# 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 Re	port (Date of earliest event reported): January	15, 2014		
	(Ex	ADVAXIS, INC. act name of registrant as specified in its charte	er)		
	Delaware	00028489	02-0563870		
(	State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)		
Regis	305 College F Princeton, Ne (Address of principal estrant's telephone number, including area code: (60	ew Jersey executive offices)	<b>08540</b> (Zip Code)		
	k the appropriate box below if the Form 8-K filing sions ( see General Instruction A.2. below):	is intended to simultaneously satisfy the filing o	bligation of the registrant under any of the followin		
	Written communications pursuant to Rule 425 un	der 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))		
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#### Item 7.01 Regulation FD Disclosure.

Attached as Exhibit 99.1 is an investor presentation dated January 15, 2014.

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 J. Rosenblum

Name: Mark J. Rosenblum

Title: Chief Financial Officer

Date: January 15, 2014

Corporate Presentation

Ticker: ADXS



Empowering the immune system from within  $\mbox{\em m}$ 

## 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.

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## Why Invest in Advaxis?



# Proprietary cancer immunotherapy platform technology -- hottest area of cancer research

 Live attenuated bacteria stimulate the immune system to view the tumor as a bacterial infection for elimination -- No other technology has the same capability

# Lead immunotherapy, ADXS-HPV, plans to initiate registrational Phase 3 trials in 2014

 Improved survival and objective tumor responses in 110 patients with recurrent cervical cancer (Phase 2 clinical study)

# Plans to file INDs and initiate Phase 1 trials in 2014 for prostate and breast cancers Multiple licensing opportunities

- · Recently licensed in Asia for ADXS-HPV -- other ADXS-HPV regional deals to follow
- Promising opportunity in animal-health based on encouraging survival data in canine osteosarcoma – second immunotherapy, validating platform

Low cost manufacturing
Orphan Drug Designations Granted
Strong balance sheet -- no debt

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## **Anticipated Milestones**



#### 1H 2014

- Execute second ex-US HPV deal to market dominate player
- · Partner ADXS-cHER2 for animal-health indications
- Conduct FDAEOP2 meeting for ADXS-HPV in recurrent cervical cancer
- Initiate Phase 1/2 high-dose study in recurrent cervical cancer
- Dose first patient in Phase 1/2 head & neck cancer trial (Mount Sinai)
- Submit IND for ADXS-PSAin prostate cancer
- Initiate Phase 1 in prostate cancer with ADXS-PSA
- Secure CMO with scale-up and commercial capabilities

#### 2H 2014

- Submit IND for ADXS-cHER2 in breast cancer
- Initiate global Phase 3 study in recurrent cervical cancer with ADXS-HPV
- Initiate Phase 1 study in HPV-associated lung cancer (GBP -- partner in Asia)
- Report data (Mount Sinai study)

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## 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 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 3



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

Acute "perceived" listeriosis stimulates a maximum immune response that bypasses immune checkpoints 4



Override Treg and MDSCs within tumor microenvironment, enabling CTLs to kill tumor cells

Advaxis immunotherapies change the tumor microenvironment specifically reducing immune protective cells within the tumor without causing autoimmunity

No other technology integrates all of these elements into a single, well-tolerated, low cost to manufacture, and easy to administer immunotherapy

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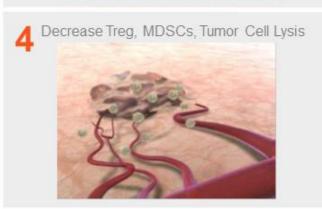
# Advaxis Approach: 4 Elements in 1







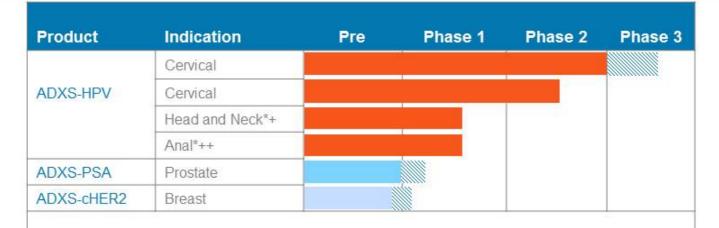




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# Proprietary Technology Platform Fuels Robust Clinical Pipeline





Animal-Health		POC	Animal	Phase 2	Phase 3
ADXS-cHER2	Canine Osteosarcoma	UPenn			

<sup>\*</sup> Orphan Drug Designation Granted

+Icahn School of Medicine at Mount Sinai & Cancer Research UK

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<sup>++</sup>BrUOG: Brown University Oncology Group Projected 2014

# Advaxis Platform Yields Numerous Drug Candidates



Tumor Antigen	Disease	Status
HPV-E7	Cervical, Head and Neck, Others	Phase 2
PSA	Prostate	Pre-IND
Her2/Neu	BrCa, Gastric, Esophageal	Pre-IND/Phase 1 Veterinary
Survivin	Lymphoma, Pan-Tumor Antigen	Pre-Veterinary Trials
PSCA	Prostate Cancer	Preclinical
HMW-MAA	Melanoma, neovascularization	Preclinical
WT-1	Pan-Tumor Antigens, Lung	Preclinical
CEA	Ovarian	Preclinical
CA9	Renal and Hypoxic Solid Tumors	Preclinical
VEGF r2	Solid Tumors	Preclinical
p53	BrCa, others	Preclinical
IL-13R Alpha2	Hypoxic solid tumors	Preclinical
FAP	Colorectal Cancer	Preclinical
SCCE (Kallikrin related peptidase 7)	Ova, BrCa, Panc, Cervix, Melanoma, Lung (non-adeno)	Preclinical
ISG-15	Bladder, others	Preclinical
Endoglin (CD-105)	Tumor (BrCa) Anti-angiogenesis	Preclinical
Dual Constructs		
PSA + HMWMAA	Prostate	Preclinical
Her2/neu + HMWMAA	BrCa + Others	Preclinical
Her2/neu + CA9	BrCa + Others	Preclinical

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# 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 high-risk HPV strains but have no effect on the millions that are already infected
- Vaccination has plateaued at 32% in the US



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

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# ADXS-HPV Opportunity in Cervical Cancer



#### Need for ADXS-HPV in cervical cancer

- 99% of cervical cancers caused by HPV
- A highly aggressive malignancy
- Poor prognosis
- · No standard of care
- · Traditional cancer therapy ineffective

#### Broad patient experience in cervical cancer

- ADXS-HPV (single course) induced Complete Responses in already treated cervical cancer patients
- Safety: predominately cytokine-release syndrome Grade 1/2 transient, non-cumulative that respond to symptomatic treatment or self resolve (<3.0% related SAEs)</li>
- Efficacy: improved survival, complete responses, partial responses, alone or in combination with chemotherapy in recurrent cervical cancer
- Activity in multiple high-risk HPV-strains

Over 500 doses administered to 200 patients and increasing

### ADXS-HPV Phase 2 Clinical Trial



#### Overview

- Multi-center Phase 2 trial conducted in India
- Patients with recurrent cervical cancer
  - Failed previous treatments, ECOG 0-2, majority with aggressive disease
- Single agent activity with a single cycle of ADXS-HPV (3 doses)

#### Results

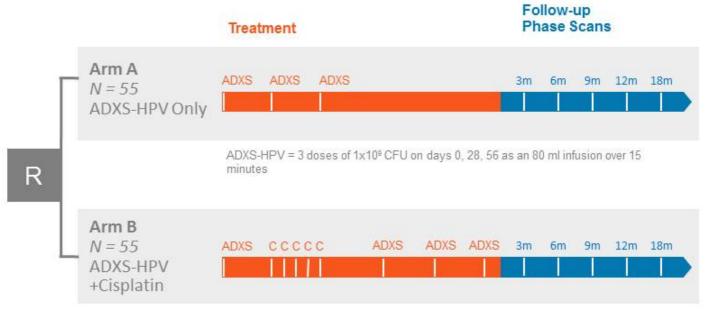
- Apparent survival benefit and objective tumor responses (CR/PR) in patients with poor prognosis
- Well-tolerated
  - 58% patients reported no AEs related/possibly related to ADXS-HPV; 42% reported only Grade 1 or 2; <2% reported SAEs related/possibly related to ADXS-HPV (1 Grade 3 and 1 Grade 4)
  - Predominately cytokine-release syndrome associated with infusion -- Grade 1/2 transient, non-cumulative toxicities that self-resolved or responded to symptomatic treatment

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# Phase 2 Recurrent Cervical Cancer Study Design



#### ADXS-HPV +/- Cisplatin (N = 110)



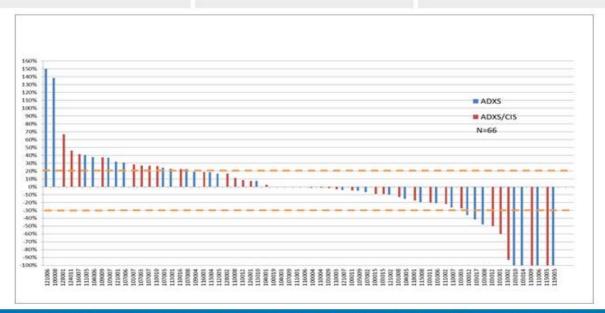
ADXS-HPV =  $1\times10^{\circ}$  CFU as an 80 ml infusion over 15 minutes on days 0, 88, 106, 134 Cisplatin =  $40 \text{ mg/m}^2 \times 5$  weekly on days 30, 37, 44, 51, 58

# ADXS-HPV Phase 2 Best Response Data



6 Complete Responses

6 Partial Responses 35 Stable Disease



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

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# Landmark Survival



Patients	Overall (N=110)	ADXS-HPV ALONE (N=56)	ADXS-HPV+ CISPLATIN (N=54)
0.11	46%	43%	50%
9-Month Survival	(51/110)	(24/56)	(27/54)
40 Marth Cardial	36%	32%	39%
12-Month Survival	(39/110)	(18/56)	(21/54)
40 Marth Carriage	28%	25%	31%
18-Month Survival	(31/110)	(14/56)	(17/54)

Overall survival observed with ADXS-HPV is consistent with an active agent in recurrent cervical cancer

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# Prognostic Factors for Overall Survival in Cervical Cancer



Trial	Regimen	N	PS (%)	1 <sup>st</sup> line	Prior Chem	Prior RT	% SAE Reported	% CR	Med. Surv.	Resp. Durat.	12-Mo. Surv.	18-Mo. Surv.	24-Mo. Surv.
Petit 2013 LM-LLO-E7-15 (SITC #258)	ADXS-HPV	110	0-2 (31/58/11)	0%	64%	89%	2% 0 deaths	5%	~9 M (prelim)	10.5M	36%	28%	TBD
**************************************	ADXS-HPV + Cisplatin						0 deaths						
Moore 2004	Cisplatin	134	0-2	6%	24%	91%	134%	8%	9M	4.5M	~36%	~12%	~5%
	Cis+ Taxol	130	(48/44/8)				0 deaths 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	Cis + Taxol	114	0-1 (58/42)	17%	0%	CT	~372% 4 deaths	15%	14.3M	5M	~56%	~34%	~27%
(ASCO Plenary #3)	Cis + Taxol + Bev	115	(Bookers)				4 deaths	28%	17.0M	7M	~68%	~49%	~34%

- Most important prognostic factors for overall survival and response rate are performance status, # of prior therapies, interval from initial therapy to time of recurrence, and local recurrence vs. distant metastases\*
- ADXS-HPV patient population had very advanced disease given the inclusion of patients with PS 2, heavily pre-treated with chemotherapy, radiation therapy or both, and majority with metastatic disease
- 12-month survival of 36% and 18 month survival of 28%, 11% objective response rate, 10.5 month duration, with a well-tolerated safety profile after 1 cycle (3 doses) of treatment compares favorably with active agents in recurrent cervical cancer

N.B. For discussion purposes only – not for direct comparisons due to differences in study designs, patient populations, data available, and Advaxis interpretation

\* Monk 2009, JCO

# Next Steps for ADXS-HPV in Recurrent Cervical Cancer



Next steps towards registration in this highly aggressive malignancy

- Conduct EOP2 meeting with FDA, finalize Phase 3 protocols, submit SPA
- Conduct 2 pivotal Phase 3 trials (multi-national trials with partner participation)
- Conduct Phase 1/2 study with high dose, immunology endpoints and repeat cycles
- Complete GOG NCI Phase 2 study of ADXS-HPV in 67 patients with recurrent/refractory cervical cancer

# Opportunity for ADXS-HPV in Head & Neck Cancer



Need for ADXS-HPV in head and neck cancer	<ul> <li>HPV-associated head &amp; neck cancer is increasing at an epidemic rate due to changing sexual practices</li> <li>25%+ of head &amp; neck cancer caused by HPV</li> <li>Current therapies lead to poor quality of life</li> </ul>
Clinical development	<ul> <li>Discuss development plan with the FDA under ODD</li> <li>Phase 1/2 "window of opportunity" study in 25 patients with early disease in US Icahn School of Medicine at Mount Sinai</li> </ul>

(REALISTIC)

Future Phase 2 and 3 studies to be determined

Phase 1 to evaluate the use of ADXS-HPV for the treatment of

HPV-associated head and neck cancer in 27 patients

### Orphan Drug Designation Granted

# Opportunity for ADXS-HPV in Anal Cancer



Need for ADXS-HPV in anal cancer	<ul> <li>80-100% caused by HPV</li> <li>Current therapies are toxic and have long-term side effects</li> <li>No therapy for recurrent disease</li> </ul>
Clinical development	<ul> <li>Discuss development plan with the FDA under ODD</li> <li>Phase 1/2 study in 25 patients with HPV-associated anal cancer Brown University Oncology Group (BrUOG)</li> <li>Future Phase 2 and 3 studies within RTOG to be determined</li> </ul>

# Orphan Drug Designation Granted

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# Commercialization and Partnering Strategy



Create long-term value for the Company by forming relationships with market dominant biopharmaceutical companies that validate our platform

 Seeking partnerships that are aligned with the Company's clinical and commercialization objectives

#### Strategy

- Retain US rights to ADXS-HPV
- License ADXS-HPV on regional basis outside the US
- License ADXS-cHER2 for animal-health
- Seek worldwide partnerships for larger indications (prostate & breast)

#### **Existing Partnerships**

Asia: Global BioPharma

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# Licensing Agreement in Asia



- Exclusive licensing agreement with Global BioPharma (GBP), funded by a group of investors led by Taiwan Biotech Company Ltd. (TBC)
- TBC is one of the top 5 biopharmaceutical companies in Taiwan
- Formed Global BioPharma (GBP) solely to focus on development and commercialization of ADXS-HPV for the treatment of HPV-associated cancers in Asia (29 countries)
- Territory covers >4B people with >200,000 annual diagnoses of cervical cancer (roughly 40% of the world's cases)

#### GBP

- Conduct registration trials for cervical cancer and explore development in lung, head and neck, and anal cancers
- Responsible for all clinical development and commercialization costs (including 150 patients in US and Asia registrational programs)
- Establish manufacturing for its own territories
- Purchased common stock from Advaxis at market with option to purchase additional shares at 150% premium

#### Advaxis will receive

- Event-based financial milestones
- Annual development fee
- Annual net sales royalty payments in the high single to double digits

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### ADXS-cHER2 for the Treatment of Canine Osteosarcoma and Human Breast Cancers



#### Immunotherapy targeting cancers overexpressing HER2

Including breast cancer and others

#### Animal-Health Program

- Phase 1 data in canine osteosarcoma (CO) show encouraging survival in companion dogs treated with ADXScHER2 vs. those untreated
- Naturally occurring tumors in companion dogs not animals bred for research
- Data validate platform technology
- Data support further development and basis for regulatory pathway to advance toward conditional approval with USDA

#### Human Program

 Preliminary canine osteosarcoma data provide rationale to advance ADXS-cHER2 into a Phase 1 for breast cancer and other HER2 driven cancers going forward

# Animal-Health -- Products in Development



#### Current Clinical Program

#### Canine Osteosarcoma (OS)

- Approximately 8,000-20,000 dogs per year in the US
- Highly aggressive mesenchymal tumor -- medium to large breeds
- Standard of care treatment: amputation and post operative chemotherapy
  - High rate of recurrence
- 9 months -- 1 year median survival, 25% of dogs survive two years

#### Targeted Indication

#### Canine Lymphoma (T-cell and B-cell)

- 5 million new cases per year in the US (1 in 15 dogs)
- 80-100% express Survivin
- Median Survival T-cell Lymphoma ~55-162 days
- Median Survival B-cell Lymphoma ~127-256 days

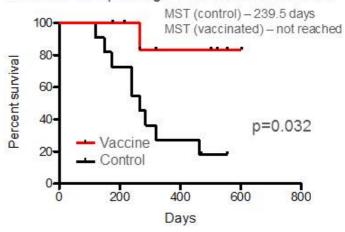
# ADXS31-164 Prolongs Survival in Dogs with OS



#### Treatment Related Adverse Events

ADXS 31-164 Dose	1x10 <sup>s</sup>	5x108	1x10 <sup>s</sup>	Total
Number of dogs recruited	N=3	N=3	N=7	N=13
General Disorders				
Pyrexia (>103)	2	1	4	7
Fatigue	1	1	2	4
GI Disorders				
Vomiting	2	1	2	5
Nausea	2	1.	3	6
Cardiovascular				
Arrhythmias	0	1.	1	2
Tachycardia	0	0	1	1
Hypotension	0	0	0	0
Hematological parameters				
Thrombocytopenia	0	0	2	2
Biochemical parameters (increase)				
y-GT	0	2	0	2
Alkaline Phosphatase	1	1	2	2
ALT	1	1	0	2
AST	1	1	3	5
BUN	0	0	0	0
CREA	0	0	0	0
Cardiac Troponin I	0	0	1	1

#### ADXS31-164 prolongs survival in HER2+ OS



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

All toxicities reported as Grade 1 and improved survival over case matched control

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# ADXS-PSA for the Treatment of Prostate Cancer



Need for ADXS-PSA in prostate cancer	<ul> <li>Large market</li> <li>Expect ADXS-PSAto have similar safety profile to that of ADXS-HPV</li> <li>Potential partnering opportunity</li> </ul>
Our approach	<ul> <li>Target cells expressing PSA with our immunotherapy</li> <li>Conducted a pre-IND meeting with the FDA to discuss the CMC, pharmacology, toxicology, and clinical plans for ADXS-PSA</li> <li>Establish proof-of-concept</li> </ul>
Clinical development	<ul> <li>Required toxicology studies completed and GMP drug product manufactured for the Phase 1 clinical study</li> <li>IND to be filed with the FDA for ADXS-PSA in the treatment of prostate cancer in the first half of 2014</li> <li>Phase 1 study to be initiated in first half of 2014 in the US</li> </ul>

## Why Invest in Advaxis?



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- Recently licensed in Asia for ADXS-HPV -- other ADXS-HPV regional deals to follow
- Promising opportunity in animal-health based on encouraging survival data in canine osteosarcoma – second immunotherapy, validating platform

Simple, robust, and compliant manufacturing process

Orphan Drug Designations Granted

Strong balance sheet -- no debt

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## 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<sup>®</sup> 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.

#### Gregory Mayes Executive Vice President, Chief Operating Officer

 20 years experience in operations and bio-pharmaceuticals, Executive Committee for Dendreon Corp., President, Unigene Laboratories, VP, GC, Chief Compliance Officer, ImClone Systems Inc., Senior Counsel, AstraZeneca Pharmaceuticals

#### Mark Rosenblum Chief Financial Officer, Secretary, and Senior Vice President

 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, Executive Director of 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, Lustros, Inc., and Neostem, Inc.

#### Thomas McKearn, MD

Founder, Cytogen Corporation

#### Thomas A. Moore

Former VP, Proctor & Gamble

#### Daniel J. O' Connor, Esq.

President & CEO, Advaxis



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