

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 27, 2013

ADVAXIS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

00028489
(Commission File Number)

02-0563870
(IRS Employer Identification No.)

305 College Road East
Princeton, New Jersey
(Address of principal executive offices)

08540
(Zip Code)

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

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 (*see* General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-

Item 7.01 Regulation FD Disclosure.

Attached as Exhibit 99.1 is an investor presentation we may make to certain existing and potential investors from time to time.

The information under this Item 7.01 shall be deemed to be “furnished” and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities under that section and shall not be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	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.

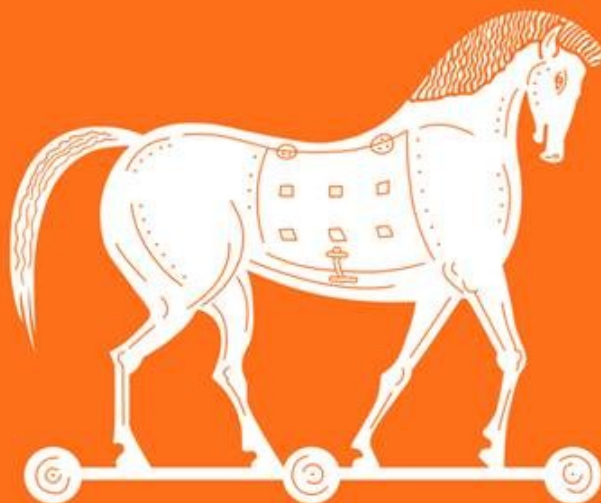
ADVAXIS, INC.

By: /s/ Mark Rosenblum

Name: Mark Rosenblum

Title: Chief Financial Officer

Date: September 30, 2013



A D V A X I S

Empowering the immune system from within™

Forward Looking Statements



This presentation contains forward-looking statements, including, but not limited to: statements as to the anticipated timing of clinical studies and other business developments, statements as to the development of new constructs, expectations as to the adequacy of our cash balances to support our operations for specified periods of time and as to the nature and level of cash expenditures, expectations as to market opportunities, our ability to take advantage of those opportunities, and 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, 2012, available at <http://www.sec.gov>.

The Company undertakes no obligation to publicly release the result of any revision to these forward-looking statements which may be made to reflect the events or circumstances after the date hereof or to reflect the occurrence of unanticipated events, except as required by law. You are cautioned not to place undue reliance on any forward-looking statements.

Experienced Management Team & Board of Directors



Management Team

Daniel J. O' Connor, Esq., President and Chief Executive Officer

- 15 years of executive, legal, regulatory, compliance, manufacturing and quality experience in the biopharmaceutical industry
- Former Senior VP and General Counsel of ImClone Systems Incorporated
- Played a key role in development, licensing and commercialization of Erbitux® and was the executive leader who enabled the company to be sold to Eli Lilly in 2008 for \$6.5B

Robert Petit, Ph.D., Executive Vice President and Chief Scientific Officer

- 25 years experience in oncology drug development
- U.S. medical strategy lead for Yervoy® program at Bristol Myers Squibb (NYSE: BMY) as the Director of Medical Strategy for oncology products and Director of Global Clinical Research
- VP of Clinical Development at MGI Pharma and Aesgen, Inc.

Mark Rosenblum, Chief Financial Officer

- 25 years experience in accounting and financial leadership: VP, Chief Accounting Officer of Wellman, Inc., a \$1.2B chemical company; CFO and Secretary, HemoBioTech, Inc.

Chris French, Vice President, Regulatory and Medical Affairs

- 20 years of research and pharmaceutical experience in drug development
- Management positions in medical affairs, regulatory affairs, business development and scientific communications,
- U.S. Director of Oncology Scientific Communications, Bristol Myers Squibb., Senior Director, MGI Pharma and VP Regulatory and Scientific Affairs, Aesgen.

Board of Directors

David Sidransky, MD

- Co-Founder & Chairman, Champions Oncology
- Professor, Johns Hopkins, Oncology Medicine

James Patton, MD, MBA, Chairman

- VP, Millennium Oncology Management
- Founder & Chairman, VAL Health

Roni A. Appel

- Managing Director, LibertyView Equity Partners

Richard Berman

- Former CEO, Easylink Services
- former SVP, Bankers Trust Company,
- Director, Lustris, Inc., and Neostem, Inc.

Thomas McKearn, MD

- Founder, Cytogen Corporation

Thomas A. Moore

- Former Chairman & CEO, Advaxis

Daniel J. O' Connor, Esq.

- President & CEO, Advaxis



Investment Highlights

Immunotherapy company with cutting-edge, proprietary platform technology in the hottest area of oncology

Lead drug candidate, ADXS-HPV (ADXS11-001), targets HPV-associated cancers with multiple registration opportunities

Comprehensive, single, well-tolerated easy to manufacture and administer immunotherapy

- Cervical cancer program advancing to registration studies
- Anal Cancer Phase 1 ongoing
- Head and Neck Cancer Phase 1 ongoing

ADXS-HPV preliminary Phase 2 Best Response Data: 6 complete responses, 6 partial responses, and 33 stable disease in 110 patients

1 Orphan Drug Designation Granted

2 Orphan Drug Designations Applications Pending

- Anal cancer - Granted
- Invasive cervical cancer - Pending
- Head & neck cancer - Pending

Broad immunotherapy-focused IP, discovery platform and pipeline

Experienced management team and board of directors

41 patents issued and 35 pending patent applications



Four Essentials of Cancer Immunotherapy

1

Access to Antigen Presenting Cells (APCs) to direct and target the immune response

Advaxis immunotherapies preferentially infect the APCs and escape into the cytoplasm to secrete antigens for the targeted tumor (Dendreon)

2

Generate STRONG cytotoxic T-cell response against tumor antigens

Advaxis immunotherapies generate a strong T-cell response to clear Listeria that is redirected to the tumor via the secreted antigens (Multiple Vaccines, TIL Therapy)

3

Get past check-point inhibitors and negative regulators of cellular immunity

Acute "perceived" listeriosis stimulates a maximum immune response that over-rides the checkpoint inhibitors (Yervoy, PD1-PD1L)

4

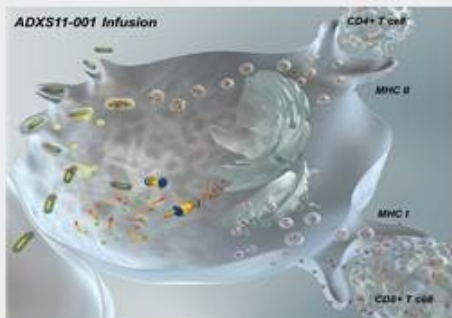
Over-ride Treg and MDSCs within tumor microenvironment, enabling CTLs to kill tumor cells

Advaxis immunotherapies generate TAA specific T-cells that access protected tumor microenvironment and suppress immune protective cells within the tumor

- Other immunotherapies are trying to accomplish these elements through various combinations
- Advaxis is developing technology to integrate all of these elements into a single, well-tolerated, easy to manufacture and administer immunotherapy

Advaxis Approach: 4 Elements in 1

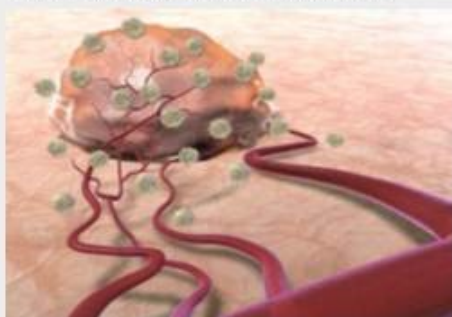
1 Access APC, Secrete LLO-TAA, MHC1



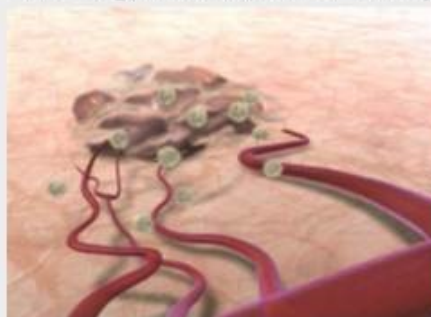
2 CD8 T cell Expansion, Pass Checkpoints



3 Chemokines, Tumor Infiltration



4 Dec. Treg, MDSCs, Tumor Cell Lysis



Proprietary Technology Platform Fuels Robust Clinical Pipeline



Product Candidate	Pre	Phase 1	Phase 2	Phase 3
ADXS-HPV ¹	Cervical Cancer, India			
ADXS-HPV ²	Head & Neck Cancer			
ADXS-HPV ³	Anal Cancer			
ADXS-PSA	Prostate Cancer			
ADXS-cHER2	Breast Cancer			
Veterinary Program				
ADXS-cHER2	Canine Osteosarcoma			

1. Gynecologic Oncology Group is conducting a P2 study in this patient population in the U.S.
2. This study is being sponsored and conducted by Cancer Research UK
3. This study is being sponsored and conducted by Brown University Oncology Group

Advaxis Platform Yields Numerous Product Candidates



Lm-LLO Immunotherapy	Tumor Antigen	Tumor model	Reference
ADXS11-001	HPV16- E7	TC-1	Gunn et al 2001
ADXS31-142	Prostate Specific antigen	TRAMPC1 /PSA	Shahabi et al. 2008, Wallecha et al. 2009
ADXS31-164	Her2/neu Chimera	NT-2 Breast/Transgenic Her2	Seavey et al 2009 Shahabi et al 2011
Lm-LLO-HMW-MAA	HMW-MAA, C-terminus fragment	NT-2 Breast/Transgenic Her2/B16F10-HMW-MAA	Maciag et al 2008
Lm-LLO-ISG15	ISG15	4T1 breast tumor model	Wood et al 2012
Lm-LLO-CD105	Endoglin	NT-2 Breast/Transgenic Her2	Wood et al 2011
Lm-LLO-flk	VEGF	NT-2 Breast/Transgenic Her2	Seavey et al 2009
Bivalent Therapy	Her-2-chimera/HMW-MAA-C	NT-2 Breast/Transgenic Her2	Ongoing



Multiple Phase 1/2 Clinical Trials

Phase 1

refractory cervical cancer
(15 patients)*

Phase 2

refractory cervical cancer
(110 patients)**

Phase 2

refractory cervical cancer
(67 patients)

Phase 1/2

head and neck cancer
(27 patients)

Phase 1/2

head and neck cancer
(expecting 25 patients),
*pending IRB approval****

Phase 1/2

anal cancer
(25 patients)

- **Safety:** predominately cytokine-release syndrome - Grade 1/2 transient, non-cumulative that respond to symptomatic treatment or self resolve (<3.0% related SAEs)
- **Efficacy:** improved survival, complete responses, partial responses, alone or in combination with chemotherapy in recurrent/refractory cervical cancer
- **Activity in multiple high risk HPV strains**

*results published, ** preliminary data reported *** Q4 2013

Over 500 doses in over 200 patients and increasing



Immunotherapy targeting HPV-associated cancers

HPV-associated cancers include: invasive cervical, HPV+ head & neck, anal, penile, vulvar, and vaginal

- Single agent activity observed in recurrent cervical cancer: preliminary data suggest:
 - Improved survival and objective tumor responses including complete responses, partial responses, and stable disease
 - Well-tolerated safety profile
- Exclusive world-wide rights licensed to Advaxis
- Applied for Orphan Drug Designation in 3 indications
 - Anal Cancer (granted); pending in invasive cervical and head & neck cancers

Growth in HPV-associated Cancers Increases Global Opportunity for ADXS-HPV



- HPV has a causative role in 5% of cancers worldwide
- 80% of sexually active Americans will have contracted at least one strain of HPV by age 50 per the CDC
- Current vaccines prevent infection by 2 (out of 15) oncogenic HPV strains but have no effect on the millions that are already infected
- Vaccination has plateaued at 32% in the US

Head & Neck
~80,000

Cervical
~527,000

Anal
~99,000

Vulvar
~27,000

Penile
~86,000

Vaginal
~13,000



WHO/ICO Information Centre on HPV and Cervical Cancer (HPV Information Centre).
Human Papillomavirus and Related Cancers in World. Summary Report 2010.

Opportunistic Business Development Strategy Initially Focusing on High Prevalence Regions



Confidential discussions with multiple partners for the licensing of immunotherapies

Licensing of ADXS-HPV



Asia

- Signed MoU for commercialization in Asia
- Clinical strategy to conduct pivotal program for cervical cancer

Strategic markets with high HPV prevalence

- Established commercial terms for the exclusive license of ADXS-HPV

Licensing of ADXS-cHER2

Diligence underway with animal health divisions of several major pharmaceutical companies

ADX5-HPV Phase 2 Study Overview

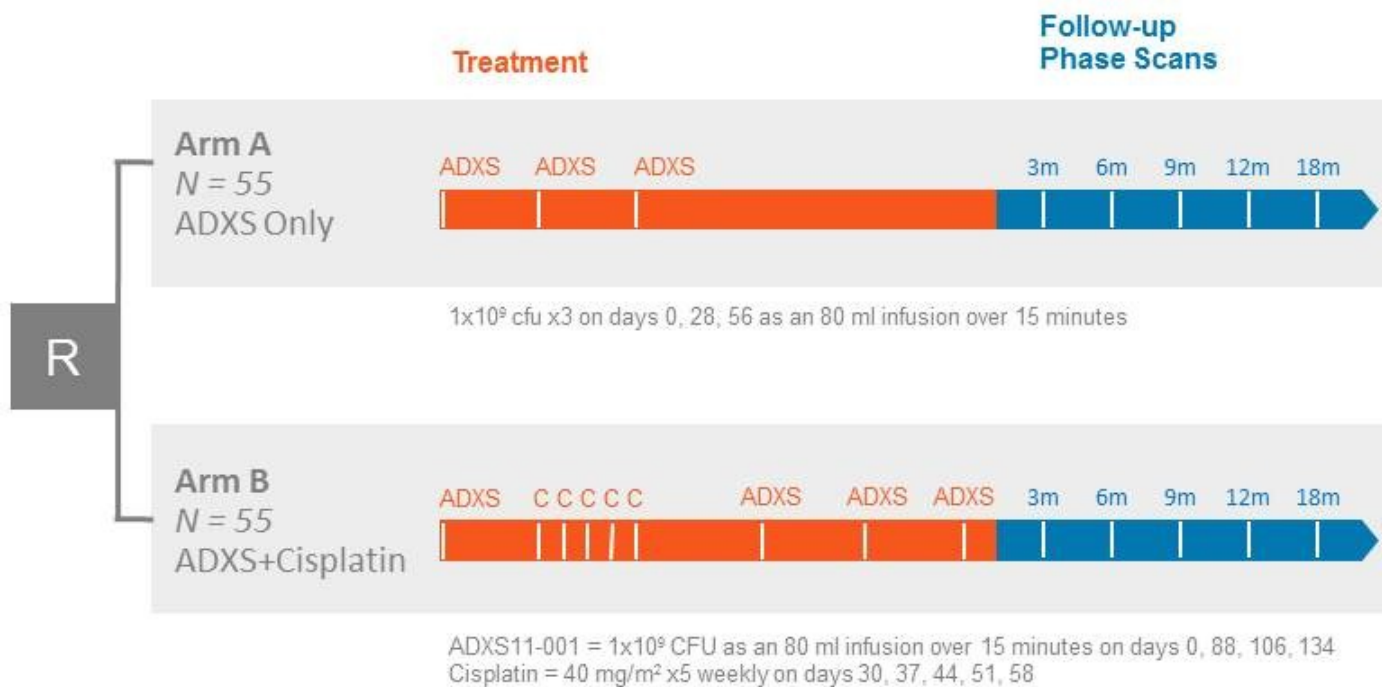


- Multi-center Phase 2 trial conducted in India
- Recurrent cervical cancer patients
 - Failed previous treatments, ECOG 0-2, majority with aggressive disease
- Single agent activity with a single cycle of ADX5-HPV (3 doses)
- Apparent survival benefit and objective tumor responses (CR/PR) in recurrent patients with poor prognosis
- Well-tolerated
 - 59% patients reported no AEs related/possibly related to ADX5-HPV; 41% reported only Grade 1 or 2; <2% reported Grade 3
 - Predominately cytokine-release syndrome associated with infusion - Grade 1/2 transient, non-cumulative toxicities that self-resolved or responded to symptomatic treatment

Phase 2 Cervical Cancer ADXS-HPV +/- Cisplatin Study Design



Recurrent/Refractory Cervical (N = 110)



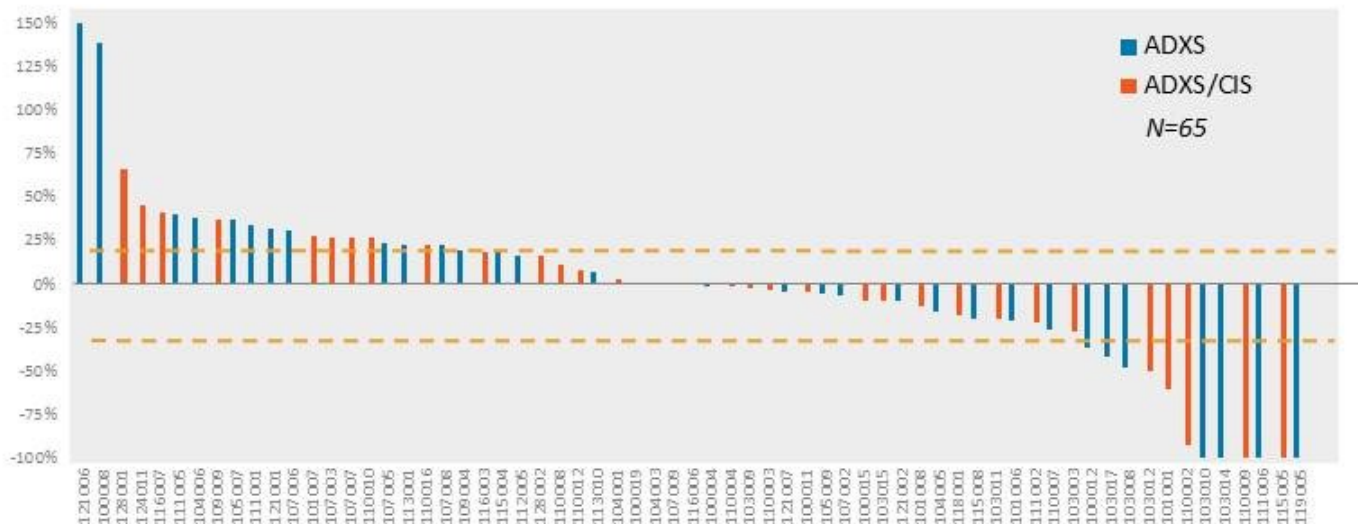
ADXS-HPV Phase 2 Best Response Data: (as of May 17, 2013)



6 Complete Responses

6 Partial Responses

33 Stable Disease

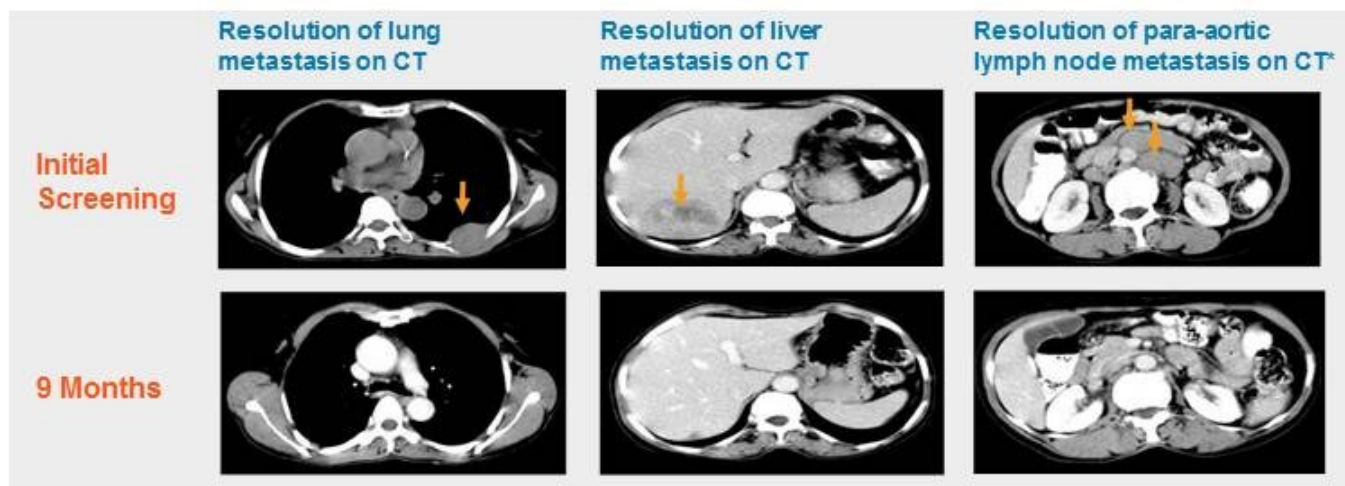


Tumor reduction observed in patients infected with different high risk HPV strains including HPV 16, 18, 31, 33 and 45, as expected.

Patient 110-002: Major Tumors Eliminated



Patient #	First Line Tx	Stage	Tx Arm	Tumor Burden (mm)						Tumor Decrease
				Baseline	3 mo.	6 mo.	9 mo.	12 mo.	18 mo.	
110-002	RT	IVB	ADXS + CIS	284	84	56	34	20	36	93%



- Patient 110-002 enrolled with 284mm (sum of linear measures) of disease at 10 sites, including liver, lung, and peri-aortic nodes. The patient was previously treated with surgery and radiation (EBRTx25), and recurred within 1 year with metastatic disease. She was randomized to receive ADXS/Cis. At 3 months, she had 84mm of tumor at 5 sites, at 6 months 56mm at 3 sites, at 9 months 34mm at 2 sites, and at 12 months 20mm in a single peri-aortic node not amenable to biopsy.

Landmark Survival



Treatment Group

Patients*	Treatment Group		
	Overall (N=110)	ADX11-001 ALONE (N=56)	ADX11-001 + CISPLATIN (N=54)
9 Months (final)			
% alive (#)	46% (51/110)	43% (24/56)	50% (27/54)
12 Months (final)			
% alive (#)	36% (39/110)	32% (18/56)	39% (21/54)
18 Months (ongoing)			
% alive (#)	22% (16/73)	18% (7/38)	26% (9/35)

- Final 12 month survival of 36% with a (current) 18 month survival of 22% we believe to be notable in this disease setting
- Overall survival observed with ADX11-001 is consistent with an active agent in recurrent cervical cancer

*Patients continue to be followed for survival

Prognostic Factors for Overall Survival in Cervical Cancer



Trial	Regimen	N	PS (%)	1 st line	Prior Chem	Prior RT	%SAE Reported	% CR	Med. Surv.	Resp. Durat.	12 Mo. Surv.	18 Mo. Surv.	24 Mo. Surv.
Moore 2004	Cisplatin	134	0-2 (48/44/8)	6%	24%	91%	134% 0 deaths	8%	9M	4.5M	~36%	~12%	~5%
	Cis+ Taxol	130	(45/42/13)				177% 0 deaths	15%			~32%	~21%	~16%
Monk 2009	Cis + Taxol	103	0-1 (55/45)	16 %	70%	86%	364% 2 deaths	3%	12M	5M	~50%	~36%	~15%
Tewari 2013 GOG 240 (ASCO Plenary #3)	Cis + Taxol	114	0-1 (58/42)	17 %	0%	83%	~372% 4 deaths	15%	14.3M	5M	~53%	~37%	~22%
	Cis + Taxol + Bev	115					4 deaths	28%	17.0M	7M	~62%	~46%	~34%

▪ Most important prognostic factors for overall survival and response rate are:

- ECOG performance status,
- Number of prior therapies,
- Interval from initial therapy to time of recurrence, and
- Local recurrence vs. distant metastases*

* Monk 2009, JCO

Registration Opportunity for ADXS-HPV in Cervical Cancer



A highly aggressive malignancy	<ul style="list-style-type: none">▪ Poor prognosis▪ No standard of care▪ Traditional cancer therapy ineffective
Rationale for registering ADXS-HPV in cervical cancer	<ul style="list-style-type: none">▪ 99% caused by HPV▪ ADXS-HPV (single course) induced CRs in already treated cervical cancer patients▪ Exclusive world-wide rights
Next steps towards registration in this highly aggressive malignancy	<ul style="list-style-type: none">▪ Report final results from Phase 2 study in India at SITC annual meeting in November▪ Orphan designation pending▪ Conduct Phase 1/2 study with high dose, immunology endpoints and repeat cycles▪ Conduct EOP2 meeting with FDA; draft Phase 3 protocols; submit SPA▪ Complete Gynecologic Oncology Group (GOG) NCI Phase 2 study of ADXS-HPV in 67 patients with recurrent/refractory cervical cancer▪ Conduct 2 pivotal Phase 3 trials

Registration Opportunity for ADXS-HPV in Head & Neck Cancer



Rationale for registering ADXS-HPV in head and neck cancer

- HPV+ head & neck cancer is increasing at an epidemic rate due to changing sexual practices
- 25%+ of head & neck cancer caused by HPV
- Current therapies lead to poor quality of life
- Exclusive world-wide rights

Next steps towards registration

- Orphan drug designation pending
- Conduct “window of opportunity” in early disease in US
- Complete Cancer Research UK (CRUK) Phase 1/2 to evaluate the use of ADXS-HPV for the treatment of 27 patients with HPV+ head and neck cancer
- Additional randomized P2 study
- Conduct Advisory Board with KOLs

Registration Opportunity for ADXS-HPV in Anal Cancer



Rationale for registering ADXS-HPV in anal cancer

- 80-100% caused by HPV
- Current therapies are toxic and have long term side effects
- No therapy for recurrent disease
- Exclusive world-wide rights

Next steps towards registration

- Discuss development plan with the FDA under ODD
- Complete Brown University Oncology Group (BrUOG) Phase 1/2 study of ADXS-HPV in 25 patients with HPV-associated anal cancer

Orphan designation granted

ADXS-PSA for the Treatment of Prostate Cancer



ADXS-PSA

- Immunotherapy targeting cells expressing PSA
- Conducted a pre-IND meeting with the FDA to discuss the CMC, pharmacology, toxicology, and clinical plans for ADXS-PSA
- Exclusive world-wide rights

Next steps

- Required toxicology studies completed and GMP drug product manufactured for the Phase 1 clinical study
- IND to be filed with the FDA for ADXS-PSA in the treatment of prostate cancer in the first half of 2014
- Phase 1 study to be initiated in first half of 2014 by Advaxis in US

ADXS-cHER2 For the Treatment of HER2 Overexpressing Cancers



Immunotherapy targeting cancers overexpressing HER2, including breast cancer in addition to others

Veterinary Program

- We believe canine osteosarcoma (CO) provides excellent animal model of naturally occurring HER2 driven cancer
- Preliminary Phase 1 data in CO have shown encouraging survival in 9 dogs treated with ADXS-cHER2 vs. 11 untreated dogs, appearing to validate activity of the platform

Human Program

- Preliminary canine data may provide rationale to advance into human clinical trials

Licensing of ADXS-cHER2

Diligence underway with animal health divisions of several major pharmaceutical companies

Key Milestones Expected to Continue to Build Momentum



Reporting of final Phase 2 data from India cervical cancer trial at SITC

Q4 2013

Response from FDA on Orphan Drug Designations for ADXS-HPV in: invasive cervical cancer and head and neck cancer

H1 2014

Filing IND application with the FDA for ADXS-PSA for the treatment of prostate cancer

Upcoming

Initiation of dialogue with the FDA to establish clear path to registration for ADXS-HPV in the treatment of cervical cancer



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www.advaxis.com

Strong Patent Portfolio



41 patents issued

- Composition of matter, methods and uses covering:
 - Live Lm
 - Four (4) different Listeria species for human use
 - LLO-antigen & ActA-antigen fusion proteins
 - Delivered by Lm or stand alone
 - Two (2) different families of adjuvant fusions
 - Nontoxic, modified LLO

35 patents pending

IP successfully defended in European Patent Court (Munich)

- No additional challenge permitted