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 21, 2018

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 2.02 Results of Operations and Financial Condition

On February 21, 2018, Advaxis, Inc. (the "Company") disclosed that, although it has not finalized its full financial results for the fiscal quarter ended January 31, 2018, it expects to report that it had \$59.4 million of cash, cash equivalents and investments as of January 31, 2018. The amount is preliminary, has not been audited and is subject to change upon completion of the Company's unaudited financial statements for the quarter ended January 31, 2018. Additional information and disclosures would be required for a more complete understanding of the Company's financial position and results of operations as of January 31, 2018.

The information provided pursuant to this Item 2.02 is "furnished" and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section or of Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), and shall not be incorporated by reference into any filing with the SEC made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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 will be made 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, 2017, 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	February 2018 Investor Presentation.

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.

Date: February 21, 2018

(Registrant)

By: /s/ Sara Bonstein

Sara Bonstein

Executive Vice President and Chief Financial Officer



Forward-Looking Statements



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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.

Advaxis, Inc: Investment Snapshot



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 that have been transient and associated with infusion

Broad pipeline with four franchises

- 3 clinical stage programs: HPV-Associated Cancers, Prostate Cancer and ADXS-NEO
- Individualized program: ADXS-NEO is in partnership with Amgen Inc.
- Novel preclinical disease focused hotspot/cancer antigen therapies program: ADXS-HOT

Lead program in Phase 3

- HPV-targeting program with axalimogene filolisbac; Conditional MAA has been submitted
 Ongoing AIM2CERV registrational study of axalimogene filolisbac in high risk locally advanced cervical cancer
- Registrational study in metastatic cervical cancer in combination with Opdivo® anticipated to start in 2018

Ability to combine with other I-O agents

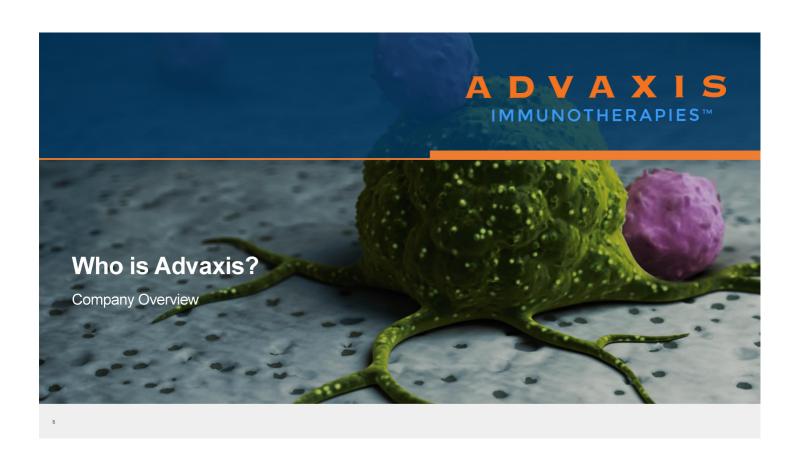
- Demonstrated preclinical synergy with multiple checkpoint inhibitors and co-stimulatory agents
- Three clinical trials in combination with PD-1/PDL-1 inhibitors

Strong partnerships

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

management team

· Deep and broad experience in pharmaceutical drug development and commercialization



Who is Advaxis?

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



Company Overview



Multiple anticipated inflection points beginning in 2018

Note: * Cash, cash equivalents and investments and shares outstanding as of October 31, 2017

Product Candidate Franchise Overviews

HPVassociated cancers

Cervical (CC), head & neck, anal

Product candidates: axalimogene filolisbac (AXAL)
(Submitted Conditional MAA, Phase 3 for Adjuvant CC; Entering Registrational Study for Metastatic CC)

Personal Multiple cancers

Neoantigen
Program

Product candidates: ADXS-NEO (IND)

Shared
Neoantigens
(Hotspot Product candidates: ADXS-HOT Constructs
Mutations) (Pre-IND)

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

CONFIDENTIAL

Who is Advaxis? **Experience and Expertise are Our Greatest Assets**





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







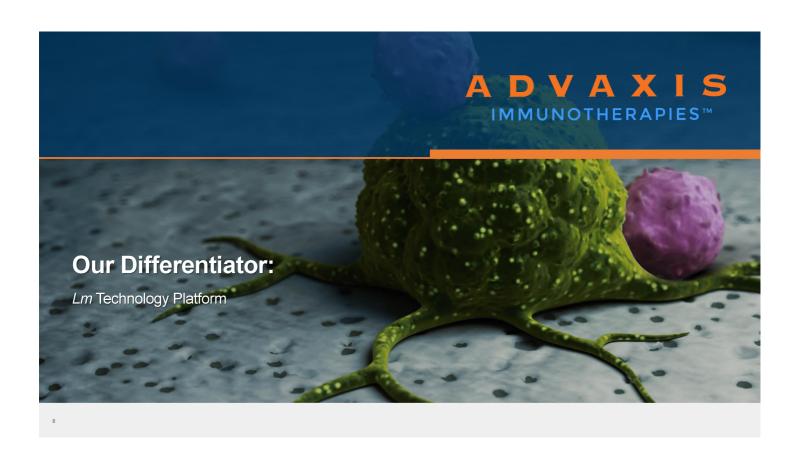
Thomas Hare Sr. VP, Product Development Incyte







Ranya Dajani VP, Corporate Development Bristol-Myers Squibb Company



Lm Technology Features



Multifaceted mechanism

Multiple immunotherapy mechanisms: potent innate immune stimulation via TLRs and PAMPs including the STING receptor, strong CD8+ and CD4+ T cell responses, epitope spreading, and immune suppression by disabling Tregs and MDSCs in the TME

No neutralizing antibodies

Unique intracellular lifecycle of Listeria avoids neutralizing antibodies, allowing for repeat dosing

Synergies with other immunotherapies

Demonstrated synergies with checkpoint inhibitors, costimulatory agonists and others based on preclinical models

Flexible/adaptable platform

Large capacity; can be adapted to target many tumor types and evolve with innovations in the field of immuno-oncology; 3 ongoing clinical programs;

Listeria is irreversibly attenuated

Manageable safety profile

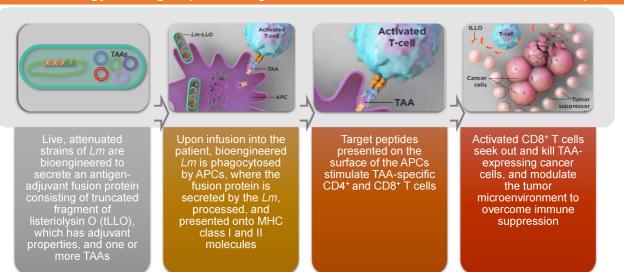
Flu-like symptoms have been transient and associated with infusion

MDSCs, myeloid derived suppressor cells; PAMPs, pathogen-associated molecular patterns; TLR, toll-like receptor; STING, stimulator of interferon genes; TME. Tumor microenvironment

Lm Technology: Mechanism of Action



Lm Technology in antigen-presenting cells can lead to an anti-tumor immune response



APC, antigen-presenting cell; Lm, Listeria monocytogenes; MHC, major histocompatibility complex; TAA, tumor-associated antigen

Harnessing the Immune System with *Lm* Technology A Promising Cancer Immunotherapy Platform



The Power of Lm

- Proprietary technology: protected by a range of patents and applications, potentially stretching into 2038
- Clinically validated: 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

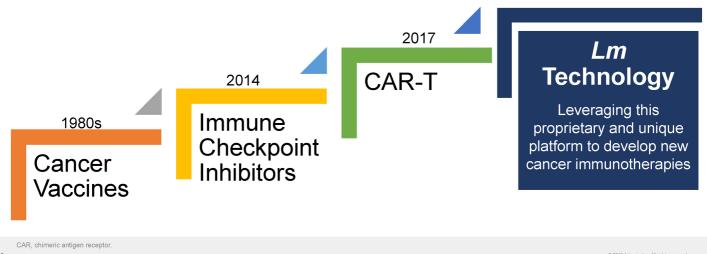
The Potential of Lm

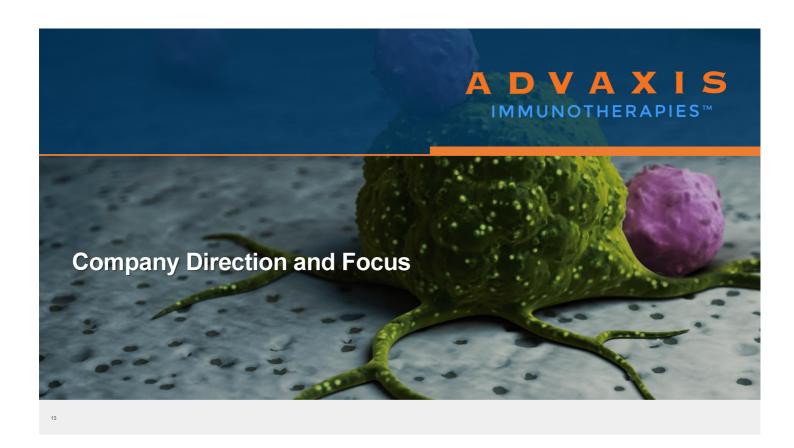
- Target and treat new cancers as additional antigens are identified and introduced into the platform
- Combine with checkpoint inhibitors (nivolumab, pembrolizumab and durvalumab) to improve outcomes
- Create breakthrough in individualized immunotherapy with ADXS-NEO
- Target shared hotspot mutations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

Building the Future of Immuno-Oncology



Lm Technology has the potential to expand the reach of immunotherapy





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



HPV-Related Cancers

The Proof of Concept

NEO

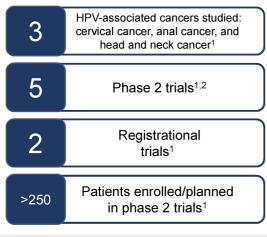
Individualized Neoantigens

HOT

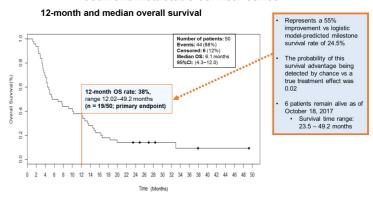
Expansion into the Most Common Cancer Types

Prostate Cancer

Primary efficacy endpoint in proof-of-concept clinical trials in HPV-associated cancer



GOG-0265: Improvement of survival rates in recurrent/metastatic cervical cancer 3,4



- www.clinicatrials.gov, second registrational trial planned to initiate in 2018
 Herzog T, et al. Presented at the Annual Meeting of Society for Immunotherapy in Cancer. November 9-13, 2016. Washington DC. Poster 145.
 Huh W, et al. Presented at the Annual Meeting on Women's Cancer. March 12-15, 2017.
 GOG/NRG Study 0265 CSR, Data On File, Advaxis 2018.

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



HPV-Related Cancers

- Axalimogene filolisbac (AXAL) demonstrated highest 12 mo. OS in metastatic CC as observed by GOG across many trials in that population
- Planned path to CC commercialization:
 - Two registrational trials planned in 2018, one in combo w/ nivolumab
 - EU Conditional application submission made in February 2018
- Opportunistic funding approaches for Head and Neck, Anal

Hotspot Mutation Therapy Program

- Proprietary program to 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

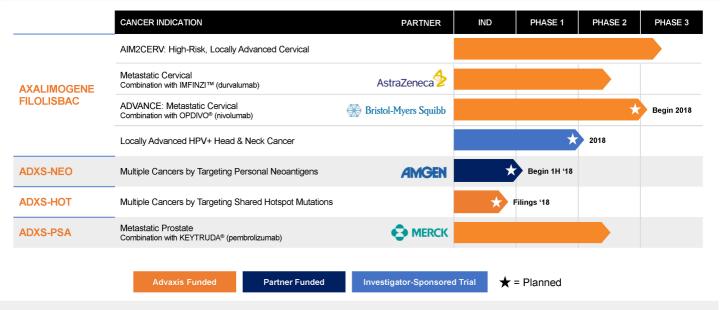
- · Partnership with Amgen Inc.
- Designed to create individualized therapies by activating the patient's immune system to respond against neoantigens identified from an individual patient's tumor through DNA sequencing.
- IND in effect; with first patient dose planned for 1H 2018

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 expected in 2018

The Future of *Lm* Technology Clinical Trial Programs – In Progress and On the Horizon





. . .

Multiple anticipated inflection points beginning in 2018



PROGRAM	MILESTONE	TARGET / STATUS
ADXS-PSA	Metastatic Prostate Ph1/2 Combination with pembrolizumab Part A Monotherapy	Completed
Axalimogene filolisbac	Persistent Recurrent / Metastatic Cervical Cancer (PRmCC) EU Conditional Approval Filing	Completed
Axalimogene filolisbac	ADVANCE Metastatic Cervical Ph 3 Combination with nivolumab Trial Initiation	2018
ADXS-NEO	Ph 1 Initiation	1H 2018
ADXS-PSA	Metastatic Prostate Ph1/2 Combination with pembrolizumab Part B Monotherapy Combination Therapy Data	2018
Axalimogene filolisbac	Announce planned IST in Head and Neck	2018
ADXS-HOT	Multiple IND Filings 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	Completed
7 Maii Tiogorie Illollobae	Part B Expansion Interim Readout	2019

EU= European Union; IND= Investigational New Drug; IST= Investigator Sponsored Trial

Business Acceleration: EU Submission for axalimogene filolisbac



Seeking approval for adult woman with Persistent Recurrent / Metastatic Cervical Cancer (PRMCC) in Europe The review process is expected to take approx. 13 months & we will plan to provide an update at the end of the review process

We are actively seeking a European Commercial

Submitted our Conditional MAA in February 2018

Conditional marketing authorizations are valid for one year, are renewable annually, and are awarded where the benefit to the public health of immediate product availability outweighs the risk.

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Cervical Cancer and Axalimogene Filolisbac: Proof of Concept for Lm Technology

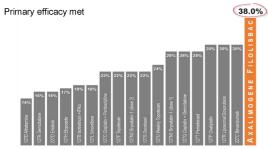


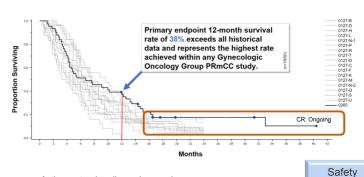
Phase 2 Study in India: Prolonged Survival and Tumor Response in Randomized, Multicenter Phase 2 Study in Recurrent/ Refractory CC Illustrated the Promise of *Lm* Technology¹

- ✓ 34.9% 12-month survival rate (38/109), 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 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





Filed for conditional approval in the EU in February 2018

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.

HPV-Related Cancers: Regulatory Pathway Our cervical franchise remains the cornerstone of our *Lm* Platform



ADVANCE Metastatic Combination Study with axalimogene filolisbac and nivolumab

- Metastatic cervical cancer is an area of high unmet need
- Combination of axalimogene filolisbac with nivolumab: significant opportunity to improve patient outcomes vs. standard of care
- · Opportunity for interim analysis
- Planned start: 2018



AIM2CERV Adjuvant Therapy with axalimogene filolisbac

- High unmet medical need with no approved treatments available
- · Currently enrolling in 13 countries
- Data expected 2020 / 2021



Two confirmatory studies supporting the EU MAA

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HPV Franchise: Strategic Harmonization to Axalimogene Filolisbac



Strategic alignment of all ongoing and planned HPV-related cancer clinical trials to axalimogene filolisbac, based on clinical profile to date in over 250 patients.

Multiple anticipated benefits

- · Enhanced global regulatory strategy
- · Developmental strategic efficiencies gained
- Streamlined commercial strategy
- Two registrational studies will be ongoing for patients in need

Axalimogene Filolisbac Shows Similar Activity in both HPV 16 and 18 Subtypes

- Tissue samples from 41 patients were analyzed
- HPV-positive results were reported for 35 patient samples (85%)

Data from GOG-0265 Exploratory Analysis¹

	HPV-16 or 33 (n = 15 *)	HPV-18 or 45 (n = 17 *)
12-month OS, n (%)	6 (40)	7 (41.2)
Median OS, months (range)	9.1 (3.9 – 14.5)	6.8 (2.5 – 15.1)

1. GOG/NRG Study 0265 CSR, Data On File, Advaxis, 2018
* One patient had both HPV 16 and 18, and another patient had both HPV 16 and 45.

One patient had both HPV To and To, and another patient had both HPV To and 40



Capitalizing on the Individualized Medicine Market with *Lm* Technology The Opportunity for ADXS-NEO





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



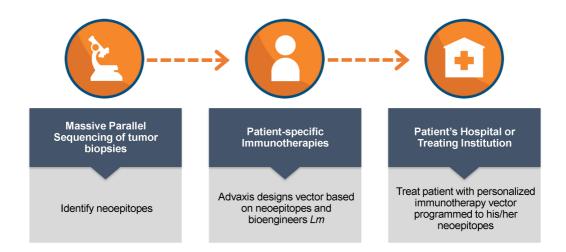
Recognizing these unique benefits, Amgen selected Advaxis' individualized *Lm* platform: ADXS-NEO



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

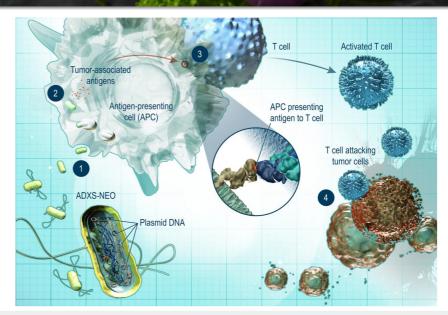




ADXS-NEO Proposed Mechanism of Action



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



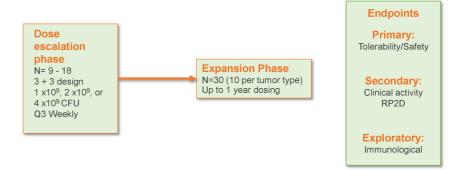
Capitalizing on the Individualized Medicine Market with *Lm* Technology ADXS-NEO Study Design



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

Tumor Types:

Metastatic Microsatellite Stable Colon Cancer Metastatic Squamous Histology Head and Neck Cancer Metastatic Non-Small Cell Lung Cancer



In partnership with **AMGEN**°

CFU= Colony-Forming Unit; RP2D= Recommended Phase 2 Dose



ADXS-HOT Program



Novel cancer immunotherapies leveraging *Lm* Technology to target hotspot mutations and proprietary immunogenic cancer antigens in multiple solid tumors



Lm, Listeria monocytogenes; IO, Immuno-oncology.

Leveraging Lm Technology to Treat Most Common Cancers The Opportunity for ADXS-HOT

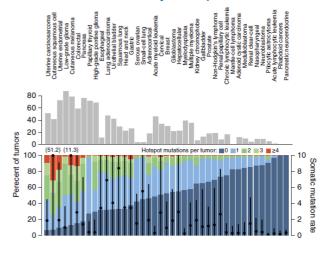


What is a "Hotspot" mutation?^{1,2}

- · 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 is designed to generate "off-the-shelf" products that target multiple shared hotspot neoantigens using the latest innovations in *Lm* Technology™

Cancers Ranked by "Hotspot" mutations³



- 1. Garraway, L.A. & Lander, E.S. Lessons from the cancer genome. Cell 153, 17–37 (2013). 2. Vogelstein, B. et al. Cancer genome landscapes. Science 339, 1546–1558 (2013). 3. Chang et al. Identifying recurrent mutations in cancer reveals widespread lineage diversity and mutational specificity. Nature Biotechnology 34, 155–163 (2016)

ADXS-HOT: Targeting Multiple OFAs, CTAs and Hotspots Designed to Increase Patient Applicability and Clinical Activity





Hotspot mutations have demonstrated pre-clinical activity in Advaxis' *Lm* Technology¹



Addition of multiple hotspot peptides and OFA/CTAs maximizes patient coverage

Each construct designed so that each patient expresses at least one target mutation

Hotspot peptides that the patient does not express do not elicit any immune response coverage up to 100%

Adding proprietary peptides increases coverage up to 100% of patient population for an indication¹

Can be used as monotherapy and/or in combination with other cancer treatments like checkpoint inhibitors, radiation therapy, or other neoepitope treatments



"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

INDs for first constructs expected in 2018

OFA, oncofetal antigen; CTA, cancer-testis antigen
1. Data on file, Advaxis, Inc. 2017.



ADXS-PSA Metastatic Prostate Cancer Phase 1/2 Combination with KEYTRUDA® (pembrolizumab) - (KEYNOTE-046)



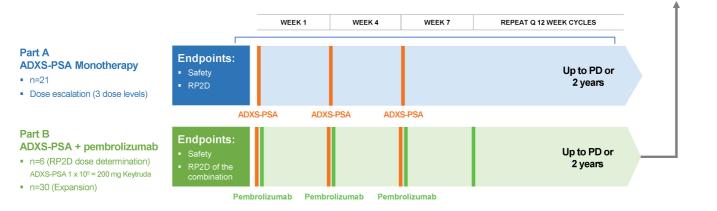
Inclusion Criteria:

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



Part B Expansion: Endpoints

- Safet
- Efficacy
- Immunologic Activity



https://clinicaltrials.gov/ct2/show/NCT02325557 RP2D= Recommended Phase 2 Dose

Phase 1/2 Study with ADXS-PSA monotherapy - Immune correlative data



Both immune-related gene expression analysis and T cell repertoire analysis have revealed significant differences between patients who have and have not achieved clinical activity on ADXS-PSA monotherapy 1,2

Baseline

- Advanced patient population diagnosed with progressive mCRPC
 - Median Gleason Score: 8
 - Median PSA levels: 20.8 ng/mL
 - 67% of patients received 3 or more prior therapies

mCRPC= metastatic castration resistant prostate cancer, SD= Stable Disease, NSD= Non-stable disease. Most common side effects include chills, fever, rigors, hypertension, fatigue, hypotension and vomiting. Side effects noted at these higher dose levels were generally consistent with those observed at the lower dose level, other than a higher occurrence rate of predominantly Grade 2/3 hypotension.

Post-Treatment with ADXS-PSA

Clinical Activity



31% of patients (4/13) achieved Stable Disease based on evaluation of 10-week scans by RECIST criteria



9/13) 69% of patients (9/13) with Non-Stable **Disease**

Immunological Activity

- · Significantly higher expression levels of gene profiles indicative of activated T helper cells, mature antigen presenting cells, and proinflammatory M1 macrophages were observed in SD patients but not in NSD patients1
- SD, but not NSD, was associated with stable and sustained expansions of new and pre-existing T cell clones²
- 5 of the 9 patients (56%) receiving 3 doses of ADXS-PSA exhibited a >3-fold increase in the magnitude of the PSA-reactive T cell response3
- · All 9 patients exhibited increases above baseline in the frequency of T cells reactive to one or more other well known prostate cancer antigen, which is indicative of antigen spreading3

- Hayes SM, et al. Gene expression profiles associated with stable disease in metastatic castration-resistant prostate cancer patients treated with ADXS-PSA immunotherapy, ICIC 2017.
 Hayes SM, et al. Persistence of expanded TCRβ clonotypes is associated with clinical activity of ADXS-PSA immunotherapy in metastatic castration-resistant prostate cancer. ICIC 2017.
 Hayes SM, et al. ADXS-PSA immunotherapy increases the magnitude and quality of prostate cancer-antigen specific T cell responses in patients with metastatic castration-resistant prostate cancer. SITC 2017.

Phase 1/2 Study with ADXS-PSA monotherapy - Immune correlative data

Both immune-related gene expression analysis and T cell repertoire analysis have revealed s between patients who have and have not achieved clinical activity on ADXS-PSA more

Combination immunotherapy data with pembrolizumab expected in 2018

Baseline

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ADXS-PSA	Metastatic Prostate Ph1/2 Combination with pembrolizumab Part B Monotherapy Combination Therapy Data	2018
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ADXS-HOT	Multiple IND Filings 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	Completed
7 Main riogene monobae	Part B Expansion Interim Readout	2019

EU= European Union; IND= Investigational New Drug; IST= Investigator Sponsored Trial

Harnessing the Immune System with *Lm* Technology A Proprietary Cancer Immunotherapy Platform

Efficacy



Primary efficacy endpoints met in proof-of-concept clinical trials in HPVassociated cancer

Safety



Consistent and manageable safety profile in multiple clinical trials across several tumor types, with no cumulative toxicity

Synergy



Enhanced therapeutic potency potential in combination with immune checkpoint inhibitors

Clinical Partnerships



Strong partnerships with leading pharma for several *Lm* Technology product candidates



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All trademarks and registered trademarks are the property of their respective own



All treated patients (n=50) experienced ≥1 AE; safety findings from both stages of the study were consistent

AE	GRADE 1–4	GRADE 1–2	GRADE 3	GRADE 4	
Patients with ≥1 TRAE, n (%)	47 (94)	30 (60)	15 (30)	2 (4)*	
TRAEs occurring in ≥25% of patients					
Fatigue	26 (52)	26 (52)	-	-	
Chills	28 (56)	28 (56)	-	-	
Hypotension	16 (32)	10 (20)	5 (10)	1 (2)	
Nausea	16 (32)	16 (32)	-	-	
Headache	17 (34)	17 (34)	-	-	
Vomiting	14 (28)	13 (26)	1(2)	-	
Fever	17 (34)	17 (34)	-	-	

Huh W, et al. Oral presentation at the Annual Meeting on Women's Cancer (SGO) 2017; 2. GOG/NRG Study 265 CSR, Data on File, Advaxis 2018.

*The observed grade 4 TRAEs were recorded in the same patient were hypotension (probably related to treatment) and cytokine related symptoms (possibly related to treatment). AE, adverse event; TRAE; treatment-related AE.

Return to 'Cervical Cancer' slide

Axalimogene Filolisbac in High-Risk, Locally Advanced Cervical Cancer

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



FDA Orphan SPA FDA FastTrack

Trial Design

Eligibility

- HRLACC
- FIGO stage I–II with positive pelvic nodes
- FIGO stage III– IVA
- Any FIGO stage with paraaortic nodes

Treatment with Cisplatin

Treatment with cisplatin (at least 4-weeks exposure) and radiation (minimum 40-Gy external beam radiation therapy)

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

Treatment with Axalimogene Filolisbac • n=300 • 1 X 10⁹ CFU • Up to 1 year

Placebo IV

- n=150
- Up to 1 year

Primary Endpoint:

Disease-free survival

Secondary Outcome Measures:

- Safety & Tolerability
- Overall survival

"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



Return to 'Regulatory Pathway' slide

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

Baseline tumor imaging must be

performed within 28 days prior to the

first study treatment infusion

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

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