Advaxis, Inc.
Form 424B5
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Registration No. 333-226988

PROSPECTUS SUPPLEMENT

2,500,000 Shares

Common Stock

We are offering on a “best efforts” basis 2,500,000 shares of our common stock, $0.001 par value per share, in this offering.

Our common stock is traded on the Nasdaq Global Select Market under the symbol “ADXS.” On April 1, 2019, the last reported sale price of our common stock on the Nasdaq Global Select Market was $6.51 per share. During the twelve calendar months immediately prior to and including the date of this prospectus supplement, we have not sold any shares of Common Stock pursuant to General Instruction I.B.6. of Form S-3.

Investing in our common stock involves a high degree of risk. See “Risk Factors” beginning on page S-8 of this prospectus supplement and in the documents incorporated by reference into this prospectus supplement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.

	Per share	Total
Public offering price	$4.00	$10,000,000
Underwriting discounts and commissions[(1)]	$0.28	$700,000
Proceeds to Advaxis (before expenses)	$3.72	$9,300,000

(1) We have agreed to reimburse the underwriters for certain expenses. See "Underwriting" beginning on page S-18 of this prospectus supplement for a description of the compensation payable to the underwriters.

This offering is being completed on a "best efforts" basis and the underwriters have no obligation to buy any shares of common stock from us or to arrange for the purchase or sale of any specific number or dollar amount of shares.

Delivery of the shares of common stock is expected to be made on or about April 5, 2019.

A.G.P.

Prospectus Supplement dated April 3, 2019

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ABOUT THIS PROSPECTUS SUPPLEMENT

This document is in two parts. The first part is this prospectus supplement, which describes the specific terms of this offering and certain other matters and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference herein or therein. The second part, the accompanying prospectus, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement and the information contained in the accompanying prospectus or any document incorporated by reference herein or therein filed prior to the date of this prospectus supplement, you should rely on the information in this prospectus supplement; provided that if any statement in one of these documents is inconsistent with a statement in another document having a later date — for example, a document incorporated by reference in the accompanying prospectus — the statement in the document having the later date modifies or supersedes the earlier statement.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference herein or therein were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

Neither we nor the underwriters have authorized anyone to provide information different from that contained in this prospectus supplement and the accompanying prospectus, including any free writing prospectus that we have authorized for use in this offering. When you make a decision about whether to invest in our common stock, you should not rely upon any information other than the information in this prospectus supplement or the accompanying prospectus, including any free writing prospectus that we have authorized for use in this offering. Neither the delivery of this prospectus supplement or the accompanying prospectus, including any free writing prospectus that we have authorized for use in this offering, nor the sale of our common stock means that information contained in this prospectus supplement and the accompanying prospectus, including any free writing prospectus that we have authorized for use in this offering, is correct after their respective dates. It is important for you to read and consider all information contained in this prospectus supplement and the accompanying prospectus, including the information incorporated by reference into this prospectus supplement and the accompanying prospectus, and any free writing prospectus that we have authorized for use in connection with this offering in making your investment decision. You should also read and consider the information in the documents to which we have referred you in the sections entitled “Where You Can Find More Information” and “Incorporation of Certain Information by Reference” in this prospectus supplement.

We are offering to sell, and seeking offers to buy, and the underwriters are soliciting offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of the common stock in certain jurisdictions may be

restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus supplement and the accompanying prospectus outside the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

Unless otherwise stated, all references in this prospectus supplement to “we,” “us,” “our,” “Advaxis,” the “Company” and simi designations refer to Advaxis, Inc. This prospectus supplement, the accompanying prospectus and the information incorporated by reference herein and therein contain trademarks, service marks and trade names of Advaxis, Inc., including our name and logo. Other trademarks, service marks and trade names referred to in this prospectus supplement or the accompanying prospectus or the information incorporated by reference herein and therein are the property of their respective owners.

SPECIAL CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This prospectus supplement includes statements that are, or may be deemed, "forward-looking statements." In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approxi 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 prospectus supplement and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned discovery and development of drug candidates, the strength and breadth of our intellectual property, our ongoing and planned preclinical studies and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, the degree of clinical utility of our product candidates, particularly in specific patient populations, expectations regarding clinical trial data, our results of operations, financial condition, liquidity, prospects, growth and strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus supplement, 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 prospectus supplement. 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 prospectus supplement, they may not be predictive of results or developments in future periods.

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

- the success and timing of our clinical trials, including patient accrual;
- our ability to obtain and maintain regulatory approval and/or reimbursement of our product candidates for marketing;
- our ability to obtain the appropriate labeling of our products under any regulatory approval;
- our plans to develop and commercialize our products;
- the successful development and implementation of our sales and marketing campaigns;
- the change of key scientific or management personnel;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- our ability to successfully compete in the potential markets for our product candidates, if commercialized;
- regulatory developments in the United States and other 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;
our intended use of the net proceeds from this offering;
the impact of the reverse stock split on the market price of our common stock;
any stockholder dilution that may result from future capital raising efforts and the exercise or conversion, as applicable, of our outstanding options and warrants;
the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
our ability to obtain additional funding;
our ability to obtain and maintain intellectual property protection for our product candidates;
the success and timing of our preclinical studies including IND enabling studies;
the ability of our product candidates to successfully perform in clinical trials and to resolve any clinical holds that may occur;
our ability to obtain and maintain approval of our product candidates for trial initiation;

- our ability to manufacture and the performance of third-party manufacturers
- our ability to identify license and collaboration partners and to maintain existing relationships;
- the performance of our clinical research organizations, clinical trial sponsors, clinical trial investigators and collaboration partners for any clinical trials we conduct; and
- our ability to successfully implement our strategy.

Any forward-looking statements that we make in this prospectus supplement 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 prospectus supplement. You should also read carefully the factors described in the "Risk Factors" section of this prospectus supplement and our Annual Report on Form 10-K for the year ended October 31, 2018, as filed with the SEC on January 11, 2019, 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 prospectus supplement will prove to be accurate.

This prospectus supplement 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.

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights information contained elsewhere or incorporated by reference in this prospectus supplement and the accompanying prospectus and in the documents we incorporate by reference. This summary does not contain all of the information that you should consider before deciding to invest in our common stock. You should read this entire prospectus supplement and the accompanying prospectus carefully, including the ''Risk Factors'' section contained in this prospectus supplement and our consolidated financial statements and the related notes and the other documents incorporated by reference herein, as well as the information included in any free writing prospectus that we have authorized for use in connection with this offering.

Our Business

We are a late-stage biotechnology company focused on the discovery, development and commercialization of proprietary *Listeria monocytogenes* ("*Lm*") based antigen delivery products. We are using our *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, we have exclusive access to this proprietary formulation of attenuated *Lm* called *Lm* Technology™. Our 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.

Our 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. We believe that *Lm* Technology immunotherapies can complement and address significant unmet needs in the current oncology treatment landscape. Specifically, we believe our product candidates have the potential to work synergistically with other immunotherapies, including checkpoint inhibitors, while, to date, having a generally predictable and manageable safety profile, 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 HPV-associated cancers (including cervical and head and neck), prostate cancer, non-small cell lung cancer and microsatellite stable colorectal cancer. We are working with, or are in the process of identifying, collaborators for many of these programs.

Moving forward, we expect that we will continue to invest in our core clinical program areas and will also remain opportunistic in evaluating Investigator Sponsored Trials ("ISTs") as well as licensing opportunities. The *Lm* Technology platform is protected by a range of patents, covering both product and process, some of which we believe can be maintained into 2039.

Clinical Pipeline

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

We are developing therapies for HPV-related cancers using axalimogene filolisbac (AXAL). Axalimogene filolisbac is an *Lm*–based antigen delivery product directed against HPV and designed to target cells expressing HPV. Axalimogene filolisbac is currently under investigation, or being considered, in two HPV-associated cancers: cervical cancer and head and neck cancer, either as a monotherapy or in combination. We have also completed clinical studies of axalimogene filolisbac for the treatment of anal cancer and non-squamous carcinoma of the cervix. While we have decided at this time not to pursue further studies in anal cancer and non-squamous carcinoma of the cervix , we remain opportunistic about ISTs and licensing opportunities in these tumor types.

Cervical Cancer: Axalimogene Filolisbac

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

Ongoing Registrational and Phase 3 Study: Axalimogene Filolisbac

Women who are diagnosed with high risk, locally-advanced carcinoma of the cervix ("HRLACC") face a higher chance that their cancer may recur following initial treatment when compared to earlier stages of the disease. When cervical

cancer recurs, there are very few treatment options and the prognosis is dire. To address this unmet need, in 2016 we reached an agreement with the FDA, under its Special Protocol Assessment ("SPA") process, for a Phase 3 trial evaluating axalimogene filolisbac in patients with HRLACC ("AIM2CERV" or "Advaxis Immunotherapy 2 Prevent Cervical Recurrence") to be conducted in collaboration with the GOG/NRG Oncology.

AIM2CERV is a double-blind, randomized, placebo-controlled, Phase 3 trial of adjuvant axalimogene filolisbac following primary chemoradiation treatment of women with HRLACC. The primary objective of AIM2CERV is to compare the disease free survival of axalimogene filolisbac to placebo administered in the adjuvant setting following standard concurrent chemotherapy and radiotherapy ("CCRT") administered with curative intent to patients with HRLACC. Secondary endpoints include examining overall survival and safety. Our goal is to develop a treatment to prevent or reduce the risk of cervical cancer recurrence after primary, standard of care treatment in women who are at high risk of recurrence. The current trial design has a planned sample size of 450 subjects to maintain adequate statistical power over a broader range of survival outcomes. In late 2018, we submitted a request to FDA to accelerate the interim analysis (IA) timeline and establish a more stringent futility and efficacy boundary. In January 2019, we announced that we received notice from FDA that they were placing a partial clinical hold on AIM2CERV. FDA's communication stated that the partial hold relates to their requests for additional information pertaining to certain AXAL chemistry, manufacturing and controls (CMC) matters. The Agency did not cite any safety issues related to the trial and all currently enrolled patients will continue to receive treatment, per the trial protocol. However, no new patients can enroll in AIM2CERV until resolution of this partial hold. We have submitted our initial response to their requests for additional CMC data and are currently in discussions with the Agency. In parallel, we are also in discussions with the Agency regarding our earlier IA request. We are working diligently to come to a resolution on both of these items.

Head and Neck Cancer

Squamous Cell Carcinoma of the Head and Neck ("SCCHN") is the most frequently occurring malignant tumor of the head and neck and is a major cause of morbidity and mortality worldwide. More than 90% of SCCHNs originate from the mucosal linings of the oral cavity, pharynx, or larynx and 70% of these cancers are caused by HPV. According to the American Cancer Society, head and neck cancer accounts for about 3% of all cancers in the United States. But while the Pap smear and other HPV tests have reduced rates of cervical cancer, rates of oral cavity and pharynx cancer are growing, with 51,540 new cases projected to be diagnosed in the United Stated in 2018 according to the Surveillance, Epidemiology, and End Results ("SEER") database.

A study published in the Annals of Internal Medicine found that approximately 12% of U.S. men and 3% of women were actively infected with oral HPV between 2011 and 2014. That totals 11 million men and 3 million women who are at risk for developing SCCHN. SCCHN is typically asymptomatic until it has metastasized, and screening options do not exist. The only way to prevent infection is the HPV vaccine, but compliance has been low to date. Another challenge is that preventative vaccines cannot protect those already infected or older than 26, leaving several generations of Americans vulnerable to SCCHN with no way of knowing if cancer is silently growing.

We conducted a clinical trial in collaboration with MedImmune to collaborate on a Phase 1/2, open-label, multicenter, two part trial to evaluate safety and efficacy of axalimogene filolisbac, in combination with durvalumab (MEDI4736), for patients with metastatic squamous or non-squamous carcinoma of the cervix and metastatic HPV-associated

SCCHN. Part 1 of this trial is complete and we and MedImmune have decided to not continue further enrollment into the expansion phases of this study.

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

Prostate Cancer (ADXS-PSA)

According to the American Cancer Society, prostate cancer is the second most common type of cancer found in American men and is the second leading cause of cancer death in men, behind only lung cancer. More than 160,000 men are estimated to be diagnosed with prostate cancer in 2018, with approximately 30,000 deaths each year. Unfortunately, in about 10 – 20% of cases, men with prostate cancer will go on to develop castration-resistant prostate cancer ("CRPC"), which refers to prostate cancer that progresses despite androgen deprivation therapy. Metastatic CRPC ("mCRPC") occurs when the cancer spreads to other parts of the body and there is a rising prostate-specific antigen ("PSA") level. This stage of prostate cancer is associated with deterioration in quality of life, and has few therapeutic options available.

According to a data review published by MD Anderson Cancer Center in 2016, checkpoint inhibitor monotherapy has not shown significant activity in mCRPC to date. The authors hypothesize that may be due to the inability of the checkpoint inhibitor to infiltrate the tumor microenvironment, and that combination therapy with agents that induce T cell infiltration within the tumor may improve performance of checkpoints in prostate cancer. Data from the Keynote-199 trial in bone predominant-mCRPC patients treated with KEYTRUDA® (pembrolizumab) was presented at the 2018 ASCO Annual Meeting. In this trial, only 4 out of 60 patients (7%) had decrease PSA post-baseline, with only 1 case that was ≥50%. The total SD/disease stabilization rate was 37%.

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

We have 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 x 10^9 cfu (n=7) and successfully escalated to higher dose levels of $5x10^9$ cfu (n=3) and $1x10^{10}$ cfu (n=3) without achieving a maximum tolerated dose. Treatment emergent adverse events noted at these higher dose levels were generally consistent with those observed at the lower dose level (1 x 10^9 cfu) other than a higher occurrence rate of Grade 2/3 hypotension. The ADXS-PSA monotherapy dose-determination phase of the trial has been completed. The Recommended Phase II Dose (RP2D) of ADXS-PSA monotherapy was determined to be 1x 10^9 cfu based on a review of the totality of the clinical data. This dose was used in combination with 200mg of pembrolizumab in a cohort of six patients to evaluate the safety of the combination before moving into an expanded cohort of patients. The safety of the combination was confirmed and enrollment in the expansion cohort phase was initiated. Enrollment in this phase of the trial (n = 37) was completed in January 2017.

Data of this study in mCRPC patients treated with ADXS-PSA monotherapy (Part A) and in combination with pembrolizumab (Part B) were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2018 and then further reported with updated data on April 1, 2019 at the American Association of Cancer Research (AACR) Annual Meeting. At entry, Part A and Part B patients were similar in age (~70 yrs), Gleason score (~8.3), absence of visceral metastases (71% vs. 70%) and prior abiraterone use. Part B patients had higher median baseline PSA values (40.6 vs. 20.8 ng/ml), and more prior enzalutamide (53% vs. 26%) and chemotherapy (49% vs. 36%) use versus Part A patients. A total of 49 patients (98%) experienced treatment-related adverse events (TRAE), mainly chills, fever, nausea and hypotension. Five Part A and 13 Part B patients had grade 3-4 events: fatigue, hypotension, hypertension, anemia. Treatment-related adverse events (TRAEs) were mostly mild or moderate constitutional symptoms such as fever, chills, rigors, hypotension, nausea and fatigue, consistent with immune activation and manageable with standard care. One patient in the monotherapy arm was discontinued from the study due to a grade 4 TRAE related to cytokine release, which resolved within 24 hours using medical management. Overall, two Part A (14%) v 16 Part B patients (43%) had a decreased PSA post-baseline. Of these, six Part B (22%) versus 0 Part A patients achieved a PSA reduction ≥50% from baseline. Part B patients had higher rates (56.8%) of stable disease/disease stabilization than Part A patients (38.5%). Part B patients had higher rates (27%) of stable disease than monotherapy patients (7.7%). In all treated patients, an improvement in survival was observed in Part B patients with ≥ 50% PSA declines from baseline versus those with < 50% PSA declines. As of the data cutoff date of

February 1, 2019, survival benefit was seen regardless of PSA decline or prior treatment with chemotherapy and/or next-generation hormonal agents and median overall survival was 21 months (95%CI 17.4-NR) in the combination arm. Correlative immune analyses show T-cell responses against PSA in 75% of subjects in the combination arm and antigen spreading in 85% of subjects in the combination arm. In this population of heavily pretreated mCRPC patients, ADXS-PSA + pembrolizumab had a manageable safety profile (mostly grade 1-2 TRAEs) and showed a greater level of activity compared to monotherapy.

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.

The FDA has allowed the IND application of ADXS-NEO and in June 2018, we announced the commencement of a Phase 1 trial with the dosing of the first patient with ADXS-NEO. ADXS-NEO is being evaluated in an open-label, dose-escalation, multicenter clinical trial in the United States. The study is open to patients with metastatic non-small cell lung cancer (NSCLC), metastatic microsatellite stable colon cancer and metastatic squamous head and neck cancer. The study had been in development in collaboration with Amgen until December 2018, when Amgen provided us with a notice of termination of their existing collaboration. We provided an update on this program in March 2019 and disclosed that four patients have been evaluated across two dose levels. Dose level one (1X109 CFU) was determined to be above the maximum tolerated dose, dose level -1 (1X108 CFU) has been safe and well tolerated in two patients treated to date. Notable observations across both dose levels have been rapid neoantigen-specific CD8+ T cell generation, as well as evidence of antigen spreading and T cell trafficking into the tumor microenvironment.

Disease Focused Hotspot/Off-the-Shelf Neoantigen Therapies (ADXS-HOT)

We have created a new group of immunotherapy constructs for major cancers that combines our optimized *Lm* Technology vector with promising targets to generate potent anti-cancer immunity. The ADXS-HOT program is a series of novel cancer immunotherapies that target somatic mutations (“hotspots”), cancer testis antigens (“CTAs”) and oncofetal antigens (“OFAs”). These three types of targets form the basis of the ADXS-HOT program because they are designed to be more capable of generating potent, tumor specific, and high strength killer T cells, versus more traditional over-expressed native sequence TAAs. Most hotspot mutations and OFA/CTA proteins play critical roles in oncogenesis; targeting both at once could significantly impair cancer proliferation. The ADXS-HOT products combine many of the potential high avidity targets that are expressed in all patients with the target disease into one “off-the-shelf”, ready to administer treatment. The ADXS-HOT technology has a strong Intellectual Property (“IP”) position, with potential protection into 2039, and an IP filing strategy providing for broad coverage opportunities across multiple disease platforms and combination therapies.

In July 2018, we announced that the U.S. Food and Drug Administration (FDA) allowed our IND application for our ADXS-HOT drug candidate for non-small cell lung cancer (NSCLC). In February 2019, we announced that the first patient has been enrolled into the study. We anticipate an early readout of safety, tolerability and immune correlative data from the first cohort in mid-2019. In addition, we plan to file additional ADXS-HOT INDs in 2019, in prostate and bladder cancers.

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

Canine Osteosarcoma

On March 19, 2014, we entered into a definitive Exclusive License Agreement (the "Aratana Agreement") with Aratana Therapeutics, Inc. ("Aratana"), where we granted Aratana an exclusive, worldwide, royalty-bearing license, with the right to sublicense, certain of our proprietary technology that enables Aratana to develop and commercialize animal health products that will be targeted for treatment of osteosarcoma and other cancer indications in animals. A product license request was filed by Aratana for ADXS-HER2 (also known as AT-014 by Aratana) for the treatment of canine osteosarcoma with the United States Department of Agriculture ("USDA"). Aratana received communication in December 2017 that the USDA granted Aratana conditional licensure for AT-014 for the treatment of dogs diagnosed with osteosarcoma, one year of age or older. Aratana is currently conducting an extended field study which is a requirement for full USDA licensure.

Under the terms of the Aratana Agreement, Aratana paid an upfront payment to us in the amount of $1,000,000 upon signing of the Aratana Agreement. Aratana will also pay us: (a) up to $36.5 million based on the achievement of milestone relating to the advancement of products through the approval process with the USDA in the United States and the relevant regulatory authorities in the European Union ("E.U.") in all four therapeutic areas and up to an additional $15 million in cumulative sales milestones based on achievement of gross sales revenue targets for sales of any and all products for use in non-human animal health applications (the "Aratana Field") (regardless of therapeutic area), and (b) tiered royalties starting at 5% and going up to 10%, which will be paid based on net sales of any and all products (regardless of therapeutic area) in the Aratana Field in the United States. Royalties for sales of products outside of the United States will be paid at a rate equal to half of the royalty rate payable by Aratana on net sales of products in the United States (starting at 2.5% and going up to 5%). Royalties will be payable on a product-by-product and country-by-country basis from first commercial sale of a product in a country until the later of (a) the 10th anniversary of first commercial sale of such product by Aratana, its affiliates or sub licensees in such country or (b) the expiration of the last-to-expire valid claim of our patents or joint patents claiming or covering the composition of matter, formulation or method of use of such product in such country. Aratana will also pay us 50% of all sublicense royalties received by Aratana and its affiliates. In fiscal year 2018, we received approximately $3,000 in royalty revenue from Aratana.

Recent Developments

Reverse Stock Split

On March 29, 2019, following receipt of the requisite stockholder approval at our annual meeting, we amended our restated certificate of incorporation to affect a 15-for-1 reverse stock split (the "Reverse Stock Split") of our issued and outstanding shares of common stock. The Reverse Stock Split had the effect of reducing the number of outstanding shares from 82,604,764 to 5,506,984. Unless otherwise indicated, per share amounts, stock option and warrant exercise prices and numbers of shares in this prospectus supplement have been adjusted to reflect the effects of the Reverse Stock Split.

In addition to affecting the number of outstanding shares, the Reverse Stock Split had the effect of causing each outstanding Warrant to purchase one share of Common Stock for $4.50 to be adjusted to entitle the holder to purchase one-fifteenth of a share of Common Stock for $0.30.

Warrant Exchange

On March 14, 2019, we entered into private exchange agreements (the "Exchange Agreements") with certain holders of warrants issued in connection with our September 2018 public offering of common stock and warrants (the "Warrants"). The Warrants that were exchanged originally provided for the purchase of up to an aggregate of 856,865 shares of our common stock at an exercise price of $22.50, with an expiration date of September 11, 2024. Pursuant to the Exchange Agreements, on March 15, 2019, we issued 856,865 shares of common stock to the holders in exchange for such Warrants on a 1:1 basis (the "Warrant Exchanges"). No additional shares of our common stock were issued in connection with the exchanges on a fully diluted basis. The Warrant Exchanges caused the exercise price of the warrants that were not exchanged to be reduced from $1.50 to $0.30.

Authorized Share Increase