)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock compensation	6,983	27,836
Employee stock purchase plan expense	7	80
Gain on change in value of warrants	(3,400)	(20)
Loss on disposal of property and equipment	614	3
Write-off of intangible assets	1,047	315
Depreciation expense	1,113	791
Amortization expense of intangible assets	388	330
Net (accretion) amortization of premiums and discounts	(6)	184
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	683	(1,972)
Income taxes receivable	4,453	(1,903)
Other assets	151	1,325
Accounts payable and accrued expenses	(1,954)	1,160
Deferred revenue	(5,809)	(11,781)
Other liabilities	116	245
Net cash used in operating activities	(62,129)	(76,842)
INVESTING ACTIVITIES		
Restricted cash established with letter of credit agreement	(390)	(587)
Purchases of investments	(12,487)	(71,177)
Proceeds from maturities of short-term investment securities	58,891	63,930
Purchase of property and equipment	(1,425)	(3,449)
Cost of intangible assets	(1,416)	(1,173)
Net cash provided by (used in) investing activities	43,173	(12,456)
FINANCING ACTIVITIES		
Net proceeds of issuance of common stock and warrants	39,246	656
Proceeds from the exercise of warrants	-	1
Proceeds from employee stock purchase plan	52	171
Tax withholdings paid related to net share settlement of equity awards	(87)	(357)
Employee tax withholdings paid on equity awards	(474)	(1,878)
Tax shares sold to pay for employee tax withholdings on equity awards	460	1,854
Net cash provided by financing activities	39,197	447
Net increase (decrease) in cash and cash equivalents	20,241	(88,851)

Cash and cash equivalents at beginning of year	23,900	112,751
Cash and cash equivalents at end of year	$44,141	$23,900

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

Supplemental Disclosures of Cash Flow Information

	Year Ended October 31,	
	2018	2017
Cash paid for taxes	$50	$ 50

Supplemental Schedule of Noncash Investing and Financing Activities

	Year Ended October 31,	
	2018	2017
Accounts payable and accrued expenses settled with common stock	$ -	$ 75
Property and equipment included in accounts payable and accrued expenses	$-	$ 66

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 *Listeria monocytogenes* ("*Lm*") based antigen delivery products. The Company is using its *Lm* platform directed against tumor-specific targets in order to engage the patient's immune system to destroy tumor cells. Through a license from the University of Pennsylvania, Advaxis has exclusive access to this proprietary formulation of attenuated *Lm* called *Lm* Technology. Advaxis' proprietary approach deploys a unique mechanism of action that redirects the immune system to attack cancer cells in three distinct ways:

Alerting and training the immune system by activating multiple pathways in antigen-presenting cells ("APCs") with the

equivalent of multiple adjuvants;

Attacking the tumor by generating a strong, cancer-specific T cell response; and

Breaking down tumor protection through suppression of the protective cells in the tumor microenvironment ("TME") that shields

the tumor from the immune system. This enables the activated T cells to begin working to attack the tumor cells.

Advaxis' proprietary *Lm* platform technology has been clinically validated and dosed in over 500 patients across multiple clinical trials and in various tumor types. The Company believes that *Lm* Technology immunotherapies can complement and address significant unmet needs in the current oncology treatment landscape. Specifically, our product candidates have the potential to work synergistically with other immunotherapies, including checkpoint inhibitors, while having a generally well-tolerated safety profile.

Going Concern and Managements Plans

The Company's products that are being developed have not generated significant revenue. As a result, the Company has suffered recurring losses and requires significant cash resources to execute its business plans. These losses are expected to continue for an extended period of time. The aforementioned factors raise substantial doubt about the

Company's ability to continue as a going concern within one year from the date of filing. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should the Company be unable to continue as a going concern within one year after the date the financial statements are issued.

Historically, our major sources of cash have comprised proceeds from various public and private offerings of our common stock, option and warrant exercises, and interest income. From October 2013 through October 2018, the Company raised approximately $265 million in gross proceeds from various public and private offerings of our common stock.

As of December 31, 2018 and October 31, 2018, the Company had approximately $36.1 million and $45.1 million, respectively, in cash, restricted cash and cash equivalents. Management's plans to mitigate an expected shortfall of capital, to support future operations, include raising additional funds. The actual amount of cash that it will need to operate is subject to many factors.

The Company also recognizes it will need to raise additional capital in order to continue to execute its business plan in the future. 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), deferred expenses and deferred revenue, the fair value of options, 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.

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 has derived 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.

Concentration of Credit Risk

The Company maintains its cash in bank deposit accounts (checking) that at times exceed federally insured limits. Approximately $43.8 million is subject to credit risk at October 31, 2018. 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.

Restricted Cash and Letter of Credit

During July 2017 and January 2018, the Company established two letters of credit with a financial institution as security for the purchase of custom equipment and as security for application fees associated with the Company's Marketing Authorization Application ("MAA") in Europe. The letters of credit are collateralized by cash which is unavailable for withdrawal or for usage for general obligations. No amount is outstanding under either letter of credit as of October 31, 2018.

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, 2018 or 2017. 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.

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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,	
	2018	2017
Warrants	14,169,542	3,092,935
Stock options	4,951,049	3,893,558
Restricted stock units	489,270	1,363,119
Total	19,609,861	8,349,612

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.

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 Monte Carlo valuation 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.

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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 Standards

In February 2016, the Financial Accounting Standards Board, or FASB, issued ASU, No. 2016-02, Leases (Topic 842), which establishes a comprehensive new lease accounting model. The new standard: (a) clarifies the definition of a lease; (b) requires a dual approach to lease classification similar to current lease classifications; and (c) causes lessees to recognize leases on the balance sheet as a lease liability with a corresponding right-of-use asset for leases with a lease-term of more than 12 months. The new standard is effective for fiscal years and interim periods beginning after December 15, 2018, with early adoption permitted. A modified retrospective transition approach is required for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, including a number of optional practical expedients that entities may elect to apply. In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842): Targeted Improvements, an update which provides another transition method, in addition to the existing modified retrospective transition method, by allowing entities to initially apply the new lease standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. 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 No. 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.