Zacks Small-Cap Research

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Advaxis Inc. (ADXS-NASDAQ)

ADXS: Clinical hold lifted, Phase III of ADXS-HPV for cervical cancer will be initiated by the end of year---Buy

Current Recommendation	**Buy**
Prior Recommendation	Hold
Date of Last Change	11/06/2013
Current Price (12/16/15)	$10.92
12-month Target Price	**$25.00**

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 will be in Phase III trials for the treatment of cervical cancer. Recent collaborations with Merck and MedImmune may lead to license deals for Advaxis.

We rate its shares Buy.

SUMMARY DATA

52-Week High	**$28.77**
52-Week Low	**$4.37**
One-Year Return (%)	**119.72**
Beta	**0.80**
Average Daily Volume (sh)	**807,067**
Shares Outstanding (mil)	**33**
Market Capitalization ($mil)	**$364**
Short Interest Ratio (days)	**12.58**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
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)
2014	0.00 A	1.00 A	0.00 A	0.00 A	1.00 A
2015	0.00 A	0.00 A	0.00 A	0.00 E	0.00 E
2016					0.00 E
2017					5.00 E

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

	Q1 (Jan)	Q2 (Apr)	Q3 (Jul)	Q4 (Oct)	Year (Oct)
2014	-$0.37 A	-$0.16 A	-$0.30 A	-$0.15 A	-$0.97 A
2015	-$0.33 A	-$0.52 A	-$0.44 A	-$0.45 E	-$1.76 E
2016					-$1.55 E
2017					-$1.48 E

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

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WHAT'S NEW

FDA Lifts Clinical Hold

On December 16, the FDA lifted the clinical hold on all of the company's Investigational New Drug (IND) applications for its three product candidates: axalimogene filolisbac (formerly ADXS-HPV), ADXS-PSA and ADXS-HER2.

As a result, Advaxis will resume all clinical trials with axalimogene filolisbac, ADXS-PSA and ADXS-HER2 immediately.

For those who are not familiar with the event, here is the brief review of the clinical hold.

In early October, Advaxis received verbal notice from the FDA that its Investigational New Drug (IND) application for axalimogene filolisbac (ADXS-HPV) had been placed on clinical hold, affecting four clinical trials.

The clinical hold, which pertained only to axalimogene filolisbac, was issued in response to a single event of one patient with end-stage cervical cancer who last received axalimogene filolisbac in early 2013 in an investigator-initiated trial. The patient passed away in mid-August 2015 after a series of treatments. The investigator ruled that the cause of death was due to progression of her cervical cancer. The company has evaluated this case and agrees with the investigator's conclusion that the cause of death was due to cervical cancer progression. The company believes that axalimogene filolisbac played no role in the patient's death.

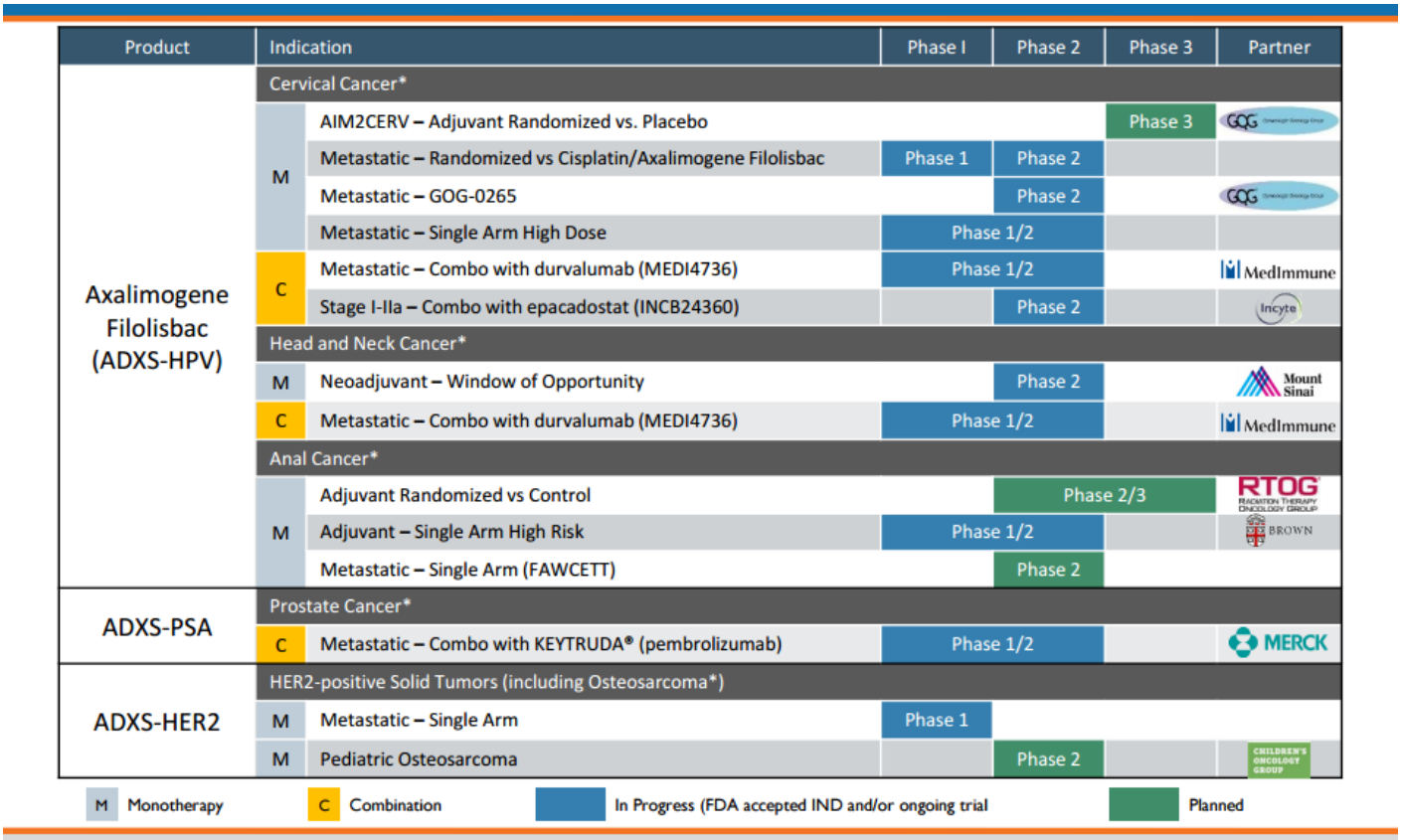
At that time, ongoing clinical trials with Advaxis's other product candidates, ADXS-PSA and ADXS-HER2, were not affected by this hold and continued to actively enroll and dose patients.

In early November, the FDA verbally notified the Company that the clinical hold also included the INDs for ADXS-PSA and ADXS-HER2.

Since early October, Advaxis has been in an ongoing dialogue with the FDA. Following discussions with the FDA and in accordance with their recommendations, the company agreed to **implement certain risk mitigation measures**, including revised study protocol inclusion / exclusion criteria, post-administration antibiotic treatment and patient surveillance and monitoring measures. Further, the FDA has concurred with the Investigator's assessment that the patient's cause of death was due to cervical cancer progression.

Advaxis Will Be Back on Track for All Clinical Trials

Following the clinical hold lift by the FDA, Advaxis will resume patient treatment in all its ongoing clinical studies for cervical, head and neck, prostate, and HER2-expressing cancers. Advaxis has implemented risk management procedures to avoid future cases of listeria recurrence.



Update on GOG-0265 Phase II Trial of ADXS-HPV

GOG-0265 is an open-label, single-arm, two-stage **Phase II** study (NCT01266460) designed to evaluate the safety, tolerability and efficacy of axalimogene filolisbac (ADXS-HPV) in approximately 67 patients with Persistent or Recurrent Metastatic Cervical Cancer (**PRmCC**) who have received at least one prior line of systemic therapy. The primary efficacy endpoint is 12-month overall survival rate, with secondary efficacy endpoints of progression-free survival, overall survival and objective tumor response. The primary safety endpoints are the number of patients with dose-limiting toxicities and the frequency and severity of adverse effects.

The trial is being conducted in the United States by GOG (now part of NRG Oncology) under the sponsorship of the Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute (NCI).

In September 2015, Advaxis announced positive data from Stage 1 of the ongoing two-stage Phase II study at the 2015 American Gynecological & Obstetrical Society (AGOS) annual meeting. The Stage 1 data showed that treatment with axalimogene filolisbac resulted in a **38.5%** 12-month overall survival rate in 26 patients.

ADXS-HPV was generally safe and well tolerated with 73% Grade 1or 2 adverse events.

Patients with PRmCC who have failed at least one line of therapy face a life threatening condition with an estimated survival of 4 to 7 months and no available treatment options. The 38.5% 12-month survival is a meaningful step forward in meeting the needs of women who require second-line treatment for PRmCC. The GOG has conducted over 17 studies of a diverse set of investigational agents and regimens, but never has the 12-month overall survival rate exceeded 30 percent in people with PRmCC.

The GOG is enrolling patients in **Stage 2** of the **Phase II** study. GOG has updated the dosing regimen for patients in Stage 2 of the study to extend treatment beyond three dosing cycles and to continue dosing

ADXS-HPV at 1 x 10^9 cfu every 28 days until disease progression or the patient's medical condition prohibits further therapy.

Total of up to 38 patients are expected to be enrolled by June 30, 2016. Final study data (Stage 1 and 2) will be available in the **1H17**.

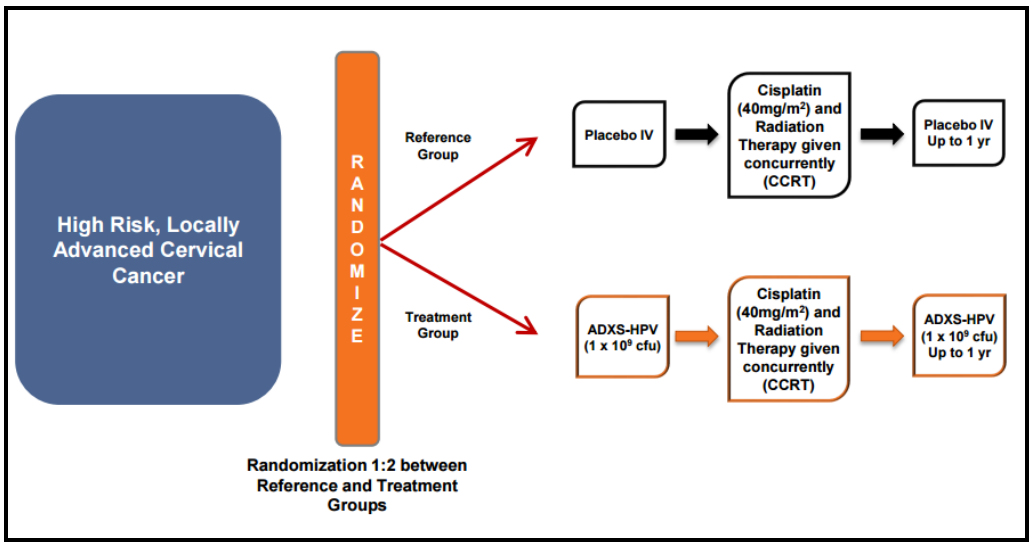
Update on Planned ADXS-HPV Phase III for Cervical Cancer

On June 15, 2015, ADXS announced that the company has submitted a Special Protocol Assessment **(SPA)** request to the FDA to initiate detailed design discussions for a Phase III clinical study of ADXS-HPV for the treatment of high-risk, locally advanced cervical cancer (HRLACC).

We believe the SPA request may facilitate a meaningful dialog with the FDA on the proposed **Phase III** study design. It may take up to 45 calendar days to provide comments to Advaxis. It's our belief that feedback from the FDA will help the appropriate design of the Phase III trial for locally advanced cervical cancer.

Advaxis plans to initiate the Phase III trial **by the end of 2015 or early 2016** depending on the length of the FDA's SPA review process.

The proposed Phase III clinical trial (**AIM2CERV**) will be a double-blind, placebo-controlled multinational study of ADXS-HPV (ADXS11-001) administered in the adjuvant setting following concurrent chemoradiation given with curative intent in patients with HRLACC for whom recurrence has not yet occurred.



We believe the ADXS-HPV for cervical cancer is the company's key value driver in the short term as this is the most advanced clinical program in the company's pipeline and will validate the company's key technology if the trial can demonstrate the efficacy and safety of the candidate. We look forward to the initiation of the Phase III trial by the end of 2015.

Phase I/II of ADXS-HPV in combination with MED14736 Initiated

In August 2015, Advaxis and MedImmune (part of AstraZeneca) began to enroll patients in a **Phase I/II** clinical trial of axalimogene filolisbac (ADXS-HPV) in combination with MedImmune's investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab (MEDI4736), for the treatment of patients with advanced, recurrent or refractory HPV-associated **cervical cancer** and HPV-associated **head and neck cancer**.

The Phase I/II trial will be a two-part, open-label study designed to evaluate the safety and efficacy of axalimogene filolisbac as a monotherapy and in combination with durvalumab in approximately 66 patients. The Phase I portion is a dose-confirmation combination study with axalimogene filolisbac and durvalumab, which is expected to establish the maximum tolerated dose. The Phase II portion will randomize patients to receive axalimogene filolisbac monotherapy, durvalumab monotherapy, or the combination. The primary efficacy endpoints include objective response rate and progression-free survival.

Data from the Phase I/II will be available in the **first half of 2016**, which will determine the future clinical development program for the combination.

Phase I ADXS-HER2 Initiated for Solid Tumors

In late September 2015, Advaxis initiated a **Phase Ib** dose-escalation clinical study of ADXS-HER2 for the treatment of patients with metastatic HER2 expressing solid tumors.

The dose escalation portion of the study will investigate the safety and tolerability of ADXS-HER2 as a monotherapy in approximately 18 patients diagnosed with metastatic HER2 expressing solid tumors, which include breast, gastric, esophageal and osteosarcoma. Once the maximum tolerated dose (MTD) and recommended Phase II dose have been identified, up to 80 patients may be enrolled in up to four HER2 expressing tumor specific cohorts in the **expansion phase** of the Phase Ib study.

Advaxis plans to establish the MTD from the Phase 1b study in pediatric patients and work with Children's Oncology Group (COG) to potentially launch a **pivotal trial** in pediatric osteosarcoma in 2016.

ADXS to Initiate Phase II Trial of ADXS-HPV in Combination with Epacadostat for the Treatment of Early Stage Cervical Cancer

In early June 2015, the FDA approved ADXS' IND application to conduct a Phase II trial of ADXS-HPV (ADXS11-001) **alone or in combination** with Incyte Corporation's **epacadostat** (INCB24360) for the treatment of Stage I-IIIb HPV-associated **cervical cancer**.

The two companies entered into a non-exclusive clinical trial collaboration agreement in February 2015. The proposed **Phase II** trial is designed as a multicenter, open-label, preoperative window-study designed to evaluate the safety and efficacy of ADXS-HPV as monotherapy and in combination with epacadostat in approximately **30 patients** with Stage I-IIIb HPV-associated cervical cancer. The results will be used to determine whether further clinical development of this combination is warranted.

Epacadostat is an investigational indoleamine 2,3-dioxygenase 1 (IDO1) inhibitor. IDO1 is an immunosuppressive enzyme that has been shown to induce regulatory T cell generation and activation, and allow tumors to escape immune surveillance. Epacadostat is an orally bioavailable small molecule inhibitor of IDO1 that has nanomolar potency in both biochemical and cellular assays, and has demonstrated potent activity in enhancing T lymphocyte, dendritic cell and natural killer cell responses in vitro, with a high degree of selectivity. Incyte has demonstrated proof-of-concept clinical data of epacadostat in patients with unresectable or metastatic melanoma in combination with the CTLA-4 inhibitor ipilimumab, and is currently in multiple proof-of-concept clinical trials with PD-1 and PD-L1 immune checkpoint inhibitors in a variety of cancer types.

We believe this program is a natural expansion of ADXS' franchise of HPV for cervical cancer.

Collaboration with Sorrento further Expands ADXS' Technology Application and Pipeline

The two companies entered into a non-exclusive research and clinical trial collaboration agreement in May 2015, which will evaluate the combination of ADXS' immunotherapy technology with Sorrento's antibody platform targeting immune checkpoints.

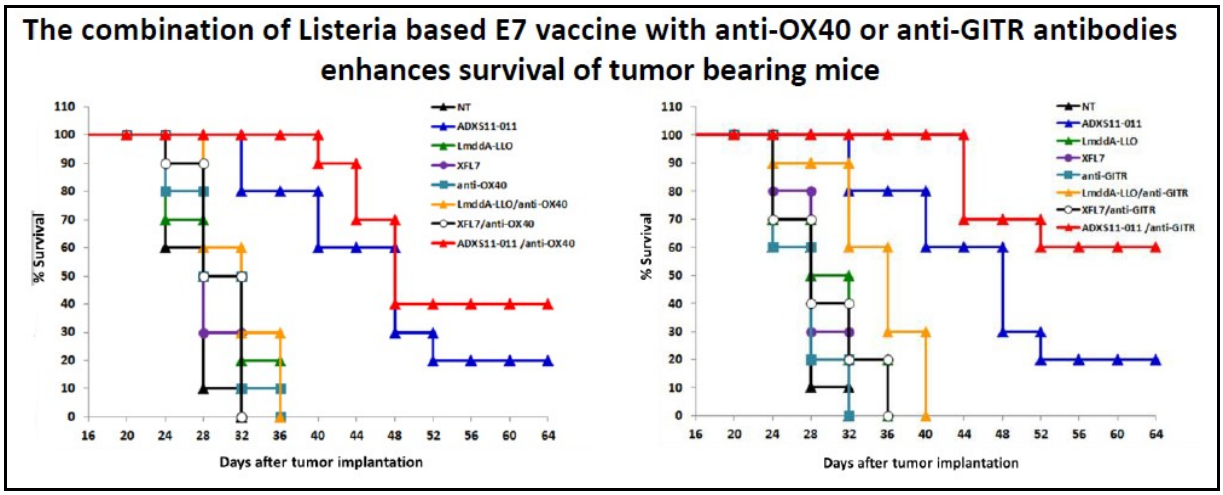
Under the terms of the agreement, Advaxis will conduct the studies and the companies will equally share the expenses. The two companies hope to commence the first of the two planned combination **studies in 2016.** Results from the studies will be used to determine whether further clinical development of specific combinations is warranted.

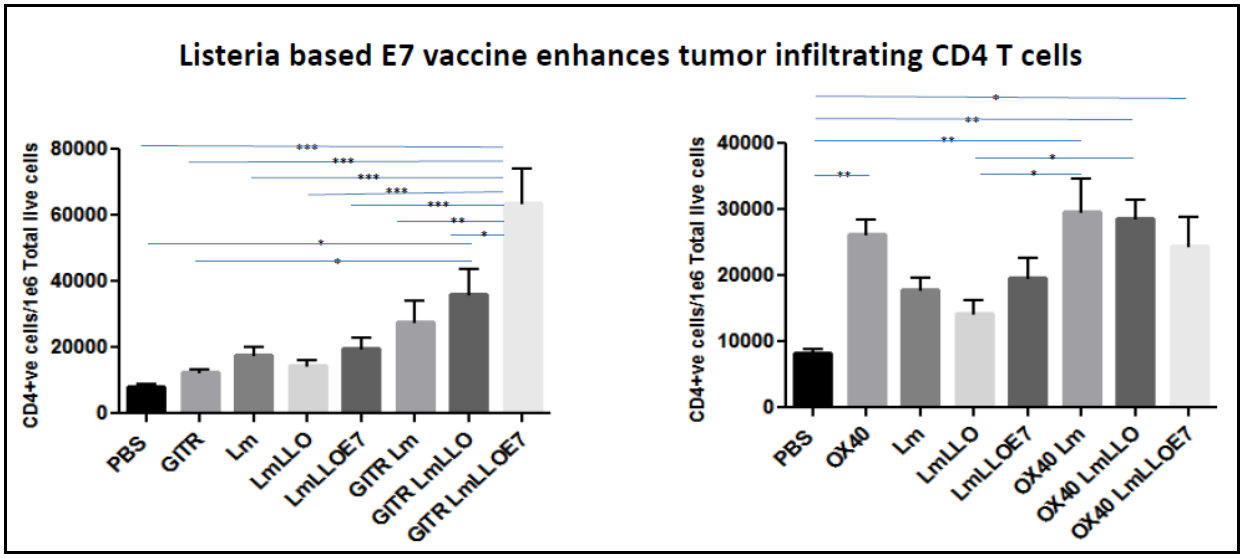
Sorrento has one of the largest and most diverse fully human antibody libraries in the industry designed to facilitate rapid identification and selection of highly specific therapeutic monoclonal antibody (mAb) product candidates.

In April 2015 at the AACR conference, ADXS presented preclinical data demonstrated that the combination of ADXS-HPV with agonistic research antibodies, including anti-OX40 and anti-GITR, led to significant inhibition of tumor growth and prolonged survival in tumor-bearing mice. Both OX40 and GITR are two types of immune checkpoints, like PD-1 and PDL-1, which play key roles in tumor development and growth.

The data demonstrated that the combination of ADXS-HPV with anti-OX40 or anti-GITR antibodies led to significant inhibition of tumor growth and prolonged survival in tumor bearing mice. Complete regression of established tumors occurred in 40% and 60% of animals treated with ADXS-HPV in combination with anti-OX40 or anti-GITR antibodies, respectively.

Both combination therapies significantly enhanced the number of tumor infiltrating CD4 T cells, which help to kill tumor cells.





We Remain Bullish On Advaxis Shares

We maintain our Buy rating for ADXS shares and reset our new 12-month price target to $25 from previous $30.00 per share to reflect current environment of biotech industry. Our call is based on the recent clinical achievements.

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. Combination of its technology with checkpoint inhibitors has the potential to become new standard of care for cancer treatment.

The recent deals are especially encouraging in our view. The deal with Aratana could get ADXS-cHER2 the first approved immunotherapy for animals in 2016. 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 programs. Recent partnership with Knight Therapeutics further expands the global market of Advaxis' product portfolio.

The collaborations with Merck and MedImmune may lead to license deals. And the collaborations with Incyte and Sorrento further expand the company's pipeline and validate its key immunotherapy technology platform.

We look forward to the announcement of initiation of the pivotal Phase III trials of ADXS-HPV for recurring cervical cancer by the end of 2015 or early 2016.

Advaxis has developed a robust pipeline based on its proprietary platform technology. In addition to cervical cancer, ADXS-HPV has potential to target other HPV-mediated cancers, such as head & neck cancer as well as anal cancer.

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).

The Company's balance sheet is strong. Current cash could last through 2017 according to our financial model.

In terms of valuation, we think Advaxis is undervalued at current market price. Currently, the Company shares are trading at about $12 per share which values the Company at about $400 million in market cap based on 33 million outstanding shares. This is still a discount compared to its peers.

We predict ADXS-HPV for cervical cancer to be approved in the US in late 2017 or early 2018 with 75% probability. Sales will reach $155 million in 2020 with earnings per share of $1.74. Using a relative valuation model, we come up with the fair value of $25.00 per share by using 35 x P/E multiple and discounted at 25% for 4 years.

Our price target of $25.00 per share values the Company at $775 million in market cap, which is still conservative in our view. Apparently, risk is still high for Advaxis at this stage. We will keep a close eye on clinical program advances.

PROJECTED INCOME STATEMENT

	2013A (Oct)	2014A (Oct)	2015E (Oct)					2016E (Oct)	2017E (Oct)	2018E (Oct)	2019E (Oct)	2020E (Oct)
$ in million except per share data	FYA	FYA	Q1	Q2	Q3	Q4	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	$85.00	$155.00
R&D revenue	$0.00	$1.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Total Revenues	**$0.00**	**$1.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$5.00**	**$30.00**	**$85.00**	**$155.00**
YOY Growth	-	-	-	-	-	-	-	-	*#DIV/0!*	*600.0%*	*283.3%*	*182.4%*
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.75	4.50	12.75	23.25
Gross Income	**$0.00**	**$1.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$4.25**	**$25.50**	**$72.25**	**$131.75**
Gross Margin	-	*100.0%*	-	-	-	-	-	*#DIV/0!*	*85.0%*	*85.0%*	*85.0%*	*85.0%*
R&D	$5.62	$8.69	$3.58	$6.14	$7.29	$7.50	$24.50	$25.50	$27.00	$29.00	$30.00	$32.00
% R&D	-	*868.7%*	-	-	-	-	-	*#DIV/0!*	*540.0%*	*96.7%*	*35.3%*	*20.6%*
SG&A	$9.07	$11.85	$3.20	$7.70	$6.34	$6.50	$23.74	$24.00	$25.00	$26.00	$27.00	$29.00
% SG&A	-	*1185.1%*	-	-	-	-	-	*#DIV/0!*	*500.0%*	*86.7%*	*31.8%*	*18.7%*
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)**	**($19.5)**	**($6.8)**	**($13.8)**	**($13.6)**	**($14.0)**	**($48.2)**	**($49.5)**	**($47.8)**	**($29.5)**	**$15.3**	**$70.8**
Operating Margin	-	-	-	-	-	-	-	-	-	*-98.3%*	*17.9%*	*45.6%*
Other Net	($6.6)	$0.7	($0.3)	($0.0)	$0.1	$0.0	($0.2)	($1.0)	($1.0)	($1.0)	($1.0)	($1.0)
Pre-Tax Income	**($21.3)**	**($18.9)**	**($7.0)**	**($13.9)**	**($13.6)**	**($14.0)**	**($48.5)**	**($50.5)**	**($48.8)**	**($30.5)**	**$14.3**	**$69.8**
Income taxes(benefit)	($0.7)	($2.4)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.00
Tax Rate	-	-	-	-	-	-	-	-	-	-	*0.0%*	*0.0%*
Reported Net Income	**($20.5)**	**($16.5)**	**($7.0)**	**($13.9)**	**($13.6)**	**($14.0)**	**($48.5)**	**($50.5)**	**($48.8)**	**($30.5)**	**$14.3**	**$69.8**
YOY Growth	-	-	-	-	-	-	-	-	-	-	*-146.7%*	*389.5%*
Net Margin	-	-	-	-	-	-	-	-	-	-	*16.8%*	*45.0%*
Shares Out	*5.0*	*17.1*	*21.6*	*26.7*	*31.0*	*31.0*	*27.5*	*32.5*	*33.0*	*35.0*	*37.0*	*40.0*
Reported EPS	**($4.10)**	**($0.97)**	**($0.33)**	**($0.52)**	**($0.44)**	**($0.45)**	**($1.76)**	**($1.55)**	**($1.48)**	**($0.87)**	**$0.39**	**$1.74**
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)**	**($16.5)**	**($7.0)**	**($13.9)**	**($13.6)**	**($14.0)**	**($48.5)**	**($50.5)**	**($48.8)**	**($30.5)**	**$14.3**	**$69.8**
Non GAAP EPS	**($3.30)**	**($0.97)**	**($0.33)**	**($0.52)**	**($0.44)**	**($0.45)**	**($1.76)**	**($1.55)**	**($1.48)**	**($0.87)**	**$0.39**	**$1.74**

Source: Company filing and Zacks Investment Research estimates

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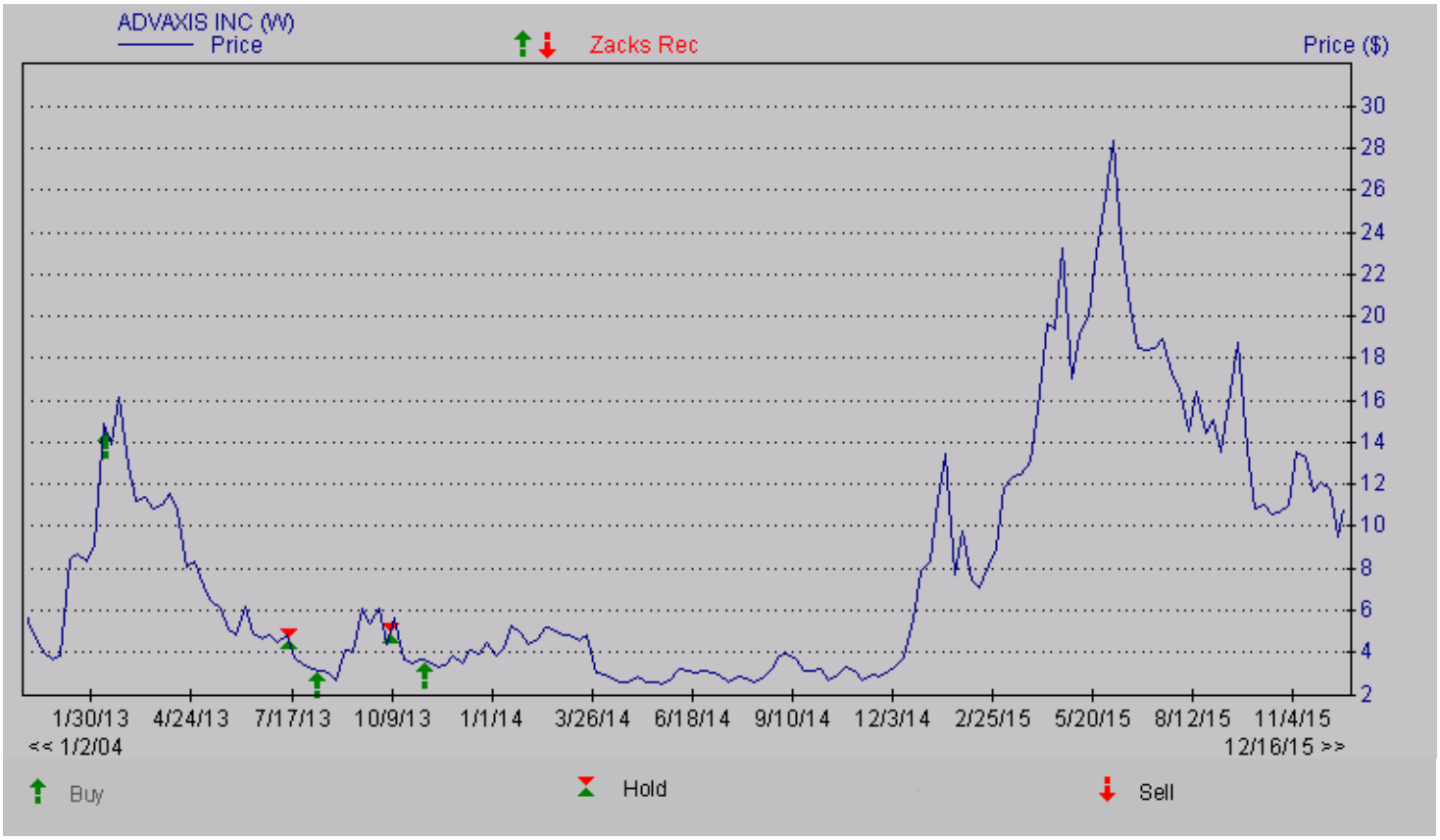
HISTORICAL ZACKS RECOMMENDATIONS



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Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters.
Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 16.6%, Hold/Neutral- 77.5%, Sell/Underperform – 5.3%. Data is as of midnight on the business day immediately prior to this publication.