Zacks Small-Cap Research

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Advaxis Inc. (ADXS-NASDAQ)

ADXS: Big deal secured for ADXS-cHER2 animal health program; Two deals in two months for ADXS-HPV; Balance sheet boosted; On track to advance its pipeline -- Outperform

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	11/06/2013
Current Price (03/19/14)	$4.90
12-month Target Price	**$10.00**

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.

SUMMARY DATA

52-Week High	**$13.63**
52-Week Low	**$2.70**
One-Year Return (%)	**-54.94**
Beta	**1.07**
Average Daily Volume (sh)	**194,812**
Shares Outstanding (mil)	**14**
Market Capitalization ($mil)	**$68**
Short Interest Ratio (days)	**1.35**
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**

Risk Level	**Above Avg.,**
Type of Stock	**N/A**
Industry	**Med Products**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Jan)	Q2 (Apr)	Q3 (Jul)	Q4 (Oct)	Year (Oct)
2013	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2014	0.00 A	1.00 E	0.00 E	2.00 E	3.00 E
2015					4.50 E
2016					5.00 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Jan)	Q2 (Apr)	Q3 (Jul)	Q4 (Oct)	Year (Oct)
2013	-$0.52 A	-$1.29 A	-$0.37 A	-$0.99 A	-$3.30 A
2014	-$0.37 A	-$0.22 E	-$0.30 E	-$0.21 E	-$1.09 E
2015					-$1.00 E
2016					-$1.05 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW

- **Big Deal for ADXS-cHER2;**
- **Great market opportunity for ADXS-HPV in combination with PD-1 inhibitors;**
- **Two deals secured in two months for ADXS-HPV;**
- **Compelling Phase II Results for ADXS-HPV presented at SITC;**
- **Ready to move ADXS-HPV to pivotal trial;**
- **Price target raised to $10.00 from previous $7.50**

A Big Deal for Advaxis' Animal Health Program

The Deal

On March 19 after market close, Advaxis announced a **global licensing agreement** with **Aratana Therapeutics, Inc.** for Advaxis' **ADXS-cHER2** for the treatment of **osteosarcoma** in dogs and three additional cancer immunotherapy products for the treatment of three other types of animal cancer. The three additional products are new constructs and are also based on Advaxis' platform immunotherapy technology.

Aratana Therapeutics is a **pet therapeutics company** focused on the licensing, development and commercialization of innovative biopharmaceutical products for cats, dogs and other companion animals.

Details of the agreement are as follows:

- Pursuant to the agreement, Aratana will have exclusive rights to develop and commercialize the licensed immunotherapies for pet health applications, and will focus initially on developing ADXS-cHER2 for osteosarcoma in dogs.

- Aratana made a $1 million one-time upfront payment to Advaxis and an additional $1.5 million equity investment in Advaxis common stock and warrants at current market price.

- Aratana agreed to pay up to an additional $6 million in **clinical and regulatory milestones** for each of the four products, assuming approvals in both cats and dogs in both United States and the European Union.

- In addition, Aratana agreed to pay up to $28.5 million in **commercial milestones**.

- Upon regulatory approval and commercialization of the immunotherapies, Aratana agreed to pay Advaxis a tiered royalty ranging from mid-single digit to 10% on net sales.

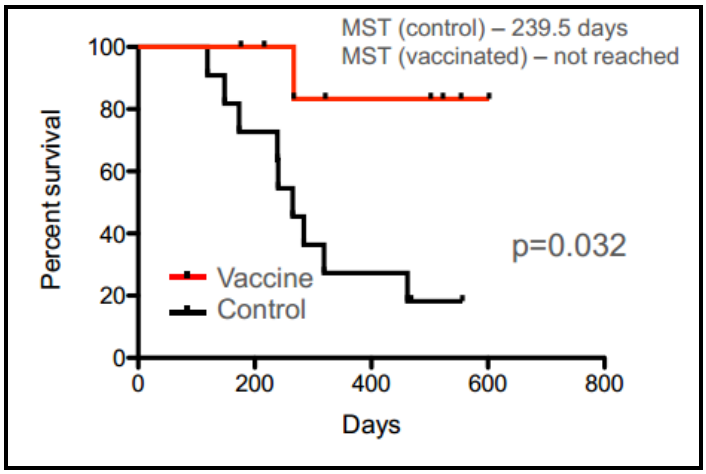
The ADXS-cHER2 Animal Health Program

ADXS-cHER2 is an Lm-LLO immunotherapy for HER2 overexpressing cancers (such as breast, gastric and other cancers in humans and for osteosarcoma in canines). ADXS-cHER2 secrets the cHER2 antigen, fused to LLO, directly inside APC that are capable of driving a cellular immune response to cHER2 overexpressing cells.

On August 2, 2012, Advaxis initiated a **Phase I study** of ADXS-cHER2 evaluating the safety and efficacy of ADXS-cHER2 in the treatment of dogs with **osteosarcoma** at the University of Pennsylvania, School of Veterinary Medicine. 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 ADXS-cHER2. This immunotherapy is designed to stimulate the dog's immune system to attack cancer cells that express the HER-2/neu marker.

The Phase I trial has treated **13 client-owned dogs** with osteosarcoma and is ongoing. In this study, dogs treated with ADXS-cHER2 immunotherapy after the standard of care (amputation and follow up chemotherapy), had a statistically significant prolonged overall survival benefit **(p=0.032)** compared with dogs that received standard of care without ADXS-cHER2. The median survival time for dogs that did not receive ADXS-cHER2 immunotherapy was eight months, whereas the median survival time for those dogs treated with ADXS-cHER2 has not yet been reached. Each of the first four dogs treated with ADXS-cHER2 has survived over 21 months. The majority of treated dogs are tumor-free.



There were no short- or long-term complications associated with the immunotherapy and only low-grade, transient toxicities were reported in the study.

Canine osteosarcoma is a leading killer of large breed dogs that causes tumors to form on long leg bones. Dogs undergoing standard of care (SOC) treatment (affected limb amputation and follow-up chemotherapy) have a median survival rate of only 1 year. We believe there is a significant commercial opportunity for ADXS-cHER2 in the veterinary medical market.

The Implications of the Deal for Advaxis

We think the agreement with **Aratana** represents a significant milestone for Advaxis.

The deal not only **boost** Advaxis' balance sheet, but further **validate** the company's immunotherapy platform technology.

With upfront and potential near term multimillion dollar milestones, this collaboration greatly strengthens Advaxis' financial ability to further advance its proprietary immunotherapies for the treatment of human cancers. As of Jan 31, 2014, ADXS held approximately $16 million in cash with no debt. The deal further boosts its balance sheet in a non-dilutive way, which is always welcome by investors.

With positive data from the Phase I trial in dogs, ADXS-cHER2 could be the **first immunotherapy** approved for animal cancer. Based on the existing Phase I clinical data, Aratana plans to apply for **conditional license** of ADXS-cHERs for dog osteosarcoma with USDA, which will greatly shorten the timeline for ADXS-cHER2 to reach the market.

While osteosarcoma is the first indication, we believe ADXS-cHER2 has great potential to target other animal cancer indications including animal breast cancer and lymphoma. Furthermore, the preliminary canine osteosarcoma data provide rationale to advance ADXS-cHER2 into a **Phase I** clinical trial for breast cancer and other HER2 driven cancers in humans. Actually, ADXS plans to file an IND with the

FDA for ADXS-cHER2 in the treatment of breast cancer in the second half of 2014 and plans to initiate Phase I study in late 2014.

Combination Therapy with Checkpoint Inhibitors Generates Great Market Opportunity

Recently, Advaxis expanded its relationship with Georgia Regents University **(GRU)** by entering into a master clinical trial agreement with GRU Cancer Center to conduct four **Phase I/II** clinical trials. The trials will be conducted under the supervision of **Dr. Samir Khleif**, Director, GRU Cancer Center and former Chief of the Vaccines Section at the National Cancer Institute (NCI).

The planned trials will be focused on Advaxis' two lead candidates: ADXS-HPV and ADXS-cHER2. The four clinical trials will include:

- High dose, repeating cycles of ADXS-HPV in recurrent or refractory cervical cancer.
- ADXS-HPV prior to surgery in patients with surgically treatable cervical cancer.
- ADXS-cHER2 in women with Her2/neu over-expressing breast cancer with measurable disease who have progressed after prior standard therapy.
- The combination of ADXS-HPV and PD-1 antibody in patients with recurrent or refractory cervical cancer.

The four new clinical trials will further expand clinical experience for Advaxis' two lead candidates ADXS-HPV and ADXS-cHER2. We are particularly impressed and optimistic about the planned **combination therapy** of ADXS-HPV and PD-1 antibody.

Advaxis and its collaborators have already generated positive **preclinical data** using ADXS-HPV in combination with anti-PD-1 therapy. In a mouse tumor model, the combination of ADXS-HPV with anti-PD-1 antibody significantly improved immune and therapeutic efficacy of treatment. The addition of PD-1 antibody to ADXS-HPV therapy resulted in significant increase of antigen specific immune response in periphery and CD-8 T cell infiltration into the tumor. As a result, this combination therapy led to significant inhibition of tumor growth and prolonged survival/complete regression of tumors in treated animals.

Checkpoint inhibitors (PD-1/PDL-1 inhibitors) are among the most promising new therapeutics under development for cancers. Big players such as Bristol-Myers Squibb, Merck, AstraZeneca and Roche are all competing in this potentially high profitable market.

PD-1/PD-L-1 inhibitors have generated positive data in clinical trials in a number of cancer indications. The combination therapy of ADVX-HPV with PD-1 antibodies or inhibitors will further expand the usage of the company's immunotherapy platform and generate significant revenue for the company if proven to be successful.

Two Deals in Two Months: Great Achievement for ADXS-HPV

Advaxis has made great achievement in expanding ADXS-HPV therapy for cervical cancer. It secured two strategic partnerships in the Asian market in two months.

The Biocon Deal

On January 20, 2014, Advaxis and India based **Biocon Limited** entered into an exclusive licensing agreement for co-development and commercialization of ADXS-HPV for the treatment of human papillomavirus (HPV)-associated cervical cancer in women, for **India and key emerging markets**.

Biocon Limited is India's largest and Asia's leading biotechnology company with a strategic focus on biopharmaceuticals and research services. It is a fully integrated, innovation-driven biopharma enterprise offering affordable solutions for chronic diseases to patients worldwide.

Pursuant to the Agreement, Advaxis granted Biocon an exclusive license:

- to use Advaxis' data from clinical development activities, regulatory filings, technical, manufacturing and other information and know-how to enable Biocon to submit regulatory filings for ADXS-HPV in the following India and key emerging markets;
- to import, promote, market, distribute and sell pharmaceutical products containing ADXS-HPV.

Under the Agreement, Biocon has agreed to obtain regulatory approvals for ADXS-HPV in **India**. In the event Phase II or Phase III clinical trials are required, Advaxis shall conduct such trials at its cost, provided that if Advaxis is unable to commence such clinical trials, Biocon may conduct such clinical trials, subject to reimbursement of costs by Advaxis. Biocon has agreed to commence commercial distribution of ADXS-HPV no later than 9 months following receipt of regulatory approvals in a country in the territory. Biocon will be responsible for the costs of obtaining and maintaining regulatory approvals in the Territory.

Advaxis will have the exclusive right to supply ADXS-HPV to Biocon and Biocon will be required to purchase its requirements of ADXS-HPV exclusively from Advaxis at the specified contract price, as such price may be adjusted from time to time. In addition, Advaxis will be entitled to a six-figure milestone payment if net sales of ADXS-HPV for the contract year following the initiation of clinical trials in India exceed certain specified thresholds.

Our Takeaways from the Biocon Deal

The BioCon deal expands the usage of ADXS-HPV for cervical cancer in the largest cervical cancer market in the world in terms of patient population.

Cervical cancer is one of the most frequent cancers in women in India. Over 366 million women of the age of over 15 years, are at a risk of developing cervical cancer. It is estimated that every year over 134,000 women are diagnosed with cervical cancer in India and nearly 73,000 die from this disease. Approximately 7.9% of women in general are estimated to harbor cervical HPV infection at a given time, and 82.5% of invasive cervical cancers are attributed to high-risk HPV strains.

According to WHO, in 2008, there were over 530,000 new cases of cervical cancer worldwide, 90% of these were reported in developing countries. While globally there were over 300,000 deaths, the African region recorded over 50,000 deaths and Asian countries reported over 150,000 deaths for the year.

As the dominant biopharmaceutical company in India, Biocon has a proven track record of successfully interacting with Indian regulatory agencies to gain approval for its own products and on behalf of its partners. They also have a powerful commercial sales force and distribution strengths to establish a high level of post-approval success.

Under the terms of this deal, ADXS will supply ADXS-HPV to Biocon and Biocon will be required to purchase ADXS-HPV exclusively from ADXS at a specified contract price. Upon commercialization of ADXS-HPV in India, ADXS will receive a **double-digit** percentage of the net sales. This has the potential to generate tens of millions of dollars in revenue to Advaxis over the lifetime of the agreement.

The deal also validates ADXS's technology and clinical data achieved with ADXS-HPV.

The Global BioPharma Deal

On December 9, 2013, Advaxis entered into an **exclusive licensing agreement** for the development and commercialization of ADXS-HPV with Global BioPharma, Inc. (GBP), a Taiwan based biotech company funded by a group of investors led by Taiwan Biotech Co., Ltd (TBC).

TBC is one of the top five pharmaceutical companies in Taiwan with annual domestic sales in excess of $100 million in the healthcare sector. TBC engages in the research, development, manufacture,

representation, and distribution of pharmaceutical drugs, medical devices, and active pharmaceutical ingredients (API).

Global BioPharma, Inc. (GBP) is formed with a group of seasoned managers with extensive experiences in research, clinical trials, CMC, manufacturing, and business development with the financial supports of VCs and individuals led by TBC.

GBP is formed solely to focus on the development and commercialization of ADXS-HPV for the treatment of human papillomavirus (HPV)-associated diseases. The GBP territory covers over 4 billion people with over 200,000 annual diagnoses of cervical cancer, accounting for roughly 40% of the world's cases, according to WHO statistics. GBP is dedicated to the development, manufacturing, and commercialization of ADXS-HPV for the treatment of HPV-associated diseases.

GBP plans to conduct registration trials with ADXS-HPV for the treatment of **advanced cervical cancer** and will explore the use of Advaxis' lead product candidate in several other indications including lung, head and neck, and anal cancer.

According to the agreement, GBP will pay Advaxis event-based financial milestones, an annual development fee, and annual net sales royalty payments in the high single to double digits. In addition, as an upfront payment, GBP will make an investment in Advaxis by purchasing from the Company shares of its common stock at market price. GBP will also have an option to purchase additional shares of Advaxis stock from the Company at a 150% premium to the stock price on the effective date of the agreement.

GBP will be responsible for all clinical development and commercialization costs in the GBP territory. In collaboration with Advaxis, GBP will also identify and pay the clinical trial costs for up to 150 patients with cervical cancer for enrollment in Advaxis' U.S. and GBP's Asia registrational programs for cervical cancer. GBP is committed to establishing manufacturing capabilities for its own territory and to serving as a secondary manufacturing source for Advaxis in the future. Under the terms of the agreement, Advaxis will exclusively license the rights to ADXS-HPV to GBP for the Asia, Africa, and former USSR territory, exclusive of India and certain other countries, for all HPV-associated indications. Advaxis will retain exclusive rights to ADXS-HPV for the rest of the world.

Our Takeaways from the GBP Deal

We are impressed with the achievements Advaxis has made in a short period of time: two deals closed to expand ADXS-HPV usage in the world largest two cervical cancer markets: India and China.

The GBP deal brings great tangible economics to Advaxis.

First, Advaxis will have the access to data from 150 patients with cervical cancer, which can be used for registrational programs in the US. Let's think about the cost of $20,000 per patient, it will save Advaxis $3 million for the clinical program. Three million dollars may not be a big number, but the data from the 150 patients will save time and other related resources.

Second, the deal secures a second manufacturing source for Advaxis. This is important because establishing manufacturing facility for immunotherapy is both time consuming and costly. The GBP manufacturing source will complement Advaxis' US manufacturing capability.

Further, this deal not only boosts Advaxis' balance sheet, but more importantly validates Advaxis' proprietary immunotherapy technology. It is impressive that a new company has been exclusively formed and funded by a team of seasoned biopharmaceutical professionals to develop and commercialize ADXS-HPV in Asia and other important markets.

Even further, the GBP deal will serve as an exemplar for other partnership talks. The GBP agreement is the first to be executed as part of Advaxis' global commercialization strategy to enter into regional

licensing deals with other market dominant biopharmaceutical companies in territories where there is a high prevalence of HPV-associated cancers. When Advaxis continues to advance its clinical programs with positive data, it will attract big pharma or biotech companies to the negotiation table. The favorable terms with GBP will serve as an example for Advaxis to get similar deals in future partnership talks.

Compelling Phase II Data of ADXS-HPV De-risks Advaxis

On November 8, Advaxis (ADXS) announced final updated 18-month survival data from **Phase II** ADXS-HPV (Lm-LLO-E7-15) study evaluating the safety and efficacy of ADXS-HPV ($1x10^9$ cfu) with and without cisplatin (40 mg/m^2, weekly x5) in 110 patients with **recurrent cervical cancer** in two treatment arms of 55 patients each. The primary endpoint of the study is overall survival. These data were presented at the 2013 Society for Immunotherapy of Cancer (SITC) Annual Meeting in National Harbor, MD, on November 9, 2013 (Poster #258).

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/m^2, weekly x5). Patients got either 3 doses of ADXS-HPV at 1 x 10^9 CFU or 4 doses of ADXS-HPV at 1 x 10^9 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 results were presented at multiple scientific meetings.

The last patient last visit (Day 545) occurred on October 18, 2013. The final 18-month survival data are 28% (31/110) which is updated from the preliminary18-month survival of 22% (16/73) reported at the 2013 ASCO Annual Meeting on June 2, 2013. The final 12-month survival was 36% (39/110). These data are comparable to the results for the landmark 2004 Moore Phase III study conducted by the Gynecologic Oncology Group of cisplatin alone and cisplatin plus paclitaxel in recurrent cervical cancer patients with the same initial performance (health) status (0-2). In that study, 12 month survival was presented as 35% for cisplatin alone and 32% for the combination and 18 month survival was presented as 20% for combination therapy and 12% for cisplatin, alone.

Patients*	Overall (N=110)	ADXS-HPV ALONE (N=56)	ADXS-HPV + 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 (#)	28% (31/110)	25% (14/56)	31% (17/54)

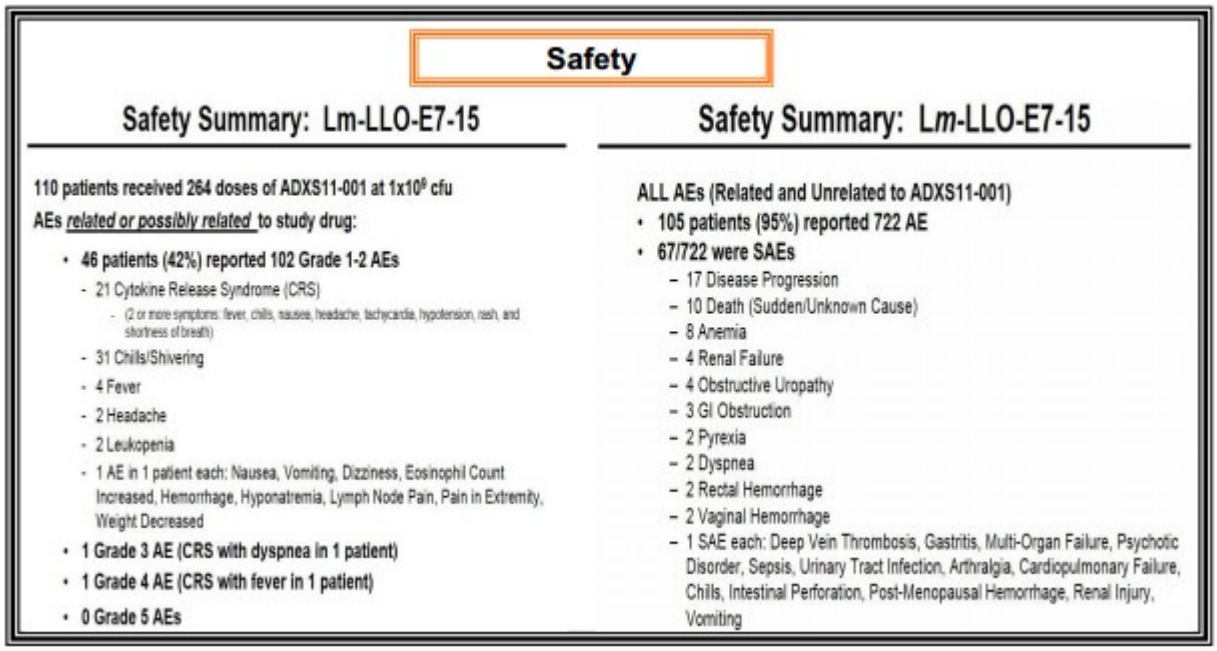
Median overall survival in the Advaxis study was approximately 8.5 months which is indicative of the late stage of disease and baseline performance status of the patients. Those patients that completed the study will continue to be followed for survival. Survival results were not significantly different between

treatment groups with or without cisplatin chemotherapy or who had previous therapy comprised of a combination of chemotherapy and radiation, radiation alone, or chemotherapy alone.

The tumor response rate was 11% with 6 complete responses and 6 partial responses/110 patients and was similar in both treatment groups per RECIST 1.1 criteria. Stable disease >3 months was observed in 35 additional patients, for a disease control rate of 43% (47/110). Average duration of response after 12 month minimum follow-up was 10.5 months for both treatment groups. In those patients treated with ADXS-HPV alone who had stable disease, the average duration of response was 6 months compared to 4.1 months in patients treated with ADXS-HPV plus cisplatin. Activity was observed against all high risk HPV strains detected, including 16, 18, 31, 33, and 45.

Subset analyses showed that the combination arm (addition of cisplatin to ADXS-HPV) did not significantly improve survival or tumor response; and survival and tumor response were equally strong in patients with aggressive disease (defined as recurrence ≤2 years from initial diagnosis) versus non-aggressive disease (defined as recurrence >2 years from initial diagnosis).

The tolerability of ADXS-HPV continues to compare favorably with single agent and combination chemotherapies active in this disease setting. 110 patients received 264 doses of ADXS-HPV at $1x10^9$ cfu per dose. 42% (46/110) of patients experienced 104 mild-moderate Grade 1-2 adverse events and 2% (2/110) of patients experienced a serious adverse event (1 Grade 3 and 1 Grade 4) related/possibly related to ADXS-HPV. This compares to published serious adverse event rates of 100%-400% related to treatment in studies on a range of chemotherapy regimens for cervical cancer.



Advaxis also presented data on initial biomarker analysis of a subset of serum samples collected from patients in Lm-LLO-E7-15, pre- and post-dosing with ADXS-HPV. Administration of ADXS-HPV immunotherapy resulted in increased expression of cytokines (IL6, IL-8, IL10, INF-γ and TNF-α) and chemokines (MIP-1α, MIP-1β and MCP-1) indicating activation of innate immunity. An association was also found between changes in the expression of cytokine and/or other serum factors and the severity of adverse events. These data may provide future screening tools to assist in predicting clinical efficacy and to monitor and manage side effects.

Relative Increase In Cytokines And Chemokines Post-Dose

Cytokine/ Chemokines	Relative Fold Increase (2h)	Relative Fold Increase (4h)
IL-6	34.00	32.68
IL-8	22.50	12.80
IL-10	28.47	33.78
IL-18	0.57	0.63
MIP-1 α	3.00	2.10
INF-γ	2.10	1.80
MCP-1	35.52	23.94
TNF-α	19.21	11.78
TNF-R2	1.94	1.84

Figure 2. *Serum samples analyzed thus far using ELISA shows relative increase in cytokines and chemokines at 2 and 4 hours post dosing. More than a 15-fold increase is observed in the level of cytokines (IL-6, IL-8, IL-10 and TNF-α) and chemokine (MCP-1) post-administration of ADXS11-001, indicating strong stimulation of innate immunity.*

Our Takeaways from the Updated Phase II Results

The data presented at the SITC 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 42% 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.

Great efficacy has been observed which are very promising. Compared to GOG historical one year survival of 5%, ADXS-HPV has achieved 36% 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 36% one year survival rate is also a 100% improvement. 18 month survival also reached 28%. Further investigation is warranted.

ADXS-HPV appears to be emerging as an active agent in recurrent/refractory cervical cancer with significantly less toxicity than chemotherapy.

The positive ADXS-HPV data may trigger partnership talks for Advaxis in our view.

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.

Ready to Move ADXS-HPV to Pivotal Trials

Advaxis plans to conduct end of Phase II meeting with FDA soon. The company is preparing the Phase III protocols and will submit a SPA to the FDA. **Two Phase III** trials will be conducted.

We believe the data presented at the SITC 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 42% 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.

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Two Phase I/II Trial of ADXS-HPV Initiated for Head and Neck Cancer

On October 23, 2013, Advaxis announced that the first patient has been dosed in ***REALISTIC*****,** a **Phase I/II** study being funded by Cancer Research UK (CRUK) to investigate the use of ADXS-HPV for the treatment of HPV-positive head and neck cancer.

As a reminder, on May 8, 2012, 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 **27 patients** with 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.

Due to regulations in the UK, the first patient was dosed on October 23, 2013.

Also on November 20, 2013, Advaxis announced that the Icahn School of Medicine at Mount Sinai (ISMMS) initiated another **Phase I/II** study of ADXS-HPV in **25 patients** with HPV-positive head and neck cancer. First patient was dosed on Jan 19, 2014.

This clinical trial will be the **first study** to evaluate the effects of ADXS-HPV in patients when they are **newly diagnosed with HPV-associated head and neck cancer**, prior to receiving any chemotherapy or radiation. This study will be an important first step toward understanding ADXS-HPV's potential to treat this type of cancer before chemotherapy and/or radiation and its potential to reduce the need for these treatments.

This non-randomized investigator-initiated study has been designed to evaluate the safety and immunogenicity of ADXS-HPV in patients with HPV-positive stage II-IV squamous cell carcinoma of the oropharynx (OPCSC). In this study, 15 patients will receive ADXS-HPV treatment followed by ablative transoral robotic surgery (TORS), and 10 patients will serve as the control group and receive only TORS. TORS is FDA-approved for head and neck cancer and is considered to be the standard of care therapy for OPCSC in appropriate patients.

These two trials further expand 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.

ADXS-HPV is granted orphan drug designation for treatment of HPV-associated head and neck cancer in the US.

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

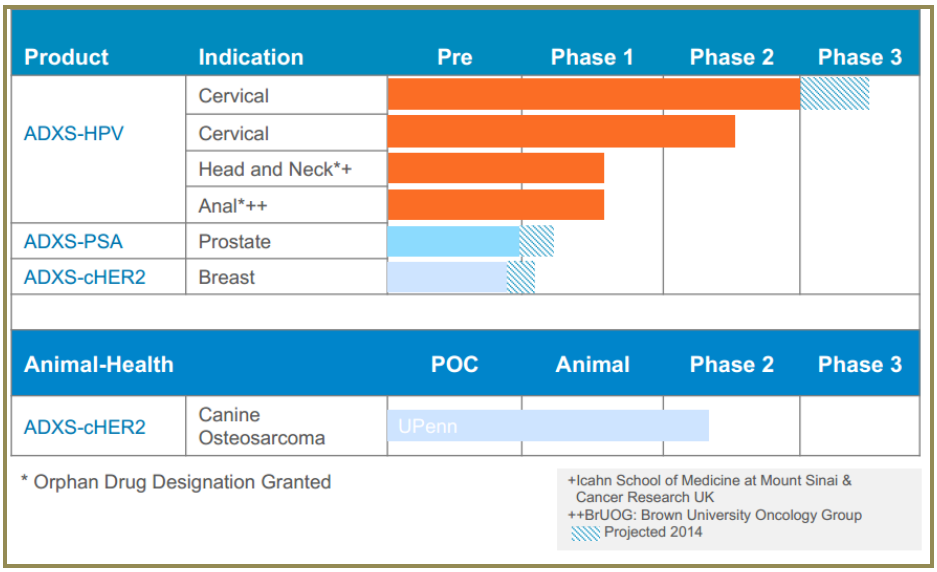
On Feb 19, 2013, Advaxis announced that the Brown University Oncology Research Group (BrUOG) will be coordinating a **Phase I/II study** of ADXS-HPV in 25 patients with HPV-associated **anal cancer**. Dr. Howard Safran, professor of medicine, will be principal investigator. Patients will be treated at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

As of July 2013, 3 patients have been enrolled in the study. Multiple institutions will collaborate.

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. This is quite unusual to a small cap biotech company.



Maintain Outperform Rating and Raise Price Target to $10.00

We maintain our Outperform rating for ADXS and raise our 12-month price target to $10.00 per share from previous $7.50 per share.

Our call is based on recent significant achievements Advaxis has made and strong fundamentals of the company.

We are optimistic about Advaxis' live, attenuated Listeria technology, which is a unique immunotherapeutic platform that can target various cancer indications and infectious diseases. This technology has advantages over other immunotherapies and has generated positive clinical data.

The recent three deals are especially encouraging in our view. The deal with Aratana could get ADXS-cHER2 the first approved immunotherapy for animals. The deals with Biocon and GBP expand the usage of ADXS-HPV therapy for cervical cancer in the world two largest markets of cervical cancer in terms of patient population. The favorable terms in the deals not only strengthen Advaxis' balance sheet in a non-dilutive way, but also validate the company's technology and clinical data. Furthermore, the deals will serve as examples for future talks which are supposed to generate similar favorable terms for Advaxis.

ADXS-HPV has a huge market potential. 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.

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 2014.

In terms of valuation, we think Advaxis is undervalued in our view. Currently, the Company shares are trading at about $4.80 per share which values the Company at about $67 million in market cap based on 14 million outstanding shares. This is certainly a deep discount.

We predict ADXS-HPV to be approved in the US in 2017. Sales will reach $100 million in 2020 with earnings per share of $1.27. Using a relative valuation model, we come up with our new price target of $10.00 per share by using 30 x P/E multiple and discounted at 25% for 6 years.

Our price target of $10.00 per share values the Company at $140 million in market cap, which is still conservative. Apparently, risk is still high for Advaxis at this stage. We will keep a close eye on cash balance and clinical program advances.

PROJECTED INCOME STATEMENT

	2013A (Oct)	2014E (Oct)					2015E (Oct)	2016E (Oct)	2017E (Oct)	2018E (Oct)	2019E (Oct)	2020E (Oct)
$ in million except per share data	FYA	Q1A	Q2E	Q3E	Q4E	FYE	FYE	FYE	FYE	FYE	FYE	FYE
Product Revenue	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$5.00	$30.00	$75.00	$100.00
R&D revenue	$0.00	$0.00	$1.00	$0.00	$2.00	$3.00	$4.50	$5.00	$5.50	$7.50	$7.50	$7.50
Total Revenues	**$0.00**	**$0.00**	**$1.00**	**$0.00**	**$2.00**	**$3.00**	**$4.50**	**$5.00**	**$10.50**	**$37.50**	**$82.50**	**$107.50**
YOY Growth	-	-	-	-	-	-	*150.0%*	*111.1%*	*210.0%*	*357.1%*	*220.0%*	*130.3%*
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.75	4.50	11.25	15.00
Gross Income	**$0.00**	**$0.00**	**$1.00**	**$0.00**	**$2.00**	**$3.00**	**$4.50**	**$5.00**	**$9.75**	**$33.00**	**$71.25**	**$92.50**
Gross Margin	-	-	-	-	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*92.9%*	*88.0%*	*86.4%*	*86.0%*
R&D	$5.62	$1.56	$1.50	$1.75	$2.50	$7.31	$12.00	$14.50	$16.50	$19.00	$22.50	$24.00
% R&D	-	-	-	-	*125.0%*	*243.7%*	*266.7%*	*290.0%*	*157.1%*	*50.7%*	*27.3%*	*22.3%*
SG&A	$9.07	$4.40	$2.50	$2.75	$3.00	$12.65	$11.50	$12.50	$14.50	$17.00	$20.00	$22.50
% SG&A	-	-	-	-	*150.0%*	*421.6%*	*255.6%*	*250.0%*	*138.1%*	*45.3%*	*24.2%*	*20.9%*
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
% Other	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	**($14.7)**	**($6.0)**	**($3.0)**	**($4.5)**	**($3.5)**	**($17.0)**	**($19.0)**	**($22.0)**	**($21.3)**	**($3.0)**	**$28.8**	**$46.0**
Operating Margin	-	-	-	-	-	-	-	-	-	*-8.0%*	*34.8%*	*42.8%*
Other Net	($6.6)	$0.1	($0.3)	($0.3)	($0.3)	($0.6)	($1.0)	($1.0)	($1.0)	($1.0)	($1.0)	($1.0)
Pre-Tax Income	**($21.3)**	**($5.8)**	**($3.3)**	**($4.8)**	**($3.8)**	**($17.6)**	**($20.0)**	**($23.0)**	**($22.3)**	**($4.0)**	**$27.8**	**$45.0**
Income taxes(benefit)	($0.7)	($0.6)	$0.0	$0.0	$0.0	($0.6)	$0.0	$0.0	$0.0	$0.0	$4.5	$4.50
Tax Rate	-	-	-	-	-	-	-	-	-	-	*16.2%*	*10.0%*
Reported Net Income	**($20.5)**	**($5.2)**	**($3.3)**	**($4.8)**	**($3.8)**	**($16.9)**	**($20.0)**	**($23.0)**	**($22.3)**	**($4.0)**	**$23.3**	**$40.5**
YOY Growth	-	-	-	-	-	-	-	-	-	-	*-681.3%*	*74.2%*
Net Margin	-	-	-	-	-	-	-	-	-	*-10.7%*	*28.2%*	*37.7%*
Shares Out	*5.0*	*13.8*	*14.5*	*16.0*	*18.0*	*15.6*	*20.0*	*22.0*	*25.0*	*27.5*	*30.0*	*32.0*
Reported EPS	**($4.10)**	**($0.37)**	**($0.22)**	**($0.30)**	**($0.21)**	**($1.09)**	**($1.00)**	**($1.05)**	**($0.89)**	**($0.15)**	**$0.78**	**$1.27**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	*$4.02*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($16.5)**	**($5.2)**	**($3.3)**	**($4.8)**	**($3.8)**	**($16.9)**	**($20.0)**	**($23.0)**	**($22.3)**	**($4.0)**	**$23.3**	**$40.5**
Non GAAP EPS	**($3.30)**	**($0.37)**	**($0.22)**	**($0.30)**	**($0.21)**	**($1.09)**	**($1.00)**	**($1.05)**	**($0.89)**	**($0.15)**	**$0.78**	**$1.27**

Source: Company filing and Zacks Investment Research estimates

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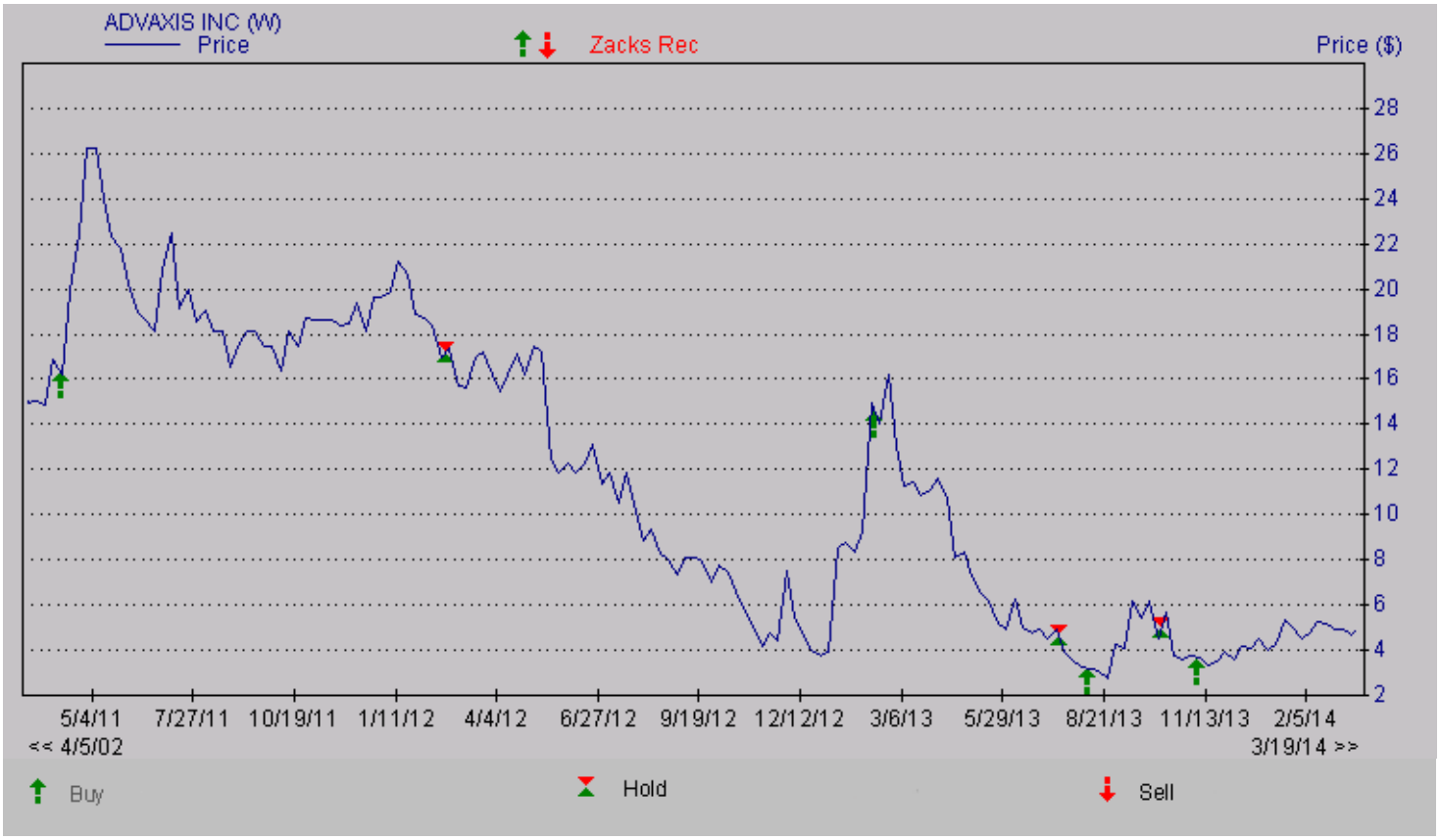

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