Zacks Small-Cap Research

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Advaxis Inc. (ADXS-NASDAQ)

ADXS: Multiple collaborations may lead to license deals; Pivotal Phase III planned, 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 (09/05/14)	$3.99
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 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	**$7.96**
52-Week Low	**$2.51**
One-Year Return (%)	**7.01**
Beta	**1.26**
Average Daily Volume (sh)	**486,279**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$79**
Short Interest Ratio (days)	**4.86**
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 A	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	-$0.16 A	-$0.25 E	-$0.20 E	-$0.97 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

- **Two collaborations may lead to license deals;**
- **ADXS-cHER2 may bring revenue to ADXS in 12 months;**
- **Higher dose of ADXS-HPV in Phase I/II trial initiated;**
- **Ready to move ADXS-HPV to pivotal trial at end of 2014;**
- **Balance sheet remains strong;**
- **Shares are undervalued;**

Multiple Collaborations Could Lead to Big License Deals

The Merck Collaboration

On August 25, 2014, Advaxis entered into a clinical trial collaboration agreement with Merck. The collaboration will evaluate the combination of Advaxis's ADXS-PSA, with Merck's investigational anti PD-1 antibody, pembrolizumab.

Under the terms of the agreement, Advaxis and Merck will collaborate to evaluate the ADXS-PSA/pembrolizumab combination in a **Phase I/II** study of patients with previously treated metastatic, castration-resistant prostate cancer. The Phase I part of the trial will establish a recommended dose regimen for ADXS-PSA alone and combined with pembrolizumab, and the Phase II portion will assess the safety and efficacy of the combination. Advaxis will sponsor and fund the study and Merck will provide pembrolizumab. The companies will collaboratively oversee the conduct of the study, which is planned to begin in **early 2015**. Results from the study will be used to determine the path for further clinical development of the combination.

According to management, if the combination of drugs shows an added effect, the companies would likely continue their collaboration, which, in our view, could lead to a license opportunity for ADXS.

Initially, Advaxis will cover the cost of the planned studies. However, if the collaboration continues it could lead to a licensing agreement between the two companies.

ADXS-PSA is bioengineered *Listeria* that initiates an immune response to PSA, a protein commonly elevated in men with prostate cancer. Pembrolizumab is PD-1 inhibitor that helps boost the immune system in response to cancer and has shown promise in melanoma and other cancers. The combination of ADXS-PSA and pembrolizumab may prove to more effectively initiate a therapeutic immune response to prostate cancer rather using either agent alone.

The MedImmune Collaboration

On July 22, 2014, Advaxis and MedImmune, which is the global biologics research and development arm of AstraZeneca, entered into an agreement to collaborate on a combination **clinical trial.**

Pursuing to the agreement, the two companies will collaborate to conduct a **Phase I/II** clinical trial to evaluate the safety and efficacy of MedImmune's **MEDI4736**, an investigational anti-PD-L1 immune checkpoint inhibitor, in combination with Advaxis' **ADXS-HPV**, as a treatment for patients with advanced, recurrent or refractory human papillomavirus (HPV)-associated **cervical cancer** and HPV-associated **head and neck cancer**.

Both MEDI4736 and ADXS-HPV are cancer immunotherapies, but have different mechanism of action. MEDI4736 is a check point inhibitor designed to counter the tumour's immune-evading tactics by blocking

a signal that helps tumours avoid detection. ADXS-HPV uses live, attenuated bioengineered *Listeria monocytogenes* and enhances the ability of immune cells to combat the tumour.

Preclinical studies have shown that the combination of ADXS-HPV with MEDI4736 can enhance overall anti-tumor response.

Under the terms of the agreement, MedImmune and Advaxis will evaluate the combination as a treatment for HPV-associated **cervical cancer** and squamous cell carcinoma of the **head and neck**. The **Phase I** portion of the trial is expected to establish a recommended dose regimen of MEDI4736 with ADXS-HPV, and the **Phase II** portion will assess the safety and efficacy of the combination. Under the terms of the deal, Advaxis will conduct and control the study and MedImmune will supply MEDI4736. Since the cost of this PDL-1 is extremely expensive, the free supply of MED14736 will save cash for Advaxis.

Positive Results from the Combination Studies Could Lead to Big License Deals for Advaxis

According to the two agreements, results from the combination Phase I/II studes will be used to determine whether further clinical development of the combinations is warranted.

Under the terms of the MedImmune deal, MedImmune has a non-exclusive relationship with respect to HPV-driven tumour types. MedImmune has **first right of negotiation** for future development of combinations involving MEDI4736 and ADXS-HPV.

Our takeaways from the two collaborations:

- This is the first time a PD-L1 checkpoint inhibitor will be used with ADXS-HPV, a new class of immunotherapies;

- Since checkpoint inhibitors are the most promising immunotherapy agents for cancer treatment, the combination of a PD-L1 inhibitor and ADXS-HPV will give Advaxis competitive advantage to get into the future PD-L1 market;

- Positive results from the Phase I/II studies could lead to big license deals for Advaxis;

ADXS-cHER2 Could Bring Revenue to ADXS in As early as in 12 months

On July 2, 2014, Advaxis filed a product license from the United States Department of Agriculture (USDA) for ADXS-cHER2 for the treatment of **canine osteosarcoma** and other HER2-overexpressing cancers.

The filing was submitted by Aratana Therapeutics, Inc., which was granted exclusive worldwide rights by Advaxis to develop and commercialize ADXS-cHER2 in animals. The companies expect a response from the USDA in the next 12 to 18 months.

Studies presented at the American College of Veterinary Internal Medicine (ACVIM) Forum by **Dr. Mason** from University of Pennsylvania have shown that ADXS-cHER2 may be able to delay or prevent metastatic disease and prolong overall survival in dogs with osteosarcoma that had minimal residual disease following standard of care (amputation and follow-up chemotherapy). At the time of the presentation, 80% of the dogs treated (n=15) were still alive and median survival had not yet been reached; median survival in case-matched control dogs (n=13) was 316 days. Currently, immunological analyses are underway for this study, and Dr. Mason is conducting a second study evaluating ADXS-cHER2 combined with radiation therapy for dogs with primary osteosarcoma that cannot undergo amputation.

With the positive data, we think it's likely that the USAD will approve ADXS-cHER2 for canine osteosarcoma, which could generate revenue for ADXS in about 12-18 months.

Higher Dose and Repeat Cycles of ADXS-HPV in Phase I/II Cervical Cancer Trial

On June 16, 2014, Advaxis, Inc. announced that the Georgia Regents University (GRU) Cancer Center has received Institutional will initiate a **Phase I/II** trial evaluating higher doses and repeat cycles of ADXS-HPV in patients with recurrent **cervical cancer**.

Advaxis's earlier Phase II clinical study in 110 women with recurrent cervical cancer had already demonstrated that a single cycle (3 doses) of ADXS-HPV at a dose of $1x10^9$ colony forming units (CFU) is well-tolerated with complete and partial tumor responses as well as an apparent survival benefit.

This Phase I/II study is designed to evaluate the safety, efficacy and immunological effect of the highest-tolerated dose of ADXS-HPV administered in repeat cycles of treatment to patients with cervical cancer whose disease recurred after receiving one prior cytotoxic treatment regimen. Higher doses, equivalent to **$1x10^{10}$ CFU**, along with multiple cycles of treatment have been administered to pet dogs with naturally occurring canine osteosarcoma and preliminary results from the on-going clinical trial show statistically significant overall survival with only minor side effects. In addition, laboratory experiments clearly show improved activity against cancer when ADXS-HPV is given at higher doses and in repeat cycles of treatment. Advaxis believes that repeat cycles of treatment at higher doses may further improve the positive clinical benefits already observed in its prior Phase II study.

This high-dose Phase I/II clinical study will run in parallel with the planned pivotal Phase III registration program for ADXS-HPV in patients with cervical cancer.

This Phase I/II study will advance in two phases, starting with the highest ADXS-HPV dose and reducing the dose only if dose limited toxicities (DLT) occur in a specified number of patients. All patients will be divided into cohorts of three each. The phase I portion of the study will enroll 3 to 12 patients based on observed adverse events and/or observation of DLT within the dose cohorts. The phase II portion of the study will enroll 31 patients to have sufficient power to detect a 1.5-month increase in progression free survival (PFS). In addition to PFS and tumor response, the study will measure immunological effects in the blood, specifically on peripheral blood mononuclear cells (PBMCs) and serum for the presence of specific activated T cells and for cytokines, chemokines and other potential markers. Exploratory studies will be to assess biomarkers, gene expression, and the potentially the immunologic tumor microenvironment for infiltration of cancer fighting T cells and the reduction of tumor protecting Tregs and MDSCs.

Phase III Trials of ADXS-HPV for Cervical Cancer is Planned

With the input from the FDA, Advaxis plans to initiate the **Phase III** trial of ADXS-HPV for **cervical cancer at the end of this year**.

Currently, the Company is talking to potential principal investigators and is preparing the Phase III protocols and will submit a SPA to the FDA. **Two Phase III** trials will be conducted according to management.

With **cash balance of $27.6 million** as of April 30, 2014, as well as data input from its Asian partners, the Company has enough cash to conduct the Phase III trials on its own. But we guess the Company still needs a commercial partner for the launch of this product considering its lack of experience and infrastructure for commercialization.

ADXS-HPV for cervical cancer is the Company's current focus. This program is granted **Orphan Drug Designation** for the treatment of Stage II-IV invasive cervical cancer.

Advaxis Presents New Survival Data at ASCO

The decision to initiate the Phase III trials is based on encouraging data from the completed **Phase II** trial of ADXS-HPV for cervical cancer.

ADXS initiated the **Phase II** study in November 2010 in India in 110 Patients with **recurrent or refractory cervical cancer**. 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**.

On May 31, 2014, Advaxis presented final results from the **Phase II** clinical study of ADXS-HPV in women with **recurrent cervical cancer** at the 2014 American Society of Clinical Oncology (ASCO) Annual Meeting.

Of the 109 patients treated in the study, long-term survivors (LTS) not only included patients with tumor shrinkage but also included patients who experienced increased tumor burden as their best tumor response overall. 17% (19/109) of the patients in the trial had recurrence of disease after at least two prior treatments for their cervical cancer; these patients comprised 8% (2/24) of LTS. Among the LTS, 25% (3/11) of patients had an ECOG performance status of 2, a patient population that is often times excluded from clinical trials because of their poor survival.

The poster presentation provided the final audited data which showed that, **32%** (35/109) of patients survived 12-months, **22%** (24/109) of patients survived 18-months, and **18%** (16/91) of patients were alive for more than 24 months, despite the poor prognosis of this patient population. The tumor response rate was 11% (including complete responses and partial responses) with a median duration of response of 9.5 months. A disease control rate (≥ three months) was observed in 38% (42/109) of patients. The addition of cisplatin chemotherapy did not improve either survival or tumor response over monotherapy with ADXS-HPV.

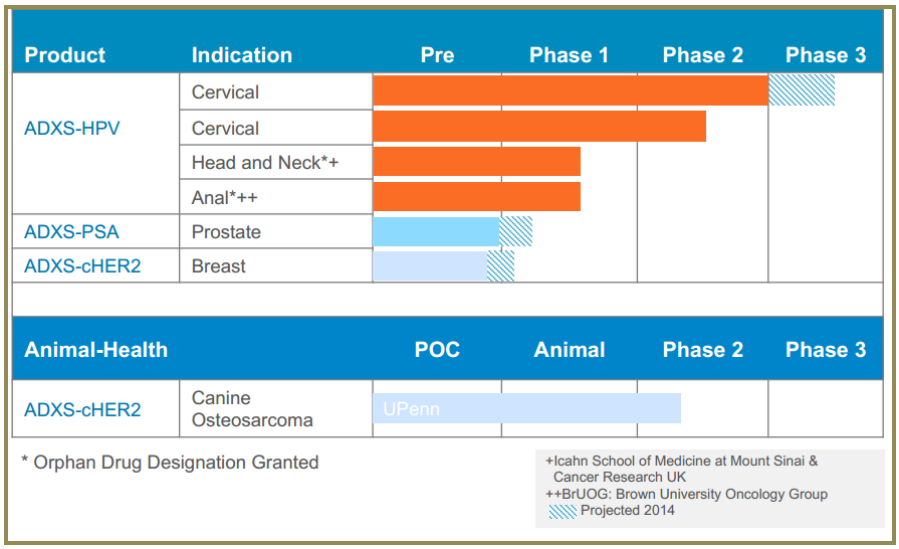
ADXS-HPV was well tolerated as 62% (68/109) of patients reported no adverse events and 38% (41/109) of patients reported mild transient adverse events (Grade 1 or 2) that occurred on the day of infusion. One patient experienced a serious adverse event which was reported as a Grade 3 fever.

		Treatment Group	
Patients at Risk, n (%)*	Overall (N=109)	ADXS11-001 ALONE (N=55)	ADXS11-001 + CISPLATIN (N=54)
12 Months			
n	109	55	54
% alive (#)	32% (35)	29% (16)	35 % (19)
18 Months			
n	109	55	54
% alive (#)	22% (24)	22% (12)	22% (12)
24 Months (Preliminary)			
n	96		
% alive (#)	18% (16/91)	8% (7/91)	10% (9/91)

The primary endpoint of OS is calculated from the efficacy population-survival-follow-up of 109 and is defined as all patients who had been treated with at least one dose of ADXS11-001

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.

Long-term survivors (LTS) in recurrent cervical cancer are rare. ADXS-HPV seems to be the first immunotherapy to be associated with objective tumor responses and also with long-term survival. The LTS included patients with poor performance status, those who had progressed after combination chemotherapy in the recurrent setting, and several patients whose best tumor response was progressive disease during the trial. To achieve these results from a single cycle of an immunotherapy in patients with poor prognoses is remarkable and supports further development.



Advaxis Shares are Undervalued

We maintain our Outperform rating for ADXS and reiterate our 12-month price target of $10.00 per share.

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 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 by the end of this year.

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, 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. The Company plans to initiate two clinical programs of ADXS-cHER2 targeting breast cancer and pediatric osteosarcoma respectively.

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. The Company plans to initiate two clinical programs of ADXS-cHER2 targeting pediatric osteosarcoma and breast cancer respectively.

In terms of valuation, we think Advaxis is undervalued in our view. Currently, the Company shares are trading at about $3.47 per share which values the Company at about $66 million in market cap based on 19 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 $190 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.

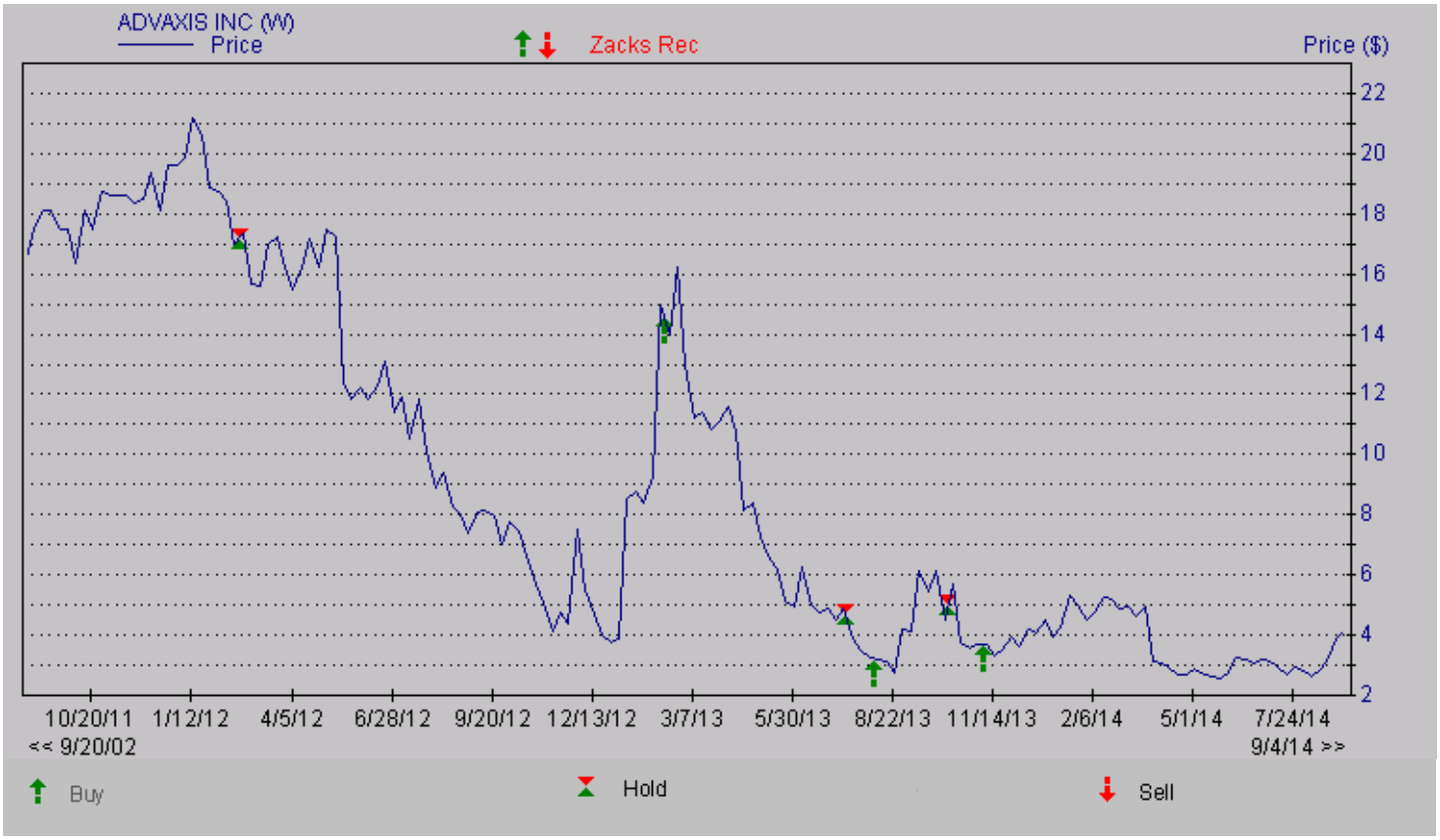
PROJECTED INCOME STATEMENT

	2013A (Oct)	2014E (Oct)					2015E (Oct)	2016E (Oct)	2017E (Oct)	2018E (Oct)	2019E (Oct)	2020E (Oct)
$ in million except per share data	FYA	Q1A	Q2A	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	$1.54	$1.75	$2.50	$7.35	$12.00	$14.50	$16.50	$19.00	$22.50	$24.00
% R&D	-	-	-	-	*125.0%*	*245.2%*	*266.7%*	*290.0%*	*157.1%*	*50.7%*	*27.3%*	*22.3%*
SG&A	$9.07	$4.40	$2.05	$2.75	$3.00	$12.20	$11.50	$12.50	$14.50	$17.00	$20.00	$22.50
% SG&A	-	-	-	-	*150.0%*	*406.6%*	*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)**	**($2.6)**	**($4.5)**	**($3.5)**	**($16.6)**	**($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	$0.0	($0.3)	($0.3)	($0.3)	($1.0)	($1.0)	($1.0)	($1.0)	($1.0)	($1.0)
Pre-Tax Income	**($21.3)**	**($5.8)**	**($2.6)**	**($4.8)**	**($3.8)**	**($16.9)**	**($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)**	**($2.6)**	**($4.8)**	**($3.8)**	**($16.3)**	**($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*	*15.7*	*18.7*	*19.1*	*16.8*	*20.0*	*22.0*	*25.0*	*27.5*	*30.0*	*32.0*
Reported EPS	**($4.10)**	**($0.37)**	**($0.16)**	**($0.25)**	**($0.20)**	**($0.97)**	**($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)**	**($2.6)**	**($4.8)**	**($3.8)**	**($16.3)**	**($20.0)**	**($23.0)**	**($22.3)**	**($4.0)**	**$23.3**	**$40.5**
Non GAAP EPS	**($3.30)**	**($0.37)**	**($0.16)**	**($0.25)**	**($0.20)**	**($0.97)**	**($1.00)**	**($1.05)**	**($0.89)**	**($0.15)**	**$0.78**	**$1.27**

Source: Company filing and Zacks Investment Research estimates

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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.