Zacks Small-Cap Research

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Advaxis Inc. (ADXS-NASDAQ)

ADXS: Balance boosted by recent financing, 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 (09/11/15)	$16.51
12-month Target Price	**$30.00**

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	**$2.56**
One-Year Return (%)	**337.93**
Beta	**0.46**
Average Daily Volume (sh)	**908,863**
Shares Outstanding (mil)	**31**
Market Capitalization ($mil)	**$518**
Short Interest Ratio (days)	**8.18**
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

Balance Sheet Boosted by Recent Financing

On May 5, 2015, ADXS completed a **public offering** of 2.8 million shares of its common stock at a public offering price of $19.00 per share.

The gross proceeds to Advaxis from the public offering were $53.2 million before underwriting discounts and commissions and other estimated offering expenses.

In late August, Advaxis entered into a licensing agreement with **Knight Therapeutics**, a Canadian-based specialty pharmaceutical company, to commercialize in Canada Advaxis's product portfolio including its three lead drug candidates: ADXS-HPV for HPV-associated cancers, ADXS-PSA for prostate cancer and ADXS-HER2 for HER2 expressing solid tumors.

In connection with the licensing agreement, Knight purchased directly from Advaxis 359,454 shares at $13.91 per share, which represented a 7 percent premium to the price of Advaxis's common stock at market close on August 25, 2015.

Meanwhile, Advaxis also announced that **Sectoral Asset Management**, a leading Canadian-based global healthcare investment advisor, purchased 1,437,815 shares at $13.91 per share directly from Advaxis on behalf of its clients.

The combined gross proceeds to Advaxis from these direct investments are $25 million.

Under the terms of the licensing agreement, Knight will be responsible for all commercial activities related to Advaxis current and future products, including axalimogene filolisbac (ADXS-HPV), ADXS-PSA and ADXS-HER2, in Canada. Advaxis is eligible to receive double digit royalty as well as sales milestones.

Furthermore, in September, Advaxis announced that the US FDA's Office of Orphan Products Development (OOPD) awarded a grant totaling $1.1 million over three years to Baylor College of Medicine in support of an ongoing Phase II trial of Advaxis's ADXS-HPV, in HPV-associated oropharynx (throat) cancer.

As of July 31, 2015, ADXS had approximately $97 million in cash. Current cash, plus the proceeds received from Knight and Sectoral transactions, is sufficient to fund the company's business plan approximately through calendar 2017 according to our financial model.

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

In August, 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.

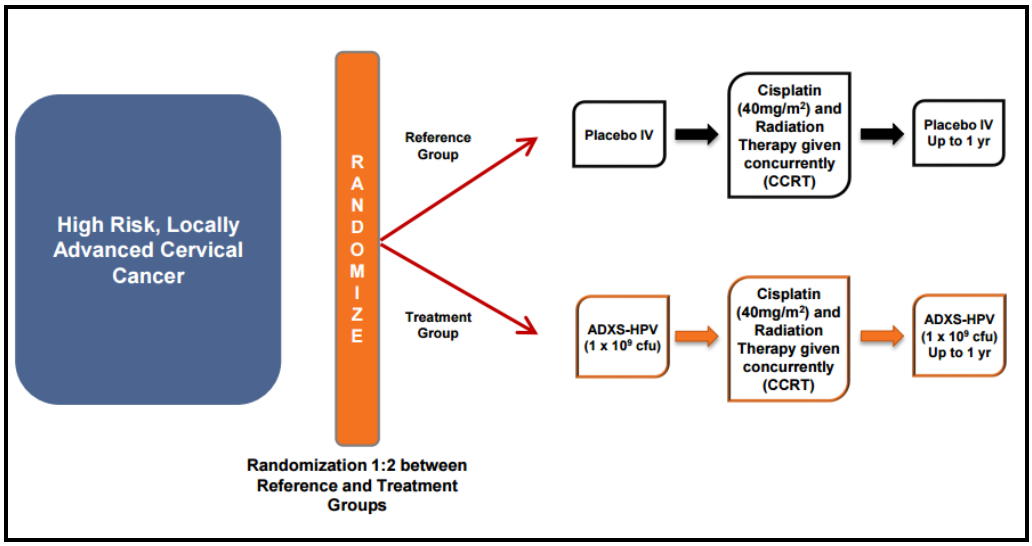
Update on Planned ADXS-HPV Phase III for Cervical Cancer

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**.

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.

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.

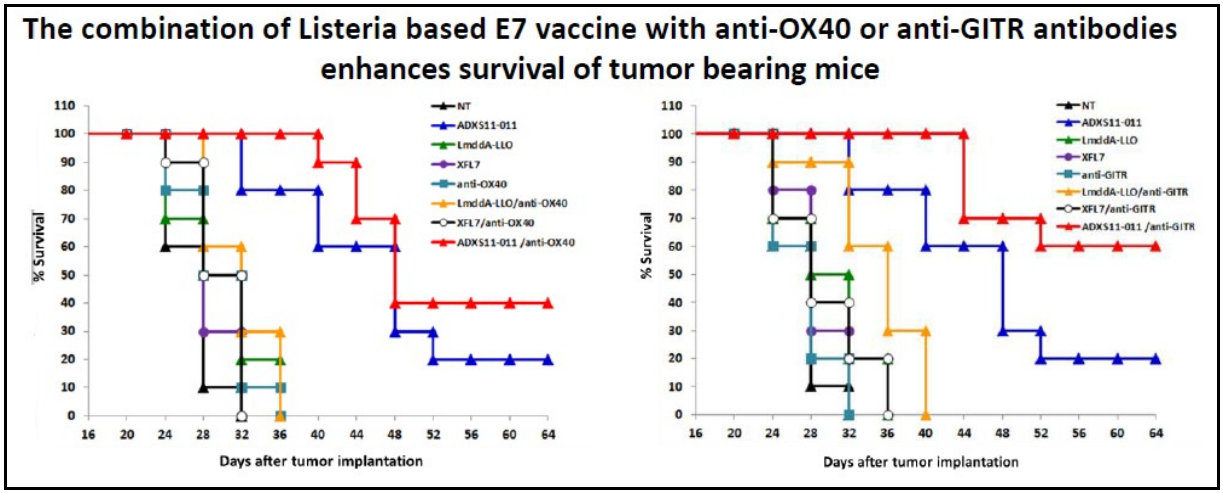
Under the terms of the agreement, Advaxis will conduct the studies and the companies will equally share the expenses. The two companies hope to commence the first of the two planned combination **studies in 2016.** Results from the studies will be used to determine whether further clinical development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

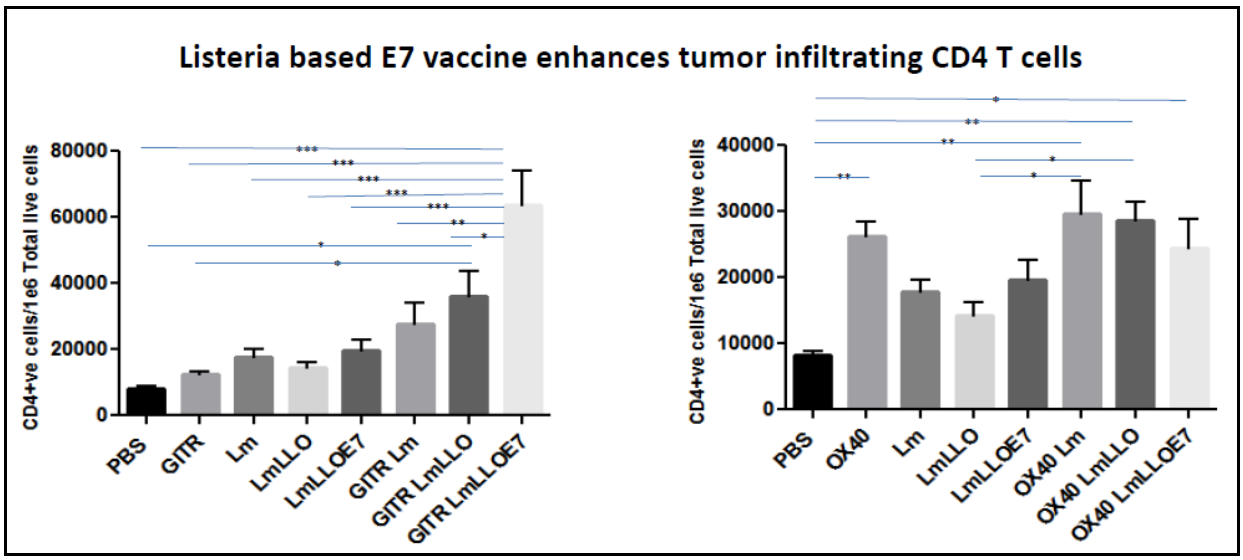
Sorrento has one of the largest and most diverse fully human antibody libraries in the industry designed to facilitate rapid identification and selection of highly specific therapeutic monoclonal antibody (mAb) product candidates.

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.





Update on Phase I ADXS-HER2 for Canine Osteosarcoma

The updated data were presented at the 2015 American College of Veterinary Internal Medicine (ACVIM) Forum in Indianapolis on June 6, 2015.

- ADXS-HER2 was safe and well tolerated with no systemic or cardiac toxicity.
- Of the 12 canine patients recruited to date, **seven are alive** with current survival times ranging from 66 to 479 days.
- The median survival time of dogs receiving palliative radiation plus ADXS-HER2 has not been reached.
- The median time to progression of these 12 canine patients is 238 days.
- The reported median survival time for historical control dogs with OSA that do not undergo amputation but instead receive the same palliative radiation protocol without ADXS-HER2 is 316 days.

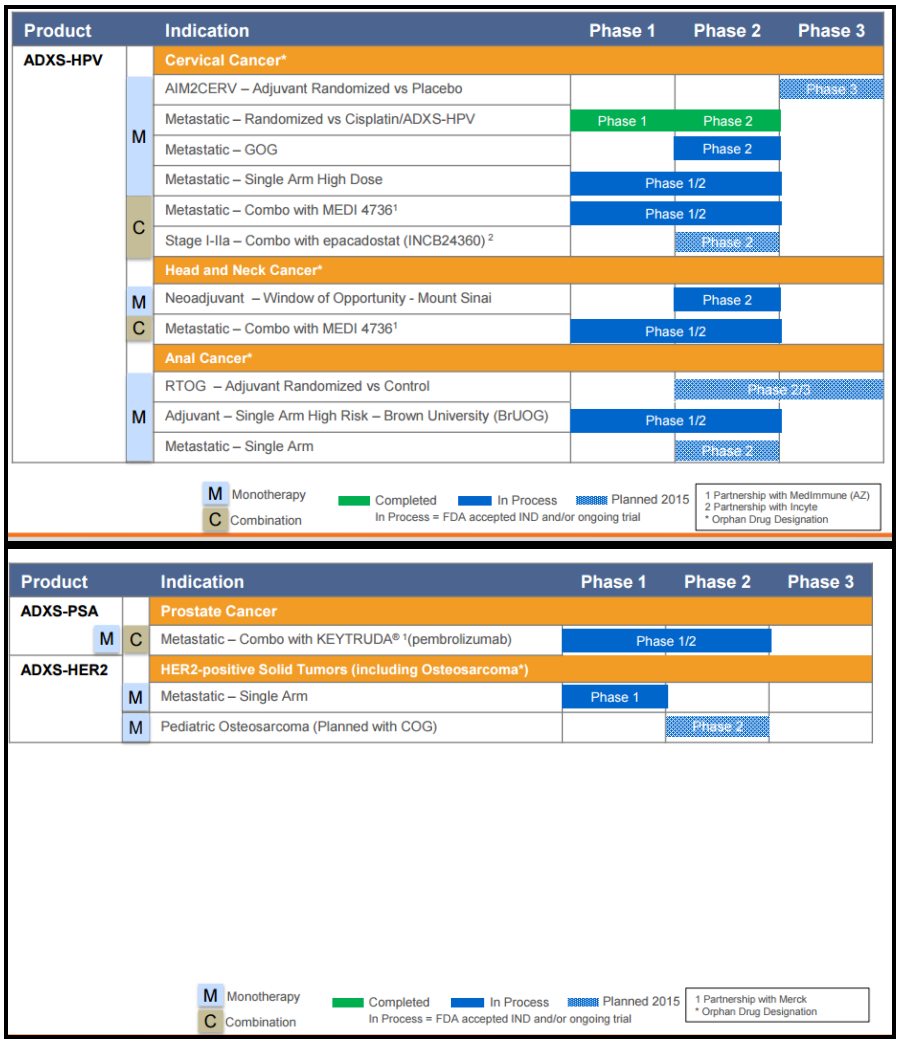
Advaxis licensed ADXS-HER2 to Aratana Therapeutics in March of 2014 for pet health indications and it is now being developed and prepared for commercialization, and Advaxis and Aratana anticipate conditional licensure of ADXS-HER2 (AT-014) for the treatment of canine OSA from the U.S. Department of Agriculture (USDA) in 2016. Advaxis will receive royalties from the sales of ADXS-HER2.

We are very pleased to see the positive clinical and preclinical data from Advaxis' two lead programs ADXS-HPV and ADXS-HER2, especially in combination with other agents.

The data demonstrate the therapeutic potential of Advaxis's Lm-LLO technology platform in combination with complementary technologies, such as anti-PD-L1 immune checkpoint inhibitors and anti-OX40 and anti-GITR antibodies.

Specifically, the positive preclinical data from the combination of ADXS-HPV with OX40, GITR or PD-L-1 antibodies may be directly translatable to clinical investigations in patients. The Phase I safety and efficacy data from the combination of ADXS-HER2 with radiation in canine osteosarcoma supports further clinical development of ADXS-HER2 in HER2 expressing cancers, such as osteosarcoma, breast, gastric and esophageal cancers.

Considering the huge market of immunotherapy, which is at the forefront for cancer treatment, it's our belief that Advaxis' Lm-LLO technology platform offers significant opportunity to address a number of key cancer indications and has the potential to make Advaxis the key player in the emerging immunotherapy space.



Other Key Milestones in 2H15 for ADXS

GOG-0265 Phase II Trial of ADXS-HPV

The GOG in enrolling patients in **Stage 2** of its ongoing **Phase II** open-label clinical study of ADXS-HPV in patients with persistent or **recurrent cervical cancer** with documented disease progression. GOG-0265 has been amended to allow patients in Stage 2 to continue to receive repeat cycles of therapy until progression.

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.

ADXS plans to complete enrollment in **Stage II** of the ongoing GOG-0265 **Phase II** trial of ADXS-HPV in persistent or recurrent cervical cancer being conducted by the Gynecologic Oncology Group (GOG). Total of up to 38 patients are expected to be enrolled by June 30, 2016.

The final Stage 1 safety and efficacy data will be presented at an upcoming major medical meeting in 2015. Final study data (Stage 1 and 2) will be available in the **1H17**.

Other ADXS-HPV clinical programs

- Complete enrollment in Part A (dose escalation) of the **Phase I** study evaluating **higher doses** of ADXS-HPV immunotherapy and repeat cycles of treatment with data available from Part A in 2016.
- Complete enrollment of the Mount Sinai investigator-sponsored **Phase I/II** study of ADXS-HPV in patients with HPV-associated head and neck cancer. Data to be available in 1H16.
- Commence enrollment in a **Phase II** study in patients with HPV-associated metastatic anal cancer by year's end with data available in 2H16.
- Commence enrollment in the second half of 2015 on the Phase I/II combination study with Incyte Corporation's (Incyte) IDO-1 inhibitor.

ADXS-PSA for Prostate Cancer

ADXS plans to complete enrollment in Part A (dose escalation) in 1H16 in the **Phase I/II** study of ADXS-PSA as a monotherapy or in combination with Merck's anti-PD-1 therapy, Keytruda® (pembrolizumab), in metastatic, castration-resistant prostate cancer (mCRPC). Data to be available in second half of 2016.

ADXS-HER2

- Enroll the first patient in a **Phase I** first-in-human trial of ADXS-HER2 in metastatic HER2 expressing **solid tumors** in the second half of 2015 with data to be available in the second half of 2016.

- Initiate a clinical study of ADXS-HER2 in pediatric osteosarcoma in partnership with the Children's Oncology Group (COG) in 2016.

- Secure conditional license for ADXS-HER2 (also known as AT-014) for the treatment of canine osteosarcoma from the U.S. Department of Agriculture in 2016.

We Maintain Our Price Target of $30

We maintain our Buy rating for ADXS and reiterate our 12-month price target of $30.00 per share. 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.

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 still undervalued at current market price. Currently, the Company shares are trading at about $17 per share which values the Company at about $577 million in market cap based on 31 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 value for HPV cervical cancer of $20.00 per share by using 35 x P/E multiple and discounted at 25% for 5 years. Adding the value of $10 for other indications of HPV and other clinical programs, we reach our price target of $30 per share for the company.

Our price target of $30.00 per share values the Company at $900 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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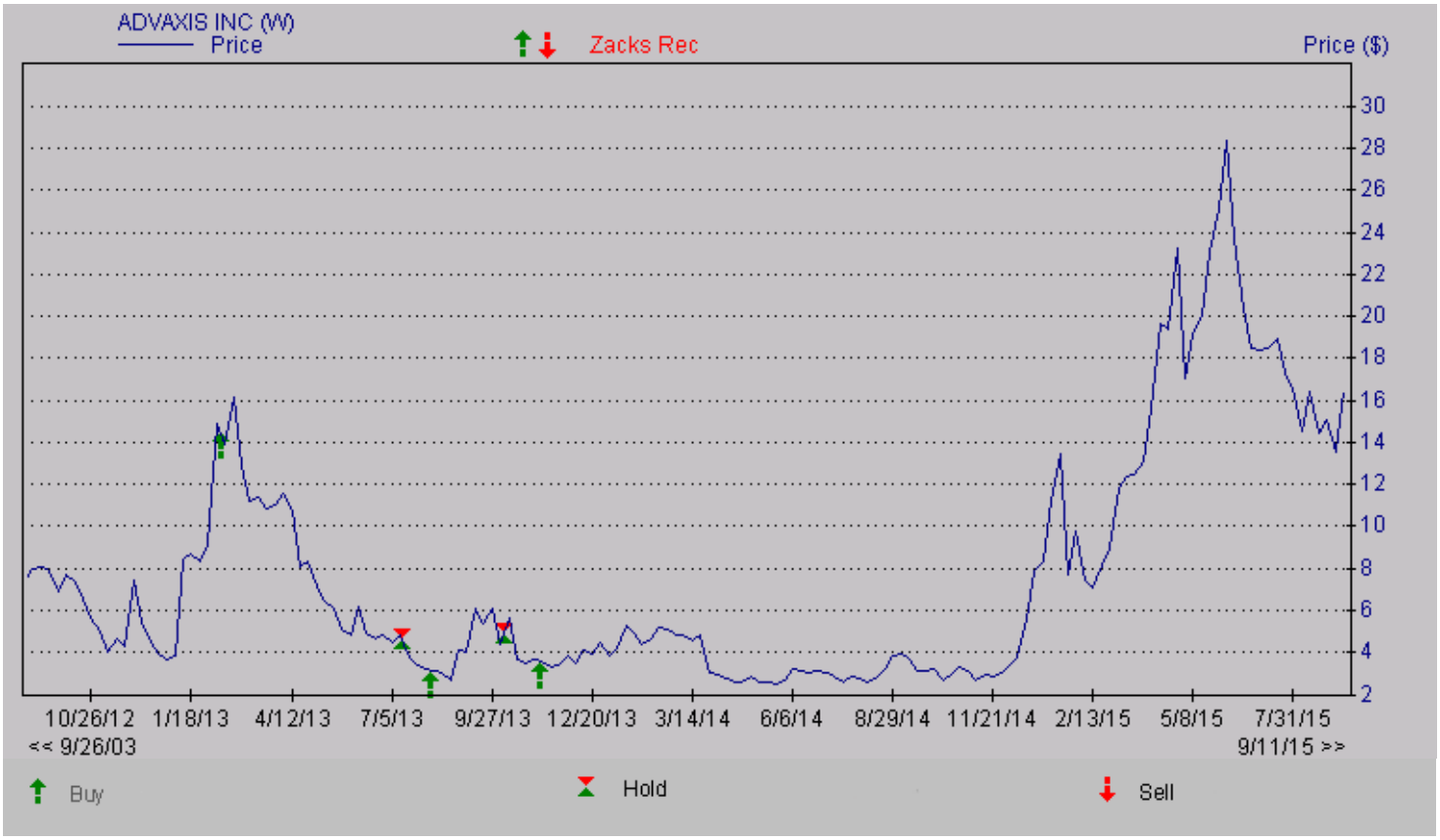

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ZIR uses the following rating system for the 1052 companies whose securities it covers, including securities covered by Zacks SCR:
Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the 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.