Advaxis, Inc.
Form 424B5
October 17, 2013

**Filed pursuant to Rule 424(b)(5)**
**Registration Statement No. 333-188637**
**Registration Statement No. 333-191769**

# 5,750,000 Shares of Common Stock

# Warrants to Purchase 2,875,000 Shares of Common Stock

We are offering 5,750,000 shares of our common stock and warrants to purchase up to an aggregate of 2,875,000 shares of our common stock. The warrants will have a per share exercise price of $5.00 per share, 125% of public offering price of the common stock. The warrants are exercisable immediately and will expire five years from the date of issuance. On July 12, 2013, we effected a 1-for-125 reverse stock split of our issued and outstanding common stock.

Our common stock is traded on the OTCQB Marketplace, operated by the OTC Markets Group, under the symbol ADXS. We have received approval to list our common stock and warrants on The NASDAQ Capital Market under the symbols ADXS and ADXSW, respectively. We expect the common stock and warrants will begin trading on The NASDAQ Capital Market on October 17, 2013. On October 16, 2013, the last reported sale price for our common stock on the OTCQB Marketplace was $4.99 per share.

**Our business and an investment in our securities involves a high degree of risk. See Risk Factors beginning on page 19 of this prospectus for a discussion of information that you should consider before investing in our securities.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

| | Per Share | Per Warrant | Total |
|---|---|---|---|
| Public offering price | $4.00 | $.001 | $23,002,875 |
| Underwriting discounts and commissions(1) | $.28 | $.00007 | $1,610,201 |
| Proceeds, before expenses, to us | $3.72 | $.00093 | $21,392,674 |

(1) There will be additional items of value paid in connection with this offering that are viewed by the Financial Regulatory Authority, Inc. as underwriting compensation. Payment of this additional underwriting compensation will reduce the proceeds to us, before expenses. See Underwriting beginning on page 110 of this prospectus for a description of compensation payable to the underwriters.

The underwriters may also purchase up to an additional 862,500 shares of common stock and 431,250 warrants from us at the public offering price, less the underwriting discount, within 45 days from the date of this prospectus to cover over-allotments, if any.

The underwriters expect to deliver the shares and warrants against payment therefor on or about October 22, 2013.

# Aegis Capital Corp

October 16, 2013

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You should rely only on the information contained in this prospectus or in any free writing prospectus that we may specifically authorize to be delivered or made available to you. We have not, and the underwriters have not, authorized anyone to provide you with any information other than that contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus may only be used where it is legal to offer and sell our securities. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date. We are not, and the underwriters are not, making an offer of these securities in any jurisdiction where the offer is not permitted.

For investors outside the United States: We have not and the underwriters have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside the United States.

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# PROSPECTUS SUMMARY

*This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our securities, you should carefully read this entire prospectus, including our financial statements and the related notes and the information set forth under the headings Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations in each case included elsewhere in this prospectus. Unless otherwise stated or the context requires otherwise, references in this prospectus to Advaxis, we, us, or our refer to Advaxis, Inc.*

# Advaxis, Inc.

## Business Overview

We are a clinical development stage biotechnology company focused on the discovery, development and commercialization of our proprietary *Lm*-LLO immunotherapy product candidates to treat cancers and infectious diseases. These immunotherapies are based on a platform technology that utilizes live attenuated *Listeria monocytogenes,* which we refer to as *Listeria* or *Lm*, that have been bioengineered to secrete antigen/adjuvant fusion proteins. We believe that these *Lm*-LLO strains are a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy because they access and direct antigen presenting cells, or APC, to stimulate anti-tumor T-cell immunity, stimulate and activate the immune system with the equivalent of multiple adjuvants, and simultaneously reduce tumor protection in the tumor microenvironment to enable the T-cells to eliminate tumors. Other immunotherapies may employ individual elements of our comprehensive approach, but, to our knowledge, none combine all of these elements together in a single, easily administered, well-tolerated yet comprehensive immunotherapy.

The effectiveness of our approach has been validated by numerous publications in multiple models of human disease. In the clinic, ADXS-HPV, our lead *Lm*-LLO immunotherapy product candidate for the treatment of Human Papilloma Virus-, or HPV-, associated diseases, is well-tolerated and has been administered to both young patients with pre-malignant dysplasia, as well as patients with advanced disease. Clinical efficacy has been demonstrated by apparent prolonged survival, complete and partial tumor responses, and the prolonged stabilization of advanced cancer. The preliminary data from our ongoing Phase 2 clinical trial of ADXS-HPV in patients with recurrent cervical cancer demonstrate that ADXS-HPV is an active agent in this disease setting with a manageable safety profile. We achieved proof of concept with this Phase 2 study, and over the next two to five years, we plan to advance ADXS-HPV through registrational Phase 3 trials and regulatory approval(s) in the United States and relevant markets for the treatment of women with cervical cancer. We are currently evaluating this same *Lm*-LLO immunotherapy in Phase 1 and Phase 1/2 clinical trials for two other HPV-associated cancers: head and neck cancer and anal cancer, respectively. In June 2013, we submitted three requests for orphan drug designation to the U.S. Food and Drug Administration, or FDA, Office of Orphan Products Development, or OOPD, for ADXS-HPV in the treatment of anal cancer (granted August 2013), invasive cervical cancer (denied in October 2013 as the target population estimate exceeded the statutory maximum allowed; we appealed the denial of our request in October 2013 and a response from OOPD is pending), and head and neck cancer (our request to OOPD is pending). In October 2013, we submitted a request for breakthrough therapy designation to the investigational new drug, or IND, application submitted to the FDA for ADXS-HPV in the treatment of invasive cervical cancer. In addition, we plan to advance ADXS-PSA, which is an *Lm*-LLO immunotherapy directed against prostate-specific antigen, or PSA, our second *Lm*-LLO immunotherapy, into a Phase 1 trial to determine the maximum tolerated dose for the treatment of prostate cancer in

the first half of 2014. We plan for this to be a dose escalation trial to evaluate safety and determine the maximum tolerated dose for the treatment of prostate cancer. A third *Lm*-LLO immunotherapy, ADXS-cHER2, is being evaluated for safety and efficacy in the treatment of companion dogs with human epidermal growth factor receptor-2, or HER2, over-expressing osteosarcoma.

We have a robust and extensive patent portfolio that protects our core *Lm*-LLO immunotherapy technology. Our current patent portfolio includes 42 issued patents and 38 pending patent applications. To develop our technology, we may enter into commercial partnerships, joint ventures, or other arrangements with competitive or complementary companies, including pharmaceutical or biotechnology companies or universities during the preclinical or clinical stages. Our current collaborations include the preclinical development of *Lm*-LLO

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immunotherapies for a number of indications. We currently have over 15 distinct immunotherapies in various stages of development, developed directly by us and through strategic collaborations with recognized centers of excellence. These include but are not limited to the following Advaxis immunotherapy and corresponding tumor antigen: ADXS11-001/HPV16-E7, ADXS31-142/Prostate Specific Antigen, ADXS31-164/HER2/neu Chimera, Lm-LLO-HMW-MAA/HMW-MAA, C-terminus fragment, Lm-LLO-ISG15/ISG15, Lm-LLO CD105/Endoglin, Lm-LLO-flk/VEGF and Bivalent Therapy, HER-2-Chimera/HMW-MAA-C. We will continue to conduct preclinical research to develop additional *Lm*-LLO constructs to expand our platform technology and may develop additional distinct immunotherapies in the future. We are exploring potential development and commercialization collaborations for certain product candidates in our development pipeline.

We have sustained losses from operations in each fiscal year since our inception, and we expect these losses to continue for the indefinite future, due to the substantial investment in research and development. As of July 31, 2013 and October 31, 2012, we had an accumulated deficit of $60,181,464 and $47,601,427, respectively, and stockholders deficiency of $6,726,819 and $5,962,724, respectively.

**Our *Lm*-LLO Immunotherapy Platform Technology**

Our *Lm*-LLO immunotherapies are based on a platform technology under exclusive license from the Trustees of the University of Pennsylvania, or Penn, that utilizes live attenuated *Lm* bioengineered to secrete antigen/adjuvant fusion proteins within APC, to generate a strong T-cell immunity. These *Lm* strains use a fragment of the protein listeriolysin, or LLO, fused to a tumor associated antigen, or TAA, or other antigen of interest. We refer to these as *Lm*-LLO immunotherapies. We believe these *Lm*-LLO immunotherapies redirect the potent immune response to *Lm* that is inherent in humans to the TAA or antigen of interest. In addition, our technology facilitates the immune response by altering the tumor microenvironment to reduce immunologic tolerance in the tumors but leave normal tissues unchanged. This makes the tumor more susceptible to immune attack.

The field of immunotherapy is a relatively new area of cancer treatment development that holds tremendous promise to generate more effective and better tolerated treatments for cancer than the more traditional, high dose chemotherapy and radiation therapies that have been the mainstay of cancer treatment thus far. There are many approaches toward immunotherapy that have been recently approved or are in development. We believe *Lm*-LLO immunotherapies will offer a more comprehensive immunotherapy in a single, well-tolerated, easy to administer treatment than other alternative immunotherapy treatments.

The following diagram illustrates how the live attenuated *Lm* in our immunotherapies are phagocytosed and processed by an APC leading to the stimulation of CD4+ T cell, or helper T cells, and CD8+ T cells, or killer T cells.

Live attenuated *Lm* bioengineered to secrete an antigen-adjuvant fusion protein (antigen + tLLO) stimulate a profound innate immune response and are phagocytized by APC. Fragments from *Lm* are processed via the major histocompatibility complex, or MHC, class II generating antigen specific CD4 + T cells. Some *Lm* escapes into the cytosol and secretes antigen-LLO fusion proteins. Fusion protein antigens are presented via MHC class I pathway to generate activated CD8+ T cells. The activated T cells will then find and infiltrate tumors and destroy

the tumor cells. Immunologic tolerance in the tumor microenvironment mediated by regulatory T cells, or Tregs, and myeloid-derived suppressor cells, or MDSC, is reduced. Thus we believe *Lm*-LLO immunotherapies may stimulate innate and adaptive tumor-specific immunity while simultaneously reducing immune tolerance to tumors.

We believe our *Lm*-LLO immunotherapies integrate all four of what we consider to be the essential elements of a cancer immunotherapy into a comprehensive, single, well-tolerated, easy to manufacture and administer immunotherapy.

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**Our Preclinical and Clinical Development Pipeline**

Our most advanced product candidates in clinical development are ADXS-HPV, ADXS-PSA and ADXS-cHER2:

***ADXS-HPV***. ADXS-HPV is an *Lm*-LLO immunotherapy directed against HPV-associated cancers. ADXS-HPV directs the patient s own APC to generate a comprehensive immune response focused around creating cytotoxic T-cells that we believe may be capable of infiltrating the tumors and directly killing HPV-transformed cancer cells. At the same time, ADXS-HPV also causes a reduction in the number and function of immunosuppressive regulatory Tregs and myeloid-derived suppressor cells, or MDSC, that protect tumors by deactivating T-cells, thereby potentially enabling the cytotoxic T-cells to be effective at killing tumor cells within the tumor microenvironment. We plan to advance ADXS-HPV through registrational Phase 3 trials and regulatory approval(s) in the United States and relevant markets for the treatment of women with cervical cancer. We are also in early stage clinical trials for head and neck cancer and for anal cancer. Future plans for the ADXS-HPV franchise are contingent upon a number of variables including available resources, types and number of studies, study initiation, patient enrollment, clinical and safety data generated, regulatory interactions and changing competitive landscape.

***ADXS-PSA***. ADXS-PSA is an *Lm*-LLO immunotherapy directed against PSA. ADXS-PSA is designed to target cells expressing PSA. ADXS-PSA secretes the PSA antigen, fused to LLO, directly inside the APC, that are cable of driving a cellular immune response to PSA expressing cells. In preclinical analysis, the localized effect is the inhibition of the Treg and MDSC cells that we believe may promote immunologic tolerance of the PSA cancer cells of the tumor. We have conducted a pre-Investigational New Drug application, or IND, meeting with the FDA to discuss the chemistry, manufacturing and controls, pharmacology, toxicity and clinical plans for ADXS-PSA. We will finalize the toxicology and good manufacturing practice, or GMP, documentation required for the IND we plan to submit to the FDA and advance ADXS-PSA into a Phase 1 dose escalation trial to determine the maximum tolerated dose for the treatment of prostate cancer. Future plans for the ADXS-PSA clinical program are contingent upon a number of variables including available resources, types and number of studies, study initiation, patient enrollment, clinical and safety data generated, regulatory interactions and changing competitive landscape.

***ADXS-cHER2***. ADXS-cHER2 is an *Lm*-LLO immunotherapy for HER2 overexpressing cancers (such as breast, gastric and other cancers in humans and for osteosarcoma in canines). ADXS-cHER2 secretes the cHER2 antigen, fused to LLO, directly inside APC that are capable of driving a cellular immune response to cHER2 overexpressing cells. In preclinical analysis, localized effect is the inhibition of the Treg and MDSC cells that we believe may promote immunologic tolerance of the HER2 overexpressing cancer cells of the tumor. We currently are conducting a Phase 1 study in companion dogs evaluating the safety and efficacy of ADXS-cHER2 in the treatment of canine osteosarcoma. Preliminary data has shown encouraging survival in 9 dogs treated with ADXS-cHER2, as compared to 11 untreated dogs, appearing to validate the activity of the platform and providing the rationale to advance into human clinical trials. We plan to meet with the U.S. Department of Agriculture, or USDA, to discuss the requirements to proceed forward with our first immunotherapy in the veterinary market. Future plans for the ADXS-cHER2 program are contingent upon a number of variables including available resources, types and number of studies, study initiation, patient enrollment, clinical and safety data generated, regulatory interactions and changing competitive landscape.

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The following table summarizes the stage of development of ADXS-HPV, ADXS-PSA and ADXS-cHER2:

***ADXS-HPV Phase 2 Data***

We have completed dosing in *Lm*-LLO-E7-15, a Phase 2 randomized trial designed to assess the safety and efficacy of ADXS-HPV ($1x10^9$ cfu) with and without cisplatin (40 mg/m2, weekly x5). 110 patients were randomized to one of two treatment arms with 55 patients per treatment. The primary endpoint of the study is overall survival. As reported at the American Society of Clinical Oncology, or ASCO, annual meeting in June 2013, the trial completed enrollment and 110 patients received 264 doses of ADXS11-001. As of June 2013, the percentage of patients at 12 months was 36% (39/110) and at 18 months was 22% (16/73), which compares favorably with published reports cited by the National Comprehensive Cancer Network Guidelines and/or the Gynecological Oncology Group, or GOG, of historical 12 month survival of 0-22% with single agent therapies considered active in recurrent cervical cancer and suggests that ADXS-HPV is an active treatment in this disease. The study is expected to be completed in August 2013.

Survival results were not significantly different between treatment groups. Survival outcomes and tumor responses were not affected by Eastern Cooperative Oncology Group (or ECOG) performance status (0 2); type of prior therapy (radiation alone, chemotherapy alone, or a combination of both); or aggressiveness of disease (defined as recurrence ≤2 years from initial diagnosis) versus non-aggressive disease (defined as recurrence >2 years from initial diagnosis).

Tumor responses have been observed in both treatment arms with six complete responses and six partial responses. 41% (45/110) of patients (33/65) had durable stable disease for at least 3 months as indicated by the orange dashed lines in the following waterfall plot. Tumor reductions have been observed against all high-risk HPV strains detected, including HPV 16, 18, 31, 33 and 45. Average duration of response after 12 month minimum follow-up was 10.5 months for both treatment groups. In those patients treated with ADXS-HPV alone who had stable disease, the average duration of response was 6 months compared to 4.1 months in patients treated with ADXS-HPV plus cisplatin.

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***Lm*-LLO-E7-15 Best Response Data**

**(as of May 17, 2013)**

ADXS-HPV continues to demonstrate a well-tolerated and manageable safety profile with 41% (45/110) of patients reporting predominately cytokine-release syndrome Grade 1 or 2 transient, non-cumulative side effects related/possibly related to ADXS-HPV. Side effects either responded to symptomatic treatment or self-resolved. Less than 2% of patients reported serious adverse events associated with ADXS-HPV. Serious adverse events are defined as resulting in death, are life-threatening, cause significant disability or require impatient hospitalization.

# Business Strategy

Our strategy is to maintain and fortify a leadership position in the discovery, acquisition and development of *Lm*-LLO immunotherapies that target for cancer and infectious disease. The fundamental goals of our business strategy include the following:

***Be the first immunotherapy company to commercialize a therapeutic HPV-associated oncology drug.*** Because we believe ADXS-HPV is the most clinically advanced cervical cancer immunotherapy, we aim to fortify our leadership position and be the first to commercialize our *Lm*-LLO immunotherapy for this unmet medical need.

***Develop and commercialize ADXS-HPV in multiple HPV-associated cancers.*** We plan to advance ADXS-HPV through registrational Phase 3 trials and regulatory approval in the United States and relevant markets for the treatment of cervical cancer. If successful, we plan to submit a Biologics License Application, or BLA, to the FDA as the basis for marketing approval in the United States of ADXS-HPV for the treatment of cervical cancer. HPV, the target for ADXS-HPV, is expressed on a wide variety of cancers including cervical, head and neck, anal, vulva, vaginal, and penile. Accordingly, we believe that ADXS-HPV should be active in these HPV-associated cancers and these indications could represent significant market opportunities for ADXS-HPV.

***Obtain Orphan Drug Designation with the FDA and the European Medicines Agency, or EMEA, for ADXS-HPV for use in the treatment of invasive cervical cancer, head and neck cancer and anal cancer.*** In June 2013, we filed three applications for Orphan Drug Designation with the FDA for ADXS-HPV for the treatment of anal cancer (granted August 2013), invasive cervical cancer (denied in October 2013 as the target population estimate exceeded the statutory maximum allowed; appealed October 2013), and head and neck cancer (pending). Orphan status is granted by the FDA

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to promote the development of products that demonstrate promise for the treatment of rare diseases affecting fewer than 200,000 individuals in the United States annually, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation would entitle our company to a seven-year period of marketing exclusivity in the United States if our request is approved by the FDA, and would enable us to apply for research funding, tax credits for certain research expenses, and a waiver from the FDA s application user fee. Orphan drug status in the European Union has similar but not identical benefits in that jurisdiction.

***Obtain Breakthrough Therapy Designation for ADXS-HPV for the treatment of invasive cervical cancer.*** On October 7, 2013, we submitted a request for breakthrough therapy designation to the IND for ADXS-HPV in the treatment of invasive cervical cancer. The FDA is required to respond with a designation letter or a nondesignation letter within 60 calendar days of receipt of the request. On July 9, 2012 the Food and Drug Administration Safety and Innovation Act (FDASIA) was signed. FDASIA Section 902 provides for a new designation Breakthrough Therapy Designation. A breakthrough therapy is a drug: intended alone or in combination with one or more other drugs to treat a serious or life threatening disease or condition; and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If our drug is designated as breakthrough therapy, it will receive all the benefits of fast track designation (opportunities for frequent interactions with the FDA review team, opportunity for a 6-month priority review if supported by clinical data at the time of the BLA submission), potential for a review of portions of the marketing application prior to submitting a complete BLA), intensive guidance on an efficient drug development program, organizational commitment involving senior managers at the FDA in a proactive, collaborative, cross-disciplinary review, will expedite the development and review of such drug.

***Develop ADXS-PSA in prostate cancer.*** We plan to advance ADXS-PSA into a Phase 1 dose escalation trial to determine the maximum tolerated dose for the treatment of patients with prostate cancer.

***Develop scale-up and commercial manufacturing processes.*** We plan to develop scale-up and commercial manufacturing processes, including the development of a lyophilized dosage form.

***Leverage our proprietary discovery platform to identify new therapeutic immunotherapies.*** We intend to conduct research relating to the development of the next generations of our *Lm*-LLO immunotherapies using new antigens of interest; improving the *Lm*-LLO based platform technology by developing new strains of *Listeria* that may be more suitable as live vaccine vectors; developing bivalent *Lm*-LLO immunotherapies; further evaluating synergy of *Lm*-LLO immunotherapies with cytotoxic therapies and continuing to develop the use of LLO as a component of a fusion protein based immunotherapy. We currently have over 15 distinct immunotherapies in various stages of development, developed directly by us and through strategic collaborations with recognized centers of excellence. These include but are not limited to the following Advaxis immunotherapy and corresponding tumor antigen: ADXS11-001/HPV16-E7, ADXS31-142/Prostate Specific Antigen, ADXS31-164/HER2/neu Chimera, Lm-LLO-HMW-MAA/HMW-MAA, C-terminus fragment, Lm-LLO-ISG15/ISG15, Lm-LLO CD105/Endoglin, Lm-LLO-flk/VEGF and Bivalent Therapy, HER-2-Chimera/HMW-MAA-C. We will continue to conduct preclinical research to develop additional *Lm*-LLO constructs to expand our platform technology and may develop additional distinct immunotherapies in the future. Our growth strategy is to expand from the ADXS-HPV franchise into larger cancer indications such as prostate and breast cancer to further validate the robustness and versatility of the platform technology and to develop immunotherapies that we believe to be of interest to big pharmaceutical partners. We also intend to further expand the research and development programs to provide multiple biomarker-specific products with applications across multiple tumor types that express those biomarkers. Additionally, we plan to partner with or acquire a target discovery company, develop multiple constructs targeting numerous

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biomarker targets to deliver the promise of biomarker driven multi-targeted immunotherapies. The overall goal with each patient is to: biopsy the patient s tumor; identify which biomarkers are expressed; treat the patient with our immunotherapies that hit multiple targets simultaneously, adding in the ability to adjust an individual s immunotherapy over time based on changes in the tumor. We believe that if successful, this has the potential to revolutionize the treatment of cancer.

***Enter into commercialization collaborations for ADXS-HPV.*** If ADXS-HPV is approved by the FDA and other regulatory authorities for first use, we plan to either enter into commercial partnerships, joint ventures, or other arrangements with competitive or complementary companies, including pharmaceutical companies or commercialize these products ourselves in North America and Europe through direct sales and distribution.

***Develop commercialization capabilities in India, China, South America, North America and Europe.*** We believe that the infrastructure required to commercialize our oncology products is relatively limited, which may make it cost-effective for us to internally develop a marketing effort and sales force. If ADXS-HPV is approved by the FDA and other regulatory authorities for first use and we do not enter into commercial partnerships, joint ventures, or other arrangements with competitive or complementary companies, including pharmaceutical companies, we plan to commercialize these products ourselves in North America and Europe through direct sales and distribution. However, we will remain opportunistic in seeking strategic partnerships in these and other markets when advantageous.

***Continue to both leverage and strengthen our intellectual property portfolio.*** We plan to continue to leverage our *Lm*-LLO immunotherapies intellectual property portfolio to create value. We intend to file new patent applications, in-license new intellectual property and take other steps to strengthen, leverage, and expand our intellectual property position.

## Short-Term Strategic Goals and Objectives

During the next 12 months, our strategic goals and objectives include the following:

Complete our Phase 2 clinical study in India of ADXS-HPV in the treatment of recurrent cervical cancer, report final 18-month overall survival Phase 2 data at the Society for Immunotherapy of Cancer, or SITC, Annual Meeting, optimize the dose and schedule through additional Phase 1/2 trials and finalize the registration strategy;

Conduct an end of Phase 2 meeting with the FDA, draft Phase 3 protocols and submit a Special Protocols Assessment for ADXS-HPV;

Continue to support the Phase 2 clinical trial of ADXS-HPV in the treatment of advanced cervical cancer with the GOG, largely underwritten by the National Cancer Institute, or NCI;

Continue our collaboration with the University of Liverpool and Aintree University Hospitals NHS Foundation Trust, United Kingdom, to support the Phase 1 clinical trial of ADXS-HPV in the treatment of head and neck cancer, entirely underwritten by Cancer Research, United Kingdom, or CRUK;

Initiate an additional Phase 1/2 study in head and neck cancer for ADXS-HPV; seek to conduct Advisory Board with key opinion leaders;

Continue our collaboration with the Brown University, Oncology Group, or BrUOG, to support the Phase 1/2 clinical trial of ADXS-HPV in the treatment of anal cancer, entirely underwritten by the BrUOG;

Discuss development plan for ADXS-HPV in anal cancer with the FDA in light of Orphan Drug Designation;

Obtain Orphan Drug Designation for two separate indications: the treatment of invasive cervical cancer and the treatment of HPV-positive head and neck cancer;

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Obtain breakthrough therapy designation for ADXS-HPV for the treatment of invasive cervical cancer;
Continue our collaboration with the School of Veterinary Medicine at the University of Pennsylvania to support the Phase 1/2 clinical trial of ADXS-cHER2 in canine osteosarcoma;
Continue to develop and maintain strategic and development collaborations with academic laboratories, clinical investigators and potential commercial partners;
Continue the preclinical analyses and manufacturing activities required to support the IND submission for ADXS-PSA for the treatment of prostate cancer in preparation for a Phase 1 study;
Continue the preclinical development of additional *Lm*-LLO constructs as well as research to expand our platform technology; and
Continue to actively pursue licensing discussions with multiple partners for our immunotherapies, execute definitive license agreement in strategic markets with high HPV prevalence consistent with already established commercial terms.

# Risks

We are a development stage company and have generated minimal revenues to date. Since our inception, we have incurred substantial losses. Our business and our ability to execute our business strategy are subject to a number of risks of which you should be aware before you decide to buy our securities. In particular, you should carefully consider the following risks, which are discussed more fully in Risk Factors beginning on page 19 of this prospectus.

We are a development stage company.
As a result of our current lack of financial liquidity and negative stockholders equity, our auditors have expressed substantial concern about our ability to continue as a going concern.
Our limited operating history does not afford investors a sufficient history on which to base an investment decision.
We can provide no assurance of the successful and timely development of new products.
Our research and development expenses are subject to uncertainty.
We are subject to numerous risks inherent in conducting clinical trials.
The successful development of immunotherapies is highly uncertain.
We must comply with significant government regulations.
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 may not obtain or maintain the benefits associated with orphan drug designation, including market exclusivity.
We may not obtain or maintain the benefits associated with breakthrough therapy designation.
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.
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.
We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

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We are dependent upon our license agreement with Penn; if we breach the license agreement and/or fail to make payments due and owing to Penn under our license agreement, our business will be materially and adversely affected.
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.
We have no manufacturing, sales, marketing or distribution capability and we must rely upon third parties for such.
If we are unable to establish or manage strategic collaborations in the future, our revenue and drug development may be limited.
We may incur substantial liabilities from any product liability claims if our insurance coverage for those claims is inadequate.
We may incur significant costs complying with environmental laws and regulations.
If we use biological materials in a manner that causes injury, we may be liable for damages.
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.