Zacks Small-Cap Research

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Advaxis Inc. (ADXS-NASDAQ)

ADXS: Zacks Company Report

ADXS: Phase III of ADXS-HPV for cervical cancer will be initiated in mid-2016

Current Price (06/05/16)	$8.97
Valuation	**$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 in mid-2016. Recent collaborations with Merck and MedImmune may lead to license deals for Advaxis.

SUMMARY DATA

52-Week High	**$28.52**
52-Week Low	**$5.46**
One-Year Return (%)	**-66.13**
Beta	**1.55**
Average Daily Volume (sh)	**693,248**
Shares Outstanding (mil)	**34**
Market Capitalization ($mil)	**$329**
Short Interest Ratio (days)	**N/A**
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)
2015	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2016	0.25 A	0.25 E	0.25 E	0.25 E	1.00 E
2017					1.00 E
2018					30.00 E

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

	Q1 (Jan)	Q2 (Apr)	Q3 (Jul)	Q4 (Oct)	Year (Oct)
2015	-$0.33 A	-$0.52 A	-$0.44 A	-$0.33 A	-$1.62 A
2016	-$0.59 A	-$0.56 E	-$0.61 E	-$0.61 E	-$2.36 E
2017					-$2.48 E
2018					-$1.33 E

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

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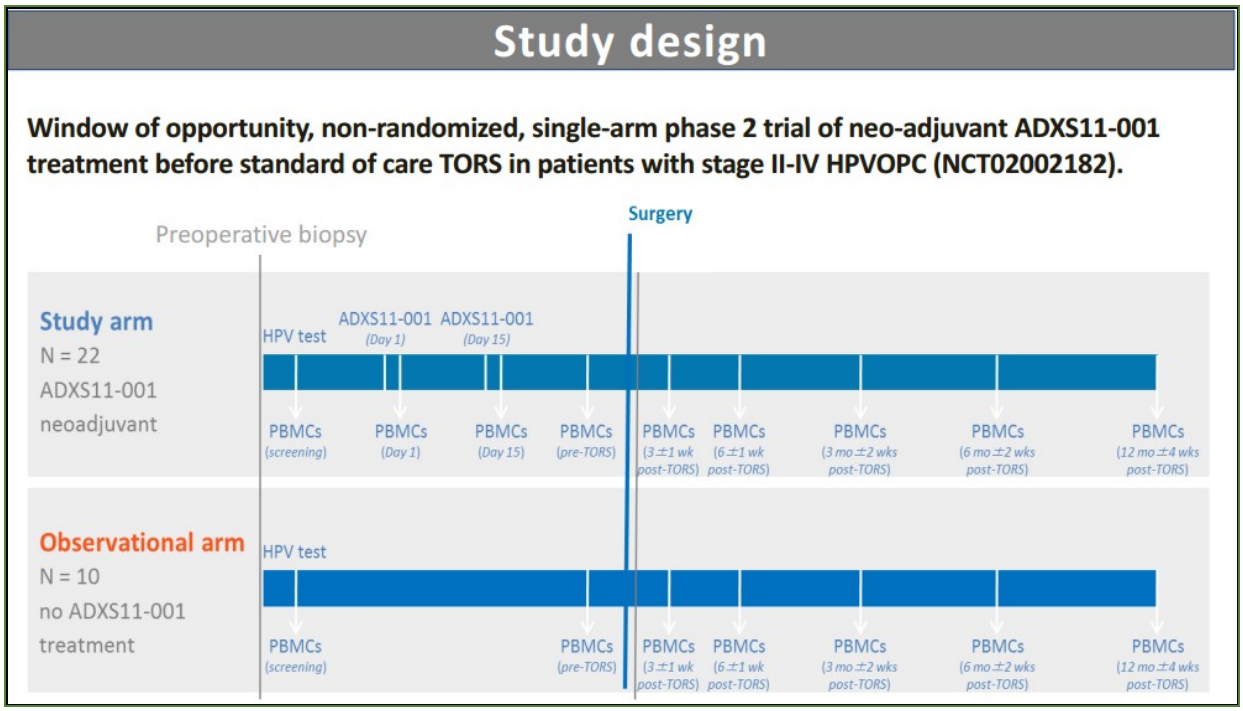
WHAT'S NEW

First Clinical Evidence that AXAL Can Induce cytotoxic T cell infiltration into TME

On April 18, 2016, Advaxis (ADXS) announced clinical data from the Company's ongoing **Phase II study** of its lead immunotherapy candidate, axalimogene filolisbac (**AXAL)**, in patients with late-stage HPV-associated **oropharyngeal cancer** (HPVOPC).

Background of the Trial

This Phase II trial is a "window of opportunity" trial, which was designed to evaluate the effect of AXAL on anti-tumor immunity in the tumor immune microenvironment (TME) of patients with HPVOPC by conducting an analyses and comparison of the TME between pre-treatment tumor biopsy and post-treatment resected tumor tissue, as well as pre and post AXAL treatment blood samples.

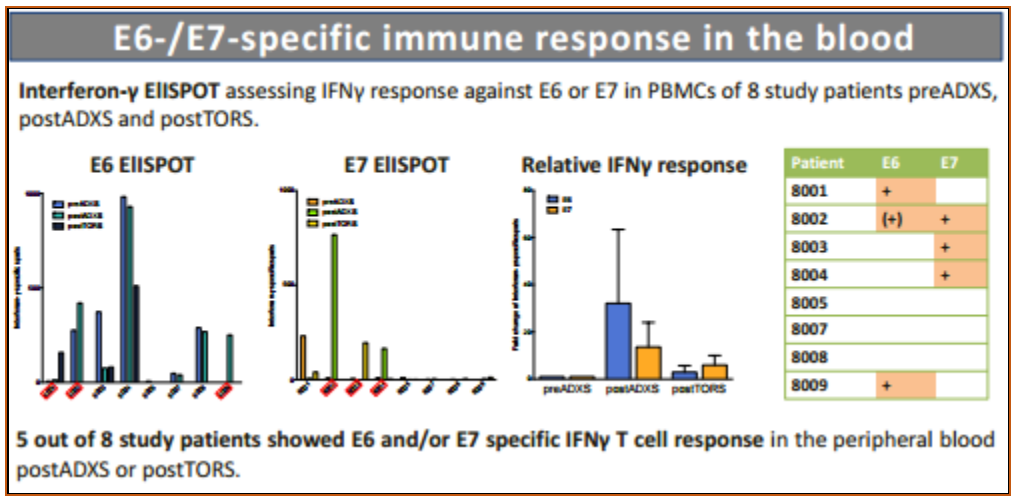


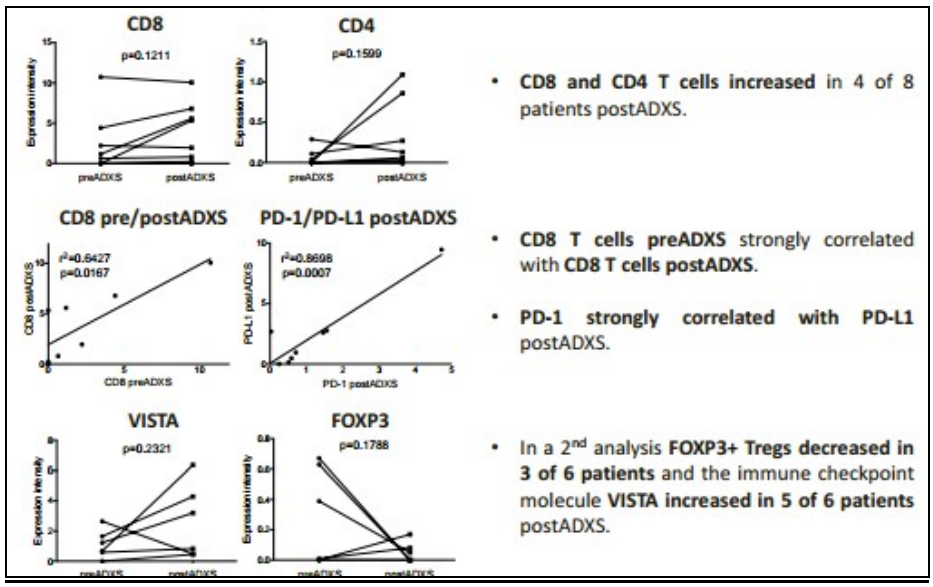
The trial has enrolled **eight** AXAL-treated patients and **six** no-treatment observational patients to date, with stage II-IV HPVOPC. The trial uniquely leveraged a 5-6 week "window of opportunity" between diagnosis and TORS (trans-oral robotic surgery) with curative intent, to administer two doses of AXAL treatment at $1x10^9$CFU 2 weeks apart. This unique clinical setting or "window of opportunity", makes it possible to analyze and compare changes to the TME after the compressed regimen of AXAL treatment as well as pre and post treatment blood samples. In this limited timeframe, patients received two doses of AXAL separated by only two weeks, followed by TOR surgery 1-2 weeks after the second dose.

The Data Presented at AACR

The clinical data were selected for "Late Breaking Abstract" status and will be presented in the poster session of the American Association for Cancer Research (AACR) Annual Meeting on April 18, 2016. The poster (abstract LB-095) is titled "HPV E7 antigen-expressing Listeria-based immunotherapy (AXAL) prior to robotic surgery for HPV-positive oropharyngeal cancer enhances HPV-specific T cell immunity"

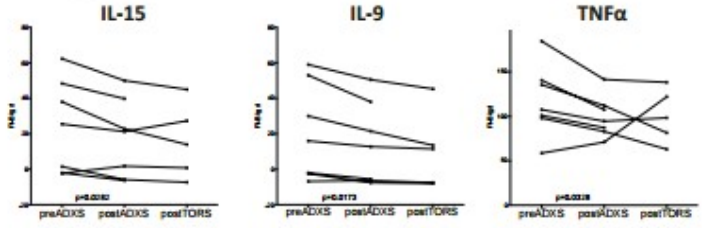
The data presented showed that HPV E7- and/or E6-specific **T cell responses** increased in the peripheral blood in **five** of the study patients. Increased infiltration of both CD4+ and CD8+ T cells were observed in the TME of four patients, with a reduction of FOXP3+ regulatory T cells within the tumors of 3/6 patients. Increased T cell responses to HPV E6 supports enhanced immune activity against additional tumor targets. Changes to the TME included cytotoxic T cell infiltration into the post-resection tumor, increased immune activation, a reduction of regulatory T cells, infiltration of cytotoxic T cells, and increased expression of inflammatory activation markers.





In addition, fluctuations of circulating serum cytokine (IL-15, IL-9, TNfa, IL-2 and MIP-1b) levels were observed potentially suggesting consumption by activated T cells and migration of T cells to the TME.

Analysis of preADXS, postADXS and postTORS serum for **38 cytokines by Luminex multiplex platform of 7 study patients.**



Decrease of serum cytokines **IL-15, IL-9, TNFα, IL-2** postADXS.

Our Takeaways

While the data presented at the AACR are preliminary, we believe AXAL has the potential to increase the immune response in cancer patients.

We are pleased to see increased T cell response, evidence of epitope spreading, and signs of increased immune activation consistent with expansion and infiltration of activated T cells into the tumor. We are also pleased to see the trends towards a reduction in immuno-suppressive Tregs. Importantly, in several patients when compared to pre-treatment tumor tissue, post-treatment tissue analysis showed conversion of the TME into a site of active inflammation characterized by infiltration of activated T cells, and increased expression of activation markers including PD-1 and PD-L1.

We thinks the preliminary data are very encouraging and suggest that AXAL and the company's Lm Technology has the potential to generate beneficial immunologic responses in patients with HPV+ head and neck cancer and other cancer patients.

Update on Expansion of Ongoing Phase II Study of AXAL for Cervical Cancer

On March 07, 2016, ADXS announced dose administration for the first patient in the **expansion phase** of an ongoing **Phase II** clinical trial of axalimogene filolisbac (AXAL) in patients with persistent or recurrent metastatic (squamous or non-squamous cell) carcinoma of the cervix **(PRmCC).**

The interventional, open-label, non-randomized dose-escalation study is designed to evaluate the safety, efficacy and immunological effect of AXAL administered at doses up to 1 x 10^{10} colony forming units (CFU) in repeat cycles of treatment in approximately 25 women with cervical cancer whose disease recurred after receiving one prior cytotoxic treatment regimen.

The initiation of the expansion phase study follows positive preliminary data from 9 patients who showed that AXAL could be safely administered with prophylactic antibiotics up to 1 x10^{10} CFU, a tenfold increase from prior dosing regimens at 1 x 10^{9}. Adverse events at this high dose were consistent with previous experience with predominately grade 1 or grade 2, transient events that self-resolved or were resolved with anti-inflammatory agents (NSAIDS) and antiemetics. The high dose expansion phase will include 15 patients.

The company plans to complete enrollment of the Phase II dose-escalation study in the first half of 2016.

We believe the high dose expansion study is an important step in AXAL's development program. A higher dose could increase the efficacy of the agent and increase the commercial opportunity in the future.

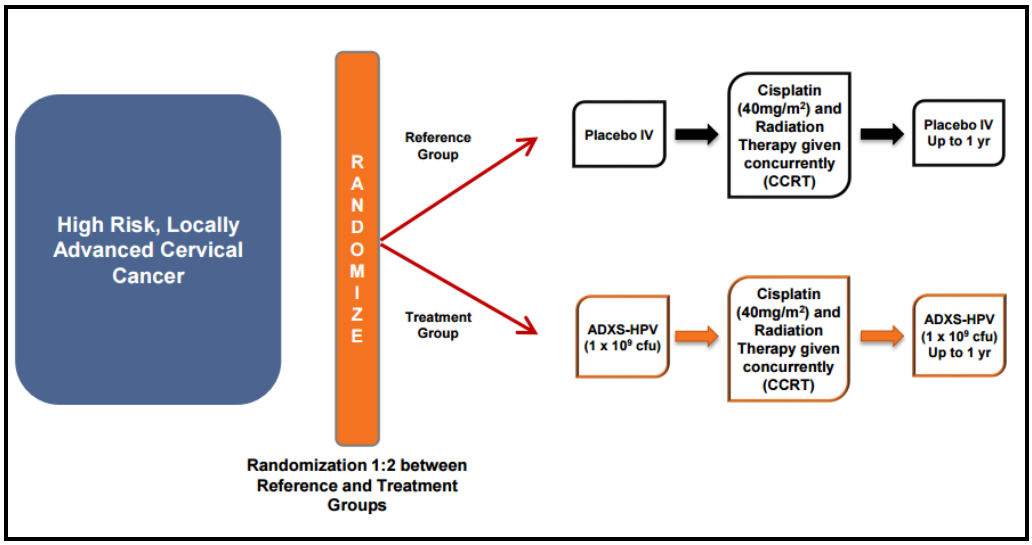
Update on Planned AXAL Phase III for Cervical Cancer

In June, 2015, ADXS submitted a Special Protocol Assessment **(SPA)** request to the FDA to initiate detailed design discussions for a Phase III clinical study of AXAL (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'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 finish the SPA process and initiate enrollment in the Phase III trial in **mid-2016.**

The proposed Phase III clinical trial (**AIM2CERV**) will be a double-blind, placebo-controlled multinational study of ADXS-HPV 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 both the short term and long term as this is the most advanced clinical program in the company's pipeline. It 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 and will update investors once we have details about the trial.

Update on GOG-0265 Phase II Trial of AXAL

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**.

Updated Stage 1 results were presented at **2016 ASCO** with 12-month OS of 38.5%. Median PFS was 3.1 months and median OS was 7.7 months.

Preliminary assessment of OR includes 1 unconfirmed PR and 9 SD. Post-hoc analysis of the 18/26 pts (69%) who received all 3 per-protocol doses of ADXS11-001 showed a median OS > 1 yr (12.1 [95% CI: 6.8–NR] mo), and 12-mo OS rate of 55.6%.

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**.

Phase I/II of AXAL 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 (AXAL, 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**.** 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.

The trial completed first dose-escalation cohort in late March 2016. The first dose-escalation cohort evaluated AXAL at 1x10^9 cfu with 3mg/kg durvalumab and the second dose-escalation cohort will now examine AXAL at 1x10^9 cfu in combination with 10mg/kg durvalumab. Upon completion of dose escalation, the Phase II study will randomize 90 patients to receive AXAL in combination with durvalumab vs. durvalumab alone. The primary efficacy endpoints include objective response rate and progression-free survival.

An abstract will be submitted to a major medical meeting on the dose-escalation portion of the study in the second half of the year.

The company plans to complete the enrollment in late 2016. Data from the Phase I/II will be available in the **first half of 2017**, which will determine the future clinical development program for the combination.

Update on ADXS-PSA

In early April 05, 2016, Advaxis and Merck announced that they have completed the first two dose-escalation cohorts and launched the third dose-escalation cohort in their KEYNOTE-046 clinical trial. The **Phase I/II study** is evaluating the combination of ADXS-PSA (ADXS31-142) and KEYTRUDA® (pembrolizumab) in patients with previously treated, metastatic castration-resistant prostate cancer **(mCRPC).**

KEYNOTE-046 is a multicenter, dose determining, open-label Phase I/II study designed to evaluate the safety and efficacy of ADXS-PSA as a monotherapy and in combination with KEYTRUDA in **51 mCRPC patients.** Part A of the study is a dose escalating study designed to establish the maximum tolerated dose of ADXS-PSA as a monotherapy. Part B of the study will commence mid-year and evaluate ADXS-PSA in combination with KEYTRUDA, followed by an expansion cohort phase. The primary objective is to evaluate the safety and tolerability of the two immunotherapies, with the secondary objective to evaluate anti-tumor activity and progression-free survival.

The companies plan to submit an abstract to a major medical meeting on the dose-escalation portion of the study in the second half of the year.

Update on ADXS-HER2 Program

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.

ADXS expects to complete enrollment of this Phase Ib study of ADXS-HER2 in the **first half of 2016**. Once a dose is selected from Part A, enrollment in a Part B expansion phase will commence in the second half of 2016.

Following completion of Part A in the Phase Ib dose escalating study, the company will commence collaboration and cooperative group trial with the Children's Oncology Group in **osteosarcoma.**

In April, 2016, the granted Fast Track Designation for ADXS-HER2 for patients with newly-diagnosed, non-metastatic, surgically-resectable osteosarcoma.

We Remain Bullish On Advaxis Shares

We continue to be optimistic about the prospect of Advaxis and reiterate our valuation at $25 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 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 soon.

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 $9.0 per share which values the Company at about $306 million in market cap based on 34 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 2018 with 75% probability. Sales will reach $180 million in 2020 with earnings per share of $1.75. 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 valuation at $25.00 per share values the Company at $850 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

	2015A (Oct)					2016E (Oct)					2017E (Oct)	2018E (Oct)	2019E (Oct)	2020E (Oct)
$ in million except per share data	Q1	Q2	Q3	Q4	FYA	Q1	Q2	Q3	Q4	FYE	FYE	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	$30.00	$85.00	$180.00
Licensing/R&D revenue	$0.00	$0.00	$0.00	$0.00	$0.00	$0.25	$0.25	$0.25	$0.25	$1.00	$1.00	$0.00	$0.00	$0.00
Total Revenues	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.25**	**$0.25**	**$0.25**	**$0.25**	**$1.00**	**$1.00**	**$30.00**	**$85.00**	**$180.00**
YOY Growth	-	-	-	-	-	-	-	-	-	-	*100.0%*	*#DIV/0!*	*283.3%*	*211.8%*
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	4.50	12.75	27.00
Gross Income	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.25**	**$0.25**	**$0.25**	**$0.25**	**$1.00**	**$1.00**	**$25.50**	**$72.25**	**$153.00**
Gross Margin	-	-	-	-	-	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*85.0%*	*85.0%*	*85.0%*
R&D	$3.58	$6.14	$7.29	$7.22	$24.22	$13.06	$12.00	$13.50	$13.50	$52.06	$50.00	$35.00	$40.00	$42.00
% R&D	-	-	-	-	-	-				*5206.5%*	*5000.0%*	*116.7%*	*47.1%*	*23.3%*
SG&A	$3.20	$7.70	$6.34	$7.21	$24.45	$7.14	$7.20	$7.50	$7.80	$29.64	$32.00	$36.00	$38.00	$40.00
% SG&A	-	-	-	-	-	-	-	-	-	*2963.7%*	*3200.0%*	*120.0%*	*44.7%*	*22.2%*
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	$0.00	$0.00
% Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	**($6.8)**	**($13.8)**	**($13.6)**	**($14.4)**	**($48.7)**	**($20.0)**	**($19.0)**	**($20.8)**	**($21.1)**	**($80.7)**	**($81.0)**	**($45.5)**	**($5.8)**	**$71.0**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	*-151.7%*	*-6.8%*	*39.4%*
Other Net	($0.3)	($0.0)	$0.1	$0.2	$0.0	$0.1	$0.1	$0.1	$0.1	$0.4	($1.0)	($1.0)	($1.0)	($1.0)
Pre-Tax Income	**($7.0)**	**($13.9)**	**($13.6)**	**($14.2)**	**($48.6)**	**($19.8)**	**($18.9)**	**($20.7)**	**($21.0)**	**($80.3)**	**($82.0)**	**($46.5)**	**($6.8)**	**$70.0**
Income taxes(benefit)	$0.0	$0.0	$0.0	($1.6)	($1.6)	$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	**($7.0)**	**($13.9)**	**($13.6)**	**($12.6)**	**($47.0)**	**($19.8)**	**($18.9)**	**($20.7)**	**($21.0)**	**($80.3)**	**($82.0)**	**($46.5)**	**($6.8)**	**$70.0**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	*-85.5%*	*-1137.0%*
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	*-7.9%*	*38.9%*
Shares Out	*21.6*	*26.7*	*31.0*	*32.9*	*28.0*	*33.7*	*33.8*	*34.0*	*34.5*	*34.0*	*33.0*	*35.0*	*37.0*	*40.0*
Reported EPS	**($0.33)**	**($0.52)**	**($0.44)**	**($0.38)**	**($1.68)**	**($0.59)**	**($0.56)**	**($0.61)**	**($0.61)**	**($2.36)**	**($2.48)**	**($1.33)**	**($0.18)**	**$1.75**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	*$0.00*	*$0.00*	*$0.00*	*$1.61*	*$1.61*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($7.0)**	**($13.9)**	**($13.6)**	**($11.0)**	**($45.4)**	**($19.8)**	**($18.9)**	**($20.7)**	**($21.0)**	**($80.3)**	**($82.0)**	**($46.5)**	**($6.8)**	**$70.0**
Non GAAP EPS	**($0.33)**	**($0.52)**	**($0.44)**	**($0.33)**	**($1.62)**	**($0.59)**	**($0.56)**	**($0.61)**	**($0.61)**	**($2.36)**	**($2.48)**	**($1.33)**	**($0.18)**	**$1.75**

Source: Company filing and Zacks Investment Research estimates

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HISTORICAL STOCK PRICE



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