

Advaxis, Inc.  
Form 424B5  
September 06, 2018

The information in this preliminary prospectus supplement is not complete and may be changed. A registration statement relating to these securities has been filed with the Securities and Exchange Commission and is effective. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell these securities and they are not soliciting an offer to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

**Filed Pursuant Rule 424(b)(5)**

**Registration No. 333-226988**

SUBJECT TO COMPLETION, DATED SEPTEMBER 6, 2018

PRELIMINARY PROSPECTUS SUPPLEMENT

(To Prospectus dated August 30, 2018)

**shares of Common Stock**

**and**

**Warrants to purchase up to                      shares of Common Stock**

We are offering                      shares of our common stock and warrants to purchase up to                      shares of our common stock (and the common stock issuable from time to time upon exercise of the offered warrants). The shares of common stock and warrants will be sold together, with each share of common stock to be sold together in a fixed

combination with a warrant to purchase \_\_\_\_\_ shares of common stock. The combined purchase price for each share of common stock and accompanying warrant is \$ \_\_\_\_\_.

Each warrant will have an exercise price of \$ \_\_\_\_\_ per share, will become exercisable commencing on the date of issuance, and will expire on September \_\_\_\_\_, 2024. The shares of common stock and accompanying warrants are immediately separable and will be issued separately, but will be purchased together in this offering.

Our common stock is traded on the Nasdaq Global Select Market under the symbol “ADXS.” On September 5, 2018, the last reported sale price of our common stock on the Nasdaq Global Select Market was \$1.52 per share. There is currently no established trading market for the offered warrants. We do not plan on applying to list the warrants on the Nasdaq Global Select Market, any other national securities exchange or any other nationally recognized trading system.

**Investing in our securities involves a high degree of risk. See “Risk Factors” beginning on page S-8 of this prospectus supplement and 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 AND ACCOMPANYING WARRANT	Total
Public offering price	\$	\$
Underwriting discounts and commissions <sup>(1)</sup>	\$	\$
Proceeds to us (before expenses) <sup>(2)</sup>	\$	\$

<sup>(1)</sup> We have agreed to reimburse the underwriters for certain expenses. See “Underwriting” beginning on page S-24 of this prospectus supplement for a description of the compensation payable to the underwriters.

<sup>(2)</sup> The amount of the offering proceeds to us presented in this table does not give effect to any exercise of the warrants being issued in this offering.

Delivery of the shares of common stock and warrants is expected to be made on or about \_\_\_\_\_, 2018.

**Cantor Oppenheimer & Co.**

Prospectus Supplement dated , 2018

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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, these securities only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of the securities 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 securities 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 similar 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,” “approximately,” and “likely,” and 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;  
any stockholder dilution that will result from this offering and 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;  
our ability to establish and manage strategic collaborations;  
our ability to initiate trials, enroll our trials, obtain and maintain approval of our product candidates;  
our ability to manufacture and the performance of third-party manufacturers;  
the performance of our clinical research organizations, clinical trial sponsors and clinical trial investigators; and  
our ability to successfully implement our strategy.

Any forward-looking statements that we make in this 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, 2017, as filed with the SEC on December 21, 2017, 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*, or *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 deploys a unique mechanism of action that redirects the immune system to attack cancer in three distinct ways by:

Alerting and training the immune system by activating multiple pathways in antigen-presenting cells, or 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, or TME, that shields the tumor from the immune system. This enables the activated T cells to begin working to eliminate the tumor.

During the second fiscal quarter, in an effort to maximize stockholder value and reduce operating expenses, we began assessing the clinical and commercial viability of our R&D programs in order to determine which were best suited for internal development and which were better suited for external development opportunities. In particular, we announced plans to take the following actions:

Minimize future investment in cervical cancer and focus on potential partnership opportunities. While our lead Human Papillomavirus, or HPV, program, axalimogene filolisbac, has shown meaningful clinical efficacy and

supports the manageable safety profile of the *Lm* platform in HPV-related cancers, we plan to expand our search for a U.S. and/or European partner, who will need to take on all development and commercialization activities and costs related to the HPV program. In the event no partner emerges, we intend to wind down the ongoing trial in high risk locally advanced cervical cancer (AIM2CERV) and not conduct the PD-1 combination trial in metastatic cervical cancer (ADVANCE), which has yet to be initiated.

Evaluate cost effective ways to invest in axalimogene filolisbac in head-and-neck cancer through internal or external partnerships, or both.

With respect to our ongoing trial in metastatic prostate cancer with ADXS-PSA in combination with KEYTRUDA® (“pembrolizumab”), Merck & Co.’s, or Merck’s, anti PD-1 antibody, early clinical data have proven worthy of continued evaluation. The Company intends to continue to evaluate our ongoing trial in metastatic prostate cancer with ADXS-PSA in combination with KEYTRUDA® (“pembrolizumab”), Merck’s anti PD-1 antibody. Early clinical data have proven worthy of continued evaluation and we intend to evaluate this program into the first quarter of 2019 to determine a path forward.

Increase internal investment in our ADXS-NEO and ADXS-HOT programs, both of which target neoantigens, which are antigens encoded by tumor-specific mutated genes, a potentially transformational, next-generation approach to treating cancer.

In addition, on June 7, 2018, we announced that we would be implementing a reduction in force to align our staffing needs with our new strategy. The reduction involved the elimination of approximately 24% of our work force to better align our resources with our strategy outlined above.

### *ADXS-HOT*

We are currently prioritizing product development in the most prevalent cancers, with the first tumor type to be non-small cell lung cancer, or NSCLC. We plan to file multiple ADXS-HOT INDs in 2018, with a first-in-human trial in NSCLC to commence in 2018. On July 30, 2018, we announced the FDA's allowance of its ADXS-HOT IND in NSCLC. Going forward, we plan to submit additional INDs for the ADXS-HOT program with prostate cancer (2018) and bladder cancer (2019) selected as our next ADXS-HOT programs along with a fourth ADXS-HOT drug candidate to be selected from breast, colorectal, ovarian or head and neck cancers.

ADXS-HOT preclinical data was presented in a poster presentation at the 2018 Annual Meeting of the American Association of Cancer Research, or AACR. The study, entitled "Targeting Shared Hotspot Cancer Mutations with a *Listeria monocytogenes* Immunotherapy Induce Potent Anti-Tumor Immunity" demonstrated that the ADXS-HOT platform could effectively target common (public or shared) mutations (hotspots) and control tumor growth with both single and multi-target constructs.

### *ADXS-NEO*

On August 1, 2016, we entered into a global agreement, or the Amgen Agreement, with Amgen Inc., or Amgen, for the development and commercialization of our ADXS-NEO program, a novel, preclinical investigational immunotherapy, using our proprietary *Listeria monocytogenes* attenuated bacterial vector, which activates a patient's immune system to respond against unique mutations, or neopeptides, 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. Under the Amgen Agreement, Amgen made an upfront payment to us of \$40 million and purchased an additional \$25 million of our common stock. Amgen will fund the clinical development and commercialization of ADXS-NEO while we will retain manufacturing responsibilities. We will collaborate with Amgen through a joint steering committee for the development and commercialization of ADXS-NEO. We will also receive development, regulatory and sales milestone payments of up to \$475 million and high single digit to double digit royalty payments based on worldwide sales.

Preclinical findings in our ADXS-NEO program were discussed in poster presentations at the 2018 AACR Annual Meeting. Additionally, portions of these data were presented by Amgen at a podium presentation during the European Neoantigen Summit 2018.

The first study, as discussed in a poster presentation at the AACR 2018 Annual Meeting entitled “Neoantigens that fail to elicit measurable T cell responses following peptide immunization can control tumor growth when delivered using a *Listeria*-based immunotherapy platform,” showed that ADXS-NEO generates T cell responses against neoantigen peptides that control tumor growth, even when they were identified as “non-immunogenic” using a conventional peptide-adjuvant immunization.

In the second study, discussed in a poster presentation at the AACR 2018 Annual Meeting entitled “Targeting frameshift mutations with a *Listeria monocytogenes* immunotherapy drives neoantigen-specific antitumor immunity in MC38 and CT26 mouse tumor models,” Our *Lm* platform was shown to target frameshift mutations and generate T cells to multiple neoantigens per frameshift in these models. This data highlighted the physical capacity of our *Lm* platform and its ability to target frameshift mutations of greater than 90 amino acids, and to generate T cells to multiple neoantigens per frameshift in tumor mouse models.

The initial tumor types for the ADXS-NEO Phase 1 trial are microsatellite stable colorectal cancer, head and neck cancer, and NSCLC. On June 11, 2018, we announced that the first patient, being treated for metastatic NSCLC, was dosed in our ADXS-NEO Phase 1 trial.

### *ADX-PSA*

We are conducting a Phase 1/2, open-label, multicenter, dose determination and expansion trial in collaboration with Merck evaluating the safety and efficacy of ADXS-PSA as a monotherapy and in combination with KEYTRUDA® in patients with previously treated metastatic, castration-resistant prostate cancer. We presented data at the 2018 American Society of Clinical Oncology, or ASCO, annual meeting. 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. Overall, the safety profile was consistent with findings from prior clinical studies using the *Lm* platform. Treatment-related adverse events 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. There were no new toxicities observed with the combination therapy. In all treated patients, those who received the combination therapy experienced the longest overall survival, or OS, at data cut-off. Additional efficacy related data include:

Median overall survival had not been reached in the combination arm after 13 months of follow-up (95%CI 7.16-NR), and was 7.79 months (95%CI 3.52-11.9) in the monotherapy arm.

56.8% of patients on combination therapy and 38.5% of patients on monotherapy did not experience disease progression.

The percentage of patients with prostate-specific antigen, or PSA, declines from baseline in the combination therapy arm was 40.5%, and 15.4% in the monotherapy arm.

In all treated patients, an improvement in survival was observed in patients with PSA declines from baseline of 50% or greater vs. those with PSA declines of less than 50%. There were 7 patients in the combination arm with 50% or greater declines in PSA from baseline, and none in the monotherapy arm.

### **HPV Related Cancers**

We have several programs in HPV-related cancers based on axalimogene filolisbac, an *Lm*-based antigen delivery product designed to target cells expressing HPV. Axalimogene filolisbac is currently under investigation in three HPV-associated cancers: cervical cancer, head and neck cancer, and anal cancer, either as a monotherapy or in combination with other therapies, and has shown encouraging safety and efficacy in numerous clinical studies to date.

#### *Cervical Cancer*

We previously completed a randomized Phase 2 clinical study (*Lm*-LLO-E7-15), conducted exclusively in India, in 110 women with recurrent/refractory cervical cancer. The final results showed that 34.9% (38/109) of patients were

alive at 12 months, 24.8% (27/109) of patients were Long-term Survivors, or LTS, alive greater than 18 months. Of the 15 patients consenting to further follow-up beyond 18 months, 12 (or 11%) achieved 24-month OS status (range 24 – 34+ months) at the time of study closure. Axalimogene filolisbac was found to be well tolerated with the majority of the AEs were mild to moderate in severity (566 of 704 reported adverse events, or 80.4%) and were not related to study drug (539 of 704 reported AEs, 76.6%). These data were published in the May 2018 edition of the peer-reviewed *International Journal of Gynecological Cancer*.

We also previously reported results from a Phase 2 clinical study (GOG-0265) in 50 patients, which showed a 12-month overall survival rate (primary efficacy endpoint) of 38% (n=19/50) in women with persistent, recurrent or metastatic carcinoma of the cervix, representing a 55% improvement over a model-predicted 12-month overall survival rate of 24.5%. As more than half of the women treated in this study had received multiple prior lines of therapy including with bevacizumab treatment, the 38% 12-month overall survival rate was unprecedented when compared against historical data. We continue to believe that the results from the GOG-0265 study are clinically meaningful and provide proof-of-concept that axalimogene filolisbac demonstrated clinical activity in metastatic cervical cancer.

Our ongoing Phase 3 trial, AIM2CERV or “Advaxis Immunotherapy 2 Prevent Cervical Recurrence”, is evaluating axalimogene filolisbac in patients with high-risk, locally advanced cervical. The study is being conducted under a Special Protocol Assessment, and has been determined by the FDA to be adequate, well-designed, and suitable for registration if successful. This study is being conducted in collaboration with the GOG/NRG Oncology, and we have initiated the AIM2CERV study to support a Biologics License Application submission in the United States and regulatory registration in other territories around the world.

AIM2CERV is a double-blind, randomized, placebo-controlled, Phase 3 study of adjuvant axalimogene filolisbac, following primary chemoradiation treatment of women with high-risk locally advanced cervical cancer, or 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 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 study is active in fourteen countries with 129 sites open to date.

In February 2018, we submitted a conditional marketing authorization application, or MAA, to the European Medicines Agency's, or EMA, Committee for our lead *Lm* Technology product candidate, axalimogene filolisbac, for the treatment of adult women who progress beyond first-line therapy of persistent/recurrent metastatic cervical cancer, or PRmCC. The MAA submission was primarily based on data from the GOG-0265 study, as well as supportive data from other clinical trials evaluating axalimogene filolisbac and was validated by the EMA in March 2018.

On July 10, 2018, we announced plans to withdraw our conditional MAA based on EMA feedback following its initial review indicating the application will likely need additional data to support a conditional approval. We continue to believe the results from the GOG-0265 study are clinically meaningful and provide proof-of-concept that axalimogene filolisbac demonstrated clinical activity in metastatic cervical cancer. The withdrawal of this application does not impact the ongoing clinical trials of axalimogene filolisbac. We are seeking a U.S. and/or European partner to fund the development and commercialization of axalimogene filolisbac in cervical cancer including the completion of the AIM2CERV study. If a partner is not found, subject to ongoing discussions with our collaboration partners over our obligations with respect the program, we anticipate winding down the program in a clinically responsible manner. We may incur additional costs in connection with such a wind-down, including in severing our relationship with our collaboration partners, some of which are indeterminable at this time and there is no guarantee that we will be able to wind down the program effectively.

#### *MedImmune Collaboration*

We have a clinical trial collaboration agreement with MedImmune, the global biologics research and development arm of AstraZeneca, and are conducting a Phase 1/2, open-label, multicenter, two-part study to evaluate the safety and efficacy of axalimogene filolisbac in combination with MedImmune's investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab, as a combination treatment for patients with metastatic squamous or non-squamous carcinoma of the cervix and metastatic HPV-associated SCCHN. For the axalimogene filolisbac and durvalumab dose escalation portion of the study, the dose-escalation phase has been completed. We have commenced enrollment in the Part A (20 patients with SCCHN) and B (90 patients with cervical cancer) expansion phases; however, this trial was placed on clinical hold by FDA on March 9, 2018. following its review of a safety report regarding a Grade 5 Serious Adverse Event occurring on February 27, 2018 and involving respiratory failure which followed a sixth combination cycle



(11th dose of axalimogene filolisbac, 21st dose of durvalumab) in the trial. Over 430 patients have received axalimogene filolisbac, and approximately 1,259 doses have been delivered across multiple trials in HPV-associated cancers, to date, and this is the first time we have seen this type of event. New guidelines for the early detection and treatment of such rare events were agreed to with the FDA and will be implemented for this combination study. Enrollment and dosing in all other Advaxis and durvalumab clinical programs were not affected by the clinical hold. On July 13, 2018, we announced that the FDA lifted its clinical hold for this trial.

*BMS Collaboration*

We entered into a clinical development collaboration agreement with Bristol-Myers Squibb to evaluate their PD-1 immune checkpoint inhibitor, OPDIVO® (nivolumab), in combination with axalimogene filolisbac as a potential treatment option for women with metastatic cervical cancer. The ADVANCE trial was planned to evaluate this combination regimen in women with persistent, recurrent or metastatic (squamous or non-squamous cell) carcinoma of the cervix who have failed at least one prior line of systemic chemotherapy. Under the terms of the agreement, each party would bear its own internal costs and provide its immunotherapy agents. This trial has not yet been initiated as the Company is seeking a U.S. and/or European partner to fund the cervical cancer program. If a partner is not found, the study will not be initiated.

### ***Head and Neck Cancer***

We have entered into a clinical trial collaboration agreement with MedImmune to collaborate on a Phase 1/2, open-label, multicenter, two part trial to evaluate safety and efficacy of axalimogene filolisbac, in combination with durvalumab (MEDI4736), for patients with metastatic squamous or non-squamous carcinoma of the cervix and metastatic HPV-associated SCCHN. Part 1 of this trial is complete, and the Company has commenced enrollment in the Part A (20 patients with SCCHN) and B (90 patients with cervical cancer) expansion phases; however, this trial was placed on clinical hold as detailed above. New guidelines for the early detection and treatment of such rare events were agreed to with the FDA and will be implemented for this combination study. On July 13, 2018, the Company announced that FDA lifted its clinical hold for this trial.

We are evaluating opportunities to conduct a capital efficient trial evaluating axalimogene filolisbac in head and neck cancer and are in discussions with third parties about a potential study.

### **Recent Developments**

#### *Financial Update*

While we have not finalized our full financial results for the fiscal quarter ended July 31, 2018, we expect to report that we had approximately \$40.4 million of cash, cash equivalents and restricted cash as of July 31, 2018. This amount is preliminary, has not been audited and is subject to change pending completion of our unaudited financial statements for the quarter ended July 31, 2018. Additional information and disclosures would be required for a more complete understanding of our financial position and results of operations as of July 31, 2018.

### **Company 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 we were uplisted to Nasdaq in 2013.

Our principal executive offices are located at 305 College Road East, Princeton, New Jersey 08540 and our telephone number is (609) 452-9813. We maintain a corporate website at [www.advaxis.com](http://www.advaxis.com) which contains descriptions of our technology, our product candidates and the development status of each drug. We are not including the information on our website as a part of, nor incorporating it by reference into, this prospectus supplement or the accompanying prospectus. For further information regarding us and our financial information, you should refer to our recent filings with the SEC. See “Where You Can Find More Information” and “Incorporation of Certain Information by Reference.”

**The Offering**

Common stock offered by us	Shares
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