Zacks Small-Cap Research

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Novelos Therapeutics, Inc. (NVLT-OTCQX)

NVLT: Initial clinical data for LIGHTare encouraging – Outperform.

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	04/15/2012
Current Price (08/16/12)	$1.05
Twelve- Month Target Price	**$2.50**

OUTLOOK

Novelos' platform technology includes three candidates with chemically identical core structure. The three candidates target cancer imaging (LIGHT), cancer radiotherapy (HOT) and cancer chemotherapy (COLD) markets respectively.

All three candidates specifically target cancer and cancer stem cells, which offers advantages over other cancer compounds such as selectivity and broad spectrum of cancer types.

Development risk for HOT is lower than other early stage candidates due to its unique chemical structure and mechanism of action. Current valuation is low and we initiate coverage with an Outperform.

SUMMARY DATA

52-Week High	**$2.00**
52-Week Low	**$0.37**
One-Year Return (%)	**-25.00**
Beta	**0.57**
Average Daily Volume (sh)	**25,278**
Shares Outstanding (mil)	**43**
Market Capitalization ($mil)	**$45**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**61.2**
Insider Ownership (%)	**35.6**
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 E	0.00 E	0.00 E
2013					0.00 E
2014					2.50 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.06 A	-$0.10 A	-$0.07 A	-$0.07 A	-$0.31 A
2012	-$0.06 A	-$0.06 A	-$0.06 E	-$0.06 E	-$0.24 E
2013					-$0.21 E
2014					-$0.17 E

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

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WHAT'S NEW

Novelos Reports Financials for the Second Fiscal Quarter of 2012

Novelos recently filed 10-Q with the SEC about its second quarter financial results ended June 30, 2012.

There was no revenue for the three months.

Research and development expense for the three months ended June 30, 2012 was approximately $1.3 million, which comprised of $167,000 in clinical project costs, $92,000 of preclinical project costs, $170,000 of manufacturing and related costs and $886,000 in general unallocated research and development costs compared to approximately $962,000 for the three months ended June 30, 2011.

General and administrative expense for the three months ended June 30, 2012 was approximately $897,000 compared to approximately $797,000 in the three months ended June 30, 2011. The approximately $100,000, or 13%, increase is related to an approximately $143,000 increase in stock-based compensation, an approximately $65,000 increase in salary and a $20,000 increase in accounting fees. These increases were partially offset by a decrease in legal fees.

Net loss was $2.6 million or $0.06 per share for the three month ended June 30, 2012.

As of June 30, 2012, cash was $7.2 million.

We think the financial report was a non-event for Novelos. Investors should be focused on the Company's clinical programs. In this regard, we think Novelos has made great progress during the second quarter of 2012.

Balance Sheet Boosted by Recent Financing

On June 14, 2012, Novelos Therapeutics, Inc. closed a public offering of 5,420,800 units at $1.00 per unit for gross proceeds of $5,420,800.

Each unit consisted of one share of common stock, a Class A Warrant with a five-year term to purchase one-half of a share of common stock at an exercise price of $1.25 per share and a Class B Warrant with a 90-day term to purchase one share of common stock at an exercise price of $1.00 per share.

While some investors view this financing as negative, we believe this financing will benefit the Company as well as its shareholders in the long term. We admit that this equity financing certainly dilutes existing shareholder base, but it provides necessary funds for advancing the development of the Company's two key programs LIGHT and HOT. With the new funds, the Company's balance sheet is boosted immediately.

As of June 30, 2012, cash was $7.2 million. Current cash balance can last into 1Q13 according to our model.

Initial Data from LIGHT Phase I/II Brain Cancer Trial Are Very Encouraging

On June 19, 2012, Novelos Therapeutics, Inc. (NVLT) announced that the University of Wisconsin Carbone Cancer Center (UWCCC) has successfully dosed three patients in a **Phase I/II** positron emission tomography (PET) imaging trial of I-124-CLR1404 (LIGHT), a cancer-targeted PET imaging agent, in patients with primary or metastatic **brain cancer**.

As a reminder, the investigator-sponsored **Phase I/II** trial of LIGHT as a PET imaging agent for **brain cancer** was initiated in December 2011 at UWCCC and first patient was enrolled on March 15, 2012. Lance Hall, M.D., is the trial's principal investigator. This trial is being funded by the UWCCC and the Institute for Clinical and Translational Research (ICTR). Up to 20 patients will be enrolled at a 5 mCi dose.

The three glioma patients were dosed with LIGHT at 5 mCi.

- LIGHT is well tolerated, and there are no adverse safety signals are observed.
- Strong and sustained uptake of LIGHT in cancerous tumors against very low background has been observed;
- Further, LIGHT's cancerous tumor to normal tissue uptake ratio exceeded 30:1 in one tumor, which compares favorably with PET agents that are generally considered good tumor biomarkers if tumor to normal tissue uptake ratios are in the range of 3:1 and 5:1.

Detailed trial results are expected to be presented at a scientific venue at a later date. Novelos expects final results to be available in 1Q13.

We think the preliminary results from these three brain cancer patients are very encouraging. The uptake is strong and cancer-specific with no safety signals. These results begin to establish proof-of-concept for LIGHT as a PET imaging agent for brain cancer, and could be used to calculate effective doses for Phase II clinical trials of I-131-CLR1404 (HOT) in this indication.

Initial LIGHT Data from Phase I/II NSCLC Trial Are also Encouraging

On April 24, 2012, Novelos Therapeutics, Inc. (NVLT) announced that the University of Wisconsin Carbone Cancer Center has successfully completed the first cohort in a Phase I/II PET imaging trial of I-124-CLR1404 (LIGHT), a cancer-targeted PET imaging agent, in patients with advanced **non-small cell lung cancer (NSCLC)**.

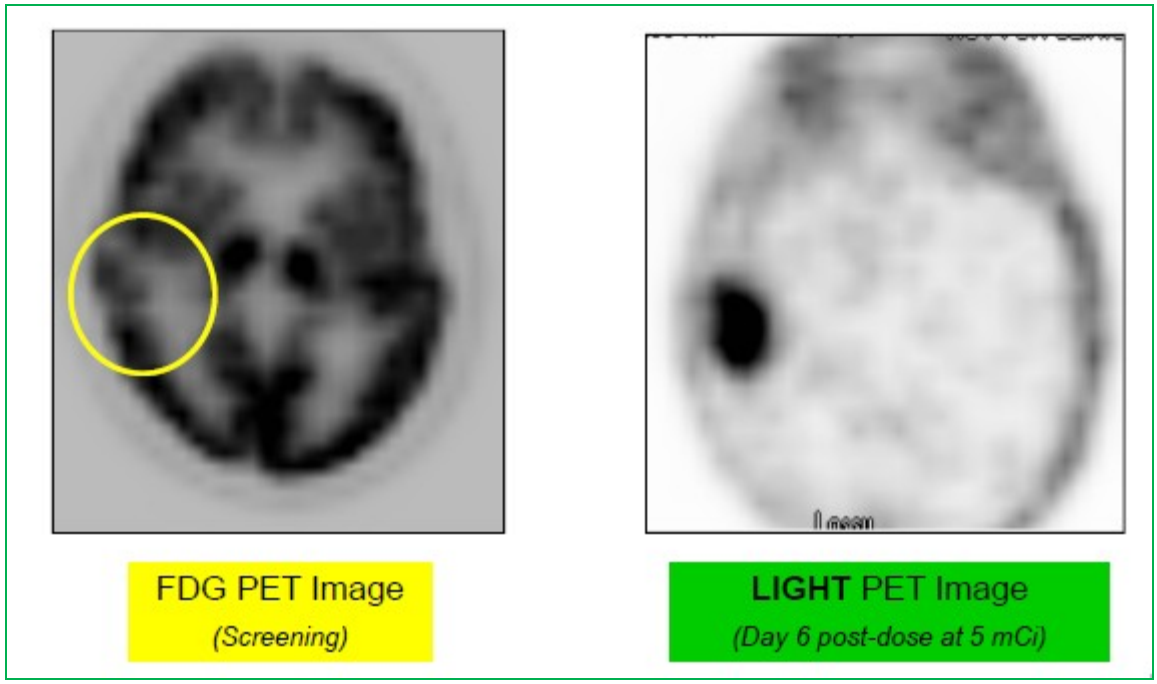
The fact:

As a reminder, an investigator-sponsored **Phase I/II** trial of LIGHT as a PET imaging agent for **lung cancer** was initiated in December 2011 at the University of Wisconsin Carbone Cancer Center (UWCCC) and first patient was enrolled in February 2012. Dr. Anne M. Traynor at UWCCC is the principal investigator. Novelos provides funding for the trial and the data is shared with Novelos while the study progresses and at the conclusion of the study. Up to 12 patients will be enrolled across two dose levels (3 mCi and 5 mCi) in this Phase I/II trial. The trial will be completed in 2012.

The first cohort comprised three patients dosed with LIGHT at 5 mCi. The first cohort has demonstrated positive initial imaging results. In fact, in one of NSCLC patients, LIGHT PET scan clearly identifies a brain metastasis that FDG missed.

- LIGHT is safe and there is no adverse safety signals;
- Strong selective uptake of LIGHT in cancerous tumors against very low background has been observed;
- LIGHT PET scan clearly identifies a brain metastasis that FDG missed in a NSCLC patient

Detailed trial results are expected to be presented at a scientific venue at a later date.



Novelos is now planning to evaluate the next dose level at 3mci in three patients as the Company seeks to identify a minimally effective dose.

Our takeaways from the initial data:

- The preliminary results from the first cohort are positive; the more tumor-selective advantage of LIGHT over FDG for one patient is especially encouraging;
- The excellent safety profile and strong efficacy data could accelerate the completion of the Phase I/II trial of LIGHT as a lung cancer PET imaging agent;
- These data begin to establish proof-of concept for LIGHT as a PET imaging agent for NSCLC; could advance Novelos' partnering discussions and could be used to calculate effective doses for Phase II clinical trials of I-131-CLR1404 (HOT);

First Cohort of HOT Phase Ib in Solid Tumor Completed

On May 15, 2012, Novelos Therapeutics, Inc. (NVLT) announced that it has successfully completed the first cohort in a U.S. multi-center **Phase Ib** dose-escalation trial of its cancer-targeted molecular radiotherapeutic compound I-131-CLR1404 **(HOT)** in cancer patients with advanced solid tumors.

The first two-patient cohort was successfully dosed with approximately 20 mCi of HOT, triggering enrollment into the second cohort at approximately 40 mCi. First patient has been enrolled in the second cohort, and additional results will be available in 3Q12.

Glenn Liu, M.D., University of Wisconsin Carbone Cancer Center, is the trial's principal investigator. Detailed trial results are expected to be presented at a scientific venue at a later date.

Based on animal data, results from a completed Phase Ia dosimetry trial, and now initial data from this Phase Ib trial, HOT appears to deliver radiation directly and selectively to cancerous tumors. Data from the first cohort indicates HOT was well-tolerated, without any grade 3 or 4 toxicities, enabling enrollment of the first patient in the second cohort. HOT uptake in cancerous tumors persisted for at least 21 days. One patient with advanced prostate cancer remains on trial at two months following treatment with HOT, while another patient with advanced colorectal cancer has completed the trial.

NVLT looks forward to adding two additional clinical investigators to the trial, Joanne Mortimer, M.D., at the City of Hope and Michael Pishvaian, M.D., Ph.D., at Georgetown University.

NVLT intends to combine the data from this trial with calculation of effective doses for HOT based on quantitative positron emission tomography (PET) tumor imaging data using I-124-CLR1404 (LIGHT), the Company's small-molecule cancer-targeted PET imaging agent. Together, these data will enable NVLT to commence HOT **Phase II** proof-of-concept trials in 1Q13 in cancer patients.

We are glad that NVLT is on track to advance its clinical programs. Current valuation for NVLT is low and represents an opportunity to get in at this time.

We are glad that NVLT is on track to advance its clinical programs. Current valuation still does not reflect the Company's fundamentals in our view. Current valuation for NVLT is low, and the risk/return profile is biased to return at this point.

VALUATION AND RECOMMENDATION

We maintain an Outperform rating on Novelos Therapeutics (NVLT) shares and reiterate our 12-month target price of $2.50 per share.

NVLT's platform technology is unique. All three candidates are generated from a single chemical structure that is the foundation of the technology platform. The three candidates target three sub-cancer markets: cancer imaging (LIGHT), cancer radiotherapy (HOT) and cancer chemotherapy (COLD).

The beauty of the Company's technology is that all three candidates specifically target cancer and cancer stem cells through interaction with **lipid rafts** which are enriched in cancer or cancer stem cells. The specific targeting of both cancer and cancer stem cells makes NVLT's HOT/COLD with the efficacy potential to target all three major drivers of mortality in cancer –**primary tumors**, **metastases** and stem cell-based **relapse**, which distinguishes HOT/COLD from all other cancer therapy modalities.
All three candidates have demonstrated excellent safety profile and efficacy in preclinical trials including animal models. The Company has moved LIGHT and HOT into the clinic with both in Phase I/II clinical trials. Preliminary data from the clinical trials have also shown excellent safety profile and efficacy activity for both LIGHT and HOT, which is in line with preclinical results.

Both LIGHT and HOT have competitive advantages over their respective competitors. LIGHT has the potential to become the new standard of care for cancer PET imaging due to its selectivity for cancer/cancer stem cells over FDG, current standard of care for cancer PET imaging. LIGHT also has the advantage of delivery range due to its four-day half-life versus F-18 labeled FDG's 110 minutes half-life.

As a new systemic radiotherapy, HOT has the advantage over existing systemic radiotherapeutic Zevalin and Bexxar. The selective interaction with lipid rafts makes HOT a **broad spectrum** cancer targeting agent since lipid rafts are overexpressed in most of cancer and cancer stem cells. Selective uptake and retention of HOT in cancer stem cells compared with normal cells also offer the prospect of **longer lasting cancer remission**.

One more important feature for HOT investors should take into account is that **development risk is relatively less for HOT** than other early stage cancer therapeutics. HOT exploits a new cancer-selective delivery and retention mechanism, but is paired with a proven and effective radioisotope (I-131) for therapy. Because, to date, HOT has been shown to reliably and near-universally accumulate in cancer cells and because the therapeutic properties of the iodine-131 are well known, the risk of non-efficacy in human clinical trials is less than that of other cancer therapies at this stage of development. Furthermore,

LIGHT PET imaging data is expected to predict efficacy and enable calculation of efficacious doses of HOT for Phase II trials (i.e. LIGHT serves as an ideal and personalized biomarker for HOT). This is important for investors because less development risk means that HOT has a higher probability for success in clinical trials and regulatory approval. Therefore, downside risk is reduced while upside potential remains the same.

Although COLD is in preclinical development, the compound has the potential to become the best-in-class. COLD can be administered by IV versus oral, which will reduce the GI dosing limiting toxicity and increase efficacy due to better toleration at higher levels of drug exposure.

With all these in mind, we think Novelos is undervalued at current price. Currently, Novelos shares are trading at around $1.05 per share, which values the Company at $43 million in market cap, which is a deep discount to its peers. We understand that all the Company's programs are in early stage, cash burn will accelerate in the coming quarters when the Company advances all its three programs. However, we remind investors that both LIGHT and HOT have relatively low development risks compared to other similar cancer programs. We also remind investors that Novelos plans to find a partner for LIGHT after the Phase I/II trial, which could happen as early as in 2013. Such a deal will not only validate the Company's technology, but also will boost the Company's balance sheet with non-dilutive upfront, milestone and royalty.

We are aware of that most small biotech companies of development stage are valued from $50 million to $500 million depending on how advanced the pipeline is and which indications the company is targeting. We think Novelos should be valued between $80 and $150 million at this point. Our price target of $2.5 per share corresponds to a $108 million in market cap.

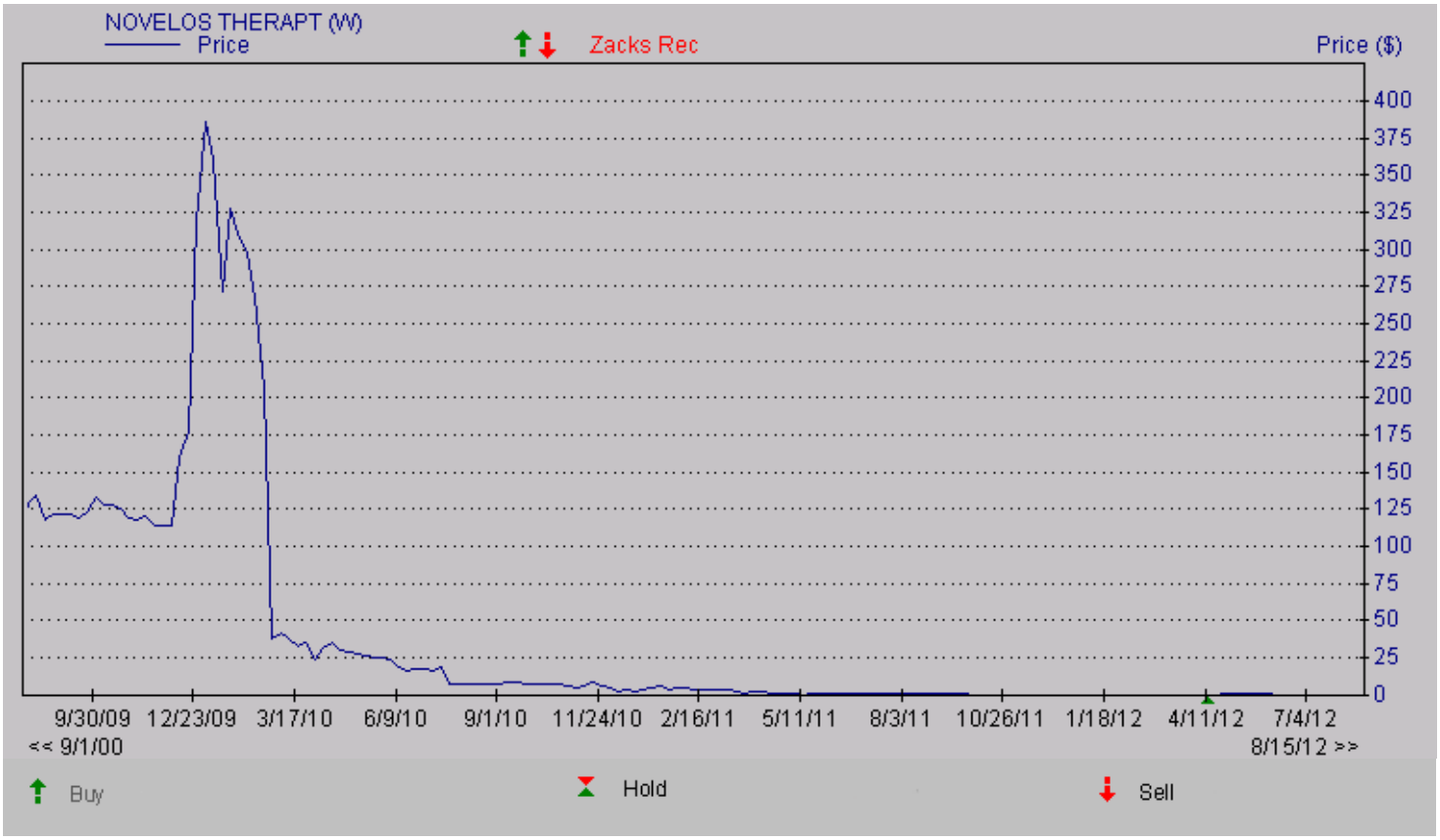
PROJECTED INCOME STATEMENT

	2011A (Dec)					2012E (Dec)					2013E (Dec)	2014E (Dec)	2015E (Dec)	2016E (Dec)
$ in million except per share data	Q1	Q2	Q3	Q4	FYA	Q1A	Q2A	Q3E	Q4E	FYE	FYE	FYE	FYE	FYE
licensing revenue	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$2.50	$5.00	$5.00
Product 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	$1.00	$3.50
Total Revenues	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$2.50**	**$6.00**	**$8.50**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	*#DIV/0!*	*140.0%*	*41.7%*
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
Gross Income	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$2.50**	**$6.00**	**$8.50**
Gross Margin	-	-	-	-	-	-	-	-	-	-	*#DIV/0!*	*100.0%*	*100.0%*	*100.0%*
R&D	$0.47	$0.96	$1.01	$1.16	$3.60	$1.33	$1.31	$1.40	$1.50	$5.54	$6.00	$7.00	$8.50	$10.00
% SG&A	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SG&A	$0.13	$0.80	$0.91	$0.86	$2.69	$1.00	$0.90	$1.05	$1.10	$4.04	$4.50	$5.00	$5.50	$6.50
% R&D	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other	$0.25	$0.50	$0.00	$0.00	$0.75	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
% Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	**($0.9)**	**($2.3)**	**($1.9)**	**($2.0)**	**($7.0)**	**($2.3)**	**($2.2)**	**($2.5)**	**($2.6)**	**($9.6)**	**($10.5)**	**($9.5)**	**($8.0)**	**($8.0)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	$0.1	($0.3)	$0.0	($0.2)	($0.4)	($0.0)	($0.0)	$0.0	$0.0	($0.1)	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	**($0.7)**	**($2.6)**	**($1.9)**	**($2.2)**	**($7.4)**	**($2.4)**	**($2.2)**	**($2.5)**	**($2.6)**	**($9.6)**	**($10.5)**	**($9.5)**	**($8.0)**	**($8.0)**
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
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%*	-
Reported Net Income	**($0.7)**	**($2.6)**	**($1.9)**	**($2.2)**	**($7.4)**	**($2.4)**	**($2.2)**	**($2.5)**	**($2.6)**	**($9.6)**	**($10.5)**	**($9.5)**	**($8.0)**	**($8.0)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Deluted Shares Out	*12.8*	*25.7*	*26.8*	*30.5*	*24.0*	*36.9*	*38.6*	*42.4*	*42.6*	*40.1*	*50.0*	*55.0*	*60.0*	*65.0*
Reported EPS	**($0.06)**	**($0.10)**	**($0.07)**	**($0.07)**	**($0.31)**	**($0.06)**	**($0.06)**	**($0.06)**	**($0.06)**	**($0.24)**	**($0.21)**	**($0.17)**	**($0.13)**	**($0.12)**
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*
Non GAAP Net Income	**($0.7)**	**($2.6)**	**($1.9)**	**($2.2)**	**($7.4)**	**($2.4)**	**($2.2)**	**($2.5)**	**($2.6)**	**($9.6)**	**($10.5)**	**($9.5)**	**($8.0)**	**($8.0)**
Non GAAP EPS	**($0.06)**	**($0.10)**	**($0.07)**	**($0.07)**	**($0.31)**	**($0.06)**	**($0.06)**	**($0.06)**	**($0.06)**	**($0.24)**	**($0.21)**	**($0.17)**	**($0.13)**	**($0.12)**

Source: Company filings and Zacks Small Cap Research

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HISTORICAL ZACKS RECOMMENDATIONS



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