Zacks Small-Cap Research

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Advaxis Inc. (ADXS-NASDAQ)

ADXS: Positive data presented at AACR, balance sheet strong ---Outperform

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	11/06/2013
Current Price (04/21/15)	$22.08
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 Outperform.

SUMMARY DATA

52-Week High	**$21.78**
52-Week Low	**$2.51**
One-Year Return (%)	**651.88**
Beta	**0.53**
Average Daily Volume (sh)	**1,841,690**
Shares Outstanding (mil)	**27**
Market Capitalization ($mil)	**$600**
Short Interest Ratio (days)	**2.97**
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 E	0.00 E	0.00 E	0.00 E
2016					3.00 E
2017					9.50 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	-$0.26 E	-$0.26 E	-$0.27 E	-$1.11 E
2016					-$1.00 E
2017					-$0.84 E

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

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WHAT'S NEW

- **Positive preclinical and clinical data presented at AACR;**
- **Balance sheet further boosted by recent financing;**
- **We raise our PT to $30.00 per share based on recent clinical advancement and boosted balance sheet;**

Update on Advaxis' Three Presentations at 2015 AACR

On April 21, Advaxis presented new data of its two lead programs ADXS-HPV and ADXS-HER2 at the American Association for Cancer Research (AACR) Annual Meeting 2015, held April 18 -- 22 in Philadelphia, Pennsylvania.

The three poster presentations included one clinical and two preclinical studies highlighting the survival outcomes and anti-tumor effects of ADXS-HPV and ADXS-HER2, two clinical programs based on its proprietary Lm-LLO cancer immunotherapy technology.

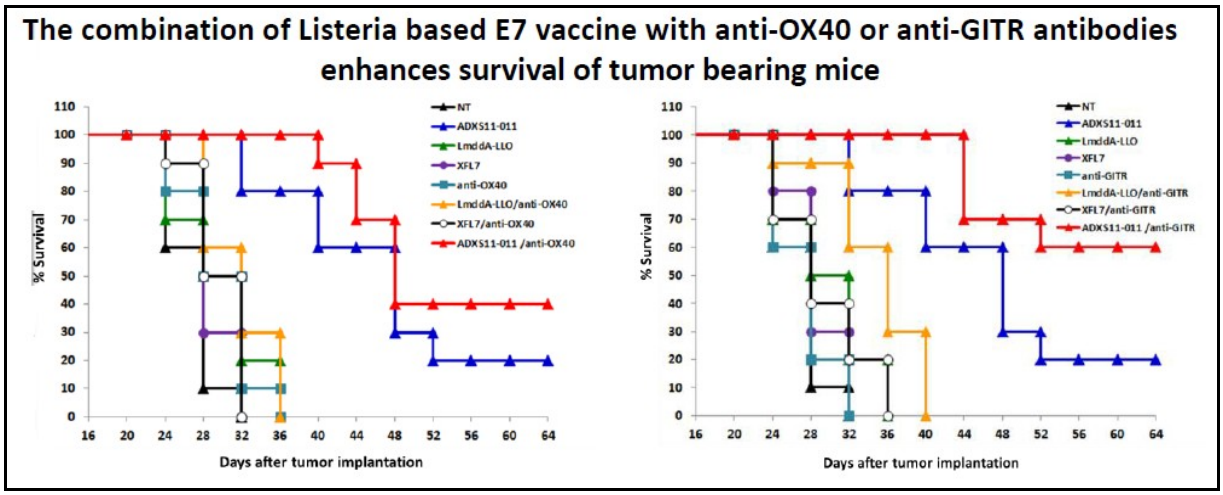
ADXS-HPV Combined with Anti-OX40 or Anti-GITR Antibodies Demonstrates Tumor Growth Inhibition and Prolonged Survival in a Preclinical Study

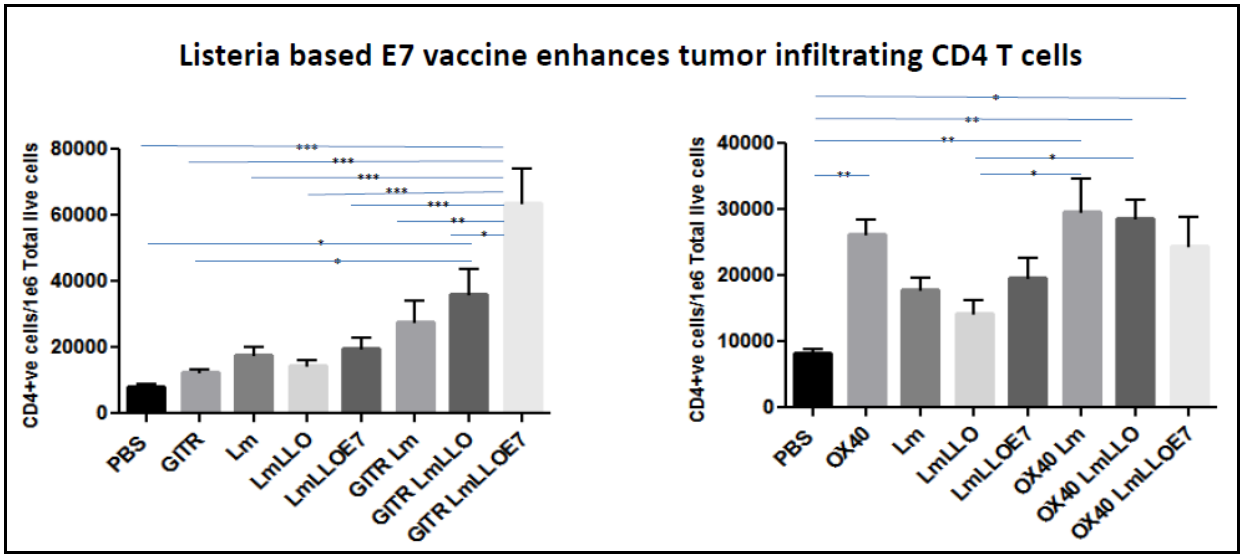
This poster presentation was presented by Samir Khleif, M.D., Director of the State of Georgia Cancer Center, Georgia Regents University Cancer Center (GRU). This preclinical study evaluated the therapeutic potential of **ADXS-HPV in combination with anti-OX40 or anti-GITR antibodies**.

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.

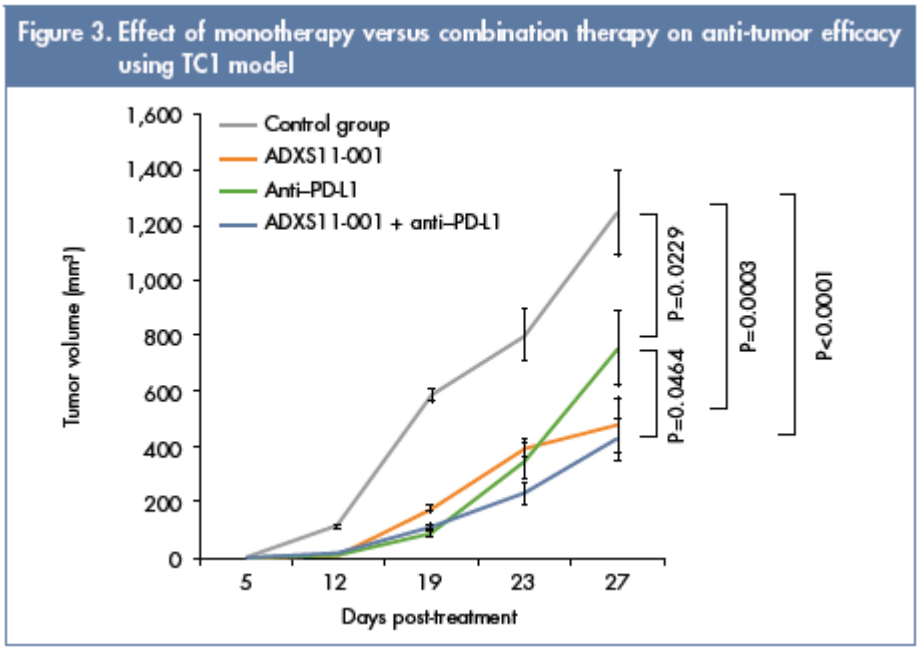




ADXS-HPV in Combination with Anti-PD-L1 Antibody Prolongs Survival in a Preclinical Study

This preclinical study was presented by Poonam Molli, Ph.D., Senior Scientist at Advaxis, Inc.. This preclinical study evaluated the therapeutic potential of ADXS-HPV in combination with **anti-PD-L1** antibody in mice.

The data from Dr. Molli's presentation indicated that the combination of ADXS-HPV with anti-PD-L1 antibody demonstrated an improved ability to control tumor growth compared with anti-PD-L1 antibody therapy alone.



The combination was well tolerated with no added toxicities.

ADXS-HER2 in Combination with Palliative Radiation Delays Tumor Progression, Prolongs Overall Survival and Maintains Limb Function from a Clinical Study in Canine Osteosarcoma

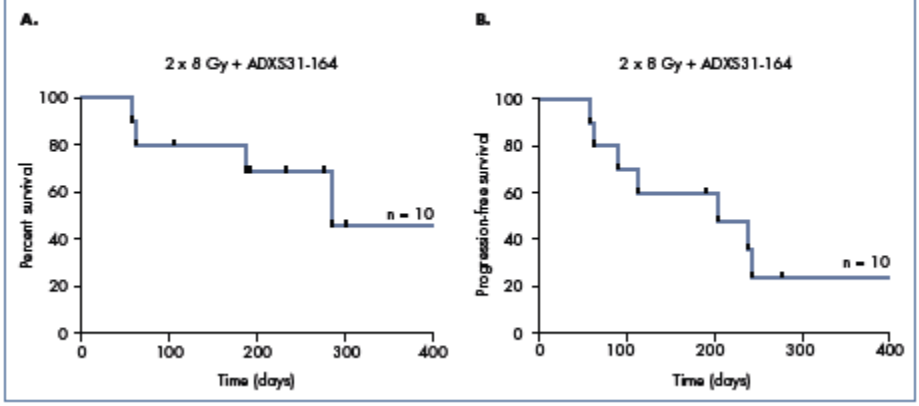
This clinical study was presented by Nicola J. Mason, BVetMed, Ph.D., DACVIM, Assistant Professor of Medicine, University of Pennsylvania's School of Veterinary Medicine.

Preliminary data from this ongoing **Phase I** clinical study of 10 companion dogs with **osteosarcoma** indicated that ADXS-HER2 in combination with palliative radiation delayed tumor progression and prolonged overall survival in dogs with spontaneous osteosarcoma that were not candidates for primary tumor removal (amputation).

The median survival time (MST) was 243 days (figure 5B).

Five of the treated dogs remain alive, with a median survival, to date, of all 10 study dogs reported at 285 days, which compares favorably to historical median survival time of 136 days in dogs treated with palliative radiation only.

Figure 5. Survival (A) and progression-free survival (B) curves



Repeat doses of ADXS-HER2 were well tolerated with no systemic or cardiac toxicity. Additionally, the combination treatment was found to maintain or improve limb function and quality of life over the study period.

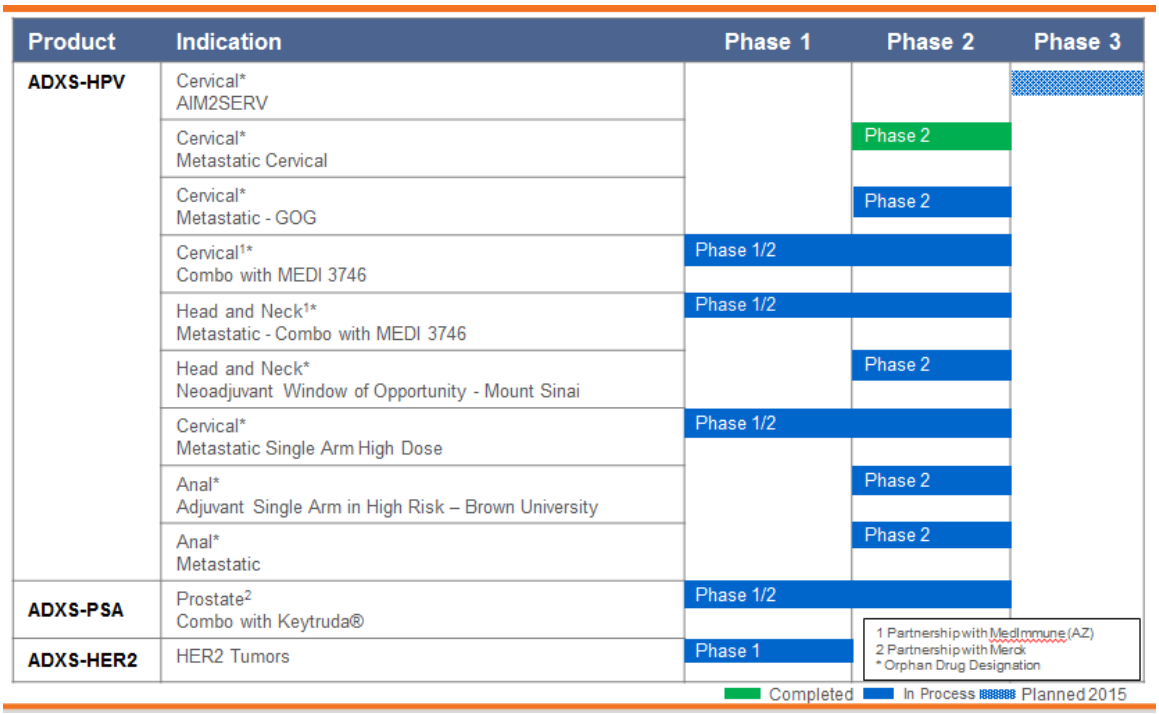
Our Takeaways from the Presentations

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 presented at AACR 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.



We Raise Our Price Target to $30

We maintain our Outperform rating for ADXS and raise our 12-month price target to $30.00 per share from previous $18.00 per share 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 2015. 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.

The collaborations with Merck and MedImmune may lead to license deals.

We look forward to the announcement of initiation of the pivotal Phase III trials of ADXS-HPV for recurring cervical cancer in 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. The Company plans to initiate two clinical programs of ADXS-cHER2 targeting breast cancer and pediatric osteosarcoma respectively. A Phase I/II trial of ADXS-PSA is also planned for the treatment of prostate 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 relatively strong. In Feb, 2015, Advaxis closed an equity financing with several institutional investors for gross proceeds of approximately $23.0 million in a registered direct offering of approximately 3.1 million shares at a price of $7.50 per share.

As of Jan 31, 2015, Advaxis held $30.6 million in cash. With the new financing, we estimate the company currently holds cash of approximately $50 million, which could last into the end of 2016 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 $22 per share which values the Company at about $600 million in market cap based on 27 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 $100 million in 2020 with earnings per share of $1.36. Using a relative valuation model, we come up with the value for HPV cervical cancer of $19.00 per share by using 45 x P/E multiple and discounted at 20% for 5 years. Adding the value of $11 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 $810 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 cash balance and 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	$75.00	$100.00
R&D revenue	$0.00	$1.00	$0.00	$0.00	$0.00	$0.00	$0.00	$3.00	$4.50	$5.50	$7.50	$7.50
Total Revenues	**$0.00**	**$1.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$3.00**	**$9.50**	**$35.50**	**$82.50**	**$107.50**
YOY Growth	-	-	-	-	-	-	-	-	*316.7%*	*373.7%*	*232.4%*	*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**	**$1.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$3.00**	**$8.75**	**$31.00**	**$71.25**	**$92.50**
Gross Margin	-	*100.0%*	-	-	-	-	-	*100.0%*	*92.1%*	*87.3%*	*86.4%*	*86.0%*
R&D	$5.62	$8.69	$3.58	$3.70	$3.90	$4.00	$15.18	$16.50	$17.50	$19.00	$22.50	$24.00
% R&D	-	*868.7%*	-	-	-	-	-	*550.0%*	*184.2%*	*53.5%*	*27.3%*	*22.3%*
SG&A	$9.07	$11.85	$3.20	$3.20	$3.20	$3.30	$12.90	$13.50	$14.50	$17.00	$20.00	$22.50
% SG&A	-	*1185.1%*	-	-	-	-	-	*450.0%*	*152.6%*	*47.9%*	*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)**	**($19.5)**	**($6.8)**	**($6.9)**	**($7.1)**	**($7.3)**	**($28.1)**	**($27.0)**	**($23.3)**	**($5.0)**	**$28.8**	**$46.0**
Operating Margin	-	-	-	-	-	-	-	-	-	*-14.1%*	*34.8%*	*42.8%*
Other Net	($6.6)	$0.7	($0.3)	$0.0	$0.0	$0.0	($0.3)	($1.0)	($1.0)	($1.0)	($1.0)	($1.0)
Pre-Tax Income	**($21.3)**	**($18.9)**	**($7.0)**	**($6.9)**	**($7.1)**	**($7.3)**	**($28.3)**	**($28.0)**	**($24.3)**	**($6.0)**	**$27.8**	**$45.0**
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)**	**($6.9)**	**($7.1)**	**($7.3)**	**($28.3)**	**($28.0)**	**($24.3)**	**($6.0)**	**$27.8**	**$45.0**
YOY Growth	-	-	-	-	-	-	-	-	-	-	*-562.5%*	*62.2%*
Net Margin	-	-	-	-	-	-	-	-	-	*-16.9%*	*33.6%*	*41.9%*
Shares Out	*5.0*	*17.1*	*21.6*	*27.0*	*27.0*	*27.0*	*25.6*	*28.0*	*29.0*	*30.0*	*31.0*	*33.0*
Reported EPS	**($4.10)**	**($0.97)**	**($0.33)**	**($0.26)**	**($0.26)**	**($0.27)**	**($1.11)**	**($1.00)**	**($0.84)**	**($0.20)**	**$0.90**	**$1.36**
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)**	**($6.9)**	**($7.1)**	**($7.3)**	**($28.3)**	**($28.0)**	**($24.3)**	**($6.0)**	**$27.8**	**$45.0**
Non GAAP EPS	**($3.30)**	**($0.97)**	**($0.33)**	**($0.26)**	**($0.26)**	**($0.27)**	**($1.11)**	**($1.00)**	**($0.84)**	**($0.20)**	**$0.90**	**$1.36**

Source: Company filing and Zacks Investment Research estimates

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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.