Zacks Small-Cap Research

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Immunovaccine Inc. (V.IMV)

IMV: Positive results reported for multiple candidates, on track to advance clinical programs-- Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	07/09/2012
Current Price (01/22/2012)	$0.35
Twelve- Month Target Price	**$0.75**

OUTLOOK

Immunovaccine Inc. (IMV) is a clinical stage biotech company focused on the development of its DepoVax™ vaccine adjuvanting platform technology. DepoVax is a unique vaccine delivery technology with very broad application and many advantages over existing vaccine technologies including long lasting and improved immune response.

IMV has built a diversified pipeline with candidates for multiple cancers and several infectious disease vaccines. Both DPX-0907 and DPX-Survivac generated positive Phase I results. Phase II is planned for DPX-Survivac.

We rate the Company shares as Outperform based on its fundamentals.

SUMMARY DATA

52-Week High	**$0.62**
52-Week Low	**$0.27**
One-Year Return (%)	**N/A**
Beta	**4.06**
Average Daily Volume (sh)	**40,000**
Shares Outstanding (mil)	**64**
Market Capitalization ($mil)	**$22**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**7.3**
Insider Ownership (%)	**4.4**
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 2012 Estimate	**N/A**
P/E using 2013 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Blend**
Industry	**Med-Biomed/Gene**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2012	0.00 A	0.00 A	0.00 A	0.00 E	0.00 E
2013					0.00 E
2014					2.00 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.03 A	-$0.04 A	-$0.03 A	-$0.03 A	-$0.13 A
2012	-$0.02 A	-$0.03 A	-$0.03 A	-$0.03 E	-$0.11 E
2013					-$0.11 E
2014					-$0.09 E

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

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WHAT'S NEW

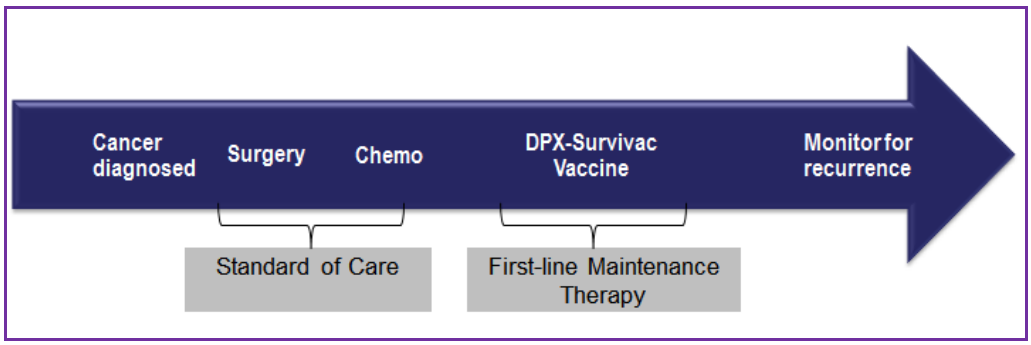
Positive Results Reported for DPX-Survivac in Phase I Ovarian Cancer Study

On January 7, 2013, Immunovaccine Inc. (TSX-V: IMV) reported positive results from a **Phase I** clinical study of the Company's cancer vaccine, DPX-Survivac, for the treatment of **ovarian cancer**.

As a reminder, Immunovaccine initiated a **Phase I** clinical trial of DPX-Survivac and vaccinated the first patient in December 2011. The Phase I clinical trial is being conducted in eight clinical sites in the US and Canada. The Phase I is an open label clinical trial designed to evaluate sequentially the safety of two DPX-Survivac dosing regimens (0.5 ml and 0.1 ml) **in approximately 15 patients**. The goal of the Phase I clinical trial is to establish the safety and immune activity of DPX-Survivac in patients with **advanced ovarian cancer**.

Under the study protocol, these patients each received a total of three DPX-Survivac vaccinations three weeks apart with a total of 18 ovarian cancer patients completing all three vaccinations. A lead-in cohort of three patients received DPX-Survivac alone to confirm the safety of the vaccine as a monotherapy. Two additional cohorts of six patients each received a low dose or a high dose of DPX-Survivac in combination with a low dose of cyclophosphamide. The trial's **primary objective** was to evaluate the safety of the vaccine and in combination with cyclophosphamide. A secondary endpoint was the evaluation of the immune response produced by the vaccine therapy.

IMV intends to use DPX-Survivac **alone or in combination with low dose oral cyclophosphamide** as a **first line maintenance therapy** following standard surgery/ radiation/ chemotherapy. The therapeutic cancer vaccine is intended to stimulate an immune response to attack the circulating cancer cells that remain in a patient's body after surgery and radiation/chemotherapy. This treatment approach has the potential to combat micro-metastases and keep the cancer in remission and prevent metastasis.



On October 9, 2012, IMV announced **positive interim results** from this **Phase I** clinical trial.

Current analysis, which now includes all patients enrolled in the study, confirmed previously reported results and uncovered **new findings** which are highlighted as follows:

- All patients receiving the DPX-Survivac combination therapy who were evaluable by tetramer staining (n=10) produced survivin-specific CD8 T cells following one or two vaccinations. Importantly the CD8 responses were maintained with booster vaccinations. The activation and maintenance of these specific immune cells is of particular interest in immunotherapy since CD8 T cells are implicated in identifying cancer cells, infiltrating tumors and killing cancer targets.

- All patients receiving the DPX-Survivac combination therapy (n=12) demonstrated antigen specific immune responses as measured by at least one of the study's three immune monitoring

assays (ELISpot, tetramer analysis and multiparametric intracellular cell staining). In 11 of 12 patients, the immune responses were confirmed by two assays (five patients) or three assays (six patients) performed. These immune responses were established with one or two vaccinations and further increased or maintained with follow-up booster vaccinations.

- Analysis of immune responses by ELISpot showed that a cohort of patients receiving the higher dose of the vaccine therapy produced an average stimulation factor of greater than 600 times (600x) over baseline following their third vaccination. For one of these patients, the stimulation factor reached greater than 1,200 times (1,200x) over baseline. These immune responses are in agreement with the previously reported average increase of 350 times (350x) over baseline for these same patients following their second vaccination.

- DPX-Survivac was deemed well tolerated with no significant systemic adverse events reported in any patients recruited in this study. Reported adverse events were restricted to injection site reactions, which were experienced by the majority of patients after repeated vaccinations. Those patients presenting the strongest immune responses were more likely to exhibit more pronounced injection site reactions. There were no dose limiting toxicities experienced during the trial and no patient withdrew consent due to adverse events.

The Phase I study is part of a **Phase I/II** trial cleared by the U.S. FDA and Health Canada. The Phase II portion of the trial will be a randomized, double-blinded, placebo-controlled study with a vaccine dose selected based on the Phase I results. The Phase II trial will assess the clinical benefit of DPX-Survivac in patients with advanced ovarian cancer.

We are encouraged by the positive data from this Phase I study. The positive data continue to demonstrate that IMV's technology can speed up immune responses and make them stronger and longer lasting, for a wide range of vaccines. We have seen positive results from IMV's candidates whether in cancer immunotherapy or in protection against infectious disease.

Phase II Trial of DPX-Survivac is on Schedule

Based on existing clinical data, Immunovaccine has already received clearance from U.S. FDA and Health Canada for the initiation of a Phase II trial of DPX-Survivac immediately following the completion of the ongoing Phase I study.

The **Phase II** trial will be a randomized, double-blinded, placebo-controlled study with a single vaccine dose selected based on the Phase I results. The Phase II trial will assess the clinical benefit of DPX-Survivac in patients with advanced ovarian cancer.

Phase I/II Clinical Design Cleared by US FDA and Health Canada	
Phase 1	**Phase 2**
Dose-finding Safety Study	Safety and Efficacy Study
Non-randomized	2:1 Randomized
Open Label	Double Blinded
Uncontrolled	Placebo Controlled
Primary endpoint: safety	Primary endpoint: Progression Free Survival
15 subjects	250 Subjects
9 USA & 2 Canadian Centers	Approx. 75 USA & 5 Canadian Centers
0.1 and 0.5 mL DPX-Survivac	Best dose DPX-Survivac
+/- immune modulation (cyclophosphamide)	+ immune modulation (cyclophosphamide)
9 weeks of Treatment	57 weeks of Treatment
Last follow up at 6 months	Last follow up at 18 months

Positive Results Reported from Ongoing Study of DepoVax-Based Anthrax Vaccines

On January 3, 2013, IMV announced positive results from an immunogenicity study that evaluated **anthrax vaccines** formulated in the Company's DepoVax™ platform. This study is part of an ongoing bio-defense research program which was initiated in February 2012 to utilize Immunovaccine's DepoVax™ adjuvanting technology in advancing the development of next generation vaccines against the most threatening biological agents.

The study, which was conducted under the National Institute of Allergy and Infectious Diseases' (NIAID) Preclinical Services Program, was designed to test multiple DepoVax-formulated anthrax vaccines in non-human primates, specifically examining immunogenicity and safety after either one or two doses of the vaccine. Study investigators compared the DepoVax-based vaccines to **BioThrax**, the only commercially available anthrax vaccine. BioThrax requires at least two doses to produce immune responses in animal models.

Below are summary for preliminary study findings:

- A single dose of DepoVax-formulated anthrax vaccine produced sustained TNA (toxin-neutralizing antibody) titers detected in six of ten animals starting between day 21 and 49. Animals receiving one dose of Biothrax had no detectable TNA titers.

- When a second dose of the DepoVax-formulated vaccine was delivered, there was a significant increase in anthrax TNAs in all immunized animals within one week of the booster administration.

- Vaccination with the DepoVax-formulated vaccines resulted in no visible injection site reactions. Detailed microscopic examination showed robust immune cell infiltration to the site of vaccination. There was no evidence of systemic or local safety issues.

The positive results from this immunogenicity study are consistent with previous research conducted by Immunovaccine that demonstrated a DepoVax-based vaccine was able to raise higher antibody levels, as compared to two doses of alum-adjuvanted control vaccines. The persisting high antibody levels were induced within four weeks following a single dose of anthrax antigen formulated within DepoVax.

We are impressed with the preliminary positive results. We are particularly encouraged by the findings that that DepoVax-formulated vaccines generate toxin neutralizing antibodies with one dose. These findings suggest the potential for DepoVax to enable the development of an effective and safe next generation anthrax vaccine.

More studies with NIAID Preclinical Services are planned to begin in early 2013. These will examine the ability of neutralizing antibody responses induced by a DepoVax-based vaccine to protect animals from challenge with anthrax.

DepoVax Cocaine Vaccine Shows Promise in Exploratory Study

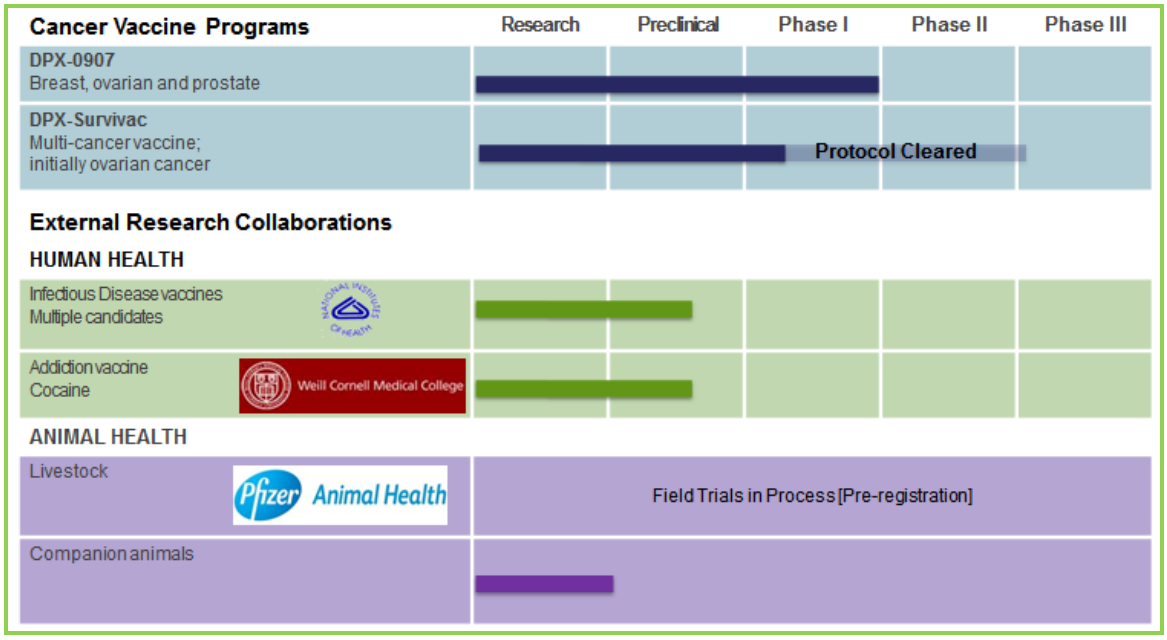
On October 24, 2012, Immunovaccine announced **positive results** from a preliminary study of an anti-**cocaine vaccine** in collaboration with Weill Cornell Medical College. The vaccine, which added Immunovaccine's DepoVax adjuvanting technology to Weill Cornell's novel anti-cocaine vaccine (dAd5GNE), was being evaluated in rodents for its ability to produce antibodies capable of blocking cocaine from being delivered to the brain in an effort to prevent its physiological effect.

The study showed that the **DepoVax-enhanced cocaine vaccine** produced high levels of target antibodies that were able to sequester cocaine in the blood of immunized mice and block its delivery to the brain.

Immunovaccine plans to build on this proof of concept work and is currently evaluating opportunities to further develop the program. Further potential studies would aim to confirm these results and explore the duration of immunity produced by the vaccine. The aim of this program is to develop an anti-cocaine vaccine that is able to effectively induce and maintain a sufficient immune response without requiring frequent immunizations.

In March 2012, Immunovaccine and Weill Cornell announced a research agreement to explore the company's DepoVax platform technology with a vaccine being developed for treating cocaine addiction. The project builds on earlier cocaine vaccine work, funded by the National Institute on Drug Abuse (NIDA) of the National Institutes of Health (NIH), at Weill Cornell. The goal of this particular study was to evaluate the ability DepoVax to trigger a strong immune response with Weill Cornell's dAd5GNE vaccine. There is a large market for cocaine vaccines. According to industry data, cocaine abuse is estimated to affect approximately 4.8 million Americans annually with an additional one million Americans using crack cocaine at least once each year. A safe and effective anti-cocaine vaccine has the potential to significantly address the healthcare and societal problem associated with cocaine abuse and addiction. There currently are no anti-cocaine vaccines approved by the FDA.

These positive findings have the potential to pave the way for a powerful and effective anti-cocaine vaccine that does not require frequent immunizations (a critical consideration for a treatment of this type). It is also important to note that there are currently no anti-cocaine vaccines approved for use so this represents a potentially first-of-its-kind vaccine development program.



VALUATION AND RECOMMENDATION

We maintain our Outperform rating on Immunovaccine (V-IMV). Our 12-month price target stays at $0.75 per share.

IMV has developed a unique vaccine delivery and adjuvanting platform DepoVax, which creates a unique depot that attracts antigen presenting cells to the injection site to potentially generate a rapid and robust

immune response. IMV's DepoVax platform holds many competitive advantages over existing vaccine delivery technologies.

Based on its DepoVax platform, Immunovaccine has built a diversified pipeline comprised of therapeutic cancer vaccines, and vaccines for infectious diseases and animal health. The Company has taken its platform technology and proprietary cancer vaccine into Phase I human trials and has demonstrated its safety and immunogenicity potential.

The Company is also capitalizing on the broad potential of its delivery platform by creating new DepoVax-based vaccines through multiple development collaborations.

In addition to the Company's human health vaccine strategy, it continues to capture value from animal health vaccine applications. The Company has several animal health partners including Pfizer Animal Health, which has licensed the Company's platform to develop vaccines for livestock. The Company will continue to monetize its DepoVax platform for application in both livestock and companion animals.

In terms of valuation, we think Immunovaccine shares are undervalued. Currently, the shares are trading at $0.35 per share, which values the Company at $22 million in market cap based on 64 million shares outstanding. This is a deep discount. As we discussed above, the Company's cancer vaccine candidate DPX-0907 has completed Phase I clinical studies, and another lead candidate DPX-Survivac will also enter into a Phase II clinical trial.

We think Immunovaccine shares should be trading at between $0.50 and $1.00 per share, which values the Company at between $28.5 and $57 million. Our price target of $0.75 corresponds to a market cap of $48 million, which we think is fair for Immunovaccine at this point.

But Keep in mind the Risks:

- **Cash burn concern:** As of September 30, 2012, IMV had $3.6 million in cash. Based on its monthly cash burn of $0.61 million per month, current cash can only last through 1Q2013. Further financing is needed.

- **Regulatory risk**: IMV's two lead cancer vaccine candidates are still in the early stage of clinical development, which poses higher risks. Any clinical failure could deny or delay the approval, and share price will suffer.

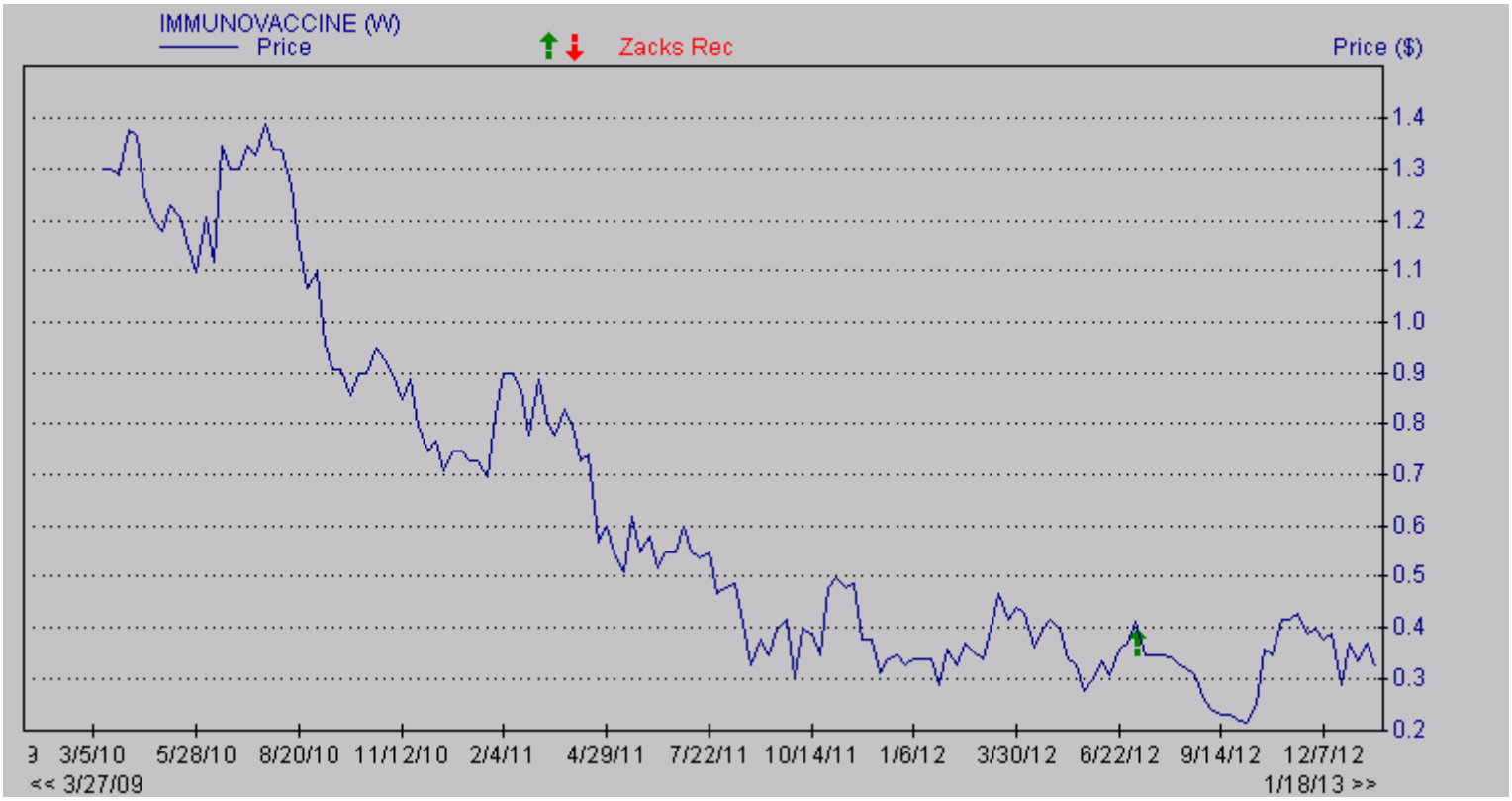
PROJECTED INCOME STATEMENT

		2011A (Dec)					2012E (Dec)					2013E (Dec)	2014E (Dec)	2015E (Dec)	2016E (Dec)
$ in million except per share data	FYA	Q1	Q2	Q3	Q4	FYA	Q1	Q2	Q3	Q4E	FYE	FYE	FYE	FYE	FYE
R&D and Contract revenue	$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	$0.00
License and Up-front revenue	$0.08	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$2.00	$5.00	$7.50
Product Sales	$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	$5.00
Total Revenues	**$0.08**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$2.00**	**$5.00**	**$12.50**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	*150.0%*	*150.0%*
CoGS	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	0.00
Gross Income	**$0.08**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$2.00**	**$5.00**	**$12.50**
Gross Margin	100%	-	-	-	-	-	-	-	-	-	-	-	-	*100.0%*	*100.0%*
R&D	$2.63	$1.24	$1.42	$0.97	$0.61	$4.24	$0.55	$0.78	$1.00	$1.00	$3.33	$4.00	$5.50	$7.00	$9.00
% SG&A		-	-	-	-	-	-	-	-	-	-	-	-	-	-
SG&A	$1.97	$0.34	$0.40	$0.34	$0.50	$1.58	$0.57	$0.47	$0.49	$0.60	$2.13	$2.60	$3.00	$3.80	$4.50
% R&D		-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other	$1.05	$0.26	$0.19	$0.16	$0.19	$0.80	$0.24	$0.33	$0.24	$0.24	$1.05	$1.00	$1.00	$1.00	$1.00
% Other		-	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	**($5.57)**	**($1.8)**	**($2.0)**	**($1.5)**	**($1.3)**	**($6.6)**	**($1.4)**	**($1.6)**	**($1.7)**	**($1.8)**	**($6.5)**	**($7.6)**	**($7.5)**	**($6.8)**	**($2.0)**
Operating Margin		-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	($0.1)	($0.0)	($0.0)	($0.0)	($0.1)	($0.2)	($0.0)	($0.0)	$0.0	($0.0)	($0.1)	($0.2)	($0.3)	($0.4)	($0.5)
Pre-Tax Income	**($5.65)**	**($1.9)**	**($2.0)**	**($1.5)**	**($1.4)**	**($6.8)**	**($1.4)**	**($1.6)**	**($1.7)**	**($1.9)**	**($6.6)**	**($7.8)**	**($7.8)**	**($7.2)**	**($2.5)**
Income taxes(benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate		*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($5.65)**	**($1.9)**	**($2.0)**	**($1.5)**	**($1.4)**	**($6.8)**	**($1.4)**	**($1.6)**	**($1.7)**	**($1.9)**	**($6.6)**	**($7.8)**	**($7.8)**	**($7.2)**	**($2.5)**
YOY Growth		-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin		-	-	-	-	-	-	-	-	-	-	-	-	-	-
Deluted Shares Out	*47.8*	*54.0*	*54.0*	*54.0*	*54.0*	*54.0*	*56.6*	*63.5*	*63.5*	*64.0*	*61.9*	*74.0*	*85.0*	*95.0*	*105.0*
Reported EPS	**($0.12)**	**($0.03)**	**($0.04)**	**($0.03)**	**($0.03)**	**($0.13)**	**($0.02)**	**($0.03)**	**($0.03)**	**($0.03)**	**($0.11)**	**($0.11)**	**($0.09)**	**($0.08)**	**($0.02)**
YOY Growth		-	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	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*	*0.00*
Non GAAP Net Income	**($5.65)**	**($1.9)**	**($2.0)**	**($1.5)**	**($1.4)**	**($6.8)**	**($1.4)**	**($1.6)**	**($1.7)**	**($1.9)**	**($6.6)**	**($7.8)**	**($7.8)**	**($7.2)**	**($2.5)**
Non GAAP EPS	**($0.12)**	**($0.03)**	**($0.04)**	**($0.03)**	**($0.03)**	**($0.13)**	**($0.02)**	**($0.03)**	**($0.03)**	**($0.03)**	**($0.11)**	**($0.11)**	**($0.09)**	**($0.08)**	**($0.02)**

Source: Company filing and Zacks Investment Research

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HISTORICAL ZACKS RECOMMENDATIONS



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