

Advaxis Inc. (ADXs-OTC)

ADXs: Balance sheet cleaned up and boosted by new financial commitment, current pipeline focus is ADXS-HPV cervical cancer---
Outperform

Current Recommendation	Outperform
Prior Recommendation	Neutral
Date of Last Change	02/12/2013
Current Price (03/22/13)	\$0.09
12-month Target Price	\$0.25

OUTLOOK

Advaxis is a Listeria based immunotherapy company focused on the development of immunotherapeutics for cancer treatment. We are optimistic about the Company's unique Listeria platform technology which has advantages over its peers. The Company's lead drug candidate ADXS-HPV is in Phase II clinical trials for the treatment of cervical cancer and cervical dysplasia. Two more Phase I/II trials are initiated for the treatment of head and neck cancer and anal cancer. Other pipeline candidates target breast, brain and prostate cancer.

We rate its shares Outperform, but risk is high.

SUMMARY DATA

52-Week High	\$0.14
52-Week Low	\$0.03
One-Year Return (%)	-21.66
Beta	-1.40
Average Daily Volume (sh)	6,229,135
Shares Outstanding (mil)	502
Market Capitalization (\$mil)	\$60
Short Interest Ratio (days)	N/A
Institutional Ownership (%)	1
Insider Ownership (%)	13.4
Annual Cash Dividend	\$0.00
Dividend Yield (%)	0.00
5-Yr. Historical Growth Rates	
Sales (%)	N/A
Earnings Per Share (%)	N/A
Dividend (%)	N/A
P/E using TTM EPS	N/A
P/E using 2011 Estimate	N/A
P/E using 2012 Estimate	N/A
Zacks Rank	N/A

ZACKS ESTIMATES

	Revenue (in millions of \$)					Above Avg., N/A Med Products N/A
	Q1 (Jan)	Q2 (Apr)	Q3 (Jul)	Q4 (Oct)	Year (Oct)	
2012	0.00 A	0.09 A	0.18 A	0.24 A	0.51A	
2013	0.00 A	0.00 E	0.00 E	1.50 E	1.50 E	
2014					2.00 E	
2015					9.50 E	
Earnings per Share (EPS is operating earnings before non recurring items)						
	Q1 (Jan)	Q2 (Apr)	Q3 (Jul)	Q4 (Oct)	Year (Oct)	
2012	-\$0.01 A	-\$0.01 A	-\$0.01 A	-\$0.01 A	-\$0.04 A	
2013	-\$0.00 A	-\$0.01 E	-\$0.01 E	-\$0.01 E	-\$0.03 E	
2014					-\$0.03 E	
2015					-\$0.02 E	
Zacks Projected EPS Growth Rate - Next 5 Years %						N/A

WHAT'S NEW

- **First fiscal quarter financials reported;**
- **Balance sheet cleaned up and boosted by financial commitment;**
- **On track to advance clinical programs, current focus is cervical cancer;**

Advaxis Reports Financial Results For Fiscal First Quarter

On March 24, 2013, Advaxis (ADXS) filed 10-Q for the first fiscal quarter ending January 31, 2013.

The Company did not record any revenue for the three months ended January 31, 2013 and 2012.

Research and development expenses were \$0.98 million for the three months ended January 31, 2013, a decrease of approximately \$1.23 million as compared with approximately \$2.21 million for the same period a year ago. This decrease is primarily attributable to clinical trial expenses, which decreased in the current year resulting from lower costs due to the near completion of dosing patients in the India trial and less clinical trial activity. In addition, overall compensation decreased in the current period resulting from fewer employees when compared with the same period a year ago.

General and administrative expenses were \$1.2 million for the three months ended January 31, 2013, an increase of approximately \$0.17 million, or 17%, as compared with approximately \$1.0 million for the same period a year ago. This was the result of higher legal fees. In addition, overall compensation expense increased during the current period resulting from additional employees and costs related to employee benefits. These increases were slightly offset by a decrease in travel and entertainment related expenses in the current period when compared with the same period a year ago.

For the three months ended January 31, 2013, interest expense decreased significantly to approximately \$0.36 million from \$1.62 million in the same period a year ago resulting from the significant reduction in overall debt from approximately \$6.3 million in outstanding principal at January 31, 2012 to approximately \$1.7 million in outstanding principal at January 31, 2013. These reductions included the \$4.5 million aggregate principal value of convertible promissory notes exchanged for shares of its common stock and warrants in May 2012 and approximately \$4.3 million aggregate principal value of various convertible promissory notes converted during 2012. During the three months ended January 31, 2013, the Company recorded approximately \$157,000 in non-cash interest expense related to the issuance of 3.5 million shares (Commitment Fee Shares) under the Hanover Purchase Agreement.

For the three months ended January 31, 2013, the Company recorded non-cash expense from changes in the fair value of the warrant liability of approximately \$4.0 million compared with income of approximately \$0.84 million in same period a year ago. In the current period, the increase in expense of approximately \$4.0 million resulted from an increase in the fair value of each liability warrant due to an increase in share price from \$0.045, at October 31, 2012 to \$0.072 at January 31, 2013 and the number of outstanding liability warrants increased during the current period compared to the same period a year ago.

In the three months ended January 31, 2013, the Company received a net cash amount of approximately \$725,000 from the sale of state NOLs and R&D tax credits for the periods ended October 31, 2010 and 2011.

GAAP loss was \$5.9 million or \$0.01 per share. Non-GAAP loss was \$1.9 million, or \$0.00 per share.

Balance Sheet Has Been Cleaned Up and Boosted By Financial Commitment

During the three months ended Jan 31, 2013, Advaxis made great efforts to clean up and boost its balance sheet.

Accounts payables decreased to \$3.9 million at the end of Jan 31, 2013 from \$5.2 million at the end of Oct 31, 2012. As a result, total current liability decreased to \$7.9 million at the end of Jan 31, 2013 from \$9.3 million at the end of Oct 31, 2012.

As of March 13, 2013, the Company had cash of approximately \$700,000. However, balance sheet has been boosted by recent financial commitment.

On October 31, 2012, Advaxis (ADXS) announced that it has secured \$10 million in equity financing from Magna Group, LLC through its flagship Equity Enhancement Program, with an additional \$1.4 million in financial commitments from a combination of sources.

Below are the highlights of the financing.

- Magna committed via the Equity Enhancement Program to purchase up to \$10 million of Common Stock by Hanover Holdings I, LLC, an affiliate of Magna Group. The purchase price will generally be 90% of the market as defined in the Agreement. In consideration for Hanover's commitment, the Company has issued them 3,500,000 shares of Common Stock. Hanover Holdings I, LLC also funded \$265,000 in two private placements during September and October, 2012.
- Magna will assume the \$740,600 of outstanding Convertible Notes, owned by third parties. The Company will deliver Convertible Notes to Magna Group in the same aggregate principal amount paid by Magna Group. As part of the \$740,600 assumption, the Company delivered a new Convertible Note in the aggregate principal amount of approximately \$400,100 to Magna Group. The Convertible Notes bear interest at 6% and are convertible into shares of Common Stock at a conversion price of 73% of the market as defined in the Agreement.
- The purchase of \$375,000 of Convertible Notes by private investors and institutional investors. The private investors include Dr. Yvonne Paterson, the scientific founder of the Company, Dr. James Patton, MD, a director of the Company, and Christine French, the Company's executive director of medical affairs.
- On October 17, 2012 warrants to purchase approximately 15.9 million shares of Common Stock containing full anti-dilution protection expired unexercised.

We think this financing comes at a crunch time. The combination of the \$10 million Equity Enhancement Program, debt assumption and funding short term capital needs matches the Company's current requirements and boosts its balance sheet. These institutional investments as well as the investments by the Company's management and directors further validate the Company's technology and clinical programs.

Most importantly, partnership talks with big pharma continue. We think this is important because this kind of financing improves balance sheet without diluting existing shareholder base. So far, the existing financing has been at the cost of share dilution. Further, any partnership, if established, validates the Company's technology and clinical programs.

Current equity line can, at the Company's current volume and pricing, deliver over \$1.2 million per month versus \$0.6 million required. This is a great achievement for ADVX. With the ease of cash concern, the Company should be able to focus on advancing its clinical programs.

Pipeline further Expanded by New Phase I/II Trial Of ADXS-HPV in Anal Cancer

On Feb 19, 2013, Advaxis announced that the Brown University Oncology Research Group (BrUOG) will be coordinating a **Phase I/II study** of ADXS-HPV in 25 patients with HPV-associated **anal cancer**. Dr. Howard Safran, professor of medicine, will be principal investigator. Patients will be treated at Rhode

Island Hospital and The Miriam Hospital (the main teaching hospitals of The Warren Alpert Medical School of Brown University). Multiple institutions will collaborate.

This non-randomized, open-label, multi-center study will evaluate the safety and effectiveness of ADXS-HPV when combined with standard chemotherapy and radiation treatment for anal cancer. The primary objectives of the trial include the evaluation of adverse events and the evaluation of 6-month clinical response. The study is expected to open for enrollment February 2013.

Virtually all cases of squamous cell cancer (SCC) of the anus are caused by a Human Papilloma Virus (HPV) infection. Anal cancer cells infected with HPV have the tumor associated antigen HPV E7. ADXS-HPV causes antigen presenting cells to stimulate other immune cells to attack cancer expressing HPV E7. In Phase I clinical trials and preliminary data from ongoing Phase II trials, ADXS-HPV has been safely administered to 193 patients with other HPV-associated diseases (recurrent/refractory cervical cancer and CIN 2/3), and has demonstrated clinical benefit as a single agent or in combination with chemotherapy.

This new indication of ADVX-HPV for anal cancer is an important step for the pipeline expansion. With this new indication, ADXS has now a series of clinical trials under study including three Phase II trials, two Phase I/II trials and three Phase I trials. This is quite unusual to a small cap biotech company.

Product	Indication	Stage
ADXS-HPV	Cervical Intraepithelial Neoplasia (CIN)	Phase II Company sponsored study, initiated in March 2010 in the US. The Company completed enrollment of the cohort 2 in June 2012.
	Cervical Cancer, India	Phase II Company sponsored study initiated in November 2010 in India in 110 Patients with recurrent or refractory cervical cancer. Enrollment completed in May 2012, preliminary results presented at 2012 SITC meeting.
	Cervical Cancer, GOG	Phase II The Gynecologic Oncology Group (GOG) of the National Cancer Institute is conducting a study in 67 patients with recurrent or refractory cervical cancer which is currently open to enrollment. 1 patient has been dosed as of Jan 11, 2012.
	Head & Neck Cancer	Phase I/II The Cancer Research UK (CRUK) is funding a study of 45 patients with head & neck cancer at 3 UK sites which began to enroll patients in May 2012
	Anal Cancer	Phase I/II Initiated By Brown University Oncology Group in Feb 2013
ADXS-PSA	Prostate Cancer	Phase I Company sponsored (timing to be determined).
ADXS-HER2	Breast and other Cancers	Phase I Company sponsored (timing to be determined).
ADXS-HER2	Canine Osteosarcoma	Phase 1 Company sponsored study, initiated in July 2011 in the US.

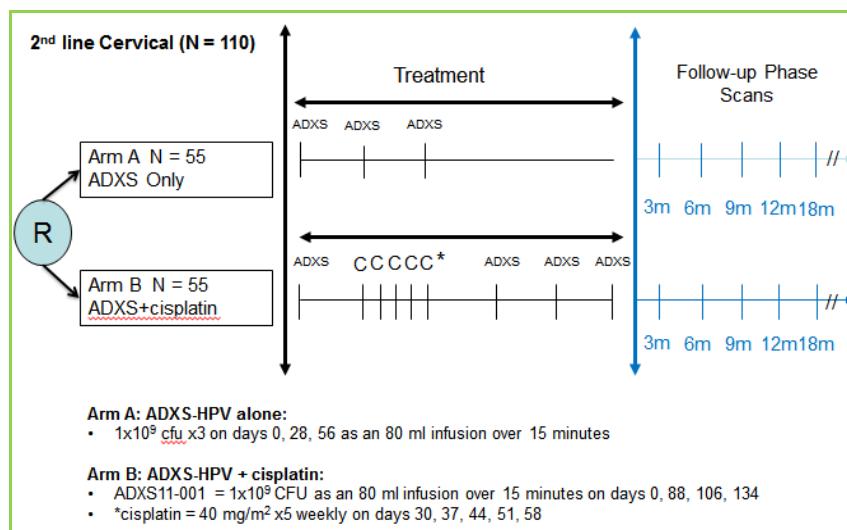
Current Focus Is ADXS-HPV For Cervical Cancer

On October 27, 2012, ADXS updated preliminary data from the ongoing randomized 110 patient **Phase II** trial of ADXS-HPV being conducted in **India** in women with recurrent/refractory **cervical cancer** who

have failed previous cytotoxic therapy. The data were presented in an oral presentation at the Society for Immunotherapy of Cancer (SITC) 27th Annual Meeting in North Bethesda, MD.

As a reminder, ADXS initiated the **Phase II** study in November 2010 in India in 110 Patients with recurrent or refractory cervical cancer. This study is being conducted at 22 sites in India. All patients randomized to the trial have been previously treated with chemotherapy, radiotherapy or both, and their cancer has progressed subsequent to treatment and has been confirmed by CT or radiologic scan.

Patients are randomized into 2 groups of 55 patients receiving: ADXS-HPV or ADXS-HPV + cisplatin (40 mg/m², weekly x5). Patients got either 3 doses of ADXS-HPV at 1 x 10⁹ CFU or 4 doses of ADXS-HPV at 1 x 10⁹ CFU with **cisplatin** chemotherapy. Naprosyn and oral promethazine are given as premedications and a course of ampicillin is given 72h after infusion thereby clearing any residual vector. Patients receive CT scans at baseline and Days 84, 184, 273, 365 and 545. **The primary endpoint is 12 month survival.**



Enrollment was completed in May 2012 and preliminary results were presented at 2012 ASCO and GOG meeting in the summer of 2012.

At the SITC meeting, ADXS reported as of October 22, 2012, landmark survival at 6, 9, 12, and 18 months of 65%, 44%, 33%, and 17% respectively. There appears to be no difference in survival between the two groups. The National Comprehensive Cancer Network Guidelines cite historical 12 month survival data of 0-22% with single agent therapy in recurrent cervical cancer. This study shows 12 month survival of 33% among a group of 70 patients.

	<u>6 mo.</u>	<u>9 mo.</u>	<u>12 mo.</u>	<u>18 mo.</u>
# Alive/N	71/109	39/88	23/70	6/36
% Survival	65%	44%	33%	17%

In February 2013 at the Bio CEO conference held in NYC, ADXS presented updated data from Phase II study conducted in India.

- The Phase II study is maturing - 80% patients have reached 12 months of treatment;
- The study is expected to “close” in June 2013;

- ADXS plans to present the updated data in June 2013 at 2013 ASCO, which will disclose updated survival and histological data;
- Following table summarizes the updated preliminary landmark survival data as of October 22, 2012 from the Bio-CEO conference:

	<u>6 mo.</u>	<u>9 mo.</u>	<u>12 mo.</u>	<u>18 mo.</u>
# Alive/N	71/109	39/88	23/70	6/36
N			87	
% Survival	65%-	44%+	33%+	17%-

6 complete (100%) responses and 6 partial (30%+) responses have been reported.

- 6 complete responses (CR): 4 in the ADXS alone group; 2 in the ADXS+ cisplatin group.
- 6 partial responses (PR): 3 in the ADXS alone group; 3 in the ADXS+ cisplatin group.

Following table summarize the data of the 12 patients with complete or partial response as of October 22, 2012.

Patient #	First Line Tx	Stage	Tx Arm	Tumor Burden (mm)						Tumor Decrease
				Baseline	3 mo.	6 mo.	9 mo.	12 mo.	18 mo.	
Complete Responses										
103-014	CT	IVB	ADXS	223	228	0	N/A	N/A	N/A	100%
115-005	RT	IIB	ADXS + CIS	30	0	0	0	0	EXP. 15 mo.	100%
110-009	CT + RT	IB	ADXS + CIS	23	0	0	0	0	N/A	100%
103-010	CT	IVA	ADXS	35	0	0	0	0	DP 15 mo.	100%
119-005	RT	IIIA	ADXS	37	35	0	N/A	N/A	N/A	100%
111-006	RT	IV	ADXS	16	16	0	N/A	N/A	N/A	100%
Partial Responses										
110-002	RT	IVB	ADXS + CIS	284	84	56	34	20	36 EXP. 20 mo.	93%
101-001	CT + RT	IVB	ADXS + CIS	50	42	44	20	EXP. 11.5 mo.	-	60%
103-012	CT + RT	IVB	ADXS + CIS	18	9	25	WC 10/22/12	N/A	N/A	50%
103-008	RT	IVA	ADXS	48	48	39	39	25	N/A	48%
103-017	CT + RT	IVB	ADXS	106	62	exp. 3.1 mo.	-	-	-	41%
100-012	CT + RT	IVB	ADXS	164	107	105	105	exp. 9.5 mo.	-	36%

N/A = not available, scan has not occurred; EXP = expired; DP = disease progression; WC = withdrew consent

Our takeaways From the Preliminary Results

The preliminary data are very encouraging.

After 110 patients and 264 doses, the safety data is encouraging. ADXS-HPV continues to demonstrate a well-tolerated and manageable safety profile with 32% of patients reporting Grade 1 or 2 transient, flu-like

symptoms that self-resolve or respond to symptomatic treatment. Less than 2% of patients reported serious adverse events associated with ADXS-HPV. Published studies on chemotherapy treated patients like these show 100% of patients experiencing severe adverse events, usually multiple times. Serious adverse events result in death, are life-threatening, cause significant disability or require inpatient hospitalization.

Great efficacy has been observed. Although it's too early to assess the primary endpoint: overall survival, the preliminary survival data and the early responses, which are the secondary endpoint, are very promising. Compared to GOG historical one year survival of 5%, ADXS-HPV has achieved 33% one year survival rate. This is a huge improvement. Other literature data showed that generally, recurrent cervical cancer has a poor 1-year survival rate of 15% and a 5-year survival rate of 3-13%. ADXS-HPV's 33% one year survival rate is also a 100% improvement. Further investigation is warranted.

This study is now well advanced, as evidenced by the fact that the majority of patients have been in the study for more than 12 months and the Company is reporting 18 month landmark survival data for the first time. ADXS-HPV appears to be emerging as an active agent in recurrent/refractory cervical cancer with significantly less toxicity than chemotherapy.

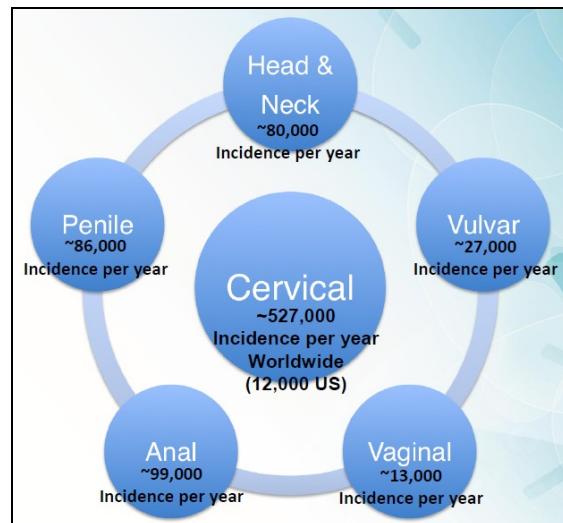
The Company plans to further update the Phase II trial data in June 2013 at ASCO meeting. The positive ADXS-HPV data may trigger partnership talks for Advaxis.

ADXS-HPV for cervical cancer is the Company's current focus. Advaxis plans to conduct new short term clinical trials to support its partnership talks as well as the planned Phase III trial of ADXS-HPV.

Huge Market Potential For ADXS-HPV

Cervical cancer is a worldwide problem and ranks as the 2nd leading cause of cancer death of women in the world. According to WHO, about 630 million people are infected with one of the over 100 strains of HPV. Global prevalence of clinically pre-malignant HPV infections is between 28 to 40 million women. Approximately 500,000 women are diagnosed of cervical cancer each year and about 11.4% of women in the general population are estimated to harbor cervical HPV infection. In the US, about 12000 new cases of cervical cancer are diagnosed each year. Prevalence of cervical cancer is higher in developing countries and India, China and South America are the three regions with highest cervical cancer prevalence (50% of cervical cancer burden).

In addition to cervical cancer, ADXS-HPV has potential to target other HPV-mediated cancers, which further expand ADXS-HPV's market. The Company already initiated clinical studies of ADXS-HPV for head & neck cancer as well as anal cancer.



Enrollment of Cohort 2 in Phase II CIN 2/3 Study Completed

On June 7, 2012, Advaxis announced that it has completed enrollment of 40 patients in the second of three dose cohorts in Lm-LLO-E7-07, a randomized, single blind, placebo controlled **Phase II** dose escalation study assessing the safety and efficacy of ADXS-HPV for the treatment of cervical intraepithelial neoplasia (CIN) 2/3.

The patients in cohort 2 were randomized 3:1 to ADXS-HPV (3 doses at 3.3×10^8 cfu) or placebo. The dose of ADXS-HPV in this cohort is six times higher than that administered in cohort 1. Patients are observed for a total of 6 months after the last dose before undergoing the standard of care surgery (LEEP) required for the treatment of this disease. Safety and efficacy results will be reported once all patients have completed LEEP.

As a reminder, Advaxis initiated the multicenter, randomized, single blind, placebo-controlled, **Phase II** clinical trial of ADXS-HPV for the treatment of cervical intraepithelial neoplasia (CIN) in March 2010. The study is designed to assess the safety and efficacy of ADXS-HPV for the treatment of CIN grade 2/3, which is late stage cervical dysplasia that requires surgery to prevent invasive cancer. Numoda Corporation is Advaxis' strategic partner in the conduction and execution of this trial.

The study has **three cohorts** consisting of 40 patients each: 30 patients receive 3 doses of ADXS-HPV at 50 million, 330 million or 1 billion cfu and 10 patients receive 3 doses of placebo. The primary objective of this study is to determine a safe dose of ADXS-HPV for the treatment of CIN 2/3. Efficacy is determined by an adjudicated panel of pathologists who are blinded to treatment and conduct microscopic assessments of the tissue removed at pretreatment biopsies and during their treatment surgery to determine if the lesions have regressed or returned to normal. Immunogenicity and HPV DNA data will be collected, as well.

Dosing of patients began in late May 2010, and total of 120 patients will be enrolled in this trial. We are very pleased that Advaxis is on track to complete the Cohort 2 enrollment. Data will be available for analysis in **1Q13**.

Summary of Positive Cohort 1 Data

On Feb 27, 2012, Advaxis (ADXS) reported positive results from the first cohort of the **Phase II** dose escalation study assessing the safety and efficacy of **ADXS-HPV** in the treatment of cervical intraepithelial neoplasia (**CIN**) **2/3**. Cohort 1 consisted of 41 patients.

- In the ADXS-HPV arm, 52% of CIN 2/3 lesions regressed from CIN 2/3 to CIN 1 or normal. This means surgery is no longer be required. The dose in cohort 1 is about 1/20th of the dose being used in trials of ADXS-HPV in cervical cancer.
- This 52% regression rate of ADXS-HPV with the lowest dose tested is very encouraging. According to the American Academy of Clinical Research's Task Force on the Treatment and Prevention of Intraepithelial Neoplasia, 50% objective regression rate with a new treatment agent is considered clinically meaningful.
- Further, according to O'Shaughnessy, et al 2002, CCR, 8:314, "An improvement in CIN 2/3 to either pathologically normal cervix or of CIN 3 to CIN 1, with no new CIN 2/3 lesions appearing in at least 50% of the treated patients, is evidence of clinical benefit of the new agent."
- In the cohort 1 trial, 40% of CIN 2/3 lesions spontaneously regressed in the placebo arm. This is within the range reported in the scientific literature of 35%-43% (Wright, et. al. 2003. Am J Obstet Gynecol, Am. J. Obstet. Gynecol. 289:295).

- ADXS-HPV is safe. Less than 1/3 (29%) of the patients treated reported any side effects associated with treatment. Those that occurred were mild and self-resolved or responded quickly to treatment.
- No SAEs (serious adverse events) were reported.

We are encouraged by the positive preliminary results of this Phase II trial especially at this low dose. ADXS-HPV at low dose meets 50% efficacy target. With cohort 2 dosage 6 times higher and cohort 3 dosage 20 times higher, higher response rates are expected to achieve.

CIN 2/3 is the precursor to cervical cancer. CIN is diagnosed in 450,000 American women annually. Progressive CIN is currently treated with surgery to prevent cancer from occurring. However, this treatment is associated with a number of problems, which include the development of an “incompetent cervix” i.e., a condition that prevents women from carrying a baby to full term. The typical CIN patient is a woman between 25 and 45 years of age. Although surgery is a viable short-term solution for the condition, it does not address the cause of the disease, which is a human papilloma virus (HPV) infection. Women who require surgery once may need it again. Current HPV vaccination products have not demonstrated effectiveness against active HPV infections.

The goal of this treatment is to prevent progression to cervical cancer and to eliminate the need for surgery and subsequent obstetric risks. With these positive preliminary results, ADXS-HPV seems on track to achieve this goal.

UPenn Doses First Two Dogs in ADXS-HER2 Canine Osteosarcoma Study

On August 2, 2012, Advaxis announced that the first two dogs have been dosed in the University of Pennsylvania School of Veterinary Medicine study of ADXS-HER2 for canine osteosarcoma.

Under the direction of Dr. Nicola Mason, Chair in Companion Animal Medicine at the University of Pennsylvania, School of Veterinary Medicine, ADXS-HER2 is being used to treat dogs suffering from bone cancer. Canine osteosarcoma is a leading killer of large breed dogs that causes tumors to form on long leg bones. The traditional treatment is immediate amputation and, even with subsequent chemotherapy, the cancer typically metastasizes to the lungs, causing death in 6-12 months. In this trial, dogs that have undergone standard of care treatment for osteosarcoma; including limb amputation and follow up chemotherapy, and that over-express the tumor marker HER-2/neu in their tumors, are treated with Advaxis agent ADXS-HER2. This immunotherapy is designed to stimulate the dog's immune system to attack cancer cells that express the HER-2/neu marker. The goal is to elicit anti-tumor immunity and prolong survival.

Cancer Research UK Initiates Phase I/II Clinical Trial of ADXS-HPV for Head and Neck Cancer

On May 8, Advaxis' partner Cancer Research UK (CRUK) began to enroll patients into REALISTIC, a Phase I/II study to investigate the use of ADXS-HPV for the treatment of HPV positive head and neck cancer. HPV is associated with 40-70% of head and neck cancers.

This trial is being conducted at the Aintree Hospital at the University of Liverpool, the Royal Marsden Hospital at the University of London, and the Cardiff Hospital at the University of Wales. The study will investigate the safety and efficacy of ADXS-HPV in **preventing recurrence** of head and neck cancer among patients who have been treated with surgery, radiotherapy, and/or chemotherapy; alone or in combination. A maximum of 45 patients are to be enrolled in this study, and all costs will be assumed by CRUK. Two patients have already been enrolled in the trial at the Aintree Hospital in Liverpool, UK.

This trial further expands the ADXS-HPV clinical development program to another HPV-associated tumor type.

According to the National Cancer Institute and the American Cancer Society, head and neck cancers represent approximately 3 percent of all cancers in the United States and are twice as common in men as in women. Historically, head and neck cancer has been associated with people over the age of 50 and with the use of alcohol and tobacco (including smokeless tobacco), however, there has been a recent rise in HPV-related oropharyngeal cancers in caucasian men under the age of 50. Recurrence rates in patients are high, in some studies over 80% within 2 years. ADXS-HPV may provide a treatment option for doctors and patients with HPV-related head and neck cancers.

VALUATION AND RECOMMENDATION

We maintain our Outperform rating for ADXS and our 12-month price target is \$0.25 per share.

We think Advaxis' live, attenuated Listeria technology is a unique immunotherapeutic platform which can target various cancer indications and infectious diseases. This technology has advantages over other immunotherapies in three unique ways:

- Advaxis' Listeria-based cancer vaccine can deliver bioengineered cancer antigen fused with a unique, proprietary strong adjuvant LLO which elicits both innate and adaptive immune systems in the body to fight cancer. The immune response elicited by Advaxis' cancer vaccines has been the most comprehensive and robust so far in the industry.
- Advaxis' cancer vaccines can reduce the amount of regulatory T cells and myeloid suppressor cells which help protect tumors from attacking by cytotoxic T cells.
- Another distinctive feature of Advaxis' cancer vaccines is its ability to change the ratio between killer T-cells and regulatory T cells (the Kill Ratio) inside the tumor from a 1:1.3 to a 22.7:1.

Based on this unique platform technology, Advaxis has established a pipeline targeting a variety of cancer indications including cervical cancer/cervical dysplasia, head and neck cancer, prostate cancer, anal cancer and breast/brain cancers. **The Company currently has three Phase II clinical trials and two Phase I/II under way and three additional Phase I trials are planned.**

Near term catalysts are shown below:

Q1 2013	Q2/Q3 2013	Q3 2013	Q4 2013
<ul style="list-style-type: none">• Report Phase 2 Mid-dose CIN 2/3 Results• Report Updated Phase 2 Cervical Cancer Results	<ul style="list-style-type: none">• File IND for Prostate Cancer Indication	<ul style="list-style-type: none">• Initiate Phase 1/2 Study for Prostate Cancer• Report Final Phase 2 Cervical Cancer Results	<ul style="list-style-type: none">• Report Phase 2 High-dose CIN 2/3 Results• Report Initial Phase 1/2 Prostate Cancer Results

In terms of valuation, we think Advaxis is undervalued. The Company should be worth more than current value of \$46 million in market cap in our view.

Currently, the Company shares are trading at about \$0.09 per share which values the Company at about \$46 million in market cap. This is certainly a discount. We believe this is mainly due to its weak balance sheet. However, we reminder investors that the Company recently announced \$11.4 million financing, which boosted the balance sheet greatly. Further, according to management, partnership talks continue

with big pharma companies about its cervical cancer program. With the preliminary positive Phase II data of ADXS-HPV for cervical cancer, partnership may be able to materialize in 2013.

Our price target of \$0.25 per share values the Company at \$128 million in market cap. Apparently, risk is high for Advaxis at this stage. We will keep a close eye on cash balance.

PROJECTED INCOME STATEMENT

	2012E (Oct)					2013E (Oct)					2014E (Oct)	2015E (Oct)
\$ in million except per share data	Q1A	Q2A	Q3A	Q4A	FYA	Q1A	Q2E	Q3E	Q4E	FYE	FYE	FYE
Product Revenue	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$5.00
R&D revenue	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$1.50	\$1.50	\$2.00	\$4.50
Total Revenues	\$0.00	\$1.50	\$1.50	\$2.00	\$9.50							
YOY Growth CoGS	-	-	-	-	-	-	-	-	-	-	133.3%	475.0%
0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Gross Income	\$0.00	\$1.50	\$1.50	\$2.00	\$9.50							
Gross Margin	-	-	-	-	-	-	-	-	100.0%	100.0%	100.0%	100.0%
R&D % R&D	\$2.21	\$2.22	\$2.25	(\$0.03)	\$6.65	\$0.98	\$2.30	\$2.50	\$3.00 200.0%	\$8.78	\$12.00	\$15.00
SG&A % SG&A	\$1.03	\$1.01	\$1.33	\$2.31	\$5.69	\$1.20	\$1.50	\$1.50	\$1.75	\$5.95	\$7.50	\$8.50
Other % Other	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Operating Income	(\$3.2)	(\$3.2)	(\$3.6)	(\$2.3)	(\$12.3)	(\$2.2)	(\$3.8)	(\$4.0)	(\$3.3)	(\$13.2)	(\$17.5)	(\$14.0)
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	(\$1.0)	\$0.6	\$0.5	(\$0.2)	(\$0.1)	(\$4.4)	(\$0.2)	(\$0.2)	(\$0.2)	(\$5.0)	(\$1.0)	(\$1.0)
Pre-Tax Income	(\$4.3)	(\$2.6)	(\$3.1)	(\$2.4)	(\$12.4)	(\$6.6)	(\$4.0)	(\$4.2)	(\$3.5)	(\$18.3)	(\$18.5)	(\$15.0)
Income taxes(benefit) Tax Rate	(\$0.3)	\$0.0	\$0.0	\$0.7	\$0.4	(\$0.7)	\$0.0	\$0.0	\$0.0	(\$0.7)	\$0.0	\$0.0
Reported Net Income	(\$3.9)	(\$2.6)	(\$3.1)	(\$3.2)	(\$12.8)	(\$5.9)	(\$4.0)	(\$4.2)	(\$3.5)	(\$17.5)	(\$18.5)	(\$15.0)
YOY Growth Net Margin	-	-	-	-	-	-	-	-	-	-	-	-
Shares Out	262.8	285.3	346.9	385.0	320.0	445.6	520.0	575.0	600.0	535.2	675.0	775.0
Reported EPS	(\$0.01)	(\$0.01)	(\$0.01)	(\$0.01)	(\$0.04)	(\$0.01)	(\$0.01)	(\$0.01)	(\$0.01)	(\$0.03)	(\$0.03)	(\$0.02)
YOY Growth One time charge	-	-	-	-	-	-	-	-	-	-	-	-
Non GAAP Net Income	(\$0.00)	\$0.00	\$0.00	\$0.00	\$0.00	\$4.02	\$0.00	\$0.00	\$0.00	\$4.02	\$0.00	\$0.00
Non GAAP EPS	(\$0.01)	(\$0.01)	(\$0.01)	(\$0.01)	(\$0.04)	(\$0.00)	(\$0.01)	(\$0.01)	(\$0.01)	(\$0.03)	(\$0.03)	(\$0.02)

Source: Company filing and Zacks Investment Research estimates

HISTORICAL ZACKS RECOMMENDATIONS



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