
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): **September 25, 2017**

ADVAXIS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36138
(Commission
File Number)

02-0563870
(IRS Employer
Identification No.)

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

(609) 452-9813
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act.
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act.
- Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act

Item 8.01. Other Events.

Attached hereto as Exhibit 99.1 and incorporated herein by reference is a PowerPoint presentation, including a corporate overview of Advaxis, Inc., which will be made available on its website at www.advaxis.com.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is filed as part of this report:

Exhibit Number	Description
99.1	Company PowerPoint presentation.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Advaxis, Inc.
(Registrant)

Date: September 25, 2017

By: /s/ Sara Bonstein
Sara Bonstein
Executive Vice President and
Chief Financial Officer

INDEX TO EXHIBITS

**Exhibit
Number**

Description

99.1 [Company PowerPoint presentation.](#)



ADVAXIS
IMMUNOTHERAPIES™

Harnessing *Lm* Technology™
Bringing New Treatments to Market

This presentation contains forward-looking statements, including, but not limited to, statements regarding Advaxis' ability to develop and commercialize the next generation of cancer immunotherapies, and the safety and efficacy of Advaxis' proprietary immunotherapies. These forward-looking statements are subject to a number of risks including the risk factors set forth from time to time in Advaxis' SEC filings including, but not limited to, its report on Form 10-K for the fiscal year ended October 31, 2016, which is available at <http://www.sec.gov>.

Any forward-looking statements set forth in this presentation speak only as of the date of this presentation. We do not intend to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof other than as required by law.

ADVAXIS

IMMUNOTHERAPIES™

A late-stage biotechnology company creating cancer immunotherapies that enlist the body's own immune system to fight cancer.

Advaxis' proprietary *Lm* targeted immunotherapy is a new approach toward an effective cancer vaccine.

Our *Lm* Technology has achieved safety and efficacy endpoints in early-stage trials and is the platform for our continued focus on the science, discovery, development and commercialization of cutting-edge cancer treatments.

Flexible platform technology

- Platform based on attenuated *Lm* (*Listeria Monocytogenes*)
- Multiple approaches to impacting the immune system
- Manageable safety profile: common AEs are mostly mild to moderate and resolve within 48 hours

Broad pipeline with four franchises

- 3 clinical stage programs: HPV-Associated Cancers, Prostate Cancer and ADXS-NEO individualized targeting in partnership with Amgen Inc.
- Novel preclinical program: ADXS-HOT with multiple products targeting multiple cancers

Lead program in Phase 3

- HPV-targeting program includes axalimogene filolisbac and ADXS-DUAL
- Ongoing registrational study of axalimogene filolisbac in high risk locally advanced cervical cancer
- Registrational study of ADXS-DUAL in metastatic cervical cancer in combination with Opdivo® to start in 1H 2018

Ability to combine with other I-O agents

- Demonstrated preclinical synergy with multiple checkpoint inhibitors and co-stimulatory agents
- Three clinical trials in combination with PD-1/PDL-1 inhibitors

Strong partnerships

- 3 clinical collaborations evaluating combination therapies (Merck, AstraZeneca, Bristol-Myers Squibb)
- Global collaboration for ADXS-NEO with Amgen on novel program targeting neoepitopes

Experienced management team

- Deep and broad experience in pharmaceutical drug development and commercialization

Who is Advaxis?

Company Overview

Who is Advaxis?

Creating Next-Generation Cancer Immunotherapies, Using a Proprietary *Lm* Platform

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Company Overview



Multiple inflection points beginning in 2018

Product Franchise Overviews

HPV-associated cancers Cervical (CC), head & neck, anal
Products: axalimogene filolisbac (AXAL) (Phase 3 for CC), ADXS-DUAL (Entering Phase 3 for CC)

Personal Neoantigen Program Multiple cancers
Products: ADXS-NEO (Entering Phase 1)

Shared Neoantigens (Hotspot Mutations) Multiple cancers, Multiple products
Products: ADXS-HOT Constructs (Pre-IND)

Prostate Cancer **Products:** ADXS-PSA (Phase 2), Preclinical Product Candidates

Who is Advaxis?

Experience and Expertise are Our Greatest Assets

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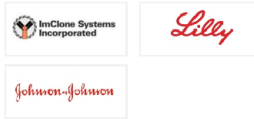
Anthony Lombardo
Interim Chief Executive Officer



Robert Petit
Chief Scientific Officer



Sara Bonstein
Chief Financial Officer



Chris Duke
Chief Operating Officer



Michael Grace
VP, Technical Operations



Thomas Hare
Sr. VP, Product Development



Robert Ashworth
Sr. VP, Regulatory, Quality & Compliance



Ranya Dajani
VP, Corporate Development



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Our Differentiator:

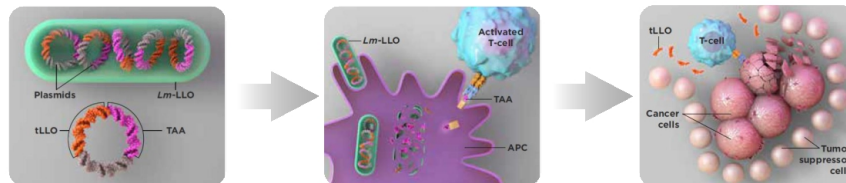
Lm Technology™ Platform

Harnessing the Immune System with *Lm* Technology™

A Demonstrated, Personalized Next-Generation Cancer Immunotherapy Platform

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How it works: Live, attenuated strain of *Listeria monocytogenes* (*Lm*) is infused into the patient where they are taken up by dendritic cells, stimulate a potent immune activation, generate new cancer targeting immune cells, and reduce the tumor's protective shield, enabling tumor destruction.



Unique Benefits:

Full immune system activation

Activation of both the innate and adaptive T cell mediated responses, as antigens present on both MHC Class I & II generating broad anti-cancer immunity

Manageable safety profile

Attenuated listeria is unable to travel between cells; Flu-like symptoms have been transient and associated with infusion; no long-term toxicity seen to date

Enhanced potency with compound MOA

Enhanced potency of the immune response due to the fusion of HPV antigen to tLLO; Multiple repeat treatments not impaired by neutralizing antibodies

Synergies with checkpoint inhibitors

Potential for combination synergies; Trials with PD-1, PD-L1, CTLA4 inhibitors and costimulatory agonists

The Power of *Lm*

- **Proprietary technology:** protected by a range of patents, stretching into 2037
- **Clinically validated:** unprecedented improvement of 12 month survival rates in Ph 2 metastatic cervical cancer studies, warranting confirmatory study
- Safety profile **generally well-tolerated** across 370 patients in multiple trials
- Flexible platform: targets **multiple cancers in multiple ways**, constantly evolving
- Strong clinical development program: built on partnerships with industry leaders, including **Amgen, AstraZeneca, BMS, Merck**

The Potential of *Lm*

- **Target and treat new cancers** as additional antigens are identified and introduced into the platform
- **Combine with checkpoint inhibitors** (nivolumab, pembrolizumab and durvalumab) to improve outcomes
- Create **breakthrough in individualized immunotherapy** with ADXS-NEO
- Target shared hotspot mutations to treat common cancers with “**off-the shelf**” ADXS-HOT

Today's Immunotherapy Landscape

Checkpoint Inhibitors/Co-stimulatory Agonists: Impressive Successes in Recent Years

- Combo therapy likely required for optimal treatment
- Not all patients respond
- Many who respond will later progress
- Not effective in all tumor types

CAR-T: May evoke responses in patients when other treatments stop working

- Limited to liquid tumors
- Meaningful toxicity concerns
- Costly; potential treatment delays

Cancer Vaccines: Activates immune system to destroy tumor

- Historically unsuccessful
- Combo therapy likely required for optimal treatment
- Neutralizing antibodies develop, preventing further treatments

Lm Technology Complements the Landscape and Addresses Unmet Needs



Immune System Activation: Potent T cell responses to multiple cancer specific targets simultaneously



Safety Profile: Generally well tolerated, with mild to moderate, transient adverse events



Combinations optimize checkpoint performance



Immediately available for treatment with low cost of goods

**Opportunity, Accomplishments &
Company Direction**

The Future of *Lm* Technology™ Next-Generation Cancer Immunotherapies

Demonstrated Achievements in CC, Poised for Expansion to Major Cancers

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Significant clinical and regulatory milestones are Proof of Concept...

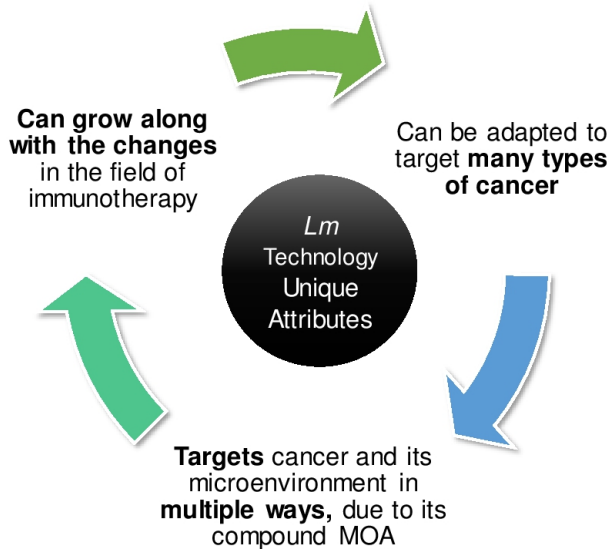
2013	2014	2016	2017	2018+
<p>Regulatory:</p> <p>FDA Orphan Designation: Anal, Head & Neck Cancers</p>	<p>Clinical:</p> <p>Ph 2 in India: 34.9% 12-month OS</p> <p>Regulatory:</p> <p>FDA Orphan designation Invasive CC</p> <p>EMA Orphan designation: Anal</p>	<p>Regulatory:</p> <p>FDA Fast Track: HRLA CC HRLA AC</p> <p>EMA ATMP: HRLA CC</p>	<p>Clinical:</p> <p>GOG-0265: 38.5% 12-month OS in CC</p> <p>BrUOG Study: 90% relapse-free survival in AC</p> <p>FAWCETT: 28% disease control rate in AC</p> <p>Regulatory:</p> <p>EMA ATMP for manufacturing quality and non-clinical data</p>	<p>Regulatory:</p> <p>EMA Marketing authorization application approval decision expected: Metastatic / recurrent cervical (2H)</p> <p>Active partnering discussions underway</p>

... Advaxis will continue to expand the utility of *Lm* Technology, **expanding beyond HPV related cancers into major cancers** to enhance the lives of more patients worldwide while maximizing shareholder value.

Lm Technology's comprehensive immune stimulation and priming redirects a "pathogen" response against the cancer



Lm Technology Vector



HPV-Related Cancers

The Proof of Concept

NEO

Individualized Neoantigens

HOT

Expansion into the Most
Common Cancer Types

Prostate Cancer

Expansion of *Lm* Technology Beyond HPV: Advaxis Focus on Four Key Franchises

HPV-Related Cancers

- Demonstrated safety and efficacy of axalimogene filolisbac (AXAL) – **highest 12 mo. OS** in metastatic CC as observed by GOG across many trials in that population
- ADXS-DUAL **increases viral coverage** of AXAL
- Path to CC commercialization:
 - **Two registrational trials** ongoing in 2018, one in combo w/ nivolumab
 - **EU Conditional application** submission Dec 2017
- Opportunistic funding approaches for Head and Neck, Anal

Hotspot Mutation Therapy Program

- Proprietary program will apply the clinical potential of *Lm* Technology to a broad array of common cancer types
- Constructs will target shared, tumor-specific hotspot mutations
- IND filing planned for the first constructs in 2018

Individualized Neoantigen Therapy

- Partnership with Amgen Inc.
- Potential to be a major step forward in individualized medicine in cancer, driving innovation and significant commercial opportunities
- IND approved; with first patient dose planned for 1H 2018

Prostate Cancer

- Significant opportunity; high unmet medical need and sizeable patient population
- Phase 1/2 trial with Merck's pembrolizumab ongoing
 - Monotherapy activity promising
 - Combination data in 2018

The Future of Lm Technology™

Clinical Trial Programs – In Progress and On the Horizon

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	CANCER INDICATION	PARTNER	IND	PHASE 1	PHASE 2	PHASE 3
AXALIMOGENE FILOLISBAC	High-Risk, Locally Advanced Cervical					
	Metastatic Cervical Combination with IMFINZI™ (durvalumab)	AstraZeneca				
ADXS-DUAL	Metastatic Cervical Combination with OPDIVO® (nivolumab)	Bristol-Myers Squibb	Begin 1H '18			
	Metastatic Head & Neck		2018			
ADXS-NEO	Multiple Cancers by Targeting Personal Neoantigens	AMGEN	Begin 1H '18			
ADXS-HOT	Multiple Cancers by Targeting Shared Hotspot Mutations		Filings '18			
ADXS-PSA	Metastatic Prostate Combination with KEYTRUDA® (pembrolizumab)	MERCK				

Advaxis Funded

Partner Funded

Investigator-Sponsored Trial

★ = Planned

Business Acceleration

Multiple inflection points beginning in 2018

PROGRAM	MILESTONE	TARGET
ADX-PSA	Metastatic Prostate Ph1/2 Combination with pembrolizumab Part A Monotherapy	<i>Completed</i>
Axalimogene filolisbac	Recurrent / Metastatic Cervical Cancer EU Conditional Approval Filing	Q4 2017
ADX-DUAL	Metastatic Cervical Ph 3 Combination with nivolumab IND Filing	2H 2017
ADX-DUAL	Metastatic Cervical Ph 3 Combination with nivolumab Trial Initiation	1H 2018
ADX-NEO	Ph 1 Initiation	1H 2018
ADX-PSA	Metastatic Prostate Ph1/2 Combination with pembrolizumab Part B Monotherapy Combination Therapy Data	2018
ADX-DUAL	Announce planned IST in Head and Neck	2018
ADX-HOT	Multiple INDs Filed First in Human – 1 Tumor Type	2018
Axalimogene filolisbac	Metastatic Cervical Ph 1/2 Combo with durvalumab Part 1 Combination Therapy: Dose Escalation, Dose Determination	<i>Completed</i>
	Part B Expansion Interim Readout	2019

**Proof of Concept: HPV-Associated
Cancers**



Expanding *Lm* Technology™ into the Cervical Cancer Market

The Opportunity for Our HPV Franchise

39,800

new U.S. cancer cases per year where HPV is found in the body; HPV causes 31,500 of these cancers²

4,210

deaths from cervical cancer expected in the U.S. in 2017¹

58,373

European women diagnosed with cervical cancer per year⁴

24,404

estimated deaths from cervical cancer per year in Europe⁴

12,820

new invasive cervical cancer cases estimated in the U.S. in 2017¹

2nd most common

female cancer for those aged 15 to 44 in Europe⁴

3 months

Average extension of life provided by current treatments for metastatic cervical cancer

Vaccination rates

vary widely from state to state³

5-year survival rates

very poor in late stage cancer¹

2nd most frequent

cause of cancer-related death worldwide, accounting for nearly 300,000 deaths annually³

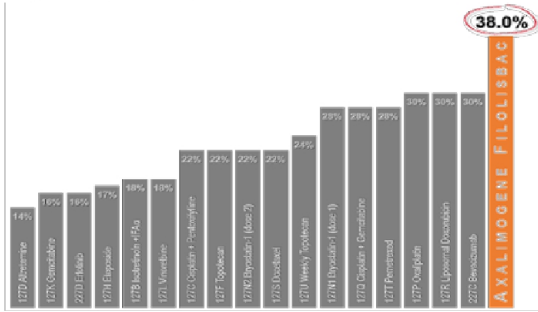
Persistent/ recurrent metastatic cervical cancer is fatal, with no FDA approved treatment available.

Phase 2 Study in India: Prolonged Survival and Tumor Response in Randomized, Multicenter Phase 2 Study in Recurrent/Refractory CC Illustrated the Promise of *Lm* Technology¹

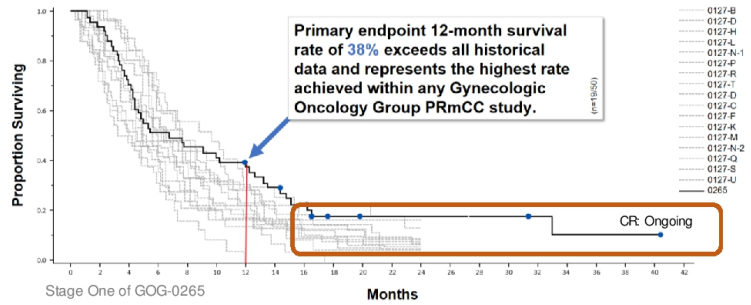
- ✓ 34.9% 12-month survival rate (38/109), 3 durable CRs observed

GOG-0265: Unprecedented improvement of survival rates in Recurrent / Metastatic Cervical Cancer Confirmed the Findings²

- ✓ 38.0% 12-month survival rate (19/50); highest achieved to-date in GOG PRmCC studies to date, 1 durable CR observed
- ✓ GOG Model-Predicted 12 month survival was 24.5%, based on the characteristics of patients in 0265
- ✓ Primary efficacy and safety endpoints met



Source: GOG-0265 Clinical Study



This strong body of clinical evidence of safety and efficacy led to decision to file for conditional approval in the EU by end of 2017. Active partnering discussions underway



PRmCC=Persistent Recurrent Metastatic Cervical Cancer; GOG= Gynecological Oncology Group; CR= complete response
1. Data Presented at ASCO 2014. 2. Data presented at SGO 2017.

ADVANCE Metastatic Combination Study with ADXS-DUAL and nivolumab

- Metastatic cervical cancer is an area of high unmet need
- Combination of ADXS-DUAL with nivolumab: significant opportunity to improve patient outcomes vs. standard of care
- ADXS-DUAL provides enhanced targeting of HPV-18
- Opportunity for interim analysis
- Planned start: 1H 2018



ADXS-DUAL

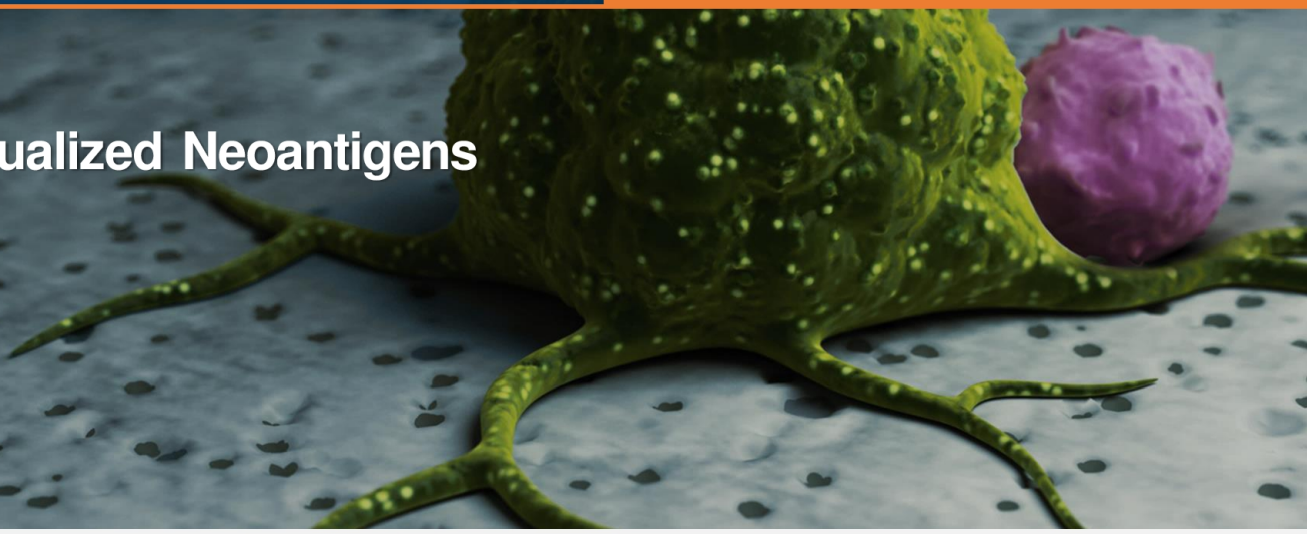
AIM2CERV Adjuvant Therapy with axalimogene filolisbac

- High unmet medical with no approved treatments available
- Currently enrolling in 8 countries
- Data expected 2020/ 2021
- Confirmatory study to support EU conditional approval (filing December 2017)

Study Design

Our cervical drug candidates remain the cornerstone of our *Lm* Platform.

Individualized Neoantigens





An individualized approach to each patient's tumor and tumor microenvironment is the future of oncology



The unique properties of the *Lm* vector make it an ideal platform to deliver individualized therapies

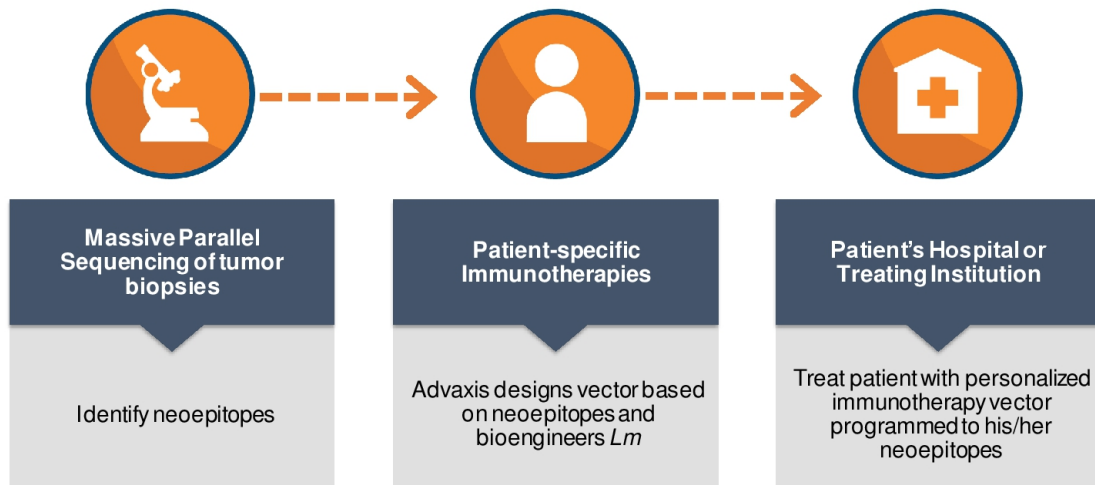
AMGEN

Recognizing these unique benefits, Amgen selected Advaxis' individualized *Lm* platform: ADXS-NEO

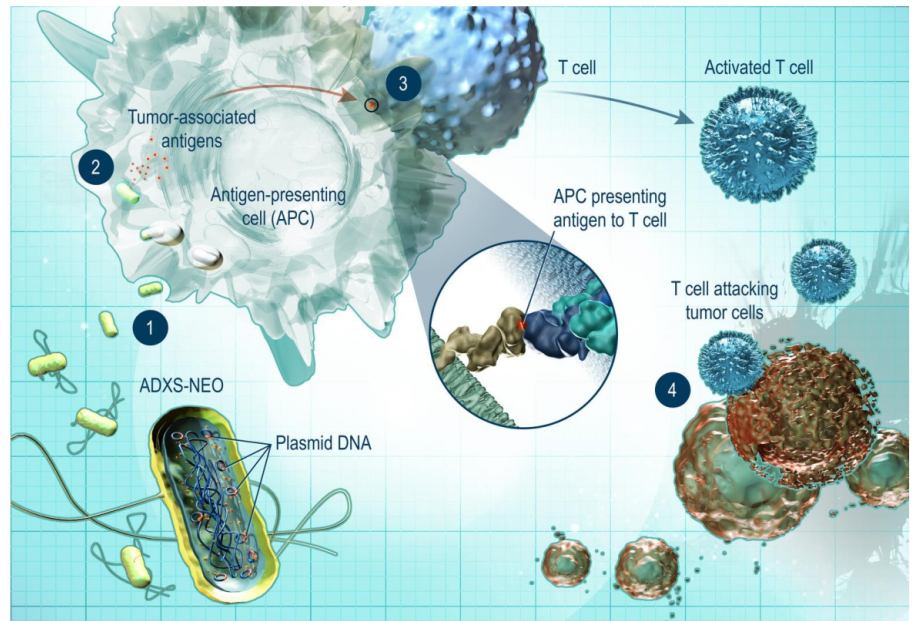


ADXS-NEO is designed to create truly individualized therapies by activating the patient's immune system to respond against their own unique mutations (neoantigens) within the tumor

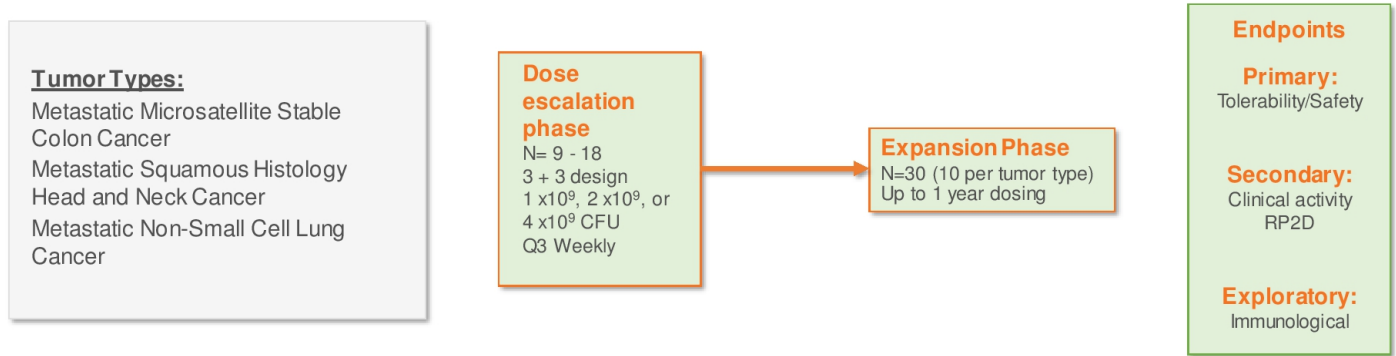
Our *Lm* Technology is ideal for applications in individualized medicine, a growing market



1. Once injected into the patient, *Lm* Technology taken up by antigen-presenting cells
2. The bacteria secrete tumor-associated antigens into the liquid interior of the APC
3. The antigens are then processed and presented to T cells
4. Goal: help T cells recognize a wide range of tumor-associated antigens and attack cancer cells with the same antigens



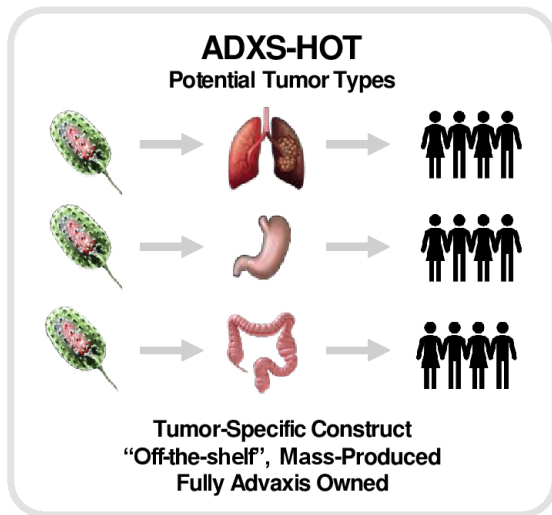
A Phase 1 Dose-Escalation Study of Advaxis (ADXS) NEO Expressing Personalized Tumor Antigens



In partnership with **AMGEN**®

**Further Expansion into Common
Cancer Types: ADXS-HOT**

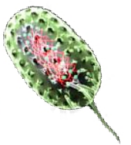
**ADXS-HOT immunotherapies combine multiple hotspot mutations (neoantigens),
designed to increase potential for immunogenicity**



- Targets: Common (public or shared) "Hot Spot" mutations in tumor driven genes, designed to increase potential for immunogenicity
- A multi-product program, with each product addressing one of the most common types of cancer
- Can be used as monotherapy and/or in combination with other cancer treatments like checkpoint inhibitors, radiation therapy, or other neoepitope treatments
- Constructs "Off the shelf" and available for patients to start treatment immediately
- Constructs can be manufactured in bulk with good stability keeping cost of goods low vs. "individualized" products
- INDs for first constructs expected in 2018

Benefits of *Lm* Technology in Hotspot Targeting

The capacity of the Lm-LL0 vector allows coverage of nearly all of the mutations that may occur in one single targeted product.

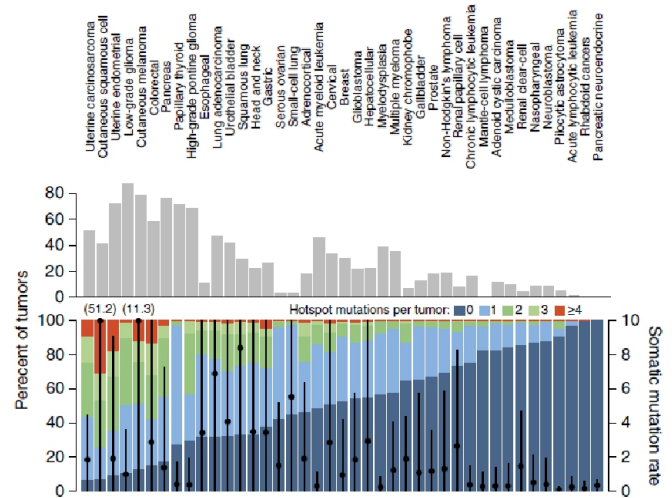


What is a “Hotspot” mutation?^{1,2}

- Growth of “Hotspot” mutations (i.e. somatic mutations) is one of the major mechanisms responsible for oncogenesis
- Genetic profiling of tumors has produced valuable insights into the “Hotspots” that define individual cancer types
- Many hotspot mutations are seen in multiple patients with cancer. These are referred to as “shared” or “public” neoantigens

The ADXS-HOT Program will generate several “off-the-shelf” products that target multiple shared hotspot neoantigens using the latest innovations in *Lm* Technology™

Cancers Ranked by “Hotspot” mutations³





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Expansion into Prostate Cancer

Expanding *Lm* Technology™ into the Prostate Cancer Market The Opportunity in Prostate Cancer

161,360

of new prostate cancer cases estimated in the U.S. in 2017¹

1 in 36

men will die from prostate cancer²

9.6%

of all new cancer cases in the U.S. are prostate cancer¹

1 in 7

men will be diagnosed with prostate cancer during his lifetime²

26,730

deaths from prostate cancer expected in U.S. in 2017¹

To date, checkpoint inhibitor monotherapy has not shown significant activity in prostate cancer.³
Combining ADXS-PSA with Keytruda® could optimize performance and improve outcomes.

ADX-PSA Metastatic Prostate Cancer

Phase 1/2 Combination with KEYTRUDA® (pembrolizumab) - (KEYNOTE-046)

Inclusion Criteria:

- Progressive metastatic CRPC
- ≤2 prior systemic treatment regimens or ≤1 prior chemotherapeutic in the metastatic setting



Part B Expansion: Endpoints

- Safety
- Efficacy
- Immunologic Activity

Part A ADX-PSA Monotherapy

- n=21
- Dose escalation (3 dose levels)



Part B ADX-PSA + pembrolizumab

- n=6 (RP2D dose determination)
ADX-PSA 1 x 10⁹ = 200 mg Keytruda
- n=30 (Expansion)



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- n=6 (RP2D dose determination)
ADX-PSA 1 x 10⁹ + 200 mg Keytruda
- n=30 (Expansion)

Current Status:

- Part A completed and presented at CRI-CIMT-EATI-AACR 2017 and SITC 2017
- Part B combination RP2D dose determination completed
- Part B expansion enrolling – preliminary clinical data in 2018

Endpoints:

- Safety
- RP2D of the combination

Pembrolizumab Pembrolizumab Pembrolizumab

12 WEEK CYCLES

Up to PD or
2 years

Up to PD or
2 years

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Upcoming Milestones

Business Acceleration Multiple inflection points beginning in 2018

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Ability to combine with other I-O agents

- Demonstrated preclinical synergy with multiple checkpoint inhibitors and co-stimulatory agents
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Strong partnerships

- 3 clinical collaborations evaluating combination therapies (Merck, AstraZeneca, Bristol-Myers Squibb)
- Global collaboration for ADXS-NEO with Amgen on novel program targeting neoepitopes

Experienced management team

- Deep and broad experience in pharmaceutical drug development and commercialization

