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, 2020

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 001-36138

ADVAXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**02-0563870**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
305 College Road East, Princeton, NJ	08540
(Address of principal executive offices)	(Zip Code)

(609) 452-9813
(Registrant's telephone number)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	ADXS	Nasdaq Capital Market
Preferred Stock Purchase Rights		Nasdaq Capital Market

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

Large Accelerated Filer	[ ]	Accelerated Filer	[ ]
Non-accelerated Filer	[X]	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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepare or issued its audit report. [ ]

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, 2020, the aggregate market value of the voting common equity held by non-affiliates was approximately $39,995,271 based on the closing bid price of the registrant's common stock on the Nasdaq Global Select 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 111,971,688 shares of common stock, par value $0.001 per share, outstanding as of January 15, 2021.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the registrant's 2021 Annual Meeting of Stockholders (the "Proxy Statement") to be filed within 120 days of the end of the fiscal year ended October 31, 2020 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," "might," "will," "should," "approximately" or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Form 10-K and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned discovery and development of drug candidates, the strength and breadth of our intellectual property, our ongoing and planned 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;*
- *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 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;*
- *any outcomes from our review of strategic transactions;*
- *our ability to successfully implement our strategy; and*
- *our ability to maintain the listing of our common stock on the Nasdaq Capital Market.*

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 is a clinical-stage biotechnology company focused on the development and commercialization of proprietary *Listeria monocytogenes*, or *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, or 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 single antigen and multiple antigen delivery products and is in various stages of clinical development. All of the Company's products 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, or MHC, I and II pathways, due to its active phagocytosis by Antigen Presenting Cells, or 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 and through its own development efforts, 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, or 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. 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

Our strategy is to advance the Lm Technology platform and leverage its unique capabilities to design and develop an array of cancer treatments. We are currently conducting or planning clinical studies of Lm Technology immunotherapies in non-small cell lung cancer and other solid tumor types, prostate cancer and HPV-associated cancers. We are working with, or are in the process of identifying, collaborators and potential licensees for these programs.

Advaxis is currently mainly concentrating on its disease-focused, hotspot/"off-the-shelf" neoantigen-directed therapies called ADXS-HOT. ADXS-HOT is a program that leverages the Company's proprietary Lm technology to target hotspot mutations that commonly occur in specific cancer types. ADXS-HOT drug candidates are designed to target acquired shared or "public" mutations in tumor driver genes along with other cancer-associated antigens that also commonly occur in specific cancer types.

We expect that we will continue to invest in our core clinical program areas and will also remain opportunistic in evaluating Investigator Sponsored Trials, or ISTs, as well as licensing opportunities as we are actively looking for partners and/or licensees for these programs. The *Lm* Technology platform is protected by a range of patents, covering both product and process, some of which we believe can be maintained into 2039.

***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 may be able to 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.

***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 myeloid-derived suppressor cells, or 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, or 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.

Clinical Pipeline

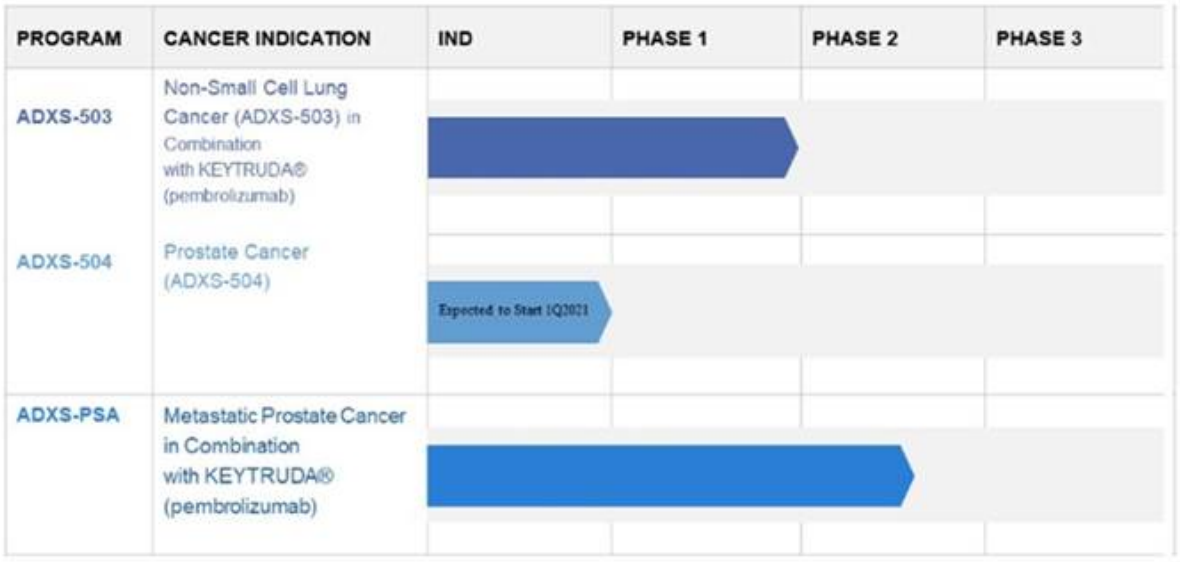
Advaxis is focused on the development and commercialization of proprietary *Lm* Technology antigen delivery products. The Company and its collaborators are currently conducting or are in the planning process for conducting clinical studies of *Lm* Technology immunotherapies in the following areas:

- Disease focused hotspot/"off-the-shelf" neoantigen-directed therapies
- Human Papilloma Virus ("HPV")-associated cancers
- Prostate cancer (ADXS-PSA)

The Company has completed the clinical study report for ADXS-NEO program—its *Lm* Technology personalized neoantigen-directed therapies clinical study and plans to close the related IND for this study shortly. In addition, the Company is winding down its AIM2CERV Phase 3 clinical trial with axalimogene filolisbac (AXAL) in high-risk locally advanced cervical cancer.

As a clinical-stage biotechnology company with no commercial products, Advaxis is aware of the need for fiscal responsibility, and is focusing its investments in areas that it anticipates will have the highest likelihood of clinical and commercial success. Additionally, the company will continue to be opportunistic by exploring ISTs, licensing and other external opportunities.

Advaxis Pipeline of Product Candidates



Disease-focused hotspot/'off -the-shelf' neoantigen therapies (ADXS-HOT)

Advaxis is creating a new group of immunotherapy constructs for major solid tumor cancers that combines our optimized *Lm* Technology vector with promising targets designed to generate potent anti-cancer immunity. The ADXS-HOT program is a series of novel cancer immunotherapies that will target somatic mutations, or hotspots, cancer testis antigens, or CTAs, and oncofetal antigens, or 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 tumor associated antigens. 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, or 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, or FDA, allowed the Company's investigational new drug, or IND, application for its ADXS-HOT drug candidate (ADXS-503) for non-small cell lung cancer, or NSCLC. ADXS-503 is currently being evaluated in a Phase 1/2 clinical trial, enrolling patients at five sites. The first two dose-levels with monotherapy in Part A, (1 $X10^8$ CFU and 5 X108 CFU) have been completed and Part B and Part C with ADXS-503 (1 $X10^8$ CFU) in combination with a checkpoint inhibitor are currently open to enrollment.

The Company presented updated clinical data from Part B of the ADXS-503 clinical study at ASCO Annual Meeting 2020, which demonstrated durable clinical benefit in 2 out of 3 evaluable patients with immediate prior progression on KEYTRUDA® including one durable response out to 34 weeks with 25% reduction in a target lesion and another sustained response out to 33 weeks with a 60% reduction in site lesions. Clinical benefit was observed after immediate prior progression on KEYTRUDA® with previous best responses of stable disease suggest ADXS-503 may re-sensitize or enhance response to KEYTRUDA®. Both patients remain on treatment in Part B, the combination arm with KEYTRUDA®. The Company has initiated ADXS-503 Part B combination arm efficacy expansion which will enroll up to 15 additional patients to evaluate the potential of ADXS-503 in combination with KEYTRUDA® to restore and/or enhance responsiveness to checkpoint inhibitors in PD-1/L-1 refractory NSCLC patients Advaxis also has initiated the ADXS-503 Part C combination arm to evaluate ADXS-503 in combination with KEYTRUDA® as a first line treatment in patients with NSCLC with PD-L1 expression ≥ 1% or who are unsuitable for chemotherapy

The Company expects to report updated clinical and immune response updated data from Part B combination therapy at upcoming scientific meetings in 2021.

On December 3, 2019, Advaxis announced that it submitted an IND to the FDA for the initiation of a Phase 1 clinical study of ADXS-504, its ADXS-HOT drug candidate for prostate cancer. On September 10, 2020, Advaxis was notified that a new IND submitted to the FDA for the initiation of an Investigator-Sponsored-Trial, a Phase 1 clinical study of ADXS-504 for biochemically recurrent prostate cancer after radical prostatectomy or radical radiotherapy, was accepted by the agency. This study is expected to start at a leading medical institution in 1Q2021.

HPV-Related Cancers

The Company conducted several studies evaluating axalimogene filolisbac, or AXAL, for HPV-related cancers. AXAL is an *Lm*-based antigen delivery product directed against HPV and designed to target cells expressing HPV.

In June 2019, the Company announced the closing of its AIM2CERV Phase 3 clinical trial with axalimogene filolisbac (AXAL) in high-risk locally advanced cervical cancer. Company estimates showed that the remaining cost to complete the AIM2CERV trial ranged from $80 million to $90 million, and initial efficacy data was not anticipated for at least three years. Therefore, results from the clinical trial were not the basis for the decision to close the study, nor was safety as the trial recently underwent its third Independent Data Monitoring Committee (IDMC) review with no safety issues noted. The Company has unblinded the AIM2CERV clinical data generated to date and currently has no plans to present it at any medical conference as the data set is incomplete and inconclusive.

In 2014, Advaxis granted Global BioPharma, or GBP, an exclusive license for the development and commercialization of AXAL 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.

Other *HPV Program Licensing Agreements*

Biocon Limited, or Biocon, our co-development and commercialization partner for AXAL in India and key emerging markets, filed a MAA for licensure of this immunotherapy in India. The companies will evaluate next steps regarding potential registration in India.

Especificos Stendhal SA de CV, or Stendhal, the Company's co-development and commercialization partner for AXAL in Mexico, Brazil, Colombia and other Latin American countries, agreed to pay $10 million in 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, or the Stendhal Agreement. The Company was in arbitration proceedings with Stendhal. For more information, see Note 9, "Commitments and Contingencies – Legal Proceedings" of the "Notes to the Financial Statements" included in Item 8.

Knight Therapeutics Inc., or Knight, holds an exclusive license to commercialize AXAL in Canada, as well as other product candidates.

Personalized Neoantigen-directed Therapies (ADXS-NEO)

ADXS-NEO is an individualized *Lm* Technology antigen delivery product developed using whole-exome sequencing of a patient's tumor to identify neoantigens. ADXS-NEO is designed to work by presenting a large payload of neoantigens directly into dendritic cells within the patient's immune system and stimulating a T cell response against cancerous cells. In October 2019, the Company announced that it has dosed its last patient in Part A, in monotherapy, and does not intend to continue into Part B, in combination with a checkpoint inhibitor. As a result, Advaxis is in the process of winding down this study. The Company has completed the clinical study report from Part A of the ADXS-NEO study and plans to close its ADXS-NEO program IND as next step.

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, or CRPC, which refers to prostate cancer that progresses despite androgen deprivation therapy. Metastatic CRPC, or 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.

Recent data regarding checkpoint inhibitor monotherapy has shown some antitumor activity that provides disease control in a subset of patients with bone predominant mCRPC previously treated with next generation hormonal agents and docetaxel. Data from the KEYNOTE-199 trial in bone predominant-mCRPC patients treated with KEYTRUDA®, or pembrolizumab, was updated at the ASCO GU meeting in 2019. In this trial, the total stable disease/disease stabilization rate was 39% with no responses reported so far, and only one patient with ≥50% decrease in the post-baseline PSA value. It is hypothesized that the limited activity in mCRPC may be due to 1) the inability of the checkpoint inhibitor to infiltrate the tumor microenvironment and 2) the presence of an immunosuppressive tumor micro-environment, or TME. The combination therapy with agents—like *Lm* constructs—that induce T cell infiltration within the tumor and decrease negative regulators in the TME may improve performance of checkpoints in prostate cancer.

Lm Technology constructs demonstrated the ability to induce anti-tumor T cell responses and T cell infiltration in the TME and to reduce the number and suppressive function of Tregs and MDSCs in the TME. For example, destruction of Tregs in the TME has been documented as soon as five days after dosing *Lm* constructs 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. Because of all these effects, it is hypothesized that *Lm* constructs can turn “cold prostate tumors” into “hot tumors” that better respond to checkpoint inhibitors. Advaxis believes that the combination of ADXS-PSA, its immunotherapy designed to target the PSA antigen, with a checkpoint inhibitor may provide an alternative treatment option for patients with mCRPC.

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®, 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 1×10^9 cfu (n=7) and successfully escalated to higher dose levels of 5×10^9 cfu (n=3) and 1×10^{10} cfu (n=3) without achieving a maximum tolerated dose. TEAEs noted at these higher dose levels were generally consistent with those observed at the lower dose level (1×10^9 cfu) other than a higher occurrence rate of Grade 2/3 hypotension. The Recommended Phase II Dose of ADXS-PSA monotherapy was determined to be 1×10^9 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 the study was completed in January 2017.

At the final data cutoff of September 16, 2019, median overall survival for 37 patients in the combination arm was 33.6 months (95% CI, range 15.4-33.6 months). This updated median overall survival is an increase from the previous data presented at the American Association for Cancer Research Annual Meeting in April 2019, where median overall survival was 21.1 months in the combination arm. The combination of ADXS-PSA with KEYTRUDA®, might be associated with prolonged OS in this population, particularly in patients with unmet medical needs like visceral metastasis (16.4 months, range 4.0 - not reached) and those with prior docetaxel (16 months, range 6.4-34.6). The majority of TEAEs consisted of transient and reversible Grade 1-2 chills/rigors, fever, hypotension, nausea and fatigue. The combination of ADXS-PSA and KEYTRUDA® has appeared to be well-tolerated to date, with no additive toxicity observed. The Company presented these new data at the ASCO Genitourinary Cancers Symposium in San Francisco, CA. on February 2020. The Company is currently seeking potential partners regarding opportunities to expand or advance this mCRPC program.

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, or 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, will be responsible for the conduct and funding of a clinical study evaluating ADXS-HER2 in recurrent, completely resected osteosarcoma. In December 2020 and January 2021, we received an aggregate of $1,345,000 from OS Therapies upon achievement of the $1,550,000 funding milestone set forth in the license agreement. For more information, see Note 15, “Subsequent Events” of the “Notes to the Financial Statements” included in Item 8.

Canine Osteosarcoma

On March 19, 2014, we entered into a definitive Exclusive License Agreement, or Aratana Agreement, with Aratana Therapeutics, Inc., or 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, or 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, or 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, or 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 2019, the Company received approximately $8,000 in royalty revenue from Aratana. Additionally, in July 2019, Aratana announced that their shareholders approved a merger agreement with Elanco Animal Health, or Elanco, whereby Elanco is now the majority shareholder of Aratana. On October 6, 2020, the Company received a notice from Aratana, dated September 17, 2020, indicating that Aratana was terminating the Exclusive License Agreement effective December 21, 2020. The Company did not incur any early termination penalties as a result of the termination. Aratana was required to make all payments to the Company that were otherwise payable under the Exclusive License Agreement through the effective date of termination.

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. 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 patent portfolio that protects our product candidates and *Lm* -based immunotherapy technology. Currently, we own or have rights to several hundred patents and applications, which are owned, licensed from, or co-owned with University of Pennsylvania, or Penn, Merck, National Institute of Health, or NIH, and/or Augusta University. We aggressively prosecute and defend our patents and proprietary technology. Our patents and applications are directed to the compositions of matter, use, and methods thereof, of our *Lm*-LLO immunotherapies for our product candidates, including AXAL, ADXS-PSA, ADXS-HOT, ADXS-HER2. We have and may continue to abandon prosecuting certain patents that are not strategically aligned with the direction of the Company.

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 AXAL, ADXS-PSA, and ADXS-HER2 in the United States, will expire between 2020 and 2032. Issued patents directed to our product candidates AXAL, ADXS-PSA, and ADXS-HER2 outside of the United States, will expire in 2032. Issued patents directed to our *Lm* -based immunotherapy platform in the United States, will expire between 2020 and 2031. Issued patents directed to our *Lm*-based immunotherapy platform outside of the United States, will expire between 2020 and 2033.

We have pending patent applications directed to our product candidates AXAL, ADXS-PSA, ADXS-HER2, and ADXS-HOT that, if issued would expire in the United States and in countries outside of the United States between 2020 and 2037. We have pending patent applications directed to methods of using of our product candidates AXAL, ADXS-PSA, ADXS-HOT, ADXS-HER2 directed to the following indications and others: 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 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.

The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies, and formulation studies in compliance with the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an Investigational New Drug Application, or IND, which must become effective before human clinical trials may begin at United States clinical trial sites;
- approval by an Institutional Review Board, or IRB for each clinical site, or centrally, before each trial may be initiated;
- adequate and well-controlled human clinical trials to establish the product candidate's safety, purity, and potency for its intended use, performed in accordance with Good Clinical Practices, or GCPs;
- development of manufacturing processes to ensure the product candidate's identity, strength, quality, purity, and potency;
- submission to the FDA of a Biologics License Application, or BLA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the products are produced to assess compliance with current Good Manufacturing Practices, or cGMPs, and to assure that the facilities, methods, and controls are adequate to preserve the therapeutics' identity, strength, quality, purity, and potency as well as satisfactory completion of an FDA inspection of selected clinical sites and selected clinical investigators to determine GCP compliance; and
- FDA review and approval of the BLA to permit commercial marketing for particular indications for use.

Preclinical studies include laboratory evaluation of chemistry, pharmacology, toxicity, and product formulation, as well as animal studies to assess potential safety and efficacy. Such studies must generally be conducted in accordance with the FDA's GLPs. Prior to commencing the first clinical trial at a United States investigational site with a product candidate, an IND sponsor must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data, any available clinical data or literature, and proposed clinical study protocols among other things, to the FDA as part of an IND. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA notifies the applicant of safety concerns or questions related to one or more proposed clinical trials and places the trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during trials due to safety concerns or non-compliance. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

Clinical testing, known as clinical trials or clinical studies, is either conducted internally by pharmaceutical or biotechnology companies or managed on behalf of these companies by Clinical Research Organizations, or CROs. 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 must be conducted in accordance with federal regulations and GCP requirements, which include the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial, as well as review and approval of the study by an IRB. Additionally, some clinical trials are overseen by an independent data safety monitoring board, which reviews data and advises the study sponsor on study continuation. A protocol for each clinical trial, and any subsequent protocol amendments, must be submitted to the FDA as part of the IND.

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, mechanism of action 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. Typically, two Phase 3 trials are required for product approval. Under limited circumstances, however, approval may be based upon a single adequate and well-controlled clinical trial plus confirmatory evidence or a single large multicenter trial without confirmatory evidence.

FDA may also consider additional kinds of data in support of a BLA, such as patient experience data and real world evidence. For genetically targeted populations and variant protein targeted products intended to address an unmet medical need in one or more patient subgroups with a serious or life threatening rare disease or condition, the FDA may allow a sponsor to rely upon data and information previously developed by the sponsor or for which the sponsor has a right of reference, that was submitted previously to support an approved application for a product that incorporates or utilizes the same or similar genetically targeted technology or a product that is the same or utilizes the same variant protein targeted drug as the product that is the subject of the application.

Reports regarding clinical study progress must be submitted to the FDA and IRB on an annual basis. Additional reports are required if serious adverse events or other significant safety information is found. Certain reports may also be required to be submitted to the IBC. Investigational biologics must additionally be manufactured in accordance with cGMPs, imported in accordance with FDA requirements, and exported in accordance with the requirements of the receiving country as well as FDA.

Additionally, under the Pediatric Research Equity Act, or PREA, BLAs or BLA supplements for a new active ingredient, dosage form, dosage regimen, or route of administration, unless subject to the below requirement for molecularly targeted cancer products, must contain data to assess the safety and effectiveness of the product in all relevant pediatric subpopulations. The FDA may, however, grant deferrals or full or partial waivers of this requirement. PREA does not apply to orphan designated products approved solely for the orphan indication.

If a product is intended for the treatment of adult cancer and is directed at molecular targets that the FDA determines to be substantially relevant to the growth or progression of pediatric cancer, even if the product has orphan designation, the application sponsors must submit, reports from molecularly targeted pediatric cancer investigations designed to yield clinically meaningful pediatric study data, gathered using appropriate formulations for each applicable age group, to inform potential pediatric labeling. Like PREA, FDA may grant deferrals or waivers of some or all of this data requirement.

Certain gene therapy studies are also subject to the National Institutes of Health's Guidelines for Research Involving Recombinant DNA Molecules, or NIH Guidelines. The NIH Guidelines include the review of the study by a local institutional committee called an institutional biosafety committee, or IBC. The IBC assesses the compliance of the research with the NIH Guidelines, assesses the safety of the research and identifies any potential risk to public health or the environment.

In addition to the regulations discussed above, there are a number of additional standards that apply to clinical trials involving the use of gene therapy. The FDA has issued various guidance documents regarding gene therapies, which outline additional factors that the FDA will consider during product development. These include guidance regarding preclinical studies; chemistry, manufacturing, and controls; the measurement of product potency; how FDA will determine whether a gene therapy product is the same as another product for the purpose of the agency's orphan drug regulations; and long term patient and clinical study subject follow up and regulatory reporting.

Biologic License Application (BLA). During clinical trials, companies usually also complete additional preclinical studies. Companies further develop additional information about the product candidate's physical characteristics and finalize the cGMP manufacturing process. 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 biologic, the sponsor submits a BLA to the FDA requesting marketing approval. The application is a comprehensive filing that includes the results of all preclinical and clinical studies, information about the product's composition, and the sponsor's plans for manufacturing, packaging, labeling and testing the investigational new product

Subject to certain exceptions, the BLA must be accompanied by a substantial user fee at the time of the first submission. FDA has 60 days from its receipt of a BLA to determine whether the application is sufficiently complete for filing and for a substantive review. If the FDA determines that the NDA is incomplete, the FDA may refuse to file the application, in which case the applicant must address the FDA identified deficiencies before refiling. After the BLA is accepted for filing, the FDA reviews the application to determine whether the product meets FDA's approval standards. The FDA aims to complete its review within ten months of the 60-day filing date. For products that present significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions FDA aims to complete its review within 6 months of the 60-day filing date. The FDA, however, does not always meet its review goal. The review goal date may also be extended if FDA requests or the sponsor provides additional information regarding the application. As part of the approval process, FDA will typically inspect one or more clinical sites, as well as the facility or the facilities at which the product is manufactured to ensure GCP and cGMP compliance.

FDA may also refer an application for review by an independent advisory committee. Specifically, for a product candidate for which no active ingredient (including any ester or salt of active ingredients) has previously been approved by the FDA, the FDA must either refer that product candidate to an advisory committee or provide in an action letter, a summary of the reasons why the FDA did not refer the product candidate to an advisory committee. While FDA is not bound by the recommendation of an advisory committee, it does carefully consider the committee's recommendations.

After evaluating the application, FDA may issue an approval letter, authorizing product marketing, or a Complete Response Letter, or CRL, indicating that the application is not ready for approval. The CRL describes the application's deficiencies and conditions that must be met for product approval. If a CRL is issued, the applicant may resubmit the application, addressing the deficiencies, withdraw the application, or request a hearing. Even with submission of additional information, the FDA ultimately may decide that the application is not approvable.

If approval is granted, the FDA may limit the indications for use, including the indicated population, require contraindications, warnings or precautions be included in the product labeling, including black box warnings, or may not approve label statements necessary for successful commercialization. FDA may also require, or companies may conduct, additional clinical trials following approval, called Phase 4 studies, which can confirm or refute the effectiveness of a product candidate, and can provide important safety information. FDA may also require the implementation of a risk evaluation and mitigation strategy, or REMS, which may include requirements for a medication guide or patient package insert, a communication plan on product risks, or other elements to assure safe use.

After approval, some types of changes to the approved product, such as adding new indications or label claims, which may themselves require further clinical testing, or changing the manufacturing process are subject to further FDA review and approval. FDA can also require the implementation REMS or the conduct of phase 4 studies after product approval.

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 biopharmaceutical and drug products. In the United States, the FDA subjects drugs to rigorous review under the Federal Food, Drug and Cosmetic Act, or FDCA, the Public Health Service Act, or PHSA, and implementing regulations.

Orphan Drug Designation

Under the Orphan Drug Act, or ODA, the FDA may grant Orphan Drug Designation, or 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. Additionally, sponsors must present a plausible hypothesis for clinical superiority to obtain ODD if there is a product already approved by the FDA that that is considered by the FDA to be the same as the already approved product and is intended for the same indication. This hypothesis must be demonstrated to obtain orphan exclusivity.

The benefits of ODD can be substantial, including research and development tax credits, grants and exemption from user fees. The tax advantages, however, were limited in the 2017 Tax Cuts and Jobs Act. Moreover, if there is no other product that the FDA considers to be the same product that is approve for the orphan indication, the orphan designated product is eligible for 7 years of orphan market exclusivity once the product is approved. 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. Other applicants, however, may receive approval of different products for the orphan indication or the same product for a different indication during the orphan exclusivity period. 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.

We currently have ODD with the FDA for AXAL for treatment of anal cancer (granted August 2013), HPV-associated head and neck cancer (granted November 2013); and treatment of Stage II-IV invasive cervical cancer (granted May 2014). We also have ODD with the FDA for ADXS-HER2 for the treatment of osteosarcoma (granted May 2014).

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

Expedited Review and Approval Programs for Serious Conditions

Four core FDA programs are intended to facilitate and expedite development and review of new biologics 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.

FDA is required to facilitate the development, and expedite the review, of products that are intended for the treatment of a serious or life-threatening disease or condition, and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new biologic product candidate may request that FDA designate the drug candidate for a specific indication as a fast track drug concurrent with, or after, the filing of the IND for the product candidate. FDA must determine if the product candidate qualifies for Fast Track Designation within 60 days of receipt of the sponsor's request. If Fast Track Designation is obtained, sponsors may be eligible for more frequent development meetings and correspondence with the FDA. FDA may also initiate review of sections of a fast track product's BLA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, FDA's time period goal for reviewing an application does not begin until the last section of the BLA is submitted.

Under FDA's accelerated approval programs, FDA may approve a product for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by FDA.

Under the provisions of the Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Products designated as breakthrough therapies are eligible for intensive guidance on an efficient development program beginning as early as Phase 1 trials, a commitment from the FDA to involve senior managers and experienced review staff in a proactive collaborative and cross-disciplinary review, rolling review, and the facilitation of cross-disciplinary review.

Another expedited pathway is the Regenerative Medicine Advanced Therapy, or RMAT, designation. Qualifying products must be a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or a combination of such products, and not a product solely regulated as a human cell and tissue product. The product must be intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, and preliminary clinical evidence must indicate that the product has the potential to address an unmet need for such disease or condition. Advantages of the RMAT designation include all the benefits of the Fast Track and breakthrough therapy designation programs, including early interactions with the FDA. These early interactions may be used to discuss potential surrogate or intermediate endpoints to support accelerated approval.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA regulated products, including biologics, are required to register and submit certain clinical trial information within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their clinicaltrials.gov website. Information related to the product, patient population, phase of investigation, Trial sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years, depending on the circumstances, after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Coverage, Pricing and Reimbursement

Successful commercialization of new drug products depends in part on the extent to which reimbursement for those drug products will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drug products they will pay for and establish reimbursement levels. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford a drug product. Sales of drug products depend substantially, both domestically and abroad, on the extent to which the costs of drugs products are paid for by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular drug products. In many countries, the prices of drug products are subject to varying price control mechanisms as part of national health systems. In general, the prices of drug products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for drug products, but monitor and control company profits. Accordingly, in markets outside the United States, the reimbursement for drug products may be reduced compared with the United States. In the United States, the principal decisions about reimbursement for new drug products are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new drug product will be covered and reimbursed under certain federal governmental healthcare programs, such as Medicare, and private payors tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists among third-party payors and coverage and reimbursement levels for drug products can differ significantly from payor to payor. In the United States, the process for determining whether a third-party payor will provide coverage for a biological product typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. With respect to biologics, third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication, or place products at certain formulary levels that result in lower reimbursement levels and higher cost sharing obligation imposed on patients. A decision by a third-party payor not to cover our product candidates could reduce physician utilization of a product. Moreover, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable a manufacturer to maintain price levels sufficient to realize an appropriate return on its investment in product development. Additionally, coverage and reimbursement for products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product does not ensure that other payors will also provide coverage for the medical product, or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process usually requires manufacturers to provide scientific and clinical support for the use of their products to each payor separately and is a time-consuming process.

Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness of pharmaceutical products, in addition to questioning safety and efficacy. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover that product after FDA approval or, if they do, the level of payment may not be sufficient to allow a manufacturer to sell its product at a profit.

In addition, in many foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. In the European Union, governments influence the price of products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed to by the government. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. The downward pressure on healthcare costs in general, particularly prescription products, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross border imports from low-priced markets exert a commercial pressure on pricing within a country (particularly in the EEA where it is illegal to impede such imports from elsewhere within the EEA).

Other Healthcare Laws

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including CMS, the HHS Office of Inspector General and HHS Office for Civil Rights, other divisions of the HHS and the Department of Justice.

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our current and future arrangements with third-party payors, healthcare providers and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any drugs for which we obtain marketing approval. In the United States, these laws include, without limitation, state and federal anti-kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, including but not limited to those described below.

The U.S. federal Anti-Kickback Statute, or AKS, prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. The AKS has been interpreted to apply to arrangements between pharmaceutical and medical device manufacturers on the one hand and prescribers, purchasers, formulary managers and beneficiaries on the other hand. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Although we would not submit claims directly to payors, drug manufacturers can be held liable under the federal False Claims Act, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Several biopharmaceutical, medical device and other healthcare companies have been prosecuted under federal false claims and civil monetary penalty laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved (e.g., or off-label), and thus non-covered, uses. In addition, the civil monetary penalties statute imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Claims which include items or services resulting from a violation of the federal AKS are false or fraudulent claims for purposes of the False Claims Act.

Our future marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products, if approved, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our product candidates, are subject to scrutiny under these laws.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit, among other actions, knowingly and wilfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretences, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, knowingly and wilfully embezzling or stealing from a healthcare benefit program, wilfully obstructing a criminal investigation of a healthcare offense and knowingly and wilfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and certain other healthcare providers. The Affordable Care Act, or the ACA, imposed, among other things, new annual reporting requirements through the Physician Payments Sunshine Act for covered manufacturers for certain payments and "transfers of value" provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties. Covered manufacturers must submit reports by the 90th day of each subsequent calendar year and the reported information is publicly made available on a searchable website.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, including the Final HIPAA Omnibus Rule published on January 25, 2013, impose specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates. Among other things, HITECH made HIPAAs security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity, although it is unclear that we would be considered a "business associate" in the normal course of our business. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same requirements, thus complicating compliance efforts.

Similar state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services. Such laws are generally broad and are enforced by various state agencies and private actions. Also, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant federal government compliance guidance, and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company’s attention from the business.

Current and Future Legislation

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

The ACA, for example, contains provisions that subject biological products to potential competition by lower-cost biosimilars and may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extend Medicaid rebates to Medicaid managed care plans, provide for mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies’ share of sales to federal healthcare programs. With the President Trump administration and current Congress, there will likely be additional administrative or legislative changes, including modification, repeal or replacement of all, or certain provisions of the ACA, which may impact reimbursement for drugs and biologics. On January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their lawsuit was dismissed by a federal judge in California on July 18, 2018. In addition, CMS has recently finalized regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, each chamber of Congress has put forth multiple bills, and may do so again in the future, designed to repeal or repeal and replace portions of the ACA.

While Congress has not passed repeal legislation, the Tax Reform Act includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.” Congress may consider other legislation to repeal and replace elements of the ACA. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. The Trump administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the same judge issued an order staying the judgment pending appeal. A Fifth Circuit U.S. Court of Appeals hearing to determine whether certain states and the House of Representatives have standing to appeal the lower court decision was held on July 9, 2019, but it is unclear when a Court will render its decision on this hearing, and what effect it will have on the status of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

Additionally, other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted:

- The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027, unless additional Congressional action is taken.
- The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- The Middle Class Tax Relief and Job Creation Act of 2012 required that CMS reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which served as a base for 2014 and subsequent years. In addition, effective January 1, 2014, CMS also began bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed and enacted bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In addition, the U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs to limit the growth of government paid healthcare costs. For example, the U.S. government has passed legislation requiring pharmaceutical manufacturers to provide rebates and discounts to certain entities and governmental payors to participate in federal healthcare programs. Further, Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs, and the current administration recently released a "Blueprint", or plan, to reduce the cost of drugs. The Blueprint contains certain measures that the U.S. Department of Health and Human Services is already working to implement. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Individual states in the United States have also been increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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 clinical 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 8, "Collaboration and Licensing Agreements" of the "Notes to the Financial Statements" included in Item 8.

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. 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

cGMPs, are the standards identified to conform to requirements by governmental agencies that control authorization and licensure for manufacture and distribution of biologic 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" 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 expedited pathway from construct discovery to clinical product delivery, while helping to keep cost of goods low.

Advaxis has entered into agreements with multiple third-party organizations, or 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.

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 potential 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: BioNtech, Moderna, Gritstone, BMS, AstraZeneca, Merck, Neon Therapeutics, 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, 2020, we had 18 employees, 17 of which were full time employees. Of our full-time employees, 1 holds a Ph.D. degree. 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.

Summary of Risk Factors

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Form 10-K and our other filings with the SEC, before making an investment decision regarding our common stock.

- We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.
- 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.
- We are significantly dependent on the success of our Lm Technology platform and our product candidates based on this platform.
- If we are unable to establish, manage or maintain strategic collaborations in the future, our revenue and drug development may be limited.
- We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.
- We need to attract and retain highly skilled personnel; we may be unable to effectively manage growth with our limited resources.
- We depend upon our senior management and key consultants and their loss or unavailability could put us at a competitive disadvantage.
- 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.
- As a matter of course, we are reviewing strategic transactions for our company. We may not be successful in identifying or completing any strategic transaction and any such strategic transaction completed may not yield additional value for stockholders.
- We can provide no assurance that our clinical product candidates will obtain regulatory approval or that the results of clinical studies will be favorable.
- Drug discovery and development is a complex, time-consuming and expensive process that is fraught with risk and a high rate of failure.
- We may face legal claims; legal disputes are expensive and we may not be able to afford the costs.
- We can provide no assurance of the successful and timely development of new products.
- Our employees, independent contractors, consultants, commercial partners, principal investigators, or CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.
- We must comply with significant government regulations.
- Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.
- 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.

- The price of our common stock and warrants may be volatile.
- The market prices for our common stock may be adversely impacted by future events.
- A limited public trading market may cause volatility in the price of our common stock.
- 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 Capital Market, which could affect the market price and liquidity for our common stock and reduce our ability to raise additional capital.
- We may be at an increased risk of securities litigation, which is expensive and could divert management attention**.**
- 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.

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 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, 2020, we had cash and cash equivalents of about $25.178 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.

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 we will continue to incur significant operational costs as we execute on our clinical development strategy. 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, 2020, we had an accumulated deficit of approximately $410.7 million and stockholders' equity of approximately $30.18 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.

We are significantly dependent on the success of our* Lm *Technology platform and our product candidates based on this platform.

We have invested, and we expect to continue to invest, significant efforts and financial resources in the development of product candidates based on our *Lm* Technology. Our ability to generate meaningful revenue, which may not occur for the foreseeable future, if ever, will depend heavily on the successful development, regulatory approval and commercialization of one or more of these product candidates, and such regulatory approval and commercialization may never occur.

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, or be delayed in reaching, 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, delays in receiving the necessary products or supplies for the conduct of clinical or pre-clinical trials, additional time requirements for data analysis, or Biologics License Application preparation, discussions with the FDA, an FDA request for additional preclinical or clinical data, FDA delays in inspecting manufacturing establishments, failure to receive FDA approval for manufacturing processes or facilities, or unexpected safety or manufacturing issues;

- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make the immunotherapy uneconomical; and

- the proprietary rights of others and their competing products and technologies that may prevent the immunotherapy from being commercialized.

Success in preclinical and early clinical studies does not ensure that large-scale clinical studies will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical studies and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one immunotherapy to the next and may be difficult to predict.

Even if our product candidates are approved, they may be subject to limitations on the indicated uses and populations for which they may be marketed. They may also be subject to other conditions of approval, may contain significant safety warnings, including boxed warnings, contraindications, and precautions, may not be approved with label statements necessary or desirable for successful commercialization, or may contain requirements for costly post-market testing and surveillance, or other requirements, including the submission of a REMS, to monitor the safety or efficacy of the products. If we do not receive FDA approval for, and successfully commercialize our product candidates, we will not be able to generate revenue from these product candidates in the United States in the foreseeable future, or at all. Any significant delays in obtaining approval for and commercializing our product candidates will have a material adverse impact on our business and financial condition.

We are limited in our manufacturing capabilities and we must rely upon third parties for such services.

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, we depend on third-party manufacturers to supply most of our clinical materials. 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. For instance, manufacturers may experience unforeseen problems, such as material or personnel shortages, temporary or permanent facility closures, or scale up challenges. 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.

There is also no guarantee that our third party manufacturers will be able to manufacture our product candidates in accordance with applicable standards or cGMPs. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of a product candidate that may not be detectable in final product testing. If these third party manufacturers are not able to comply with cGMPs, we may not be able to conduct clinical trials, may need to conduct additional studies, and may not, eventually, receive and maintain FDA approval of our manufacturing processes and facilities. Deviations from manufacturing requirements may also require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon or by us or third parties with whom we contract could materially harm our business. A failure to comply with the applicable regulatory requirements may also result in regulatory enforcement actions against our manufacturers or us.

While we are ultimately responsible for the manufacture of our product candidates, other than through our contractual arrangements, we have little control over our manufacturers' compliance with these regulations and standards. If we or our manufacturers encounter manufacturing difficulties, including cGMP compliance, we may need to find alternative manufacturing facilities, which we may not be able to on favorable terms or at all, and which would significantly impact our ability to develop, obtain and maintain regulatory approval for or market our product candidates, if approved. Any new manufacturers would need to either obtain or develop the necessary manufacturing know-how, and obtain the necessary equipment and materials, which may take substantial time and investment. We must also receive FDA approval for the use of any new manufacturers for commercial supply.

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.

Further, our collaborators may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with us. Collaborators may also fail to comply with the applicable regulatory requirements, which may subject them or us to regulatory enforcement actions. 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.

Changes in product candidate manufacturing or formulation may result in additional costs or delay.

In an effort to optimize processes and results, it is common that various aspects of the development program, such as manufacturing methods, manufacturing sites, and formulation, are altered as product candidates are developed from preclinical studies to late-stage clinical trials toward approval and commercialization. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, regulatory disclosure, or prior approval from the FDA. For instance, the FDA may require that we conduct a comparability study that evaluates the potential differences in the product candidate resulting from the change. Delays in designing and completing such a study to the satisfaction of the FDA could delay or preclude our development and commercialization plans, and the regulatory approval of our product candidates. It may also require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence product sales and generate revenue. Any of the foregoing could limit our future revenues and growth. Any changes would also require that we devote time and resources to manufacturing development, including with third-party manufacturers, and would also likely require additional testing and regulatory actions on our part, which may delay the development of our product candidates.

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.

Additional laws and regulations governing international operations could negatively impact or restrict our operations.

If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The U.S. Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, exclusion from public tenders, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

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, 2020, we had 18 employees, 17 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 products under development or approved products by competitors that are used for the prevention, diagnosis, or treatment of certain diseases we have targeted for product development. Various companies are developing biopharmaceutical products that have the potential to directly compete with our immunotherapies even though their approach may be different. The biotechnology and biopharmaceutical industries are highly competitive, and this competition comes from both biotechnology firms and major pharmaceutical companies, including companies like: Gritstone, Moderna, BMS, Merck and Neon Therapeutics, 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.

As a matter of course, we are reviewing strategic transactions for our company. We may not be successful in identifying or completing any strategic transaction and any such strategic transaction completed may not yield additional value for stockholders.

As a matter of course, we are reviewing strategic transactions and alternatives and there can be no assurance that we will be successful in identifying or completing any strategic transactions, that any such strategic transaction will result in additional value for our stockholders or that the process will not have an adverse impact on our business. These transactions could include, but are not limited to, collaboration agreements, co-development agreements, strategic mergers, reverse mergers, the issuance or buyback of public shares, or the purchase, in-license or out-license or sale of specific assets, in addition to other potential actions aimed at increasing stockholder value. There can be no assurance that the review of strategic transactions will result in the identification or consummation of any transaction. Our Board of Directors may also determine that our most effective strategy is to continue to effectuate our current business plan. The process of reviewing strategic transactions may be time consuming and disruptive to our business operations and, if we are unable to effectively manage the process, our business, financial condition and results of operations could be adversely affected. We could incur substantial expenses associated with identifying and evaluating potential strategic alternatives. No decision has been made with respect to any transaction and we cannot assure you that we will be able to identify and undertake any transaction that allows our shareholders to realize an increase in the value of their common stock or provide any guidance on the timing of such action, if any.

We also cannot assure you that any potential strategic transaction or other alternative transaction, if identified, evaluated and consummated, will provide greater value to our stockholders than that reflected in the current price of our common stock. Any potential transaction would be dependent upon a number of factors that may be beyond our control, including, but not limited to, market conditions, industry trends, the interest of third parties in our business and the availability of financing to potential buyers on reasonable terms. We do not intend to comment regarding the evaluation of strategic alternatives until such time as our Board of Directors has determined the outcome of the process or otherwise has deemed that disclosure is appropriate or required by applicable law. As a consequence, perceived uncertainties related to our future may result in the loss of potential business opportunities and volatility in the market price of our common stock and may make it more difficult for us to attract and retain qualified personnel and business partners.

A global health crisis such as a pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, may materially and adversely affect our business and operations.

The COVID-19 pandemic is affecting the United States and global economies and has affected, and may continue to affect, our operations and those of third parties on which we rely, including by causing disruptions in our raw material supply and the manufacturing of our product candidates. In addition, the COVID-19 pandemic has affected the operations of the U.S. Food and Drug Administration and other health authorities, which can result in delays of reviews and approvals, including with respect to our product candidates. The evolving COVID-19 pandemic has, and may continue to, directly or indirectly affect the pace of enrollment in our clinical trials as patients may avoid or may not be able to travel to healthcare facilities and physicians' offices unless due to a health emergency and clinical trial staff can no longer get to the clinic. Additionally, such facilities and offices have been and may continue to be required to focus limited resources on non-clinical trial matters, including treatment of COVID-19 patients, thereby decreasing availability, in whole or in part, for clinical trial services. In addition, employee disruptions and remote working environments related to the COVID-19 pandemic and the federal, state and local responses to such virus, could materially affect the efficiency and pace with which we work and develop our product candidates and the manufacturing of our product candidates. In addition, COVID-19 infection of our workforce could result in a temporary disruption in our business activities, including manufacturing and other functions. Further, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce our ability to access capital, which could negatively affect our short-term and long-term liquidity. Additionally, the stock market has been unusually volatile during the COVID-19 outbreak and such volatility may continue. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, financing or clinical trial activities, or on healthcare systems or the global economy as a whole. However, these effects could have a material impact on our liquidity, capital resources, operations and business and those of the third parties on which we rely.

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

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

There can be delays in obtaining FDA 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, or 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.

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;

- subjects may drop out of our clinical trials, be lost to follow-up at a higher rate than we anticipate, or not comply with the required clinical trial procedures;

- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and our CROs;

- the cost of clinical trials may be greater than we anticipate or we may have insufficient funds for a clinical trial or to pay the substantial FDA user fees;

- the FDA or comparable foreign regulatory authorities may disagree with our study design, including endpoints, our intended indications, or our interpretation of data;

- the risk of failure of our clinical investigational sites and related facilities, including our suppliers and CROs, to maintain compliance with the FDA's cGMP and GCP 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 or we may be required to modify our trial design such that studies are impracticable;

- regulators may require us to perform additional or unanticipated clinical trials to obtain approval or we may be subject to additional post-marketing testing, surveillance, or REMS requirements to maintain regulatory approval;

- FDA refusal to accept the data from foreign clinical trial sites, to the extent we use such sites;

- 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; legal disputes are expensive and we may not be able to afford the costs.

We may face legal claims involving stockholders, consumers, clinical trial subjects, 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, including, but not limited to, compulsory licensing of patents.

The costs of litigation or any proceeding, including, but not limited to, those 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. Legal claims may also adversely impact us in other ways, such as the withdrawal or slower enrollment in or from our clinical trials, regulatory enforcement actions, and negative media attention, any of which could materially and negatively harm us and our operations.

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

Our immunotherapies are at various stages of 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 market acceptance of our immunotherapies if we receive regulatory approval;
- 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. For example, in June 2019, we announced that we were closing our AIM2CERV Phase 3 clinical trial with AXAL in cervical cancer due to the delays we incurred as a result of the recent FDA partial clinical hold on the trial, as well as the estimated cost and time to completion of the trial. Furthermore, the Company has completed the clinical study report from Part A of the ADXS-NEO study and plans to close its ADXS-NEO program IND as next step. 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 CROs, 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 or CROs 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.

While we have agreements governing the activities of such third parties and are responsible for our third party service provider's activities and regulatory compliance, we have limited influence and control over their actual performance and activities and cannot control whether or not they devote sufficient time and resources to our ongoing clinical, non-clinical, and preclinical programs and cannot control whether they maintain regulatory compliance. Our third-party service providers may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting trials or other therapeutic development activities that could harm our competitive position.

Agreements with third parties conducting or otherwise assisting with our clinical or preclinical studies might terminate for a variety of reasons, including a failure to perform by the third parties. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, if we need to enter into alternative arrangements, it could delay our product development activities and adversely affect our business. Though we carefully manage our relationships with our third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects, and results of operations.

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.

Our employees, independent contractors, consultants, commercial partners, principal investigators, or CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee and third party fraud or other misconduct. Misconduct by employees, independent contractors, consultants, commercial partners, manufacturers, investigators, or CROs could include intentional, reckless, negligent, or unintentional failures to comply with FDA regulations, comply with applicable fraud and abuse laws, provide accurate information to the FDA, properly calculate pricing information required by federal programs, comply with federal procurement rules or contract terms, report financial information or data accurately or disclose unauthorized activities to us. This misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter this type of misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Moreover, it is possible for a whistleblower to pursue a False Claims Act case against us even if the government considers the claim unmeritorious and declines to intervene, which could require us to incur costs defending against such a claim. Further, due to the risk that a judgment in an FCA case could result in exclusion from federal health programs or debarment from government contracts, whistleblower cases often result in large settlements. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, and results of operations, including the imposition of significant fines or other sanctions.

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, distribution, 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. We, our product candidates, and our products, if we receive marketing approval are and will continue to be subject to extensive governmental regulation and regulatory authorities do and will continue to closely monitor our and our contractor's compliance through, among other methods, inspections. Noncompliance with applicable laws and requirements can result in various adverse consequences and regulatory enforcement actions, 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, restitution or disgorgement of profits, recall or seizure of products, exclusion from having our products reimbursed by federal health care programs, the curtailment or restructuring of our operations, corporate integrity agreements or consent decrees, refusal ot permit product import or export, modifications to labeling or promotional materials, issuance of corrective information, regulatory authority public statements, warning, untitled, or cyber letters, requirements for post-market studies or REMS, injunctions against shipping products and total or partial suspension of production and/or refusal to allow a company to enter into governmental supply contracts. Any of these events could prevent us from achieving or maintaining product approval and market acceptance of the particular product candidate, if approved, or could substantially increase the costs and expenses of developing and commercializing such product, which in turn could delay or prevent us from generating significant revenues from its sale. Any of these events could further have other material and adverse effects on our operations and business and could adversely impact our stock price and could significantly harm our business, financial condition, results of operations, and prospects.

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 may not obtain or maintain the benefits associated with orphan drug designation, including market exclusivity.

Although we have been granted FDA orphan drug designation for AXAL for use in the treatment of anal cancer, HPV-associated head and neck cancer, Stage II-IV invasive cervical cancer and for ADXS-HER2 for the treatment of osteosarcoma in the United States, as well as EMA orphan drug designation for AXAL for the treatment of anal cancer and for ADXS-HER2 for the treatment of osteosarcoma in the EU, 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. Moreover, while orphan drug designation does provide us with certain advantages, it neither shortens the development time or regulatory review time of a product candidate nor gives the product candidate any advantage in the regulatory review or approval process.

Under U.S. rules for orphan drugs, if such a competing product reaches the market before ours does, if such product is considered by FDA to be the same as ours, and if such product is intended for the same orphan indication, 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 unless we can demonstrate that our product is clinically superior. 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 to ours 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. Moreover, we may not be able to maintain our orphan drug designation or exclusivity and our product candidates would not be eligible for exclusivity if the approved indication is broader than the orphan drug designation.

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 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. Further, we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

We may not receive Fast Track Designation, Breakthrough Therapy Designation or any other designation that we may apply for from the FDA and, if granted, such designations may not actually lead to a faster development or regulatory review or approval process.

The FDA has granted Fast Track Designation for AXAL for adjuvant therapy for high-risk locally advanced cervical cancer patients, and has granted Fast Track Designation for ADXS-HER2 for patients with newly-diagnosed, non-metastatic, surgically-resectable osteosarcoma. We may seek Breakthrough Therapy Designation for our product candidates or Fast Track Designation for certain of our other product candidates. There is no guarantee, however, that we will be able to obtain or maintain such designations.

The FDA has broad discretion whether or not to grant any special designation, so even if we believe one of our product candidates is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Additionally, even if we do receive a special designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may also withdraw the designation if it believes that the designation is no longer supported by data from our clinical development program.

The results of clinical trials conducted at clinical trial sites outside the United States might not be accepted by the FDA, and data developed outside of a foreign jurisdiction similarly might not be accepted by such foreign regulatory authority.

Some of the clinical trials for our product candidates that are being or will be conducted through our partnerships and collaborations may be conducted outside the United States, and we intend in the future to conduct additional clinical trials outside the United States. Although the FDA, European Medicines Agency ("EMA") or comparable foreign regulatory authorities may accept data from clinical trials conducted outside the relevant jurisdiction, acceptance of these data is subject to certain conditions. For example, the FDA requires that the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles such as IRB or ethics committee approval and informed consent, the trial population must adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, acceptance of the data by the FDA will be dependent upon its determination that the trials were conducted consistent with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the United States as adequate support of a marketing application. Similarly, we must also ensure that any data submitted to foreign regulatory authorities adheres to their standards and requirements for clinical trials and there can be no assurance a comparable foreign regulatory authority would accept data from trials conducted outside of its jurisdiction.

Our relationships with healthcare providers and physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, or FCA, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;

- the federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose, among other things, requirements on certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, as well as their respective business associates, independent contractors that perform services for covered entities that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, as amended, or ACA, and its implementing regulations, which require some manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services, or CMS, of the U.S. Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. Pharmaceutical companies may also be subject to federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies continue to closely scrutinize interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time and resource-consuming and can divert a company's attention from the business.

It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Any action for violation of these laws, even if successfully defended, could cause a biopharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, the EMA or comparable foreign regulatory authorities must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if we receive regulatory approval of any product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, distribution, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, EMA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. Certain endpoint data we hope to include in any approved product labeling also may not make it into such labeling, including exploratory or secondary endpoint data such as patient-reported outcome measures. The FDA may also require a risk evaluation and mitigation strategies, or REMS, program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, EMA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The policies of the FDA, EMA and comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates profitably.

The success of our product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates, once approved. Patients are unlikely to use our product candidates, once approved, unless coverage is provided and reimbursement is adequate

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. biopharmaceutical industry. The ACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. For example, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, the Tax Reform Act includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." As a result of the individual mandate repeal, subsequent litigation challenged the validity of the ACA. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, or TCJA, the remaining provisions of the ACA are invalid as well. The Trump administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the same judge issued an order staying the judgment pending appeal. A Fifth Circuit U.S. Court of Appeals hearing to determine whether certain states and the House of Representatives have standing to appeal the lower court decision was held on July 9, 2019, but it is unclear when the court will render its decision on this hearing, and what effect it will have on the status of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Further, the Trump administration has concluded that cost-sharing reduction, or CSR, payments to insurance companies required under the ACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until those appropriations are made. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Bipartisan bills to appropriate funds for CSR payments were proposed in 2017 and 2018, but the proposals have not been enacted into law. Multiple state Attorneys General filed suit to stop the administration from terminating the subsidies, but their case was dismissed by a federal judge in California on July 18, 2018. Furthermore, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace and providers, and the potential effect on our business, are not yet known.

Inadequate funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, upon completion of this offering and in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

We are not currently marketing our product candidates, nor can we until they are approved; however, we are seeking partnering and commercial opportunities for our products. We cannot assure you that we will be able to commercialize any of our product candidates 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, or GCPs, 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 several hundred patents and applications, which are owned, licensed from, or co-owned with Penn and Merck. 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.

Some of our products 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 may 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, 2019, we did not have 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 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 Capital 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 Capital Market, which could affect the market price and liquidity for our common stock and reduce our ability to raise additional capital.

In order to maintain listing on the Nasdaq Capital Market, 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 April 8, 2020, the Company received written notice from Nasdaq indicating that the Company was not in compliance with this minimum bid price requirement because the Company's common stock had closed below $1.00 per share for the previous 30 consecutive business days. On April 17, 2020, the Company received an additional notice from Nasdaq indicating that, due to extraordinary market conditions, Nasdaq had tolled the compliance period for the bid-price requirement through June 30, 2020 (the "tolling period") and that on April 16, 2020, Nasdaq filed an immediately effective rule change with the SEC to implement the tolling period. In accordance with the April 17, 2020 notice from Nasdaq, the Company had until December 21, 2020 to regain compliance with the minimum bid price requirement.

As of December 21, 2020, the Company was yet to be in compliance with the minimum bid requirement as discussed above. On December 22, 2020, the Company received notification from the Nasdaq that the Company's application to transfer the listing of its common stock from the Nasdaq Global Select Market to the Nasdaq Capital Market had been approved. The Company's securities were transferred to the Nasdaq Capital Market at the opening of business on December 24, 2020 and the Company will have an additional 180 days, or until June 21, 2021, to regain compliance with the minimum bid price per share requirement.

If compliance cannot be demonstrated by June 21, 2021 or the Company does not comply with the terms of this extension, Nasdaq will provide written notification that the Company's securities will be delisted which could adversely affect the market price and liquidity of our common stock and reduce our ability to raise additional capital.

Unless our common stock continues to be listed on a national securities exchange it will become subject to the so-called "penny stock" rules that impose restrictive sales practice requirements.

If we are unable to maintain the listing of our common stock on The Nasdaq Capital Market or another national securities exchange, our common stock could become subject to the so-called "penny stock" rules if the shares have a market value of less than $5.00 per share. The SEC has adopted regulations that define a penny stock to include any stock that has a market price of less than $5.00 per share, subject to certain exceptions, including an exception for stock traded on a national securities exchange. The SEC regulations impose restrictive sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. An accredited investor generally is a person whose individual annual income exceeded $200,000, or whose joint annual income with a spouse exceeded $300,000 during the past two years and who expects their annual income to exceed the applicable level during the current year, or a person with net worth in excess of $1.0 million, not including the value of the investor's principal residence and excluding mortgage debt secured by the investor's principal residence up to the estimated fair market value of the home, except that any mortgage debt incurred by the investor within 60 days prior to the date of the transaction shall not be excluded from the determination of the investor's net worth unless the mortgage debt was incurred to acquire the residence. For transactions covered by this rule, the broker-dealer must make a special suitability determination for the purchaser and must have received the purchaser's written consent to the transaction prior to sale. This means that if we are unable maintain the listing of our common stock on a national securities exchange, the ability of stockholders to sell their common stock in the secondary market could be adversely affected.

If a transaction involving a penny stock is not exempt from the SEC's rule, a broker-dealer must deliver a disclosure schedule relating to the penny stock market to each investor prior to a transaction. The broker-dealer also must disclose the commissions payable to both the broker-dealer and its registered representative, current quotations for the penny stock, and, if the broker-dealer is the sole market-maker, the broker-dealer must disclose this fact and the broker-dealer's presumed control over the market. Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the customer's account and information on the limited market in penny stocks.

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.

In addition, our Board of Directors recently adopted a short-term stockholder rights agreement with an expiration date of September 28, 2021 and an ownership trigger threshold of 10%. This stockholder rights agreement could render more difficult, or discourage a merger, tender offer, or assumption of control of the Company that is not approved by our Board of Directors. The rights agreement, however, should not interfere with any merger, tender or exchange offer or other business combination approved by our Board of Directors. In addition, the rights agreement does not prevent our Board of Directors from considering any offer that it considers to be in the best interest of the Company's stockholders.

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.

Stendhal

On September 19, 2018, Stendhal filed a Demand for Arbitration before the International Centre for Dispute Resolution (Case No. 01-18-0003-5013) relating to the Co-development and Commercialization Agreement with Especificos Stendhal SA de CV (the "Stendhal Agreement"). In the demand, Stendhal alleged that (i) the Company breached the Stendhal Agreement when it made certain statements regarding its AIM2CERV program, (ii) that Stendhal was subsequently entitled to terminate the Agreement for cause, which it did so at the time and (iii) that the Company owes Stendhal damages pursuant to the terms of the Stendhal Agreement. Stendhal is seeking to recover $3 million paid to the Company in 2017 as support payments for the AIM2CERV clinical trial along with approximately $0.3 million in expenses incurred. Stendhal is also seeking fees associated with the arbitration and interest. The Company has answered Stendhal's Demand for Arbitration and denied that it breached the Stendhal Agreement. The Company also alleges that Stendhal breached its obligations to the Company by, among other things, failing to make support payments that became due in 2018 and that Stendhal therefore owes the Company $3 million. Advaxis is also seeking fees associated with the arbitration and interest.

From October 21-23, 2019, an evidentiary hearing for the arbitration was conducted. On April 1, 2020, the Arbitrator issued a final award denying Stendhal's claim in full. The Arbitrator found that the Company had not repudiated the Agreement and did not owe Stendhal damages, fees, or interest associated with the arbitration. The Arbitrator also denied the Company's claim that Stendhal breached its obligations to the Company. The parties were ordered to bear their own attorneys' fees and evenly split administrative fees and expenses for the arbitration.

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 Capital Market under the symbol “ADXS”.

As of January 15, 2021 there were approximately 23,176 holders of our common stock.

We have not declared or paid any cash dividends on our common stock, and we do not anticipate declaring or paying cash dividends for the foreseeable future.

Recent Sales of Unregistered Securities

On January 21, 2020, the Company completed a private placement of warrants to purchase the Company’s common stock with purchasers who purchased common stock in a concurrent registered offering. The warrants became exercisable for an aggregate of 5,000,000 shares of common stock beginning on the six-month anniversary of their issuance. The warrants have an exercise price of $1.25 per share and will expire on the fifth anniversary from the date on which they became exercisable. The description of the warrants above is qualified in its entirety be reference to the full and complete terms of the warrant, the form of which is filed as Exhibit 4.9 to this Annual Report on Form 10-K.

Additionally, on October 16, 2020, we entered into private exchange agreements with Anson Investments Master Fund LP and CVI Investments, Inc. (the “Investors”) of warrants issued in connection with our January 2020 public offering of common stock and concurrent private placement of warrants (the “Warrants”). The Warrants exchanged provided for the purchase of up to an aggregate of 5,000,000 shares of our common stock at an exercise price of $1.25 per share. The warrants became exercisable on July 21, 2020 and had an expiration date of July 21, 2025. Pursuant to such exchange agreements, we agreed to issue 3,000,000 shares of common stock to the Investors in exchange for such Warrants on a 1:0.6 basis. The exchanges were consummated to ensure that we are well-positioned to take advantage of any strategic, collaboration, financing or other potential transactions in the near future. Except as otherwise disclosed above, no additional shares of common stock have been issued in connection with the exchanges on a fully diluted basis. The exchange of the warrants for the shares of common stock was exempt from registration under Section 3(a)(9) of the Securities Act of 1933. The description of the exchange agreements above is qualified in its entirety by reference to the full and complete terms of such agreements, the form of which is filed as Exhibit 4.9 to this Annual Report on Form 10-K.

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 clinical-stage biotechnology company focused on the development and commercialization of proprietary *Lm* Technology antigen delivery products based on a platform technology that utilizes live attenuated *Listeria monocytogenes*, or *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 innate immune system with the equivalent of multiple adjuvants, and simultaneously reduce tumor protection in the Tumor Microenvironment, or 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, our product candidates (i.e., ADXS-PSA and ADXS-503) have the potential to optimize checkpoint performance, while having a generally well-tolerated safety profile, and most of our product candidates have an expected low cost of goods. A new Investigator-Sponsored-Study with our FDA-approved IND is expected to start with ADXS-504-HOT construct in biochemically recurrent prostate cancer patients at a leading US Medical Institution in the first quarter of 2021.

Advaxis is currently winding down clinical studies of *Lm* Technology immunotherapies in three program areas:

- Human Papilloma Virus ("HPV")-associated cancers
- Personalized neoantigen-directed therapies
- Human epidermal growth factor receptor-2 (HER-2) associated cancers

All these 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. While we are currently winding down clinical studies of *Lm* Technology immunotherapies in these three program areas, our license agreements continue with OS Therapies, LLC for ADXS-HER2 and with Global BioPharma, or GBP, for the exclusive license for the development and commercialization of AXAL in Asia, Africa, and the former USSR territory, exclusive of India and certain other countries.

Results of Operations for the Fiscal Year Ended October 31, 2020 Compared to the Fiscal Year Ended October 31, 2019

Revenue

Revenue decreased $20.6 million to $0.3 million for the fiscal year ended October 31, 2020 compared to $20.9 million for the fiscal year ended October 31, 2019. The decrease was due to the fact that the Company did not have another large collaboration in current year after the Amgen agreement was terminated. On December 10, 2018, we received a written notice of termination from Amgen with respect to the global agreement with Amgen (the "Amgen Agreement"). The termination was effective as of February 8, 2019. As of the notification date, we adjusted revenue on a cumulative catch-up basis considering the revised measure of progress for the combined performance obligation based on the modified service period up to and through the contract termination date of February 8, 2019 resulting in total revenue of $18.7 million in the prior period. In addition, the reimbursement of research and development costs of approximately $2.0 million by Amgen was included in revenue in the prior period.

Research and Development Expenses

We invest in research and development to advance our *Lm* technology through our preclinical and clinical development programs. Research and development expenses for the years ended October 31, 2020 and 2019 were categorized as follows (in thousands):

	Fiscal Years Ended October 31,		Increase (Decrease)	
	2020	2019	$	%
Hotspot/Off-the-Shelf therapies	$ 3,515	$ 3,221	$ 294	9%
Prostate cancer	948	863	85	10%
HPV-associated cancers	3,667	8,139	(4,472)	(55)%
Personalized neoantigen-directed therapy	1,266	2,932	(1,666)	(57)%
Other expenses	6,216	11,522	(5,306)	(46)%
Total research & development expense	$ 15,612	$ 26,677	$ (11,065)	(41)%
Stock-based compensation expense included in research and development expense	$ 308	$ 1,036	$ (728)	(70)%

Hotspot/Off-the-Shelf Therapies (ADXS-HOT)

Research and development costs associated with our hotspot mutation-based therapy for the fiscal year ended October 31, 2020 increased approximately 9% to $3.5 million compared to the same period in 2019. The increase is attributable to the costs associated with the Part B and Part C expansion of the study.

Prostate Cancer Therapy (ADXS-PSA)

Research and development costs associated with our prostate cancer therapy for the fiscal year ended October 31, 2020 increased approximately $0.1 million, or 10%, compared to the same period in 2019. The increase is attributable to a change order from the contract research organization during the current period. The Phase 1/2 study of our ADXS-PSA compound is in combination with KEYTRUDA® (pembrolizumab), Merck's humanized monoclonal antibody. During 2020, we presented updated data from this study which demonstrated an increase in the median overall survival, or mOS, to 33.7 months for patients in the combination arm of this study and mOS of 16.4 for patients with visceral metasteses (n=11). We are in currently seeking potential partners on next steps for this therapy.

HPV-Associated Cancers (AXAL)

The majority of the HPV-associated research and development costs include clinical trial and other related costs associated with our AXAL programs in cervical and head and neck cancers. HPV-associated costs for the fiscal year ended October 31, 2020 decreased approximately $4.5 million, or 55%, compared to the same period in 2019. The decrease resulted from the announcement made in June 2019 regarding the closing of our Phase 3 AIM2CERV study in high-risk locally advanced cervical cancer. We anticipate that we will continue to incur costs associated with the wind down of the study. Additionally, a winding down of several studies, including our Fawcett study in anal cancer and our MEDI4736 study in combination with MedImmune's investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab, drove further reduction in costs as compared to the prior period. We anticipate that our costs surrounding HPV-associated studies will continue to decline as we wrap up the remaining clinical and regulatory obligations of the program. We currently do not anticipate funding any new AXAL studies.

Personalized Neoantigen-Directed Therapies (ADXS-NEO)

Research and development costs associated with personalized neoantigen-directed therapies for the fiscal year ended October 31, 2020 decreased approximately $1.7 million, or 57%, compared to the same period in 2019. In October 2019, we announced that we enrolled our last patient in the ADXS-NEO program in monotherapy and will not continue into Part B of this study. As a result, the costs incurred for ADXS-NEO during the fiscal year ended October 31, 2020 consisted of wind down costs associated with terminating the study. We anticipate that we will incur wind down costs for this study and we plan to close our ADXS-NEO program IND as a next step.

Other Expenses

Other expenses include salary and benefit costs, stock-based compensation expense, professional fees, laboratory costs and other internal and external costs associated with our research & development activities. Other expenses for the fiscal year ended October 31, 2020 decreased approximately $5.3 million, or 46%, compared to the same period in 2019. The decrease was primarily attributable to a decrease in salary related expenses, including stock compensation, and travel expenses resulting from cost control measures put in place beginning in June 2018. In addition, there were decreases in laboratory and manufacturing costs, as we are focused on the clinical development of our HOT program and less on early research programs. Additionally, we announced in October 2019 that we are winding down ADXS-NEO and therefore no longer incurring costs to manufacture ADXS-NEO.

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, outside legal and professional services, and facilities costs. General and administrative expenses for the years ended October 31, 2020 and 2019 were as follows (in thousands):

	Years Ended October 31,		Increase (Decrease)	
	2020	2019	$	%
General and administrative expense	$ 11,090	$ 12,179	$ (1,089)	(9)%
Stock-based compensation expense included in general and administrative expense	$ 583	$ 966	$ (383)	(40)%

General and administrative expenses for the fiscal year ended October 31, 2020 decreased approximately $1.1 million, or 9%, compared to the same period in 2019. The decrease is attributable to lower legal fees and business development costs partially offset by increased abandonment of certain non-strategic intellectual property.

Changes in Fair Values

For the fiscal year ended October 31, 2020, we recorded non-cash expense from changes in the fair value of the warrant liability of $0.

For the fiscal year ended October 31, 2019, we recorded non-cash income from changes in the fair value of the warrant liability of approximately $2.6 million. The decrease in the fair value of liability warrants resulted from a decrease in our share price from $0.56 at October 31, 2018 to $0.32 at October 31, 2019, as well as a decrease in the number of liability warrants as a result of the warrant exchange (see *Loss on shares issued in settlement of warrants* below*).*

Loss on shares issued in settlement of warrants

On October 16, 2020, the Company entered into private exchange agreements with certain holders of warrants issued in connection with the Company's January 2020 public offering of common stock and warrants. The warrants being exchanged provide for the purchase of up to an aggregate of 5,000,000 shares of our common stock at an exercise price of $1.25 per share. The warrants became exercisable on July 21, 2020 and have an expiration date of July 21, 2025. Pursuant to such exchange agreements, the Company agreed to issue 3,000,000 shares of common stock to the investors in exchange for the warrants. In connection with the exchange of warrants for common stock, the Company recorded a loss of approximately $77 thousand as the fair value of the shares issued exceeded the fair value of warrants exchanged.

On March 14, 2019, we entered into private exchange agreements with certain holders of warrants issued in connection with our September 2018 public offering of common stock and warrants. Pursuant to the exchange agreements, we issued 856,865 shares of common stock to the investors in exchange for warrants on a 1:1 basis. In connection with the warrant exchange, we recorded a loss of approximately $1.6 million for the fiscal year ended October 31, 2019.

Liquidity and Capital Resources

Management's Plans

Similar to other development stage biotechnology companies, our products that are being developed have not generated significant revenue. As a result, we have suffered recurring losses and we require significant cash resources to execute our business plans. These losses are expected to continue for the foreseeable future.

Historically, our major sources of cash have comprised proceeds from various public and private offerings of our securities (including our common stock), debt financings, clinical collaborations, option and warrant exercises, income earned on investments and grants, and interest income. From October 2013 through October 31, 2020, we raised approximately $309.4 million in gross proceeds ($17.2 million in fiscal year 2020) 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, 2020 and 2019, we had an accumulated deficit of approximately $410.7 million and $384.3 million, respectively, and stockholders' equity of approximately $30.2 million and $39.5 million, respectively.

The COVID-19 pandemic has negatively affected the global economy and created significant volatility and disruption of financial markets. An extended period of economic disruption could negatively affect our business, financial condition, and access to sources of liquidity. As of October 31, 2020, we had approximately $25.2 million in cash and cash equivalents. The actual amount of cash that we will need to continue operating 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.

The Company has reduced its operating expenses to $26.7 million for the fiscal year ended October 31, 2020 as compared to $38.9 million during the comparable prior period. Based on this, we expect to have sufficient capital to fund our obligations as they become due in the ordinary course of business until at least January 2022. In addition, we expect to adjust spending accordingly based on the budgeted cash flow requirements developed and the excess cash on hand.

We recognize that we will need to raise additional capital in order to continue to execute our 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 further scale back our operations.

On May 8, 2020, the Company entered into a sales agreement related to an at-the-market equity offering program pursuant to which the Company may sell, from time to time, common stock with an aggregate offering price of up to $40 million through A.G.P./Alliance Global Partners, as sales agent, for general corporate purposes.

On July 30, 2020, the Company entered into a purchase agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Over the 36-month term of the purchase agreement, the Company has the right, but not the obligation, from time to time, in its sole discretion and subject to certain conditions, to direct Lincoln Park to purchase up to an aggregate amount of $20,000,000 of its common stock, subject to certain limitations.

Due to the current state of the Company's stock price and general market conditions, these programs have not been utilized to their fullest extent, thereby resulting in lower capital availability than anticipated. Management's plans to mitigate an expected shortfall of capital and to support future operations include obtaining additional funds through partnerships or strategic or financing investors.

Cash Flows

Operating Activities

Net cash used in operating activities was approximately $21.9 million for the fiscal year ended October 31, 2020 compared to $36.1 million for the fiscal year ended October 31, 2019. Net cash used in operating activities includes reduced spending associated with our clinical trial programs and general and administrative activities. The decrease was due to measures to control costs for non-essential items in areas that did not support our strategic direction, and as a result, we have continued to reduce non-strategic operating expenditures over the past several quarters.

Investing Activities

Net cash used in investing activities was approximately $0.7 million for the fiscal year ended October 31, 2020 compared to $1.2 million for the nine months ended July 31, 2019. The reduction is a result of the abandonment of certain non-strategic intellectual property.

Financing Activities

Net cash provided by financing activities was approximately $15.5 million for the fiscal year ended October 31, 2020 as compared to $24.6 million for the fiscal year ended October 31, 2019. In January 2020, we completed a public offering of 10,000,000 shares of our common stock, which resulted in net proceeds of approximately $9.7 million. Additionally, during the year end October 31, 2020, we sold 2,489,104 shares under the ATM program for net proceeds of $1.531 million, and we sold 11,242,048 shares of common stock under the Lincoln Park Purchase Agreement for net proceeds of approximately $5.1 million. In fiscal year 2019, we received net proceeds of approximately $24.5 million from the sales of 13,150,000 shares of our common stock and 13,656,000 pre-funded warrants in public offerings.

On November 27, 2020, the Company completed an underwritten public offering of 26,666,666 shares of common stock and common stock warrants to purchase up to 13,333,333 shares of common stock (the "November 2020 Offering"). On November 24, 2020, the underwriters notified us that they had exercised their option to purchase an additional 3,999,999 shares of common stock and 1,999,999 warrants in full. After giving effect to the full exercise of the underwriters' option, we issued and sold an aggregate 30,666,665 shares of common stock and warrants to purchase up to 15,333,332 shares of common stock pursuant to our existing shelf registration statement on Form S-3 (File No. 333-226988). We received gross proceeds of approximately $9.2 million, before deducting the underwriting discounts and commissions and fees and expenses payable by us in connection with the November 2020 Offering.

Off-Balance Sheet Arrangements

As of October 31, 2020, we had no off-balance sheet arrangements.

Critical Accounting Policies

Revenue Recognition

Effective November 1, 2018, the Company adopted ASC Topic 606, *Revenue form Contracts with Customers* (ASC 606), using the modified retrospective transition method. Under this method, results for reporting periods beginning on November 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with ASC Topic 605, *Revenue Recognition* (ASC 605). The Company only applied the modified retrospective transition method to contracts that were not completed as of November 1, 2018, the effective date of adoption for ASC 606. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company enters into licensing agreements that are within the scope of ASC 606, under which it may exclusively license rights to research, develop, manufacture and commercialize its product candidates to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, upfront license fees; reimbursement of certain costs; customer option exercise fees; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for these arrangements, the Company must use significant judgment to determine: (a) the number of performance obligations based on the determination under step (ii) above; (b) the transaction price under step (iii) above; and (c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above. The Company uses judgment to determine whether milestones or other variable consideration, except for royalties, should be included in the transaction price as described further below. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied.

Amounts received prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

Exclusive Licenses. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. In assessing whether a performance obligation is distinct from the other performance obligations, the Company considers factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the collaboration partner can benefit from a performance obligation for its intended purpose without the receipt of the remaining performance obligation, whether the value of the performance obligation is dependent on the unsatisfied performance obligation, whether there are other vendors that could provide the remaining performance obligation, and whether it is separately identifiable from the remaining performance obligation. For licenses that are combined with other performance obligation, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the research and development and licensing agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

Research and Development Services. The performance obligations under the Company's collaboration agreements may include research and development services to be performed by the Company on behalf of the partner. Payments or reimbursements resulting from the Company's research and development efforts are recognized as the services are performed and presented on a gross basis because the Company is the principal for such efforts.

Milestone Payments. At the inception of each arrangement that includes research or development milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. An output method is generally used to measure progress toward complete satisfaction of a milestone. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and earnings in the period of adjustment.

Royalties. For arrangements that include sales-based royalties, including milestone payments based on a level of sales, which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied.

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. The fair value of the award is measured on the grant date and 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.

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 simulation 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 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 fiscal year ended October 31, 2017.

Leases

Effective November 1, 2019, the Company adopted ASC Topic 842, *Leases* ("ASC 842") using the modified retrospective transition approach by applying the new standard to all leases existing as of the date of initial application. Results and disclosure requirements for reporting periods beginning after November 1, 2019 are presented under ASC 842, while prior period amounts have not been adjusted and continue to be reported in accordance with the previous guidance in ASC 840, *Leases*.

At the inception of an arrangement, the Company determines whether an arrangement is or contains a lease based on the facts and circumstances present in the arrangement. An arrangement is or contains a lease if the arrangement conveys the right to control the use of an identified asset for a period of time in exchange for consideration. Most leases with a term greater than one year are recognized on the balance sheet as operating lease right-of-use assets and current and long-term operating lease liabilities, as applicable. The Company has elected not to recognize on the balance sheet leases with terms of 12 months or less. The Company typically only includes the initial lease term in its assessment of a lease arrangement. Options to extend a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew.

Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as prepaid or accrued rent. The interest rate implicit in the Company's leases is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. In transition to ASC 842, the Company utilized the remaining lease term of its leases in determining the appropriate incremental borrowing rates.

New Accounting Standards

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

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.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and interim Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures reflects the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

As required by Rule 13a-15(b) under the Exchange Act, our management, under the supervision and with the participation of our Chief Executive Officer and interim Chief Financial Officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures as of October 31, 2020. Based on such evaluation, our Chief Executive Officer and interim Chief Financial Officer concluded that, as of October 31, 2020, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. With the participation of our Chief Executive Officer and interim Chief Financial Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of October 31, 2020. In conducting such evaluation, management used the criteria set forth in the report entitled "*Internal Control — Integrated Framework*" published by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) to evaluate the effectiveness of our internal control over financial reporting. Based on this evaluation, management has concluded that our internal control over financial reporting was effective as of October 31, 2020, based on those criteria.

This report does not include an attestation report of our independent registered public accounting firm regarding our internal control over financial reporting, in accordance with applicable SEC rules that permit us to provide only management's report in this report.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting during the fiscal year ended October 31, 2020, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements prepared for external purposes in accordance with generally accepted accounting principles. Because of 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 because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2021 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 2020 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 2021 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 2021 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 2021 Annual Meeting of Stockholders.

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	Certificate of Designation of Series C Junior Participating Preferred Stock of Advaxis, Inc. Incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the SEC on September 29, 2020.
3.11	Amended and Restated Bylaws. Incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K filed with the SEC on September 29, 2020.
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)
4.7	Form of Common Stock Warrant dated January 21, 2020. Incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on January 23, 2020.
4.8	Form of Common Stock Warrant dated November 27, 2020. Incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on November 27, 2020.
4.9*	Form of Warrant Exchange Agreement, dated October 16, 2020.
4.10	Rights Agreement, dated as of September 29, 2020, by and between Advaxis, Inc. and Continental Stock Transfer and Trust Company, as rights agent. Incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on September 29, 2020.
10.1	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.
10.2	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.
10.3	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.
10.4	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.

10.5	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.
10.6	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.
10.7	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.
10.8	Indemnification Agreement. Incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed with the SEC on August 20, 2013.
10.9 ‡	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.
10.10	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.
10.11‡	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.
10.12	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.
10.13	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.
10.14‡	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.
10.15	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.
10.16	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.
10.17	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.
10.18	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.
10.19	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.
10.20	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
10.21‡	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.

10.22	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.
10.23‡	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.
10.24	2015 Incentive Plan of registrant. Incorporated by reference to Annex A to DEF 14A Proxy Statement filed with the SEC on April 7, 2015.
10.25	Amendment to the Advaxis, Inc. 2015 Incentive Plan. Incorporated by reference to Exhibit B to DEF 14A Proxy Statement filed with the SEC on February 11, 2016.
10.26	Amendment to the Advaxis, Inc. 2015 Incentive Plan. Incorporated by reference to Exhibit A to DEF 14A Proxy Statement filed with the SEC on February 10, 2017.
10.27	Amendment to the Advaxis, Inc. 2015 Incentive Plan. Incorporated by reference to Exhibit A to DEF 14A Proxy Statement filed with the SEC on March 20, 2020.
10.28‡	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.
10.29	2018 Employee Stock Purchase Plan. Incorporated by reference Exhibit B to the DEF14A Proxy Statement filed with the SEC on February 6, 2018.
10.30	Sales Agreement, dated May 8, 2020, by and between Advaxis, Inc. and A.G.P./Alliance Global Partners (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on May 8, 2020)
10.31	Purchase Agreement, dated July 30, 2020, by and between Advaxis, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 3, 2020)
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 interim 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 interim 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 22nd day of January 2021.

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 (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, Director and interim Chief Financial Officer (Principal Executive Officer, Principal Financial and Accounting Officer)	January 22, 2021
/s/ David Sidransky David Sidransky	Chairman of the Board	January 22, 2021
/s/ James Patton James Patton	Vice Chairman of the Board	January 22, 2021
/s/ Richard Berman Richard Berman	Director	January 22, 2021
/s/ Samir Khleif Samir Khleif	Director	January 22, 2021
/s/ Roni Appel Roni Appel	Director	January 22, 2021

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, 2020 and 2019, the related statements of operations, stockholders' equity and cash flows for each of the two years in the period ended October 31, 2020, 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 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended October 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

As discussed in Note 2 to the financial statements, the Company has changed its method of accounting for leases in 2020 due to the adoption of the guidance in ASC Topic 842, Leases ("Topic 842"), as amended, effective November 1, 2019, using the modified retrospective transition approach.

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 Public Company Accounting Oversight Board (United States) ("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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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 22, 2021

ADVAXIS, INC.
BALANCE SHEETS
(In thousands, except share and per share data)

	October 31, 2020	October 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 25,178	$ 32,363
Deferred expenses	1,808	2,353
Prepaid expenses and other current assets	865	1,433
Total current assets	27,851	36,149
Property and equipment (net of accumulated depreciation)	2,393	4,350
Intangible assets (net of accumulated amortization)	3,261	4,575
Operating right-of-use asset (net of accumulated amortization)	4,839	-
Other assets	182	183
Total assets	$ 38,526	$ 45,257
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 410	$ 976
Accrued expenses	1,737	3,478
Current portion of operating lease liability	962	-
Deferred revenue	165	-
Common stock warrant liability	17	19
Other current liabilities	-	48
Total current liabilities	3,291	4,521
Operating lease liability, net of current portion	5,055	-
Other liabilities	-	1,205
Total liabilities	8,346	5,726
Commitments and contingencies – Note 9		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; Series B Preferred Stock; 0 shares issued and outstanding at October 31, 2020 and 2019. Liquidation preference of $0 at October 31, 2020 and 2019.	-	-
Common stock - $0.001 par value; 170,000,000 shares authorized, 78,074,023 and 50,201,671 shares issued and outstanding at October 31, 2020 and 2019.	78	50
Additional paid-in capital	440,840	423,750
Accumulated deficit	(410,738)	(384,269)
Total stockholders' equity	30,180	39,531
Total liabilities and stockholders' equity	$ 38,526	$ 45,257

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,	
	2020	2019
Revenue	$ 253	$ 20,884
Operating expenses:		
Research and development expenses	15,612	26,677
General and administrative expenses	11,090	12,179
Total operating expenses	26,702	38,856
Loss from operations	(26,449)	(17,972)
Other income (expense):		
Interest income	110	435
Net changes in fair value of derivative liabilities	-	2,589
Loss on shares issued in settlement of warrants	(77)	(1,607)
Other expense	(3)	(7)
Net loss before income tax benefit	(26,419)	(16,562)
Income tax expense	50	50
Net loss	$ (26,469)	$ (16,612)
Net loss per common share, basic and diluted	$ (0.43)	$ (1.09)
Weighted average number of common shares outstanding, basic and diluted	61,003,839	15,207,637

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

ADVAXIS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share and per share data)

	Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Shareholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance at October 31, 2018	-	$ -	4,634,189	$ 5	$ 391,703	$ (367,657)	$ 24,051
Stock-based compensation			12,220		2,002	-	2,002
Tax withholdings paid on equity awards	-	-	-	-	(15)	-	(15)
Tax shares sold to pay for tax withholdings on equity awards	-	-	-	-	14	-	14
Issuance of shares to employees under ESPP Plan	-	-	7,435	-	20	-	20
ESPP Expense	-	-	-	-	2		2
Pre-funded warrant exercises	-	-	13,656,000	13	-	-	13
Warrant exercises	-	-	17,884,962	18	104	-	122
Shares issued in settlement of warrants	-	-	856,865	1	5,462	-	5,463
Advaxis public offerings	-	-	13,150,000	13	24,458	-	24,471
Net Loss	-	-	-	-		(16,612)	(16,612)
Balance at October 31, 2019	-	$ -	50,201,671	$ 50	$ 423,750	$ (384,269)	$ 39,531
Stock-based compensation	-	-	8,870	-	891	-	891
Tax withholdings paid on equity awards	-	-	-	-	(1)	-	(1)
Tax shares sold to pay for tax withholdings on equity awards	-	-	-	-	1	-	1
Issuance of shares to employees under ESPP Plan	-	-	14,148	-	7	-	7
ESPP Expense	-	-	-	-	1	-	1
Warrant exercises	-	-	33,916	-	2	-	2
Shares issued in settlement of warrants	-	-	3,000,000	3	74	-	77
Advaxis public offerings	-	-	10,000,000	10	9,618	-	9,628
At-the-market shares issued	-	-	2,489,104	3	1,435	-	1,438
Commitment fee shares issued for equity line	-	-	1,084,266	1	643	-	644
Shares issued under equity line	-	-	11,242,048	11	4,419	-	4,430
Net Loss	-	-	-	-	-	(26,469)	(26,469)
Balance at October 31, 2020	-	$ -	78,074,023	$ 78	$ 440,840	$ (410,738)	$ 30,180

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,	
	2020	2019
OPERATING ACTIVITIES		
Net loss	$ (26,469)	$ (16,612)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock compensation	891	2,002
Employee stock purchase plan expense	1	3
Gain on change in value of warrants	-	(2,589)
Loss on shares issued in settlement of warrants	77	1,607
Loss on disposal of property and equipment	-	344
Loss on write-down of property and equipment	1,060	943
Abandonment of intangible assets	1,725	1,104
Depreciation expense	897	1,097
Amortization of deferred offering costs	644	-
Amortization expense of intangible assets	337	386
Amortization expense of right-of-use assets	744	-
Change in operating assets and liabilities:		
Accounts receivable	-	1,664
Prepaid expenses and other current assets	1,113	(103)
Other assets	1	18
Accounts payable and accrued expenses	(2,307)	(7,377)
Deferred revenue	165	(18,665)
Operating lease liabilities	(819)	-
Other liabilities	-	50
Net cash used in operating activities	(21,940)	(36,128)
INVESTING ACTIVITIES		
Purchase of property and equipment	-	(54)
Proceeds from disposal of property and equipment	-	83
Cost of intangible assets	(748)	(1,227)
Net cash used in investing activities	(748)	(1,198)
FINANCING ACTIVITIES		
Net proceeds from issuance of common stock and pre-funded warrants	15,496	24,471
Warrant exercises	-	68
Pre-funded warrant exercises	-	13
Proceeds from employee stock purchase plan	7	20
Employee tax withholdings paid on equity awards	(1)	(15)
Tax shares sold to pay for employee tax withholdings on equity awards	1	14
Net cash provided by financing activities	15,503	24,571
Net decrease in cash and cash equivalents	(7,185)	(12,755)
Cash and cash equivalents at beginning of year	32,363	45,118
Cash and cash equivalents at end of year	$ 25,178	$ 32,363

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

Supplemental Disclosures of Cash Flow Information

	Year Ended October 31,	
	2020	2019
Cash paid for taxes	$ 50	$ 50

Supplemental Schedule of Noncash Investing and Financing Activities

	Year Ended October 31,	
	2020	2019
Shares issued in settlement of warrants	$ 77	$ 5,463
Warrant liability reclassified into equity	$ -	$ 54
Reclass of security deposit to property and equipment for delivered equipment	$ -	$ 79
Commitment fee shares issued for equity line	$ 644	$ -
Cashless exercise of warrants	$ 2	$ -

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

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Advaxis, Inc. ("Advaxis" or the "Company") is a clinical-stage biotechnology company focused on the 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 is designed to deploy a unique mechanism of action that redirects the immune system to attack cancer 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 demonstrated clinical activity in several of its programs and has been dosed in over 470 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, its product candidates have the potential to work synergistically with other immunotherapies, including checkpoint inhibitors, while having a generally well-tolerated safety profile.

Liquidity and Managements Plans

The Company has not yet commercialized any human products and the 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.

Historically, the Company's major sources of cash have been comprised of proceeds from various public and private offerings of its common stock, debt financings, clinical collaborations, option and warrant exercises, income earned on investments and grants and interest income. From October 2013 through October 2020, the Company raised approximately $309.4 million in gross proceeds ($17.2 million in fiscal year 2020) from various public and private offerings of its common stock.

As of October 31, 2020, the Company had approximately $25.2 million in cash and cash equivalents. Although the Company expects to have sufficient capital to fund its obligations, as they become due, in the ordinary course of business until at least January 2022, the actual amount of cash that it will need to operate is subject to many factors. Over the past several months, the Company has taken steps to obtain additional financing, including the at-the-market ("ATM") program and the equity line with Lincoln Park Capital. Due to the current state of the Company's stock price and general market conditions, these programs have not been utilized to the fullest extent, thereby resulting in lower capital availability than anticipated. Management's plans to mitigate an expected shortfall of capital and to support future operations include obtaining additional funds through partnerships or strategic or financing investors. The Company was able to raise additional funds subsequent to year end more fully described in the subsequent events footnote (Note 15). The Company has reduced its operating expenses to $26.7 million for the fiscal year ended October 31, 2020 as compared to $38.9 million during the comparable prior period. With these funds raised and a reduction in the operating expenses the Company believes that it has enough cash to fund its operations for one year from the date of filing. Therefore, such conditions of substantial doubt as of October 31, 2020 have subsequently been alleviated.

The Company 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 further 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), determining the Incremental Borrowing Rate ("IBR") for calculating Right-Of-Use ("ROU") assets and lease liabilities, deferred expenses, deferred revenue, the fair value of options, warrants and related disclosure of contingent assets and liabilities. The Company bases its estimates on historical experience and on various other assumptions that it believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. On an ongoing basis, the Company reviews its estimates to ensure that they appropriately reflect changes in the business or as new information becomes available. Actual results may differ from these estimates.

Revenue Recognition

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company enters into licensing agreements that are within the scope of ASC 606, under which it may exclusively license rights to research, develop, manufacture and commercialize its product candidates to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, upfront license fees; reimbursement of certain costs; customer option exercise fees; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for these arrangements, the Company must use significant judgment to determine: (a) the number of performance obligations based on the determination under step (ii) above; (b) the transaction price under step (iii) above; and (c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above. The Company uses judgment to determine whether milestones or other variable consideration, except for royalties, should be included in the transaction price as described further below. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied.

Amounts received prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

Exclusive Licenses. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. In assessing whether a performance obligation is distinct from the other performance obligations, the Company considers factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the collaboration partner can benefit from a performance obligation for its intended purpose without the receipt of the remaining performance obligation, whether the value of the performance obligation is dependent on the unsatisfied performance obligation, whether there are other vendors that could provide the remaining performance obligation, and whether it is separately identifiable from the remaining performance obligation. For licenses that are combined with other performance obligation, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the research and development and licensing agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

Research and Development Services. The performance obligations under the Company's collaboration agreements may include research and development services to be performed by the Company on behalf of the partner. Payments or reimbursements resulting from the Company's research and development efforts are recognized as the services are performed and presented on a gross basis because the Company is the principal for such efforts.

Milestone Payments. At the inception of each arrangement that includes research or development milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. An output method is generally used to measure progress toward complete satisfaction of a milestone. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and earnings in the period of adjustment.

Royalties. For arrangements that include sales-based royalties, including milestone payments based on a level of sales, which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied.

Collaborative Arrangements

The Company analyzes its collaboration arrangements to assess whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities and therefore within the scope of ASC Topic 808, *Collaborative Arrangements* (ASC 808). This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and which elements of the collaboration are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to ASC 606. Amounts that are owed to collaboration partners are recognized as an offset to collaboration revenue as such amounts are incurred by the collaboration partner. For those elements of the arrangement that are accounted for pursuant to ASC 606, the Company applies the five-step model described above under ASC 606.

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 $24.1 million is subject to credit risk at October 31, 2020. The Company has not experienced any losses in such accounts.

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 periodically assesses the carrying value of intangible and other long-lived assets, and whenever events or changes in circumstances indicate that the carrying amount of an asset might not be recoverable. The assets are considered to be impaired if the Company determines that the carrying value may not be recoverable based upon its assessment, which includes consideration of the following events or changes in circumstances:

- the asset's ability to continue to generate income from operations and positive cash flow in future periods;
- loss of legal ownership or title to the asset(s);
- significant changes in the Company's strategic business objectives and utilization of the asset(s); and
- the impact of significant negative industry or economic trends.

If the assets are considered to be impaired, the impairment recognized is the amount by which the carrying value of the assets exceeds the fair value of the assets. Fair value is determined by the application of discounted cash flow models to project cash flows from the assets. In addition, the Company bases estimates of the useful lives and related amortization or depreciation expense on its subjective estimate of the period the assets will generate revenue or otherwise be used by it. Assets to be disposed of are reported at the lower of the carrying amount or fair value, less selling costs. The Company also periodically reviews the lives assigned to long-lived assets to ensure that the initial estimates do not exceed any revised estimated periods from which the Company expects to realize cash flows from its assets.

Leases

Effective November 1, 2019, the Company adopted ASC Topic 842, *Leases* ("ASC 842") using the modified retrospective transition approach by applying the new standard to all leases existing as of the date of initial application. Results and disclosure requirements for reporting periods beginning after November 1, 2019 are presented under ASC 842, while prior period amounts have not been adjusted and continue to be reported in accordance with the previous guidance in ASC 840, *Leases*.

At the inception of an arrangement, the Company determines whether an arrangement is or contains a lease based on the facts and circumstances present in the arrangement. An arrangement is or contains a lease if the arrangement conveys the right to control the use of an identified asset for a period of time in exchange for consideration. Most leases with a term greater than one year are recognized on the balance sheet as operating lease right-of-use assets and current and long-term operating lease liabilities, as applicable. The Company has elected not to recognize on the balance sheet leases with terms of 12 months or less. The Company typically only includes the initial lease term in its assessment of a lease arrangement. Options to extend a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew.

Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as prepaid or accrued rent. The interest rate implicit in the Company's leases is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. In transition to ASC 842, the Company utilized the remaining lease term of its leases in determining the appropriate incremental borrowing rates.

Net Income (Loss) per Share

Basic net income or loss per common share is computed by dividing net income or loss available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted earnings per share give effect to dilutive options, warrants, restricted stock units 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, 2020, 327,338 warrants are included in the basic earnings per share computation because the exercise price is $0, and as of October 31, 2019, 13,079,000 pre-funded warrants are included in the basic earnings per share computation because the exercise price is nominal):

	As of October 31,	
	2020	2019
Warrants	398,226	432,142
Stock options	1,011,768	560,490
Restricted stock units	5,556	14,706
Total	1,415,550	1,007,338

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. The fair value of the award is measured on the grant date and 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.

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 simulation model to value the derivative instruments at inception and on subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the instrument could be required within 12 months of the balance sheet date.

Income Taxes

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

Recent Accounting Standards

In December 2019, the FASB issued authoritative guidance intended to simplify the accounting for income taxes (ASU 2019-12, "*Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*"). This guidance eliminates certain exceptions to the general approach to the *income* tax accounting model and adds new guidance to reduce the complexity in accounting for income taxes. This guidance is effective for annual periods after December 15, 2020, including interim periods within those annual periods. The Company is currently evaluating the potential impact of this guidance on its consolidated financial statements.

Recently Adopted Accounting Standards

On November 1, 2019, the Company adopted Accounting Standards Update No. 2016-02, *Leases* (Topic 842) (ASU 2016-02), as amended, which establishes ASC 842 and supersedes the lease accounting guidance under ASC 840, and generally requires lessees to recognize operating and financing lease liabilities and corresponding right-of-use (ROU) assets on the balance sheet and to provide enhanced disclosures surrounding the amount, timing and uncertainty of cash flows arising from leasing arrangements. We adopted the new guidance using the modified retrospective transition approach by applying the new standard to all leases existing at the date of initial application and not restating comparative periods.

In adopting the new standard, the Company elected to utilize the available package of practical expedients permitted under the transition guidance within the new standard, which does not require the reassessment of the following: (i) whether existing or expired arrangements are or contain a lease, (ii) the lease classification of existing or expired leases, and (iii) whether previous initial direct costs would qualify for capitalization under the new lease standard. Additionally, the Company elected to combine lease and non-lease components and to exclude leases with a term of 12 months or less.

As of the November 1, 2019 effective date, the Company had identified one operating lease arrangement and one short-term lease in which it is a lessee. The adoption of ASC 842 resulted in the recognition of an operating lease liability and a right-of-use asset of approximately $6.8 million and $5.6 million, respectively, on the Company's balance sheet relating to its leases, with the difference relating to reclassifications of the current accrued rent liability and the current lease incentive obligation of approximately $0.9 million and $0.3 million, respectively, as reductions to the right-of-use-asset for its operating lease. The adoption of the standard did not have a material effect on the Company's statements of operations or statements of cash flows.

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

3. PROPERTY AND EQUIPMENT

Property and equipment consists of the following (in thousands):

	October 31,	
	2020	2019
Leasehold improvements	$ 2,335	$ 2,335
Laboratory equipment	1,218	3,405
Furniture and fixtures	744	744
Computer equipment	409	409
Construction in progress	19	83
Total property and equipment	4,725	6,976
Accumulated depreciation and amortization	(2,332)	(2,626)
Net property and equipment	$ 2,393	$ 4,350

Depreciation expense for the years ended October 31, 2020 and 2019 was approximately $0.9 million and $1.1 million, respectively. Disposals of laboratory equipment resulted in losses of approximately $0 and $0.3 million for the years ended October 31, 2020 and 2019, respectively, that was charged to research and development expenses in the statement of operations.

Management has reviewed its property and equipment for impairment whenever events and circumstances indicate that the carrying value of an asset might not be recoverable. During the years ended October 31, 2020 and 2019, the Company recorded impairment losses on idle laboratory equipment of $1.1 million and $0.9 million, respectively, that was charged to research and development expenses in the statement of operations. Fair value for the idle assets was determined by a quoted purchase price for the assets.

4. INTANGIBLE ASSETS

Intangible assets consist of the following (in thousands):

	October 31,	
	2020	2019
Patents	$ 4,479	$ 5,833
License	777	777
Software	117	117
Total intangibles	5,373	6,727
Accumulated amortization	(2,112)	(2,152)
Net intangible assets	$ 3,261	$ 4,575

The expirations of the existing patents range from 2020 to 2040 but the expirations can be extended based on market approval if granted and/or based on existing laws and regulations. Capitalized costs associated with patent applications that are abandoned without future value are charged to expense when the determination is made not to pursue the application. Patent applications having a net book value of approximately $1.7 million and $1.1 million were abandoned and were charged to general and administrative expenses in the statement of operations for the years ended October 31, 2020 and 2019, respectively. Intangible asset amortization expense that was charged to general and administrative expense in the statement of operations was approximately $0.3 million and $0.4 million for each of the years ended October 31, 2020 and 2019, respectively.

Management has reviewed its intangible assets for impairment whenever events and circumstances indicate that the carrying value of an asset might not be recoverable. Net assets are recorded on the balance sheet for patents and licenses related to axalimogene filolisbac (AXAL), ADXS-HOT, ADXS-PSA ADXS-HER2 and other products that are in development or out-licensed. 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. Lastly, if the Company is unable to raise enough capital to continue funding our studies and developing its intellectual property, the Company would likely record an impairment to certain of these assets.

At October 31, 2020, the estimated amortization expense by fiscal year based on the current carrying value of intangible assets is as follows (in thousands):

2021	$ 289
2022	289
2023	289
2024	289
2025	289
Thereafter	1,816
Total	$ 3,261

5. ACCRUED EXPENSES:

The following table represents the major components of accrued expenses (in thousands):

	October 31,	
	2020	2019
Salaries and other compensation	$ 737	$ 158
Vendors	671	3,194
Professional fees	329	126
Total accrued expenses	$ 1,737	$ 3,478

6. COMMON STOCK PURCHASE WARRANTS AND WARRANT LIABILITY

Warrants

As of October 31, 2020, there were outstanding warrants to purchase 398,226 shares of our common stock with exercise prices ranging from $0 to $281.25 per share. Information on the outstanding warrants is as follows:

Exercise Price	Number of Shares Underlying Warrants	Expiration Date	Summary of Warrants
$ -	327,338	July 2024	July 2019 Public Offering
$ 281.25	25	N/A	Other Warrants
$ 0.372	70,863	September 2024	September 2018 Public Offering
Grand Total	398,226		

As of October 31, 2019, there were outstanding warrants to purchase 432,142 shares of our common stock with exercise prices ranging from $0 to $281.25 per share. Information on the outstanding warrants is as follows:

Exercise Price	Number of Shares Underlying Warrants	Expiration Date	Summary of Warrants
$ -	359,838	July 2024	July 2019 Public Offering
$ 281.25	25	N/A	Other Warrants
$ 0.372	72,279	September 2024	September 2018 Public Offering
Grand Total	432,142		

A summary of warrant activity was as follows (In thousands, except share and per share data):

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life In Years	Aggregate Intrinsic Value
Outstanding and exercisable warrants at October 31, 2018	944,635	$ 22.50	5.87	$ -
Issued	31,885,500	-		
Exercised *	(31,540,962)	-		
Exchanged	(856,865)	0.37		
Expired	(166)	56.25		
Outstanding and exercisable warrants at October 31, 2019	432,142	$ 0.08	4.76	$ 114,069
Issued	5,000,000	1.25		
Exercised **	(33,916)	0.02		
Exchanged	(5,000,000)	1.25		
Outstanding and exercisable warrants at October 31, 2020	398,226	$ 0.08	3.76	$ 110,640

* Includes the cashless exercise of 17,869,662 warrants that resulted in the issuance of 17,869,662 shares of common stock.

** Includes the cashless exercise of 32,500 warrants that resulted in the issuance of 32,500 shares of common stock.

At October 31, 2020, the Company had 327,363 of its total 398,226 outstanding warrants classified as equity (equity warrants). At October 31, 2019, the Company had 359,863 of its total 432,142 outstanding warrants classified as equity (equity warrants). At issuance, equity warrants are recorded at their relative fair values, using the Relative Fair Value Method, in the shareholders equity section of the balance sheet.

Shares Issued in Settlement of Equity Warrants

On October 16, 2020, the Company entered into private exchange agreements with certain holders of warrants issued in connection with the Company's January 2020 public offering of common stock and warrants. The warrants being exchanged provide for the purchase of up to an aggregate of 5,000,000 shares of our common stock at an exercise price of $1.25 per share. The warrants became exercisable on July 21, 2020 and have an expiration date of July 21, 2025. Pursuant to such exchange agreements, the Company agreed to issue 3,000,000 shares of common stock to the investors in exchange for the warrants. The fair value of these warrants approximated the fair value of shares issued in the exchange for these warrants. The Company used the closing stock price to value the shares and Black Scholes model to value these warrants on the date of the exchange. In determining the fair warrant of the warrants issued on October 16, 2020, the Company used the following inputs in its Black-Sholes model: exercise price $1.25, stock price $0.406, expected term 4.76 years, volatility 101.18% and risk-free interest rate 0.32%. In connection with the exchange of warrants for common stock, the Company recorded a loss of approximately $77 thousand as the fair value of the shares issued exceeded the fair value of warrants exchanged.

Shares Issued in Settlement of Liability Warrants

On March 14, 2019, the Company entered into private exchange agreements with certain holders of warrants issued in connection with the Company's September 2018 public offering of common stock and warrants. The warrants being exchanged provided for the purchase of up to an aggregate of 856,865 shares of the Company's common stock at an exercise price of $22.50, with an expiration date of September 11, 2024. Pursuant to such exchange agreements, the Company issued 856,865 shares of common stock to the investors in exchange for such warrants on a 1:1 basis. The exchange of warrants for common stock caused the down round provision to be triggered for the first time and the exercise price of the warrants that were not exchanged were reduced from $22.50 to $4.50. The warrants were valued at approximately $3.9 million on the March 14, 2019 using the Monte Carlo simulation model. In determining the fair warrant of the warrants issued on March 14, 2019, the Company used the following inputs in its Monte Carlo simulation model: exercise price $22.50, stock price $6.45, expected term 5.50 years, volatility 96.37% and risk-free interest rate 2.44%. In connection with the exchange of warrants for common stock, the Company recorded a loss of approximately $1.6 million as the fair value of the shares issued exceeded the fair value of warrants exchanged.

Warrant Liability

At October 31, 2020, the Company had 70,863 of its total 398,226 outstanding warrants classified as liabilities (liability warrants). At October 31, 2019, the Company had 72,279 of its total 432,142 outstanding warrants classified as liabilities (liability warrants). These warrants contain a down round feature, except for exempt issuances as defined in the warrant agreement, in which the exercise price would immediately be reduced to match a dilutive issuance of common stock, options, convertible securities and changes in option price or rate of conversion.

As of October 31, 2020, the down round feature was triggered three times and the exercise price of the warrants were reduced from $22.50 to $0.372. The warrants require liability classification as the warrant agreement requires the Company to maintain an effective registration statement and does not specify any circumstances under which settlement in other than cash would be permitted or required. As a result, net cash settlement is assumed and liability classification is warranted. For these liability warrants, the Company utilized the Monte Carlo simulation model to calculate the fair value of these warrants at issuance and at each subsequent reporting date.

At October 31, 2020 and October 31, 2019, the fair value of the warrant liability was approximately $17,000 and $19,000, respectively. For the years ended October 31, 2020 and 2019, the Company reported income of approximately $0 and $2.6 million, respectively, due to changes in the fair value of the warrant liability.

In measuring the warrant liability, the Company used the following inputs in its Monte Carlo simulation model:

	October 31, 2020	October 31, 2019
Exercise Price	$ 0.37	$ 0.37
Stock Price	$ 0.34	$ 0.32
Expected Term	3.87 years	4.87 years
Volatility %	105.58%	100.99%
Risk Free Rate	0.29%	1.51%

7. SHARE BASED COMPENSATION

The following table summarizes share-based compensation expense included in the statement of operations by expense category for the years ended October 31, 2020 and 2019 (in thousands):

	Year Ended October 31,	
	2020	2019
Research and development	$ 308	$ 1,036
General and administrative	583	966
Total	$ 891	$ 2,002

Amendments

The Advaxis, Inc. 2015 Incentive Plan (the "2015 Plan") was originally ratified and approved by the Company's stockholders on May 27, 2015. Subject to proportionate adjustment in the event of stock splits and similar events, the aggregate number of shares of common stock that may be issued under the 2015 Plan is 240,000 shares, plus a number of additional shares (not to exceed 43,333) underlying awards outstanding as of the effective date of the 2015 Plan under the prior plan that thereafter terminate or expire unexercised, or are cancelled, forfeited or lapse for any reason.

At the Annual Meeting of Stockholders of the Company held on February 21, 2019, the Company's stockholders voted to approve an amendment to increase the number of authorized shares of common stock from 95,000,000 to 170,000,000 and also voted to approve an amendment to allow the Company to execute a reverse stock split of common stock at the discretion of the Board of Directors. The amendment to increase the number of authorized shares of common stock became effective upon filing of the amendment with the Secretary of State of the State of Delaware on February 28, 2019. Additionally, on March 29, 2019, the Company executed a 1 for 15 reverse stock split. On January 1, 2020, 166,667 shares were added to the 2015 Plan.

At the Annual Meeting of Stockholders of the Company held on May 4, 2020, the Company's stockholders voted to approve an amendment to increase the number of shares authorized for issuance under the 2015 Plan from 877,744 shares to 6,000,000 shares.

As of October 31, 2020, there were 4,856,116 shares available for issuance under the 2015 Plan.

Restricted Stock Units (RSUs)

A summary of the Company's RSU activity and related information for the fiscal year ended October 31, 2020 and 2019 is as follows:

	Number of RSU's	Weighted-Average Grant Date Fair Value
Unvested as of October 31, 2018	32,614	$ 70.41
Vested	(12,257)	78.41
Cancelled	(5,651)	112.39
Unvested as of October 31, 2019	14,706	$ 47.62
Vested	(8,870)	60.59
Cancelled	(280)	98.80
Unvested as of October 31, 2020	5,556	$ 24.32

The fair value of the RSUs as of the respective vesting dates was approximately $5,000 and $51,000 for the years ended October 31, 2020 and 2019, respectively.

As of October 31, 2020, there was approximately $64,000 of unrecognized compensation cost related to non-vested RSUs, which is expected to be recognized over a remaining weighted average vesting period of approximately 0.47 years.

As of October 31, 2020, the aggregate intrinsic value of non-vested RSUs was approximately $2,000.

Employee Stock Awards

Common stock issued to executives and employees related to vested incentive retention awards, employment inducements, management purchases and employee excellence awards totaled 8,870 shares and 12,245 shares during the years ended October 31, 2020 and 2019, respectively. Total stock compensation expense associated with these awards for the years ended October 31, 2020 and 2019 was approximately $0.2 million and $0.8 million, respectively.

Stock Options

A summary of changes in the stock option plan for the years ended October 31, 2020 and 2019 is as follows (in thousands, except share and per share data):

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life In Years	Aggregate Intrinsic Value
Outstanding as of October 31, 2018	330,071	$ 122.79	6.56	$ -
Granted	265,882	2.36		
Cancelled or expired	(35,463)	29.52		
Outstanding as of October 31, 2019	560,490	$ 71.56	7.34	$ 1
Granted	645,000	0.61		
Cancelled or expired	(193,722)	34.47		
Outstanding as of October 31, 2020	1,011,768	$ 33.43	8.04	$ 4
Vested and exercisable at October 31, 2020	307,467	$ 105.69	4.91	$ 1

The following table summarizes information about the outstanding and exercisable options at October 31, 2020:

Options Outstanding					Options Exercisable			
Exercise Price Range	Number Outstanding	Weighted Average Remaining Contractual	Weighted Average Exercise Price	Intrinsic Value	Number Exercisable	Weighted Average Remaining Contractual	Weighted Average Exercise Price	Intrinsic Value
$ .30-$10.00	746,579	9.41	$ 1.10	$ 1	68,655	8.67	$ 2.62	$ -
$ 10.01-$100.00	102,951	7.23	$ 28.77	$ -	76,574	7.16	$ 29.67	$ -
$100.01-$200.00	92,847	2.76	$ 166.04	$ -	92,847	2.76	$ 166.04	$ -
$200.01-$277.50	69,391	1.58	$ 210.79	$ -	69,391	1.58	$ 210.79	$ -

The fair value of each option granted from the Company's stock option plans during the years ended October 31, 2020 and 2019 was estimated on the date of grant using the Black-Scholes option-pricing model. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of the Company's common stock price, (ii) the periods of time over which employees and Board Directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on the Company's common stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating expected lives of the options. The Company used their own historical volatility in determining the volatility to be used. The expected term of the stock option grants was calculated using the "simplified" method in accordance with the SEC Staff Accounting Bulletin 107. The "simplified" method was used since the Company believes its historical data does not provide a reasonable basis upon which to estimate expected term and the Company does not have enough option exercise data from its grants issued to support its own estimate as a result of vesting terms and changes in the stock price. The expected dividend yield is zero as the Company has never paid dividends to common shareholders and does not currently anticipate paying any in the foreseeable future.

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

	Year Ended	
	October 31, 2020	October 31, 2019
Expected term	5.50-6.50 years	5.50-6.51 years
Expected volatility	100.27-105.21%	90.24-104.99%
Expected dividends	0%	0%
Risk free interest rate	0.36-0.62%	1.35-3.15%

Total compensation cost related to the Company's outstanding stock options, recognized in the statement of operations for the years ended October 31, 2020 and 2019 was approximately $0.7 million and $1.2 million, respectively.

During the fiscal year ended October 31, 2020, 645,000 options were granted with a total grant date fair value of approximately $0.3 million. During the fiscal year ended October 31, 2019, 265,882 options were granted with a total grant date fair value of approximately $0.5 million.

As of October 31, 2020, there was approximately $0.6 million of unrecognized compensation cost related to non-vested stock option awards, which is expected to be recognized over a remaining weighted average vesting period of approximately 1.50 years.

Employee Stock Purchase Plan

The Advaxis, Inc. 2018 Employee Stock Purchase Plan (ESPP) was approved by the Company's shareholders on March 21, 2018. The 2018 ESPP allows employees to purchase common stock of the Company at a 15% discount to the market price on designated exercise dates. Employees were eligible to participate in the 2018 ESPP beginning May 1, 2018. 1,000,000 shares of the Company's Common stock are reserved for issuance under the 2018 ESPP.

During the fiscal year ended October 31, 2020, 14,148 shares were issued under the 2018 ESPP and the Company recorded an expense of approximately $1,000. During the fiscal year ended October 31, 2019, 7,435 shares were issued under the 2018 ESPP and the Company recorded an expense of approximately $2,000.

As of October 31, 2020, 976,517 shares of Company's common stock remain available for issuance under the 2018 ESPP.

8. COLLABORATION AND LICENSING AGREEMENTS

OS Therapies LLC

On September 4, 2018, the Company entered into a development, license and supply agreement with OS Therapies ("OST") 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, as amended, OST will be responsible for the conduct and funding of a clinical study evaluating ADXS-HER2 in recurrent, completely resected osteosarcoma. Under the most recent amendment to the licensing agreement, OST agrees to pay Advaxis $25,000 per month ("Monthly Payment") starting on April 30, 2020 until it achieves its funding milestone of $2,337,500. Upon receipt of the first Monthly Payment, Advaxis will initiate the transfer of the intellectual property and licensing rights of ADXS31-164, which were licensed pursuant to the Penn Agreement, back to the University of Pennsylvania. Contemporaneously, OST will enter negotiations with the University of Pennsylvania to establish a licensing agreement for ADXS31-164 to OST for clinical and commercial development of the ADXS31-164 technology.

Provided that OST meets its ongoing obligation to make its Monthly Payments to Advaxis for six consecutive months, Advaxis agrees to transfer, and OST agrees to take full ownership of, the IND application for ADXS31-164 in its entirety to OST, along with agreements and promises contained therein, as well as all obligations associated with this IND or any HER2 product/program development. Until OST makes its Monthly Payments to Advaxis for six consecutive months, Advaxis will continue to bear the costs of the regulatory filing services related to the IND application for ADXS31-164.

Within five business days of achieving the funding milestone of $2,337,500 for the performance of the Children's Oncology Group study (knowns as the "License Commencement Date"), OST will make a non-refundable and non-creditable payment to Advaxis of $1,550,000 less the cumulative Monthly Payments previously made (the "License Commencement Payment"). Within five days following the License Commencement Date, Advaxis will provide existing drug supply "as is" to OST, and until the drug supply is supplied to OST, Advaxis will bear the storage costs for the drug product. Pursuant to the agreement, the Company is also to receive sales-based milestone payments and royalties on future product sales. In addition, the Company and OST will establish a Joint Steering Committee to oversee the R&D activities.

The promises to (1) Maintain the HER2 product until transfer to OST, (2) Provide the IND application ownership for ADX321-164 to OST, (3) Participate in the Joint Steering Committee, (4) Transfer of IP & licensing rights of ADXS31-164 and related Patents, and (5) Provide Clinical Drug Supply represent one combined performance obligation for revenue recognition purposes. The Company concluded that the transfer of the IP and licensing rights provides OST with a functional, or "right to use," license, and thus the Company will recognize the upfront fees of $1,550,000 from the license at a point in time. The revenue from the transfer of the license cannot be recognized until the transfer of the corresponding IP to OST has occurred and OST has the ability to benefit from the right to use the license. As the right to use the license begins when OST makes the upfront payment within five days of the License Commencement Date and the IP transfers to OST at that time, the upfront fees from the license will be recognized upon the transfer of the intellectual property to OST.

Since OST is making $25,000 monthly payments that will be creditable against the $1,550,000, as well as additional upfront payments not specified in the contract, the Company will receive payments prior to the performance of the single distinct performance obligation. Due to this, the Company will defer any of the monthly payments until the IP and licensing rights are transferred to OST. However, if OST terminates the contract, which they are able to do with 60-day notice, the Company would recognize any of the payments received when the contract terminates. As of October 31, 2020, OST has made payments totaling $164,653 and this has been recorded as other liabilities in the balance sheet.

Amgen

On August 1, 2016, the Company entered into a global agreement (the "Amgen Agreement") with Amgen for the development and commercialization of the Company's ADXS-NEO, a then- preclinical investigational immunotherapy, using the Company's proprietary Listeria monocytogenes attenuated bacterial vector which activates a patient's immune system to respond against unique mutations, or neoepitopes, contained in and identified from an individual patient's tumor. Under the terms of the Amgen Agreement, Amgen received an exclusive worldwide license to develop and commercialize ADXS-NEO. Amgen made an upfront payment to Advaxis of $40 million and purchased directly from Advaxis 203,163 shares of the Company's common stock, at approximately $123.00 per share (representing a purchase at market using a 20 day VWAP methodology) for a total of $25 million. Amgen assisted in funding the clinical development and commercialization of ADXS-NEO and Advaxis retained manufacturing responsibilities. Advaxis and Amgen collaborated through a joint steering committee for the development and commercialization of ADXS-NEO. Advaxis received reimbursements for research and development costs and Advaxis was eligible to receive future contingent payments based on development, regulatory and sales milestone payments of up to $475 million and high single digit to double digit royalty payments based on worldwide sales by Amgen.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, Amgen, is a customer. The Company identified the following material promises under the arrangement: (1) licenses, (2) research and development activities, (3) clinical supplies, (4) regulatory responsibilities and (5) participation on a Joint Steering Committee (JSC). The Company determined that the licenses and research and development activities were not distinct from another, as the licenses had limited value without the performance of the research and development activities. Participation on the JSC to oversee the research and development activities was determined to be quantitatively and qualitatively immaterial and therefore was excluded from performance obligations. The clinical supply and regulatory responsibilities did not represent separate performance obligations based on their dependence on the research and development efforts. Based on this assessment, the Company identified one performance obligation at the outset of the Amgen Agreement, which consists of: (1) licenses, (2) research and development activities, (3) clinical supplies and (4) regulatory responsibilities.

Under the Amgen Agreement, in order to evaluate the appropriate transaction price, the Company determined that the upfront amount of $40 million constituted the entirety of the consideration to be included in the transaction price as of the outset of the arrangement, which is allocated to the single performance obligation. The Company concluded that a time-based method was most appropriate to measuring progress toward completion given that the research and development services are satisfied reasonably evenly over the agreement and the Company has a stand-ready obligation to perform over such time. Accordingly, progress toward completion and related revenue recognition is measured using the input method of time elapsed relative to the estimated timeline for Advaxis to submit the Phase 2 package to Amgen, or perform the contractual research and development services, which was the predominant promise in the Company's combined performance obligation to Amgen.

The reimbursement for the research and development costs was variable consideration that was included in the transaction price at the outset, subject to the constraint. The Company estimated the consideration from the reimbursement of the research and development costs using the most-likely amount. When the research and development costs are no longer constrained, they are added to the transaction price for the single, combined performance obligation and recognized over the same recognition period as the rest of the performance obligation's allocated revenue. The potential milestone and sales-based royalty payments that the Company was eligible to receive were excluded from the transaction price, as all milestone and sales royalty amounts were fully constrained based on the probability of achievement. The Company reevaluated the transaction price at the end of each reporting period and as uncertain events were resolved or other changes in circumstances occurred, and, as necessary, adjusted its estimate of the transaction price.

On December 10, 2018, the Company received a written notice of termination from Amgen with respect to the Amgen Agreement. The termination became effective as of February 8, 2019, and the Company regained worldwide rights for the development and commercialization of its ADXS-NEO program. On October 24, 2019, Advaxis announced that it has enrolled its last patient in its ADXS-NEO program in monotherapy and will not enter Part B.

The remaining deferred revenue of approximately $18.2 million on December 10, 2018 related to the $40 million non-refundable, up-front payment received from Amgen was accounted for as of the modification date. As of that notification date, the Company adjusted revenue on a cumulative catch-up basis considering the revised measure of progress for the combined performance obligation based on the modified service period up to and through the contract termination date of February 8, 2019. The Company recognized cumulative catch-up revenue of approximately $15.6 million on December 10, 2018. The remaining $2.6 million was recognized over the subsequent 60 days until the performance obligation was satisfied on February 8, 2019.

During the years ended October 31, 2020 and 2019, the Company recognized revenue from the Amgen Agreement of approximately $0 and $20.6 million, respectively. During the years ended October 31, 2020 and 2019, the Company received reimbursement of research and development costs of approximately $0 and $2.0 million, which was included in revenue.

Merck & Co., Inc.

On August 22, 2014, the Company entered into a Clinical Trial Collaboration and Supply Agreement (the "Merck Agreement") with Merck, pursuant to which the parties collaborated on a Phase 1/2 dose-determination and safety trial. The Phase 1 portion of the trial evaluated the safety of our *Lm* -LLO based immunotherapy for prostate cancer, ADXS-PSA (the "Advaxis Compound") as monotherapy and in combination with KEYTRUDA® (pembrolizumab), Merck's humanized monoclonal antibody against PD-1, (the "Merck Compound") and has determined a recommended Phase 2 combination dose. The Phase 2 portion evaluated the safety and efficacy of the Advaxis Compound in combination with the Merck Compound. Both phases of the trial were in patients with previously treated metastatic castration-resistant prostate cancer. The last patient was dosed in August 2019 and the Company is in the surveillance stage of the study. A joint development committee, comprised of equal representatives from both parties, is responsible for coordinating all regulatory and other activities under, and pursuant to, the Merck Agreement.

Each party is responsible for their own internal costs and expenses to support the trial, while the Company was responsible for all third-party costs of conducting the trial. Merck was responsible for manufacturing and supplying the Merck Compound. The Company was responsible for manufacturing and supplying the Advaxis Compound. The Company is the sponsor of the trial and holds the IND related to the trial.

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

During the each of the years ended October 31, 2020 and 2019, the Company incurred approximately $0.9 million in expenses pertaining to the Merck agreement, and such expenses were a component of research and development expenses in the statement of operations.

Elanco Animal Health (formerly Aratana Therapeutics)

On March 19, 2014, the Company and Aratana entered into a definitive Exclusive License Agreement (the "Aratana Agreement"). Pursuant to the Agreement, Advaxis granted Aratana an exclusive, worldwide, royalty-bearing, license, with the right to sublicense, certain Advaxis proprietary technology that enables Aratana to develop and commercialize animal health products that will be targeted for treatment of osteosarcoma and other cancer indications in animals. Under the terms of the Aratana Agreement, Aratana paid an upfront payment to the Company, of $1 million. As this license has stand-alone value to Aratana (who has the ability to sublicense) and was delivered to Aratana, upon execution of the Aratana Agreement, the Company recorded the $1 million payment as licensing revenue during the fiscal year ended October 31, 2014. Aratana will also pay the Company up to an additional $36.5 million based on the achievement of certain milestones with respect to the advancement of products pursuant to the terms of the Aratana Agreement. In addition, Aratana may pay the Company an additional $15 million in cumulative sales milestones pursuant to the terms of the Aratana Agreement.

During the fiscal year ended October 31, 2018, the USDA's Center for Veterinary Biologics granted Aratana conditional approval for its canine osteosarcoma vaccine using Advaxis' technology. During the years ended October 31, 2020 and 2019, Advaxis recognized royalty revenue totaling approximately $3,000 and $8,000, respectively, from Aratana's sales of the canine osteosarcoma vaccine. On July 16, 2019, Aratana announced their shareholders approved a merger agreement with Elanco Animal Health ("Elanco") whereby Elanco will be the majority shareholder in Aratana. On October 6, 2020, the Company received a notice from Aratana, dated September 17, 2020, indicating that Aratana was terminating the Exclusive License Agreement effective December 21, 2020. The Company did not incur any early termination penalties as a result of the termination. Aratana was required to make all payments to the Company that were otherwise payable under the Exclusive License Agreement through the effective date of termination.

Global BioPharma Inc.

On December 9, 2013, the Company entered into an exclusive licensing agreement for the development and commercialization of axalimogene filolisbac with Global BioPharma, Inc. (GBP), a Taiwanese based biotech company funded by a group of investors led by Taiwan Biotech Co., Ltd (TBC). During each of the years ended October 31, 2020 and 2019, the Company recorded $0.25 million in revenue for the annual license fee renewal. Since Advaxis has no significant obligation to perform after the license transfer and has provided GBP with the right to use its intellectual property, performance is satisfied when the license renews.

9. COMMITMENTS AND CONTINGENCIES

Legal Proceedings

Stendhal

On September 19, 2018, Stendhal filed a Demand for Arbitration before the International Centre for Dispute Resolution (Case No. 01-18-0003-5013) relating to the Co-development and Commercialization Agreement with Especificos Stendhal SA de CV (the "Stendhal Agreement"). In the demand, Stendhal alleged that (i) the Company breached the Stendhal Agreement when it made certain statements regarding its AIM2CERV program, (ii) that Stendhal was subsequently entitled to terminate the Agreement for cause, which it did so at the time and (iii) that the Company owes Stendhal damages pursuant to the terms of the Stendhal Agreement. Stendhal is seeking to recover $3 million paid to the Company in 2017 as support payments for the AIM2CERV clinical trial along with approximately $0.3 million in expenses incurred. Stendhal is also seeking fees associated with the arbitration and interest. The Company has answered Stendhal's Demand for Arbitration and denied that it breached the Stendhal Agreement. The Company also alleges that Stendhal breached its obligations to the Company by, among other things, failing to make support payments that became due in 2018 and that Stendhal therefore owes the Company $3 million. Advaxis is also seeking fees associated with the arbitration and interest.

From October 21-23, 2019, an evidentiary hearing for the arbitration was conducted. On April 1, 2020, the Arbitrator issued a final award denying Stendhal's claim in full. The Arbitrator found that the Company had not repudiated the Agreement and did not owe Stendhal damages, fees, or interest associated with the arbitration. The Arbitrator also denied the Company's claim that Stendhal breached its obligations to the Company. The parties were ordered to bear their own attorneys' fees and evenly split administrative fees and expenses for the arbitration.

10. LEASES

Operating Leases

The Company leases its corporate office and manufacturing facility in Princeton, New Jersey under an operating lease that expires in November 2025. The Company has the option to renew the lease term for two additional five-year terms. The renewal periods were not included the lease term for purposes of determining the lease liability or right-of-use asset. The Company has provided a security deposit of approximately $182,000, which is recorded as Other Assets in the balance sheet.

The Company identified and assessed the following significant assumptions in recognizing its right-of-use assets and corresponding lease liabilities:

- As the Company does not have sufficient insight to determine an implicit rate, the Company estimated the incremental borrowing rate in calculating the present value of the lease payments. The Company utilized a synthetic credit rating model to determine a benchmark for its incremental borrowing rate for its leases. The benchmark rate was adjusted to arrive at an appropriate discount rate for the lease.

- Since the Company elected to account for each lease component and its associated non-lease components as a single combined component, all contract consideration was allocated to the combined lease component.

- Renewal option periods have not been included in the determination of the lease terms as they are not deemed reasonably certain of exercise.
- Variable lease payments, such as common area maintenance, real estate taxes, and property insurance are not included in the determination of the lease's right-of-use asset or lease liability.

Supplemental balance sheet information related to leases as of October 31, 2020 was as follows (in thousands):

Operating Leases:	
Operating lease right-of-use assets	$ 4,839
Operating lease liability	$ 962
Operating lease liability, net of current portion	5,055
Total operating lease liabilities	$ 6,017

Supplemental lease expense related to leases was as follows (in thousands):

Lease Cost (in thousands)	Statements of Operations Classification	For the Year Months Ended October 31, 2020
Operating lease cost	General and administrative	$ 1,158
Short-term lease cost	General and administrative	320
Variable lease cost	General and administrative	547
Total lease expense		$ 2,025

Other information related to leases where the Company is the lessee is as follows:

	For the Fiscal Year Ended October 31, 2020
Weighted-average remaining lease term	5.1 years
Weighted-average discount rate	6.5%

Supplemental cash flow information related to operating leases was as follows:

	For the Fiscal Year Ended October 31, 2020
Cash paid for operating lease liabilities	$ 1,233

Future minimum lease payments under non-cancellable leases as of October 31, 2020 were as follows:

Fiscal Year ending October 31,	
2021	$ 1,318
2022	1,369
2023	1,395
2024	1,419
2025	1,444
Thereafter	120
Total minimum lease payments	7,065
Less: Imputed interest	(1,048)
Total	$ 6,017

Under ASC 840, future minimum payments under the Company's operating lease were as follows (in thousands):

Fiscal Year ending October 31,	
2021	$ 1,318
2022	1,369
2023	1,395
2024	1,419
2025	1,444
Thereafter	120
Total	$ 7,065

Under ASC 840, rent expense for the fiscal year ended October 31, 2019 was approximately $1.2 million.

11. INCOME TAXES

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

	October 31, 2020	October 31, 2019
Federal		
Current	$ -	$ -
Deferred	(4,578)	32,673
State and Local		
Current	-	-
Deferred	(1,445)	(1,634)
Change in valuation allowance	6,023	(31,039)
Income tax provision (benefit)	$ -	$ -

The Company has U.S. federal net operating loss carryovers ("NOLs") of approximately $89.4 million and $74.0 million at October 31, 2020 and 2019 respectively, available to offset taxable income which expire beginning in 2023. If not used, these NOLs may be subject to limitation under Internal Revenue Code Section 382 should there be a greater than 50% ownership change as determined under the regulations. During the years ended October 31, 2020 and 2019, the Company performed a detailed analysis of any historical and/or current Section 382 ownership changes that may limit the utilization of the net operating loss carryovers. From the entire federal NOL of $299.2 million as of October 31, 2020, approximately $89.4 million is available for use based on Internal Revenue Code Section 382 analysis. The NOL and the deferred tax asset table below does not include approximately $209.8 million of NOL's that may expire unused. The Company also has New Jersey State Net Operating Loss carryovers of approximately $137.7 million as of October 31, 2020 available to offset future taxable income through 2040.

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

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

If applicable, interest costs related to the unrecognized tax benefits are required to be calculated and would be classified as other expense in the statement of operations. Penalties would be recognized as a component of general and administrative expenses in the statement of operations.

No interest or penalties on unpaid tax were recorded during the years ended October 31, 2020 and 2019, respectively. As of October 31, 2020 and 2019, no liability for unrecognized tax benefits was required to be reported. The Company does not expect any significant changes in its unrecognized tax benefits in the next year.

The Company files tax returns in the U.S. federal and state jurisdictions and is subject to examination by tax authorities beginning with the fiscal year ended October 31, 2017.

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

	Years Ended	
	October 31, 2020	October 31, 2019
Deferred Tax Assets		
Net operating loss carryovers	$ 28,553	$ 22,627
Stock-based compensation	10,132	11,767
Research and development credits	10,742	10,234
Capitalized R&D costs	13,822	13,399
Deferred revenue	-	-
Adoption of ASC 842 – Lease Liability	1,691	-
Other deferred tax assets	224	405
Total deferred tax assets	$ 65,164	$ 58,432
Valuation allowance	(62,845)	(56,822)
Deferred tax asset, net of valuation allowance	$ 2,319	$ 1,610
Deferred Tax Liabilities		
Adoption of ASC 842 – ROU Asset	(1,360)	-
Patent Cost	(917)	-
Other deferred tax liabilities	(42)	(1,610)
Total deferred tax liabilities	$ (2,319)	$ (1,610)
Net deferred tax asset (liability)	$ -	$ -

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

	Years Ended	
	October 31, 2020	October 31, 2019
US Federal statutory rate	21.00%	21.00%
State income tax, net of federal benefit	5.48	9.84
Permanent differences	(0.05)	1.23
Research and development credits	1.73	17.30
Change in valuation allowance	(22.82)	186.84
§382 Impact on NOL	-	(233.87)
Stock Option Expirations	(5.33)	(2.34)
Income tax (provision) benefit	0.00%	0.00%

The statement of operations discloses income tax expense of $50. This is a Taiwan Excise tax of 50 levied in connection with the GPP Revenue.

12. STOCKHOLDERS' EQUITY

Public Offerings

In April 2019, the Company issued 2,500,000 shares of the Company's common stock in a public offering at $4.00 per share, less underwriting discounts and commissions. The net proceeds to the Company from the transaction was approximately $9 million.

In July 2019, the Company closed on an underwritten public offering of 10,650,000 shares of its common stock, pre-funded warrants to purchase 13,656,000 shares of common stock and warrants to purchase up to 17,142,000 shares of common stock for gross proceeds of $17.0 million. Each share of common stock was sold together in a fixed combination with a warrant to purchase 0.75 shares of common stock for $0.70, and each pre-funded warrant was sold together in a fixed combination with a warrant to purchase 0.75 shares of common stock for $0.699. The pre-funded warrants are exercisable immediately, do not expire and have an exercise price of $0.001 per share. The warrants are exercisable immediately, expire five years from the date of issuance, have an exercise price of $2.80 per share and are subject to anti-dilution and other adjustments for certain stock splits, stock dividends, or recapitalizations. The warrants also provide that if during the period of time between the date that is the earlier of (i) 30 days after issuance and (ii) if the common stock trades an aggregate of more than 35,000,000 shares after the pricing of the offering, and ending 15 months after issuance, the weighted-average price of common stock immediately prior to the exercise date is lower than the then-applicable exercise price per share, each Common Warrant may be exercised, at the option of the holder, on a cashless basis for one share of Common Stock. After deducting the underwriting discounts and commissions and other offering expenses, the net proceeds from the offering were approximately $15.5 million.

In January 2020, the Company closed on a public offering of 10,000,000 shares of its common stock at a public offering price of $1.05, for gross proceeds of $10.5 million. In addition, the Company also undertook a concurrent private placement of warrants to purchase up to 5,000,000 shares of common stock. The warrants have an exercise price per share of $1.25, are exercisable during the period beginning on the six-month anniversary of the date of its issuance (the "Initial Exercise Date") and will expire on the fifth anniversary of the Initial Exercise Date. The warrants contain a change of control provision whereby if the change of control is within the Company's control, the warrants could be settled in cash based on the Black-Scholes value of the warrants at the option of the warrant holder. The warrants also provide that if there is no effective registration statement registering, or no current prospectus available for, the issuance or resale of the warrant shares, the warrants may be exercised via a cashless exercise. After deducting the underwriting discounts and commissions and other offering expenses, the net proceeds from the offering were approximately $9.6 million.

In May 2020, the Company entered into a sales agreement related to an ATM equity offering program pursuant to which the Company may sell, from time to time, common stock with an aggregate offering price of up to $40 million through A.G.P./Alliance Global Partners, as sales agent. From May 2020 to October 2020, the Company sold 2,489,104 shares of its common stock under the ATM program for $1.583 million, or an average of $0.64 per share, and received net proceeds of $1.531 million, net of commissions of $52,000.

Lincoln Park Purchase Agreement

On July 30, 2020, the Company entered into a Purchase Agreement (the "Purchase Agreement") and a Registration Rights Agreement (the "Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Over the 36-month term of the Purchase Agreement, the Company has the right, but not the obligation, from time to time, to sell to Lincoln Park up to an aggregate amount of $20,000,000 of shares of common stock, in its sole discretion and subject to certain conditions, including that the closing price of its common stock is not below $0.10 per share, to direct Lincoln Park to purchase up to 1,000,000 shares (the "Regular Purchase Share Limit") of its Common Stock (each such purchase, a "Regular Purchase"). Lincoln Park's maximum obligation under any single Regular Purchase will not exceed $1,000,000, unless the parties mutually agree to increase the maximum amount of such Regular Purchase. The purchase price for shares of Common Stock to be purchased by Lincoln Park under a Regular Purchase will be the equal to the lower of (in each case, subject to the adjustments described in the Purchase Agreement): (i) the lowest sale price for the Company's common stock on the applicable purchase date, and (ii) the arithmetic average of the three lowest sale prices for the Company's common stock during the ten trading days prior to the purchase date.

As consideration for entering into the Purchase Agreement, the Company issued 1,084,266 shares of common stock to Lincoln Park as a commitment fee. The shares were valued at approximately $0.6 million and were recorded as deferred offering expenses in the balance sheet. The deferred charges were charged against paid-in capital upon future proceeds from the sale of common stock under the Lincoln Park Purchase Agreement.

From August 2020 to October 2020, Lincoln Park purchased 11,242,048 shares of common stock for gross proceeds of approximately $5.1 million. Approximately $50,000 of legal fees were netted against the gross proceeds.

13. FAIR VALUE

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

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

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

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

The following table provides the assets and liabilities carried at fair value measured on a recurring basis as of October 31, 2020 and October 31, 2019:

October 31, 2020	Level 1	Level 2	Level 3	Total
Common stock warrant liability, warrants exercisable at $0.372 through September 2024	-	-	$ 17	$ 17

October 31, 2019	Level 1	Level 2	Level 3	Total
Common stock warrant liability, warrants exercisable at $0.372 through September 2024	-	-	$ 19	$ 19

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

	Year Ended October 31,	
	2020	2019
Beginning balance	$ 19	$ 6,517
Shares issued in settlement of warrants	-	(3,856)
Warrant exercises	(2)	(53)
Change in fair value	-	(2,589)
Ending Balance	$ 17	$ 19

14. EMPLOYEE BENEFIT PLAN

The Company sponsors a 401(k) Plan. Employees become eligible for participation upon the start of employment. Participants may elect to have a portion of their salary deferred and contributed to the 401(k) Plan up to the limit allowed under the Internal Revenue Code. The Company makes a matching contribution to the plan for each participant who has elected to make tax-deferred contributions for the plan year. The Company made matching contributions which amounted to approximately $0.1 million and $0.2 million for the years ended October 31, 2020 and 2019, respectively. These amounts were charged to the statement of operations. The employer contributions vest immediately.

15. SUBSEQUENT EVENTS

In November 2020, the Company closed on a public offering of 30,666,665 shares of its common stock at a public offering price of $0.30, for gross proceeds of $9.2 million, which gives effect to the exercise of the underwriter's option in full. In addition, the Company also undertook a concurrent private placement of warrants to purchase up to 15,333,332 shares of common stock. The warrants have an exercise price per share of $0.35, are exercisable immediately and will expire five years from the date of issuance. The warrants also provide that if there is no effective registration statement registering, or no current prospectus available for, the issuance or resale of the warrant shares, the warrants may be exercised via a cashless exercise. After deducting the underwriting discounts and commissions and other offering expenses, the net proceeds from the offering were approximately $8.5 million.

Subsequent to year end, warrant holders from the Company's November 2020 offering exercised 4,610,000 warrants in exchange for 4,610,000 shares of the Company's common stock. Pursuant to these warrant exercises, the Company received aggregate proceeds of about $1.6 million which were payable upon exercise.

In December 2020 and January 2021, the Company received an aggregate of $1,345,000 from OS Therapies upon achievement of the $1,550,000 funding milestone set forth in the license agreement. For more information on the license agreement with OS Therapies, please see Note 8 – "Collaboration and Licensing Agreements" above.

Exhibit 4.9

AGREEMENT TO EXCHANGE WARRANTS

Advaxis, Inc.
305 College Road East
Princeton, NJ 08540

Ladies and Gentlemen:

This is to record the agreement between Advaxis, Inc. (the "Company") and [____] (the "Warrantholder") regarding the terms on which the Company will issue shares of Common Stock ("Common Stock"), par value $0.001 per share, to the Warrantholder in exchange for warrants originally issued under a Securities Purchase Agreement, dated January 21, 2020, by and among the Company, the Warrantholder and [____] entitling the holders to purchase Common Stock, which Agreement is as follows:

1. The Company hereby agrees to issue [____] shares (the "Exchange Shares") of Common Stock to the Warrantholder in exchange for [____] warrants (such warrants being exchanged, the "Warrants").

2. In order to carry out the exchange of the Exchange Shares for the Warrants described in Section 1, at or prior to 11:00 a.m., Eastern time on October 16, 2020 (the "Exchange Date") (a) the number of Warrants stated in Section 1 shall be automatically deemed cancelled upon receipt of the Exchange Shares, and (b) the Company will cause Continental Stock Transfer and Trust Company, as transfer agent for the Company, to issue via the Deposit / Withdrawal at Custodian system into an account with The Depositary Trust Company ("DTC") specified by the Warrantholder, the number of shares of Common Stock stated in Section 1. No later than three (3) Nasdaq Global Market trading days following the date hereof, the Warrantholder shall deliver the original certificate representing the Warrants stated in Section 1 above to the Company for cancellation. For the avoidance of doubt, as of the Exchange Date, all of the Warrantholder's rights under the terms and conditions of the Warrants shall be extinguished. However, failure to deliver the original certificate will not affect the automatic cancellation of the Warrants described in clause (a).

3. During the period of 15 days beginning on the Exchange Date, the Warrantholder will not on any day sell a number of shares of Common Stock (including shares issuable by exercise of securities that are convertible into or exercisable for Common Stock) that exceeds 10% of the cumulative trading volume of the Common Stock for such date (which cumulative trading volume shall include pre-market, market and post-market trading volume for such date) as reported by Bloomberg, LP. The Company will be entitled to injunctive relief to prevent violation or threatened violation of this Section 3.

4. The Warrantholder represents and warrants to the Company that:

    a. The Warrantholder owns all the Warrants described in Section 1 and has all right, power and authority that is necessary to enable the Warrantholder to exchange them for Common Stock as contemplated by this Agreement, without requiring consent of any other person or any governmental authority.

b. After the Warrants described in Section 1 are automatically cancelled as described in Section 2, neither the Warrantholder nor any other person will have any rights under or with regard to the Warrants.

c. The Warrantholder is aware that:

i. The last sale price of the Common Stock reported on the Nasdaq Global Market on October 15, 2020 was $0.42 per share. The Company is not aware of any trading in the Warrants.

ii. The Company files annual, quarterly and current reports and other information with the SEC. The materials the Company files with the SEC are available on the SEC's website, www.sec.gov. They also are available on the Company's website, www.advaxis.com.

d. The Warrantholder has had a reasonable opportunity to discuss the Company's business, management and financial affairs with management of the Company. The Warrantholder has also had a reasonable opportunity to ask questions of and receive answers from the Company and its management regarding the terms and conditions of this exchange. The Warrantholder acknowledges that except as set forth herein, no representations or warranties have been made to the Warrantholder, or to the Warrantholder's advisors or representatives, by the Company or others with respect to the business or prospects of the Company or its financial condition.

5. The Company represents and warrants to the Warrantholder as follows:

a. The Company has all right, power and authority, and has obtained all approvals, that are necessary to enable it to issue Common Stock in exchange for Warrants as contemplated by this Agreement.

b. When the Company issues the Exchange Shares, those shares (i) will be issued in reliance on an exemption from the registration requirements of the Securities Act contained in Section 3(a)(9) of the Securities Act of 1933, as amended (the "Securities Act), and such shares shall be "restricted securities" (as defined in Rule 144 promulgated under the Securities Act), and (ii) will be duly authorized and issued, fully paid and non-assessable and will be eligible for trading on the Nasdaq Global Market.

6. The Warrantholder is aware that the issuance of Exchange Shares in exchange for Warrants as described in this Agreement has not been registered under the Securities Act and that those shares are being issued in reliance on an exemption from the registration requirements of the Securities Act contained in Section 3(a)(9) of the Securities Act. The Warrantholder further acknowledges Company is relying upon the truth and accuracy of the representations, warranties, agreements, acknowledgments and understandings of the Warrantholder set forth herein for purposes of qualifying for exemptions from registration under the Securities Act and applicable state securities laws.

7. The Warrantholder understands that the Exchange Shares are "restricted securities" and have not been registered under the Securities Act or any applicable state securities law and the Warrantholder is acquiring the Exchange Shares as principal for its own account and not with a view to or for distributing or reselling such Exchange Shares or any part thereof in violation of the Securities Act or any applicable state securities law, has no present intention of distributing any of such Exchange Shares in violation of the Securities Act or any applicable state securities law and has no direct or indirect arrangement or understandings with any other persons to distribute or regarding the distribution of such Exchange Shares in violation of the Securities Act or any applicable state securities law (this representation and warranty not limiting such Warrantholder's right to sell the Securities in compliance with applicable federal and state securities laws). Such Warrantholder is acquiring the Exchange Shares hereunder in the ordinary course of its business.

8. Following such time as the restricted shares are eligible for sale under Rule 144 without the need to satisfy the current public information requirement under Rule 144 and without volume or manner-of-sale restrictions, the Company agrees to use commercially reasonable efforts to, no later than two (2) business days following the delivery by the Warrantholder of all of (i) an instrument, whether certificated or uncertificated, representing the Exchange Shares issued with a restrictive legend, (ii) a written request addressed to the Company that such restrictive legend be removed, and (iii) customary broker and representation letters reasonably satisfactory to the Company and the Company's counsel, deliver or cause to be delivered to the Warrantholder, via DRS transfer, an instrument, certificated or uncertificated, representing that such Exchange Shares are free from such restrictive legends; *provided*, *however* that each party will be solely responsible for any fees it incurs in connection with such request and removal.

9. The Company agrees from and after the date hereof that if any of the terms offered to any other holder of Warrants in connection with any exchange of Warrants for any assets or other securities (each an "Exchange Document"), is or will be more favorable to such other Person (as defined in the Warrants) than those of the Warrantholder under this Agreement (other than with respect to the reimbursement of legal fees). If, and whenever on or after the date hereof, the Company enters into an Exchange Document which contains any terms that are more favorable to another holder of Warrants than this Agreement, then (i) the Company shall provide notice thereof to the Warrantholder promptly following the occurrence thereof and (ii) the terms and conditions of this Agreement shall be, without any further action by the Warrantholder or the Company, automatically amended and modified in an economically and legally equivalent manner such that the Warrantholder shall receive the benefit of the more favorable terms and/or conditions (as the case may be) set forth in such Exchange Document, provided that upon written notice to the Company at any time the Warrantholder may elect not to accept the benefit of any such amended or modified term or condition, in which event the term or condition contained in this Agreement shall apply to the Warrantholder as it was in effect immediately prior to such amendment or modification as if such amendment or modification never occurred with respect to the Warrantholder. Without limiting what is said above in this Section 7, if the Exchange Document with a Person calls for issuance of more shares of Common Stock per Warrant exchanged than this Agreement, within five Nasdaq Global Market trading days after the issuance of the shares to the other person, the Company will issue to the Warrantholder the number of additional shares of Common Stock such that the Warrantholder will have received the same number of shares of Common Stock per exchanged Warrant as the other Person. The provisions of this paragraph shall apply similarly and equally to each Exchange Document.

10. Prior to 5:30 pm ET on October 16, 2020, the Company shall issue a press release (or file a Report on Form 8-K), reasonably acceptable to the Warrantholder disclosing the material terms of the transactions contemplated hereby (the "Press Release"). From and after the issuance of the Press Release, the Company represents to the Warrantholder that the Warrantholder shall not be in possession of any material, nonpublic information received from the Company, any of its Subsidiaries (as defined below) or any of their respective officers, directors, employees or agents, that is not disclosed in the Press Release. In addition, effective upon the issuance of the Press Release, the Company acknowledges and agrees that any and all confidentiality or similar obligations under any agreement, whether written or oral, between the Company, any of its subsidiaries or any of their respective officers, directors, employees or agents, on the one hand, and the Warrantholder or any of its affiliates, on the other hand, shall terminate. The Company shall not, and shall cause each of its subsidiaries and its and each of their respective officers, directors, employees and agents, not to, provide the Warrantholder with any material, nonpublic information regarding the Company or any of its subsidiaries from and after the date hereof without the express prior written consent of the Warrantholder. To the extent that the Company, any of its Subsidiaries or any of their respective officers, directors, employees or agents, delivers any material, non-public information to the Warrantholder without the Warrantholder's consent, the Company hereby covenants and agrees that the Warrantholder shall not have any duty of confidentiality with respect to such material, non-public information.

11. The Company and the Warrantholder hereby mutually agree and acknowledge to execute and/or deliver such other documents and agreements as are reasonably necessary to effectuate the exchange pursuant to the terms of this Agreement.

12. Neither the Company nor the Warrantholder has paid or given, or will pay or give, to any person, any commission, fee or other remuneration, directly or indirectly, in connection with the transactions contemplated by this Agreement.

13. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to the other party, it being understood that both parties need not sign the same counterpart. In the event that any signature is delivered by facsimile or .pdf transmission, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or .pdf signature page were an original thereof. If any provision of this Agreement is held to be invalid or unenforceable in any respect, the validity and enforceability of the remaining terms and provisions of this Agreement shall not in any way be affected or impaired thereby and the parties will attempt to agree upon a valid and enforceable provision that is a reasonable substitute therefor, and upon so agreeing, shall incorporate such substitute provision in this Agreement. All questions concerning the construction, validity, enforcement and interpretation of this Agreement shall be determined pursuant to the internal law of the State of New York.

(Signatures on following page)

Please sign a copy of this Agreement which, when it is signed by the Company, will constitute a legally binding agreement between the Warrantholder and the Company.

Very truly yours,

[____]

Dated: October 16, 2020

By _____

AGREED TO:

ADVAXIS, INC.

By: _____
Name: Kenneth A. Berlin
Title: President and Chief Executive Officer

EXHIBIT 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of Advaxis, Inc. on Form S-3 File No. 333-226988 and Form S-8 File Nos. 333-130080, 333-193007, 333-197465, 333-204939, 333-210285, 333-217218, 333-222483, 333-223851, and 333-239469 of our report, dated January 22, 2021, with respect to our audits of the financial statements of Advaxis, Inc. as of October 31, 2020 and 2019 and for each of the two years in the period ended October 31, 2020, which report is included in this Annual Report on Form 10-K of Advaxis, Inc. for the year ended October 31, 2020.

Our report on the financial statements refers to a change in the method of accounting for leases in 2020 due to the adoption of ASU No. 2016-02, Leases (Topic 842), as amended, effective November 1, 2019 using the modified retrospective transition approach.

/s/ Marcum LLP

Marcum LLP
New York, NY
January 22, 2021

EXHIBIT 31.1

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

I, Kenneth Berlin, certify that:

1. I have reviewed this annual report on Form 10-K for the fiscal year ended October 31, 2020 of Advaxis, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

January 22, 2021

By: */s/ Kenneth Berlin*
Name: Kenneth Berlin
Title: President & Chief Executive Officer

EXHIBIT 31.2

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

I, Kenneth Berlin, certify that:

1. I have reviewed this annual report on Form 10-K for the fiscal year ended October 31, 2020 of Advaxis, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

January 22, 2021

By: */s/ Kenneth Berlin*
Name: Kenneth Berlin
Title: President, Chief Executive Officer and interim Chief Financial Officer

EXHIBIT 32.1

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

In connection with the Annual Report of Advaxis, Inc., a Delaware corporation (the "Company"), on Form 10-K for the fiscal year ended October 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, the Chief Executive Officer, hereby certifies pursuant to 18 U.S.C. Sec. 1350 as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002 that, to the undersigned's knowledge:

(1) the Report of the Company filed today fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

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

Date: January 22, 2021

By: */s/ Kenneth Berlin*
Name: Kenneth Berlin
Title: President., Chief Executive Officer and interim Chief Financial Officer

EXHIBIT 32.2

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

In connection with the Annual Report of Advaxis, Inc., a Delaware corporation (the "Company"), on Form 10-K for the fiscal year ended October 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, the Chief Financial Officer, hereby certifies pursuant to 18 U.S.C. Sec. 1350 as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002 that, to the undersigned's knowledge:

(1) the Report of the Company filed today fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

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

Date: January 22, 2021

By: */s/ Kenneth Berlin*
Name: Kenneth Berlin
Title: President, Chief Executive Officer and interim Chief Financial Officer