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): **February 7, 2019 (February 6, 2019)**

ADVAXIS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-36138**	**02-0563870**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 the Company, which is available on its website at www.advaxis.com.

Also attached hereto as Exhibit 99.2 and incorporated herein by reference is a PowerPoint presentation, which the Company presented at the Immuno-Oncology 360° Conference on February 6, 2019. The presentation is also available on its website at www.advaxis.com.

Forward-Looking Statements

This report contains forward-looking statements, including, but not limited to, statements regarding the Company's ability and strategies to develop and commercialize cancer immunotherapies, timing of planned clinical trials and regulatory milestones, potential partnership opportunities and the safety and efficacy of the Company's proprietary immunotherapies. These forward-looking statements are subject to a number of risks including the risk factors set forth from time to time in the Company's SEC filings including, but not limited to, its report on Form 10-K for the fiscal year ended October 31, 2018, which is available at www.sec.gov. Any forward-looking statements set forth in this report speak only as of the date of this report. 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. You are cautioned not to place undue reliance on any forward-looking statements. Information contained on the Company's website does not constitute part of this report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished as part of this report:

Exhibit Number	Description
99.1	Corporate Overview Presentation – February 2019
99.2	Immuno-Oncology 360° Conference Presentation - February 2019

SIGNATURES

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

ADVAXIS, INC.
(Registrant)

Date: February 7, 2019

By: */s/ Molly Henderson*
Molly Henderson
Chief Financial Officer

Forward-Looking Statements

This presentation contains forward-looking statements, including, but not limited to, statements regarding the ability and strategies of Advaxis, Inc. (the "Company") to develop and commercialize cancer immunotherapies, timing of planned clinical trials and regulatory milestones, potential partnership opportunities and the safety and efficacy of the Company's proprietary immunotherapies. These forward-looking statements are subject to a number of risks including the risk factors set forth from time to time in the Company's SEC filings including, but not limited to, its report on Form 10-K for the fiscal year ended October 31, 2018 as well as its Forms 10-Q and 8-K, which are available at http://www.sec.gov.

Any forward-looking statements set forth in this presentation speak only as of the date of this presentation. The Company does 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. Our fiscal year ends October 31. Throughout this presentation, all references to quarters and years are to the calendar quarters and years unless otherwise noted.

Advaxis Overview

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

ADVAXIS IMMUNOTHERAPIES™

Unique *Lm Technology* Platform: Enables broad and diverse pipeline of Phase 1 to Phase 3 programs across several tumor types

Platform Validation: Demonstrated manageable safety profile along with clinical activity – Nearly 500 patients treated to date

Multiple Neoantigen Programs: Innovative, personalized and 'off the shelf', approaches to neoantigen-directed therapy

Strong IP: Over 400 patents/patent applications

Experienced New Management Team: Chief Executive Officer, Chief Financial Officer and Chief Medical Officer joined within past year

Multiple Catalysts (Read-outs) Anticipated in 2019

Clinical Pipeline Overview

ADVAXIS IMMUNOTHERAPIES™

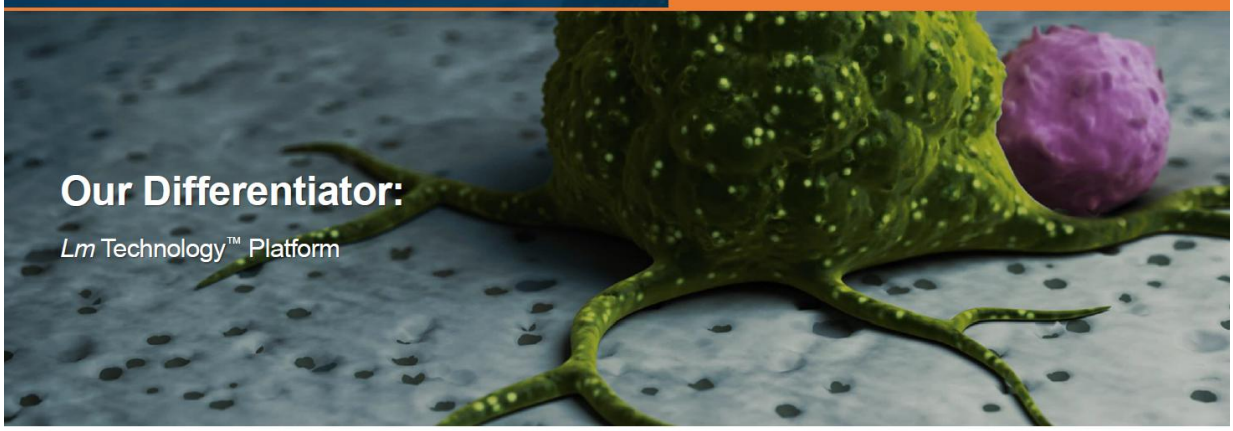
	CANCER INDICATION	IND	PHASE 1	PHASE 2	PHASE 3
ADXS-HPV (AXAL)	AIM2CERV, High-Risk, Locally Advanced Cervical[1]				
	HPV+ Head and Neck (Partners to be announced)			★ Q1 2019	
ADXS-PSA	Metastatic Prostate in Combination with KEYTRUDA® (pembrolizumab) MERCK				
ADXS-NEO	Multiple Cancers by Targeting Personal Neoantigens *(NSCLC, CRC, Head & Neck)*				
ADXS-HOT	Non-Small Cell Lung			Q1 2019 *Anticipated First Patient*	
	Prostate		★	IND Submission 2019	
	Bladder		★	IND Submission 2019	

Advaxis Funded | Investigator Funded

★ = Planned

1 FDA has placed a partial clinical hold on this study due to CMC requests which allows continued dosing of already enrolled patients but which prevents enrollment of new patients until resolution of this partial hold.

ADVAXIS
IMMUNOTHERAPIES™



Our Differentiator:

Lm Technology™ Platform

How Our *Lm* Platform is Designed

ADVAXIS IMMUNOTHERAPIES™

***Lm* vectors: Mimic natural infection and redirect immune response against cancer through:**

1. **INNATE IMMUNITY:** *Enhanced antigen presentation activates multiple pathways* and alerts and trains the immune system

2. **ADAPTIVE IMMUNITY:** Mobilizes and generates a *cancer-specific T cell* response to attack the tumor

3. **CHANGES TO TUMOR MICROENVIRONMENT (TME):** *Reduces tumor-protective cells (Tregs and MDSCs in the TME)* that shield the tumor from the immune system

The *Lm* platform has been *clinically evaluated* in nearly 500 patients across multiple clinical trials and *antigen spreading* demonstrated in clinical studies of ADXS-HPV and ADXS-PSA

ADXS-HPV

ADVAXIS IMMUNOTHERAPIES™

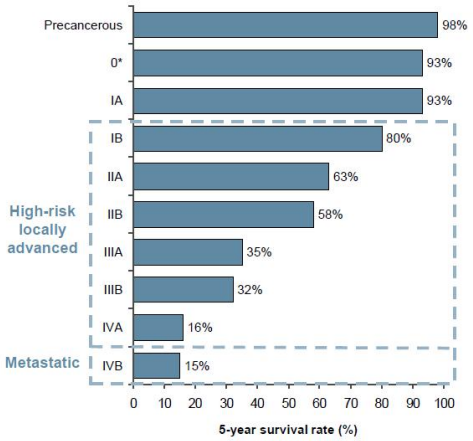
AIM2CERV – Phase 3 clinical trial in high-risk, locally advanced cervical cancer

Cervical cancer: Statistics and Unmet Need

ADVAXIS IMMUNOTHERAPIES™

5-year survival rates are poor for high-risk locally advanced patients; represents area of great unmet need

Cervical cancer 5-year survival rate, by disease stage



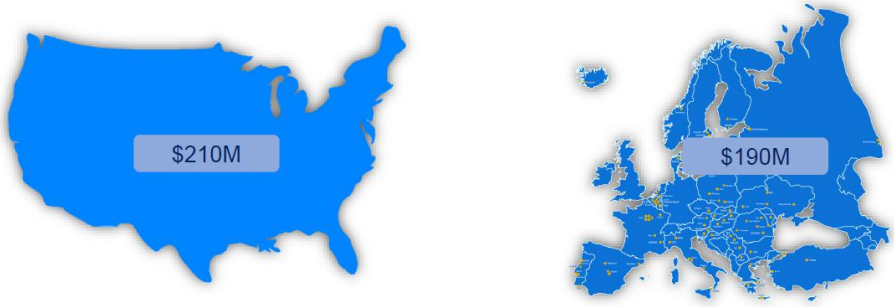
- An estimated 91% of all cervical cancers are caused by an HPV infection
- While the overall incidence rate is expected to remain relatively stable, the number of incident cases is expected to increase slightly due to an increase in the total U.S. female population
- HRLA patients range from stage IB with clinical lesions in the cervix to stage IVA with cancer that has spread to adjacent organs
  - ~53% of overall cervical cancer incidence is HRLA while ~8% of incidence is metastatic

Note: *Stage 0 is carcinoma in situ (CIN III) and is considered pre-invasive cancer
Source: American Cancer Society; National Cancer Institute

Annual, Worldwide Peak Revenue Opportunity of $500M for AXAL in High-Risk Locally Advanced Cervical Cancer

ADVAXIS IMMUNOTHERAPIES™

Market Opportunity in the U.S and Europe - Estimated Annual Revenues



Combined Worldwide Estimated Market Opportunity of ~$500M

* Source: December 2016, LEK AXAL Assessment Report

Cervical Cancer and Axalimogene Filolisbac: Supportive Clinical Trials

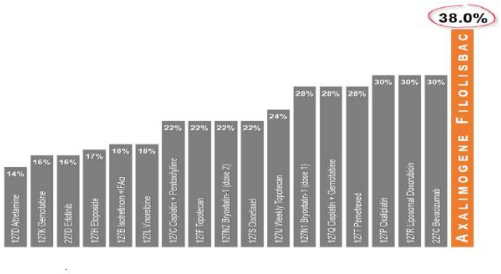
ADVAXIS IMMUNOTHERAPIES™

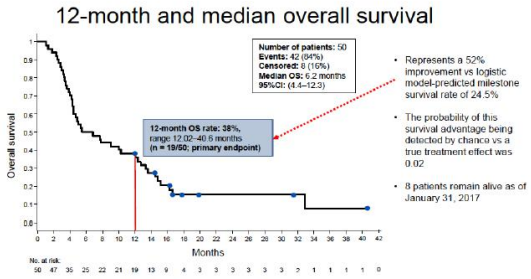
Phase 2 Study in India: Prolonged Survival and Tumor Response in Randomized, Multicenter Phase 2 Study in Recurrent/ Refractory CC Illustrated the Promise of *Lm* Technology[1]

- ✓ 34.9% 12-month survival rate (38/109), 24.8% (27/109) 18-month survival rate, 3 confirmed CRs observed (RECIST 1.1)
- ✓ Accepted for publication in the May edition of peer-reviewed *International Journal of Gynecological Cancer*

GOG-0265: Improvement of survival rates in Recurrent / Metastatic Cervical Cancer Confirmed the Findings[2]

- ✓ 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 endpoint met





PRmCC, Persistent Recurrent Metastatic Cervical Cancer; GOG, Gynecological Oncology Group; CR= complete response

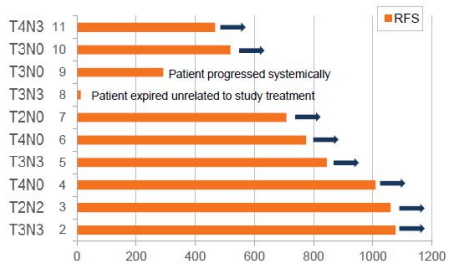
1. Data Presented at ASCO 2014. 2. Data presented at SGO 2017.

Additional Supportive Clinical Trials
AXAL Phase 1/2 BrUOG Study – High Risk Advanced Anal Cancer
Study Results

ADVAXIS IMMUNOTHERAPIES™

Promising efficacy results in challenging population:
8 of 9 patients recurrence free at median follow-up of 42 months

Relapse Free Survival Data



Relapse-Free Survival (Days)*
Median Follow-up 42 months

TRAE	N (%)	
	Grade 2	Grade 3
Chills/Rigors	4 (40)	2 (20)
Fatigue	1 (10)	0
Pyrexia	3 (30)	0
Headache	1 (10)	0
Flu-like symptoms	1 (10)	0
Pain (back/neck)	0	1 (10)
Hypotension	2 (20)	0
Hypertension	0	1 (10)

Commentary

- 11 total patients enrolled
- All patients who completed RT and received treatment achieved a CR at six months (N = 9)
- 8/9 patients (89%) were recurrence free at a median follow up of 42 months
- Safety profile consistent with previous clinical experience
- No Grade 4 adverse events
- Encouraging data to support AXAL in adjuvant setting

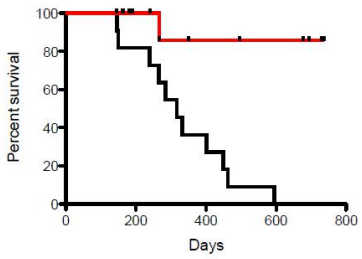
Note: Patient #1 enrolled but was never treated on study

Safran et at., Poster Presentation at ASCO 2016
Manuscript accepted for publication in the International J of Radiation Oncology *BrUOG, Brown University Oncology Group. CR, Complete response; TRAE, Treatment related adverse events

ADXS31-164 Phase I - Survival Data from Canine Osteosarcoma Study with ADXS-HER2

ADVAXIS IMMUNOTHERAPIES™

ADXS31-164 prolongs OS in HER2+ OSA



4 dogs censored from vaccine arm:
- 3 came off trial after first vaccine due to progressive metastatic disease (developed prior to vaccination)
- 1 dog died from aspiration pneumonia

MST (control) – 239.5 days
MST (vaccinated) – not reached

Final Study Publication: Clin Cancer Res. 2016 Sep 1;22(17):4380-90.

- This trial compared SOC amputation and chemotherapy (in case matched controls) to SOC followed by 3 doses of ADXS31-164 (ADXS-HER2)
- These data show a **highly significant improvement in progression free survival and overall survival** with treatment that led to UDSA expedited approval
- Without treatment 100% will recur and expire within 1-2 years; with treatment using ADXS-HER2, after SOC, **the likelihood of recurrence is significantly reduced, delayed, or eliminated**
- This study exemplifies **the ability of ADXS *Lm* vectors to control the sub-clinical micro-metastases** that would ultimately have progressed into a "recurrence"
- **Monetization of ADXS-HER2**: Licensing deals signed with a) Aratana in 2014 for canines and b) OS Therapies in 2018 for pediatric osteosarcoma

These data were sufficient for USDA to grant expedited approval for treat canine osteosarcoma in December 2017

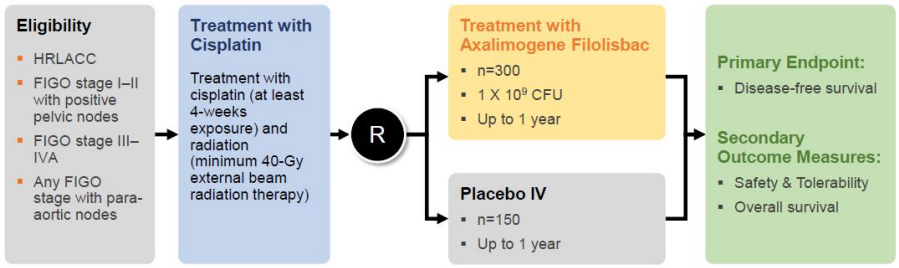
Axalimogene Filolisbac in High-Risk, Locally Advanced Cervical Cancer[1]

AIM2CERV Phase 3 Study as Adjuvant Monotherapy to Prevent Recurrence in High-Risk Cervical Cancer

ADVAXIS IMMUNOTHERAPIES™

FDA Orphan · FDA SPA · FDA FastTrack

Trial Design



AIM2CERV – Axalimogene Filolisbac Immunotherapy Following Chemo/Radiation in Patients who have High Risk Locally Advanced Cervical Cancer (HRLACC)

Study on partial clinical hold due to certain items identified by FDA relating to AXAL's Chemistry, Manufacturing and controls (CMC)

"Just as we need options to prevent HPV-related cancers, there is a significant need for more therapeutic options to treat those with cancer. No woman should die from cervical cancer."

Deborah Arrindell
Vice President, Health Policy
asha American Sexual Health Association

Currently seeking to modify trial design to include earlier Interim Analyses (IA)
(IA for futility now anticipated in 2H 2020 contingent upon FDA acceptance of modification)

1 FDA has placed a partial clinical hold on this study due to CMC requests which allows continued dosing of already enrolled patients but which prevents enrollment of new patients until resolution of this partial hold.

SPA= Special Protocol Assessment; FIGO= International Federation of Gynecology and Obstetrics; HRLACC= high-risk locally advanced cervical cancer; IV= intravenous.

Herzog T, et al. SITC 2016. Poster 145. https://clinicaltrials.gov/ct2/show/NCT02853604

ADVAXIS IMMUNOTHERAPIES™

ADXS-PSA

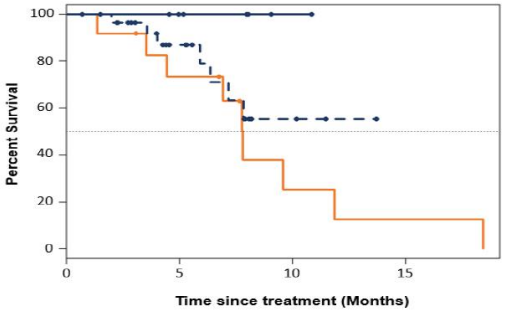
Combination Therapy of ADXS-PSA with Pembrolizumab in Late-Stage Prostate Cancer

Efficacy: Overall Survival – PSA Decline ≥ 50% vs. PSA < 50% Decline

Part B - in Combination with Pembrolizumab

ADVAXIS IMMUNOTHERAPIES™

In all treated patients, an improvement in survival was observed in patients with ≥50% PSA declines from baseline vs. those <50% PSA declines.



	N	Events	Median	95% CI
Part A: PSA Drop <50%	12	9	7.79	3.52 – 11.9
Part B: PSA Drop ≥50%	7	0	NR	-
Part B: PSA Drop <50%	29	7	NR	6.37 -

Update on Survival Rates and Correlative Biomarker Analysis Anticipated in Q1 2019

Part A: ADXS-PSA monotherapy; Part B: ADXS-PSA + pembrolizumab combination therapy
NR = Not Reached

Combination Therapy of ADXS-PSA with Pembrolizumab in Metastatic Castration-Resistant Prostate Cancer Study Results

ADVAXIS IMMUNOTHERAPIES™

Safety Profile

- Combination of ADXS-PSA and pembrolizumab appeared safe and tolerable in highly refractory patient population
- Mostly grade 1-2 treatment related adverse events
- There was no additive toxicity observed with the combination therapy

In Combination

- In the treated population, patients who received combination therapy with ADXS-PSA and pembrolizumab experienced the longest overall survival (OS)

Efficacy

- The percentage of patients with PSA declines from baseline in the combination therapy arm was 40.5%, and 15.4% in the monotherapy arm
- 7 patients in the combination arm with 50% or greater PSA declines from baseline, and none in the monotherapy arm


ADVAXIS
IMMUNOTHERAPIES™
Neoantigen-Directed Programs:
ADXS-NEO - Patient Specific
ADXS-HOT - 'Off the Shelf'

Why Neoantigens?

ADVAXIS IMMUNOTHERAPIES™

- Mutations cause cancer and also create neoantigens
  - Neoantigens are only found in cancer cells which makes them good therapeutic targets
    - T cells that target neoantigens are the common link among successful immunotherapies developed to date (e.g., checkpoint inhibitors, Tumor Infiltrating Lymphocytes or TILS)
  - Our *Lm* platform is effective at generating T cells that target multiple neoantigens
- Preclinical data demonstrate that over 90% of neoantigens in an ADXS-NEO vector generated T cell responses that controlled tumor growth[1]

[1]Presented at AACR 2018 by Coder et al

Neoantigen Competitive Landscape: How We Measure Up

ADVAXIS IMMUNOTHERAPIES™

Advaxis' *Lm* platform + Antigen Targets: Directed against tumor-specific targets and engaging the patient's immune system to destroy tumor cells.

Select Companies in the Space: NEON THERAPEUTICS, moderna, gritstone oncology, BIONTECH

OTHER NEOANTIGEN APPROACHES[1]

- Limited clinical evidence and immune response
- No demonstrated effect on TME
- Typically have poor priming, may require addition of adjuvants/co-stims
- Practical limitations in number of peptides administered

VS

Advaxis' *Lm* Platform + Antigen Targets

- Proven clinical activity in pre-clinical models
- Demonstrated effect on the TME (MDSCs, Tregs)
- Immunogenic proprietary targets
- Priming via innate immune stimulation; adjuvant/co-stims not required
- Ability to "convert" non-immunogenic peptides into immunogenic peptides and "turn cold tumors hot"

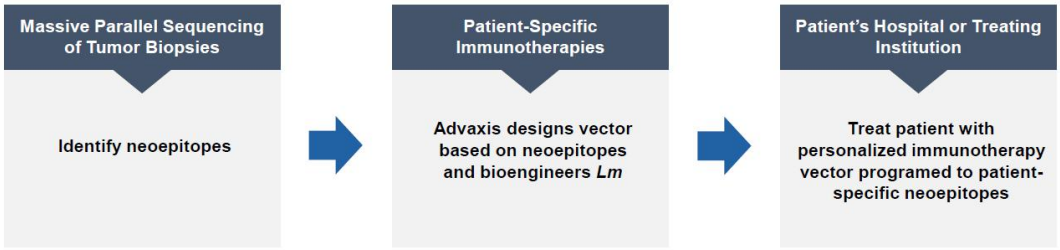
1 Not all challenges apply to all companies/platforms


ADVAXIS
IMMUNOTHERAPIES™
ADXS-NEO
Patient-specific, neoantigen-directed therapies

ADXS-NEO: The Personalized Approach

ADVAXIS IMMUNOTHERAPIES™

- Activates a patient's immune system, creating a targeted T cell response to personal neoantigens based on unique, patient-specific mutations
- The *Lm* platform's impact on the immune system (i.e., innate immunity, adaptive immunity, and changes to TME) provides potential for strong anti-cancer effects
- Platform capacity allows for targeting a large number of personal neoantigens
- Potential application **in any solid tumor type**



ADXS-NEO: Study Design

ADVAXIS IMMUNOTHERAPIES™

A Phase 1 dose-escalation study of ADXS-NEO expressing personal tumor antigens

★ **First patient dosed June 2018**

Tumor Types:

- Metastatic microsatellite stable **colon cancer**
- Metastatic squamous histology **head-and-neck cancer**
- **Metastatic non-small cell lung cancer**

Dose Escalation Phase

n= 9-18
3 + 3 design
1 x10^9, 2 x10^9, or 4 x10^9 CFU
Q3 weekly

Dose Expansion Phase

n=30
(10 per tumor type)
Up to 1 year dosing

Endpoints:

Primary
Tolerability/Safety
Secondary
Clinical activity
RP2D
Exploratory
Immunological

Clinical Data From Initial Cohort (safety, immune response) Anticipated 1H 2019

CFU, Colony-Forming Unit; RP2D, Recommended Phase 2 Dose
ClinicalTrials.gov Identifier: NCT03265080


ADVAXIS
IMMUNOTHERAPIES™
ADXS-HOT
Cancer-type specific, neoantigen-directed drug candidates

ADXS-HOT: Targeting Multiple OFAs, CTAs and Hotspots Increases Patient Applicability and Clinical Activity Potential

ADVAXIS IMMUNOTHERAPIES™

Hotspot mutations have demonstrated **pre-clinical activity** in Advaxis' *Lm* Technology[1]

ADXS-HOT constructs target both public, or shared, hotspot neoantigens and multiple proprietary tumor associated antigen targets, including oncofetal antigens (OFAs) and cancer testis antigens (CTAs)

Over 10 drug candidates designed using this approach

coverage of nearly

100%

of solid tumors

ADXS-HOT constructs can include **over 30 targets** allowing for multiple shots on goal to control the tumor

Antigen spreading could further increase the potential number of targets

Can be used as **monotherapy and/or in combination** with other cancer treatments like checkpoint inhibitors

"Off the shelf" and available for patients to start treatment immediately

Manufactured in bulk with good stability keeping **cost of goods low** vs. "individualized" products

1. Data on file, Advaxis, Inc. 2017.

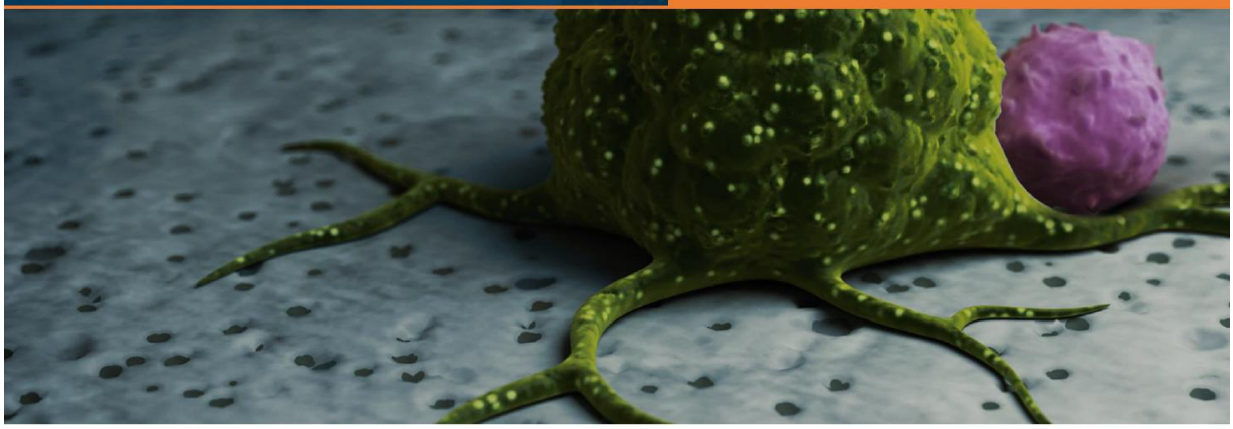
ADXS-HOT: Priority Tumor Types

- ADXS-503 for Non-small Cell Lung Cancer
  - IND allowed
  - First patient is anticipated soon
- ADXS-504 for Prostate Cancer – IND anticipated in 2019
- ADXS-506 for Bladder Cancer – IND anticipated in 2019

First patient in ADXS-503 for NSCLC expected in early 2019

ADVAXIS
IMMUNOTHERAPIES™

Corporate Information



Anticipated Catalysts Over the Next 12-24 Months

ADVAXIS IMMUNOTHERAPIES™

PROGRAM	ANTICIPATED MILESTONES	TARGET
ADXS-HPV (axalimogene filolisbac)	• Announce planned Investigator Sponsored Trial in Head and Neck Cancer	Q1 2019
ADXS-PSA	• Metastatic Prostate Ph1/2 Combination with pembrolizumab-- Part B Monotherapy Combination Therapy Data (12-mo PFS and OS)	Q1 2019
ADXS-NEO	• Data from initial clinical cohort (safety, immune response)	Q1 2019
ADXS-HOT NSCLC	• Data from initial clinical cohort (safety, immune response)	1H 2019
ADXS-HOT Prostate	• IND Submission	2H 2019
ADXS-HOT Bladder	• IND Submission	2H 2019
ADXS-HPV	• AIM2CERV Interim Analysis	Q4 2020*

NSCLC= Non-small cell lung cancer; IND = Investigational New Drug
* Contingent upon FDA acceptance of proposed new interim analysis plan and an expeditious resolution of the partial clinical hold

Executive Management Team

ADVAXIS IMMUNOTHERAPIES™

Kenneth A. Berlin
Chief Executive Officer

ROSETTA GENOMICS™
Johnson & Johnson
Ortho Clinical Diagnostics
VERIDEX LLC

Molly Henderson
Chief Financial Officer

IDVANCE
VIRTUALSCOPICS
PRICEWATERHOUSECOOPERS

Robert Petit
Chief Scientific Officer

Bristol-Myers Squibb Company
PHARMACIA
MGI PHARMA
AESGEN

Dr. Andres Gutierrez
Chief Medical Officer

ONCOLYTICS BIOTECH INC
Bristol-Myers Squibb Company
ΣELLAS
sunesis
PROTEOLIX
BIOMARIN

Financial Information, as of October 31, 2018 (fiscal year end)

- Cash on hand - $45.1 million
  - Reduced annual net cash burn to ~$50 million, from ~$80 million
- No debt
- Shares outstanding: 69.6 million
  - Fully diluted shares outstanding: 89.2 million

Advaxis Overview

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

ADVAXIS IMMUNOTHERAPIES™

Unique *Lm Technology* Platform: Enables broad and diverse pipeline of Phase 1 to Phase 3 programs across several tumor types

Platform Validation: Demonstrated manageable safety profile along with clinical activity – Nearly 500 patients treated to date

Multiple Neoantigen Programs: Innovative, personalized and 'off the shelf', approaches to neoantigen-directed therapy

Strong IP: Over 400 patents/patent applications

Experienced New Management Team: Chief Executive Officer, Chief Financial Officer and Chief Medical Officer joined within past year

Multiple Catalysts (Read-outs) Anticipated in 2019


IO360
ADVAXIS
IMMUNOTHERAPIES™
Lm-Based Immunotherapies: Leveraging the Advantages of a Unique Vector to Attack Cancer
Robert Petit PhD
Chief Scientific Officer
Advaxis, Inc.
Andres A Gutierrez MD PhD
Chief Medical Officer
Advaxis, Inc.
6 February 2019

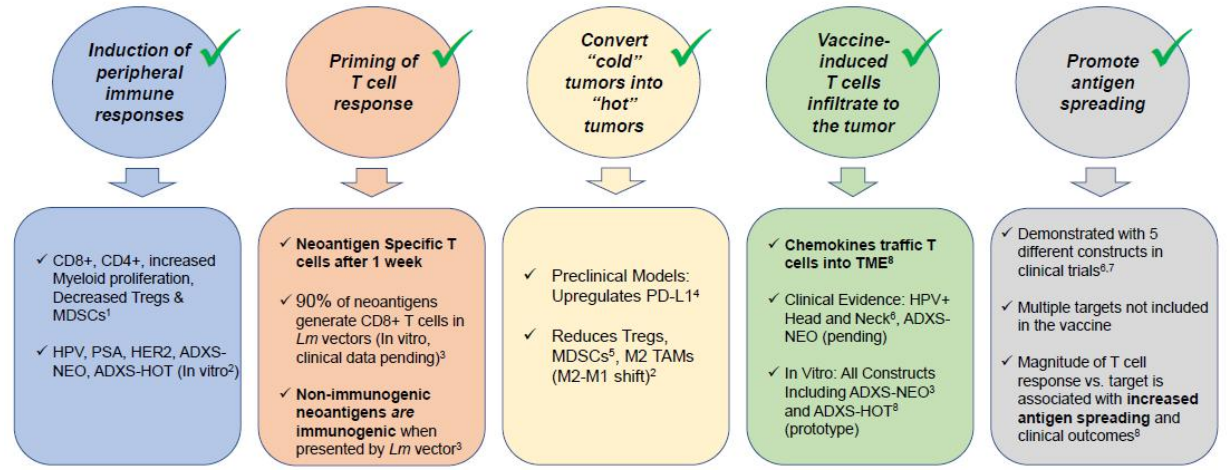
Advaxis Overview

ADVAXIS IMMUNOTHERAPIES™

- *Listeria monocytogenes (Lm):* Bacterial vector optimized to deliver large antigen payloads directly inside dendritic/antigen presenting cells
- Ability to generate CD8+T cells **rapidly** and against **large percentage** of peptide/neoantigen targets
  - > 90% in pre-clinical studies
- Preliminary clinical data in neoantigen-directed program suggests **best-in-class** CD8+T cell response
  - > 80% of neoantigen pools
  - T cell responses observed 1 week after initial/priming dose
- Leveraging the large, antigen-payload capacity of our *Lm* vector in our neoantigen-directed programs
- Antigen spreading demonstrated in clinical trials including our neoantigen-directed drug constructs
- Efficacy signals include: Single agent Complete Responses (CRs), prevention of recurrence and improved survival
- Manageable safety profile – nearly 500 patients treated to date with mostly Grade 1 and 2 TRAEs
- *Lm*-platform enables broad pipeline
  - **ADXS-HPV** (AXAL) in Phase 3 for high-risk cervical cancer
  - **ADXS-PSA** in Phase 1/2, Keynote-046 combination with pembrolizumab in advanced prostate cancer
  - **ADXS-NEO**, personalized-drug constructs, in Phase 1 for multiple cancers
  - **ADXS-HOT:** > 12 "off-the-shelf" hotspot, neoantigen-targeting drug constructs with first candidate, **ADXS-503** (HOT Lung) for NSCLC about to enter the clinic

Anti-Tumor Immunity: Building Blocks for Clinical Success

ADVAXIS IMMUNOTHERAPIES™



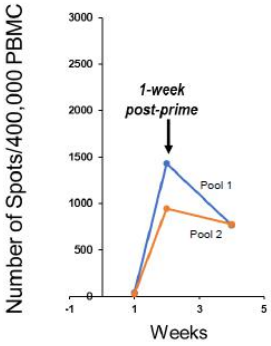
Lm-based drug candidates have demonstrated broad anti-tumor immunity through achieving these

Best-in-Class Potential in Neoantigen Field

ADVAXIS IMMUNOTHERAPIES™

- Advaxis neoantigen programs leverage our *Lm* vector's capacity for large number of antigens
  - ADXS-NEO constructs currently utilize **40 *private* neoantigens per patient**
  - ADXS-HOT constructs utilize **> 30 *public* hotspots + other immunogenic antigens**
- Preliminary clinical data from ADXS-NEO clinical trials demonstrate broad and rapid anti-tumor immunity
  - Strong T cell **neoantigen responses 1 week after priming/initial dose**
  - **T cell responses in >80% of neoantigen pools** tested (individual peptide data pending)
- Antigen spreading documented in both single antigen Advaxis clinical constructs as well as in ADXS-NEO
  - Immunologic context promotes antigen spreading, extending effects beyond included targets
  - Magnitude of T cell response to primary targets correlated with antigen spreading and clinical outcomes
- Repeat dosing without neutralizing antibodies

ELISPOT data
ADXS-NEO
MSS-CRC patient



MSS CRC, microsatellite stable colon cancer

ADXS-HPV: Vaccine Expressing HPV 16 (tLLO-E7)

IV administration every 3-4 weeks at 1X10⁹ CFU

ADVAXIS IMMUNOTHERAPIES™

ADXS-HPV (AXAL)

Clinical data: Prolonged survival and ***complete responses*** in cervical and anal cancer subjects and ***antigen spreading*** observed

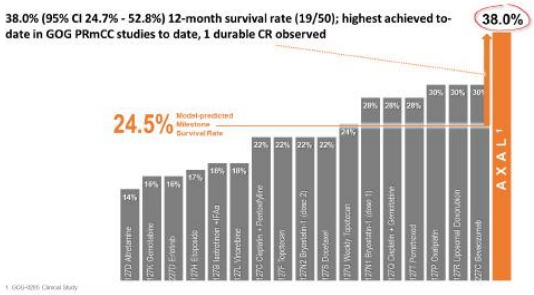
GOG-0265

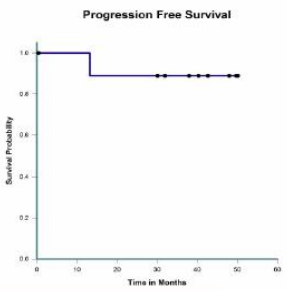
- Phase 2 (n=50)
- Recurrent metastatic cervical cancer
- Comparison to historical GOG studies

BrUOG-276

- Phase 1-2 (n=11)
- Adjuvant therapy with CCRT– anal cancer

38.0% (95% CI 24.7% - 52.8%) 12-month survival rate (19/50); highest achieved to-date in GOG PRmCC studies to date, 1 durable CR observed





- Mostly Grade 1-2 (mild-moderate) chills, pyrexia, nausea, fatigue, headache and hypotension, shortly after infusion.
- High grade, manageable hypotension has been reported in up to 7% of subjects after infusion
- AEs usually resolve within 2 to 4 hours after infusion with symptomatic treatment

Hu W et.al. AXAL-GOG0265. SGO Annual Meeting, 2017; Safran H et.al. Int J Radiat Oncol Biol Phys. 2018

AXAL Phase 3 AIM2CERV – Registration Trial[1]

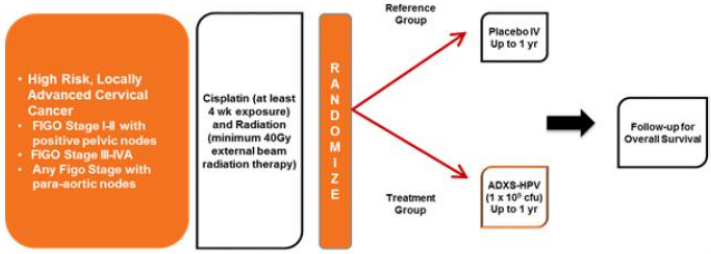
Study Design

ADVAXIS IMMUNOTHERAPIES™

Adjuvant AXAL Following Chemo/Radiation to Prevent Recurrence in HRLA Cervical Cancer

FDA Orphan · FDA SPA · FDA FastTrack

Total no. patients = 450



Baseline tumor imaging must be performed within 28 days prior to the first study treatment infusion

Randomization 1:2 Reference and Treatment Groups

Primary Objective is Disease Free Survival

Primary Endpoint:

- Disease-free survival

Secondary Outcome Measures:

- Safety & Tolerability
- Overall survival
- Patient reported outcomes
- **Exploratory:**
- Association between biomarkers of immunologic response

Advaxis addressing FDA's comments on CMC package and inclusion of second interim analysis

1 FDA has placed a partial clinical hold on this study due to CMC requests which allows continued dosing of already enrolled patients but which prevents enrollment of new patients until resolution of this partial hold.

Herzog T, et al. Poster Presentation at SITC 2016; https://clinicaltrials.gov/ct2/show/NCT02853604
"FIGO: International Federation of Gynecology and Obstetrics; HRLACC: high-risk locally advanced cervical cancer; IV, intravenous; SPA: Special Protocol Assessment".
AIM2CERV: AXAL Immunotherapy Following Chemo/Radiation in Patients who have High Risk Locally Advanced Cervical Cancer (HRLACC)

GOG Gynecologic Oncology Group

ADXS-PSA ± Pembrolizumab in Metastatic Castration Resistant Prostate Cancer
Phase 1 /2 Clinical Study: Keynote 046

ADVAXIS IMMUNOTHERAPIES™

ADXS-PSA

Clinical evidence of ***disease stabilization*** and ***antigen spreading*** in prostate cancer subjects along with reductions in levels of PSA

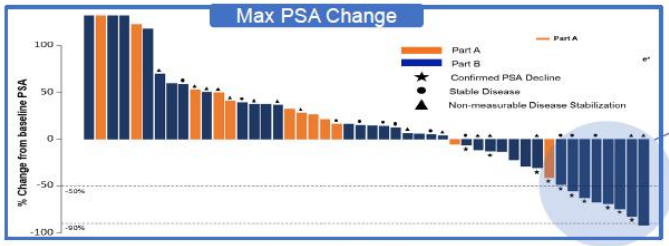
50* subjects, predominantly bone disease only
Part A (ADXS-PSA monotherapy; N=13)
Part B (ADXS-PSA + pembrolizumab; N=37)

In collaboration with: MERCK

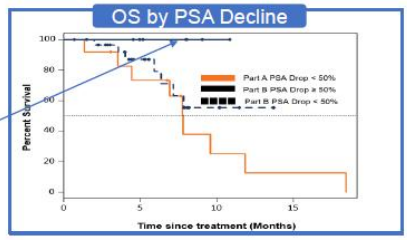
No added toxicity with PSA-pembro combination treatment was observed
- Most commonly Grade 1-2 chills, pyrexia, nausea, fatigue, headache and hypotension shortly after the infusion.

Improvement in survival observed in subjects with ≥ 50% PSA declines from baseline

Max PSA Change



OS by PSA Decline



Stein M et.al. Keynote 046. ASCO 2018

ClinicalTrials.gov Identifier: NCT02325557

7

Update on Survival Rates and Correlative Biomarker Analysis Anticipated in Q1 2019

*31 patients had grade 1-2 events, 18 patients (5 Part A and 13 Part B) had grade 3-4 events, 1 discontinued for grade 4 event

ADXS-NEO: Personalized Neoantigen Vaccine

Phase 1 Clinical Study Design – Initiated June 2018

ADVAXIS IMMUNOTHERAPIES™

ADXS-NEO

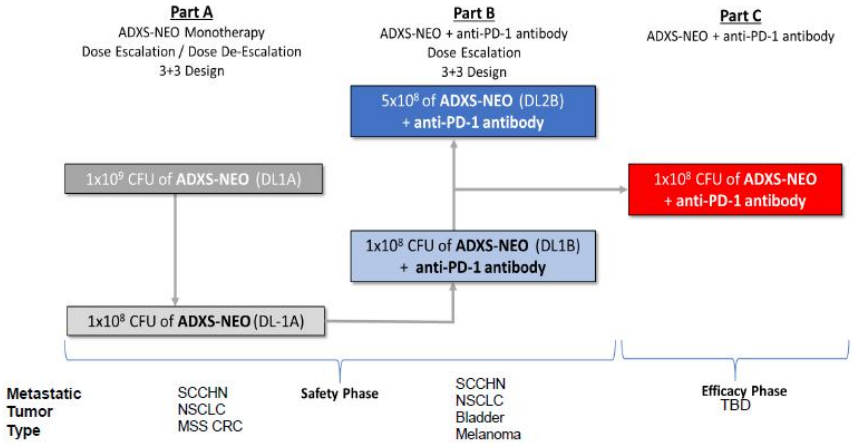
Personalized, patient-specific candidates based on sequencing of each subject's tumor

Endpoints:

Primary
Tolerability/ Safety

Secondary
Clinical activity
RP2D

Exploratory
Immunological



CFU, Colony-Forming Unit; SCCHN, squamous cell carcinoma head and neck; NSCLC, non-small cell lung cancer; MSS CRC, microsatellite stable colon cancer; RP2D, recommended phase 2 dose

Clinical Data From Initial Cohort (safety, immune response) Anticipated 1H 2019

ClinicalTrials.gov Id: NCT03265080

ADXS-HOT (503): NSCLC-Specific Vaccine

Phase 1/2 Clinical Study Design: Open to enrollment

ADVAXIS IMMUNOTHERAPIES™

ADXS-HOT

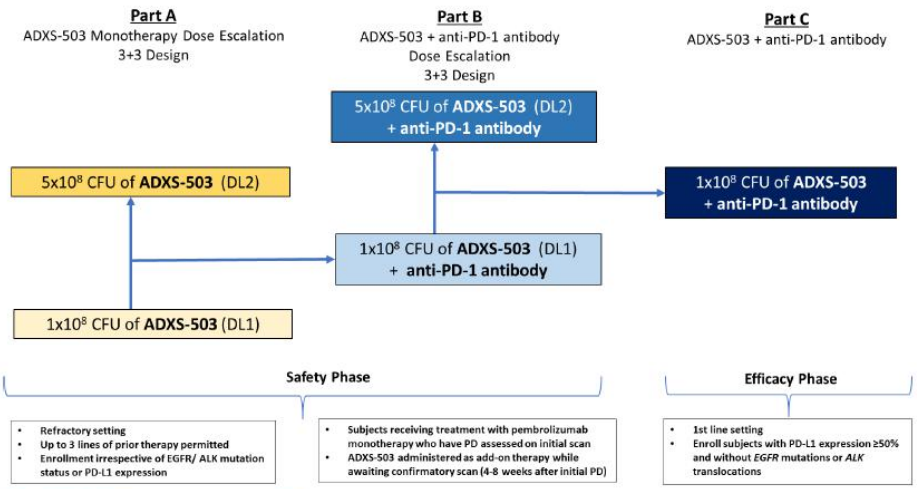
Cancer type-specific candidates based on commonly expressed public hotspot mutations and proprietary cancer antigens

Endpoints:

Primary
Tolerability/ Safety

Secondary
Clinical activity
RP2D

Exploratory
Immunological



Clinical Data From Initial Cohort (safety, immune response)
Anticipated 1H 2019

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

ADVAXIS IMMUNOTHERAPIES™

- Leveraging unique properties of *Lm* vector
  - Capable of delivering large antigen payloads directly inside dendritic/antigen presenting cells
- Broad pipeline of drug candidates for multiple cancer types
  - From Phase 1 to Phase 3 programs in several solid tumor types
- Preliminary clinical data from first neoantigen-directed program demonstrate broad and rapid anti-tumor immunity
  - Ability to generate CD8+T cells rapidly and against large percentage of peptide/neoantigen targets
- Clinical and correlative immune data readouts anticipated throughout 2019

References

1. Wood L, Paterson Y. Front Cell Infect Microbiol. 2014;4:51.
2. Coder B. Targeting shared hotspot cancer mutations with a Listeria monocytogenes immunotherapy induce potent anti-tumor immunity. Poster Presentation, AACR 2018. *Manuscript in preparation.*
3. Coder B. Neoantigens that fail to elicit measurable T cell responses following peptide immunization can control tumor growth when delivered using a Listeria-based immunotherapy platform. Poster Presentation, AACR 2018, *Manuscript in preparation.*
4. Data on file at Advaxis
5. Kosoff R. Advaxis' Listeria monocytogenes-based immunotherapies rapidly impair intratumoral regulatory T cell survival and function and promote effector T cell recruitment, activation and differentiation SITC, November 13, 2017
6. Krupar R. HPV E7 antigen-expressing Listeria-based immunotherapy (ADXS11-001) prior to robotic surgery for HPV-positive oropharyngeal cancer enhances HPV-specific T cell immunity. AACR 2017 Poster Discussion (#7632)
7. Villareal D. Targeting shared hotspot cancer mutations with a Listeria monocytogenes immunotherapy induce potent anti-tumor immunity. AACR 2018
8. Hayes S. Magnitude of anti-PSA T cell response is associated with antigen spreading and slowing in PSA and PAP velocity in ADXS-PSA-treated mCRPC patients. Oral and poster presentation, Keystone Cancer Vaccines, January 2019