Zacks Small-Cap Research

November 18, 2013
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Bio-Path Holdings (BPTH-OTC)

BPTH: Balance sheet remains strong, to advance L-Grb-2 into Phase II study in early 2014—maintaining Outperform rating

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	02/11/2013
Current Price (11/17/13)	$2.01
12–Month Target Price	**$3.50**

OUTLOOK

BPTH recently reported encouraging interim Phase I results of its lead drug candidate Liposomal Grb-2, which is well tolerated and has possible anti-leukemia benefits. Doses have been increased in the Phase I trial due to excellent safety profile of Grb-2. Phase II is expected to start in early 2014 when drug supply is available.

Pipeline is further expanded with the new indications of L-Grb-2.

Valuation is attractive at this point. We maintain our Outperform rating on BPTH shares.

SUMMARY DATA

52-Week High	**$2.94**
52-Week Low	**$0.28**
One-Year Return (%)	**559.02**
Beta	**1.08**
Average Daily Volume (sh)	**44,929**
Shares Outstanding (mil)	**75**
Market Capitalization ($mil)	**$152**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**24**
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 2010 Estimate	**N/A**
P/E using 2011 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Growth**
Industry	**Med-Drugs**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2013	0.00 A	0.00 A	0.00 A	0.00 E	0.00 E
2014					5.00 E
2015					7.50 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	-$0.01 A	-$0.01 A	-$0.01 A	-$0.01 A	-$0.04 A
2013	-$0.01 A	-$0.01 A	-$0.02 A	$0.01 E	-$0.05 E
2014					-$0.03 E
2015					-$003 E

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

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WHAT'S NEW

- ***BPTH exits third quarter with strongest balance sheet in company's history;***
- ***BPTH achieves major milestone;***
- ***BPTH is to advance lead program L-Grb-2 into Phase II in 2014 when drug supply is available;***
- ***New indications of L-Grb-2 expands pipeline;***
- ***We maintain our Outperform rating on BPTH and raise our price target to $3.50 per share.***

BPTH Reports Third Quarter 2013 Financial Results With Boosted Balance Sheet

On November 14, Bio-Path (BPTH) reported financial results for the three month ended September 30, 2013.

There were no operating revenues for the 3Q13.

Research and development expense was $568,576 for the three month period ended September 30, 2013, an increase of $21,755 from the three month period ended September 30, 2012. The increase in research and development expense for the three months ended September 30, 2013 compared to the comparable period ended September 30, 2012 was primarily due to an approximate $37,000 increase from development costs for a clinical trial data management system, offset to some extent by lower expense for drug material used and drug testing services.

Research and development expense-related party was $15,000 for the three month period ended September 30, 2013, a decrease of $32,582 compared to the comparable three month period ended September 30, 2012. The decrease in research and development expense-related party was due primarily to lower clinical trial hospital expense in the three month period ended September 30, 2013.

General and administrative expenses were $810,152 for the three month period ended September 30, 2013, an increase of $564,066 compared to the three month period ended September 30, 2012. The increase was due to an approximate $595,000 stock option expense resulting from a stock option grant made during the three month period ending September 30, 2013 to officers and management.

Net loss was $1,393,207 for the three month period ended September 30, 2013 compared to a net loss of $840,552 for the three month period ended September 30, 2012. The increase was due to general and administrative expense being higher in the quarter ended September 30, 2013 due to non-cash expense of approximately $595,000 resulting from a stock option grant made to officers and management.

Net loss per share, both basic and diluted, was $0.02 per share for the three month period ending September 30, 2013 and $0.01 for the three month period ending September 30, 2012.

At September 30, 2013, BPTH had cash of $4.1 million compared to $534,046 at December 31, 2012. Bio-Path sold approximately $3.2 million in shares of common stock, during the third quarter, in a private placement. According to our model, current cash on hand and ongoing capital raising efforts will be sufficient to fund its operations through the second quarter of 2014.

BPTH has had significant success over the last few months raising capital through the sale of shares of its common stock, culminating in excess of $4 million raised. This not only boosted the Company's balance sheet, more importantly, it also reflects investors' positive sentiments about Bio-Path's delivery technology and progress made in clinical development.

We are impressed by management's commitment to minimize dilution of existing shareholders. We are reminded that management intentionally keeps only enough cash (plus a reasonable buffer) to fund

operations through the next set of milestones. This strategy help minimizes dilution of early-stage investors.

Fifth Cohort of Phase I Liposomal Grb-2 Completed, Sixth Cohort is Underway

On June 6, 2013, BPTH announced that it has completed treatment of the fifth dosage cohort in its **Phase I** clinical trial of its lead product candidate Liposomal Grb-2.

The drug's safety profile continues to be favorable with no treatment-related serious adverse events reported and data continues to suggest possible anti-leukemia activity.

A total of three patients were enrolled and dosed in the fifth cohort of the study. All three patients completed the 28-day treatment cycle and were evaluable. Liposomal Grb-2 is systemically delivered by intravenous injection. Patients received a dose of 60 mg/m^2 twice a week for four weeks, for a total of eight doses. Preliminary results suggest that Liposomal Grb-2 at a dose of 60 mg/m^2 is well tolerated.

As was the case with the four previous cohorts, there continues to be a suggestion of possible anti-leukemia activity. All three patients in this cohort were of the more proliferative AML type compared to some of the more indolent patients that have been enrolled into the study and treated in the past. Two of the three patients had a transient decrease in the peripheral blood blast percentage with Liposomal Grb-2. The third AML patient had more than a 90 percent blast count and did not respond to treatment at this dose level to the degree that the other two patients responded.

As a result of the favorable safety profile, the Company closed Cohort 5 of the trial and opened Cohort 6 for enrollment, in which patients will be treated at a dose of **90 mg/m^2.**

During the third quarter, **two patients** completed treatment in the sixth dosage cohort of the Phase I clinical trial. The drug's safety profile continues to be favorable with no treatment-related serious adverse events reported and data continues to suggest possible anti-leukemia activity. Of the two patients enrolled into the sixth dosage cohort that were evaluable, both stabilized and there was sufficient drug on hand for one patient to receive an extended treatment cycle.

To date, the Company has successfully completed five cohorts of the study and has completed two-thirds of the sixth cohort. A total of 33 patients have been enrolled into the Phase I clinical trial, of which 20 have been evaluable. The Company is waiting on drug resupply to complete the sixth cohort, which is not expected to be received **until 1Q14**.

Phase II Trial for Grb-2 to Be Initiated in Early 2014

The Company recently announced its development plans for Liposomal Grb-2 and expects to conduct **three Phase II clinical trials** of Liposomal Grb-2 salvage therapy **in combination with** the frontline therapy in three of the types of leukemia that are currently being evaluated in the Company's Phase I clinical trial. These indications include AML, CML and MDS. These clinical trials are expected to take place at four of the leading cancer centers in the U.S. in early 2014.

While not yet finalized, the outline of the proposed clinical program for Liposomal Grb-2 is to evaluate the compound in a Phase I/II clinical trial in combination with the frontline therapy for each of the leukemia types: AML, CML and MDS. The Phase I portion of the trial will be a single cohort in three patients to test for any potential negative synergies of using the two drugs together. After successfully passing that test, the clinical trial would immediately proceed into a Phase II trial.

The Phase II trial in each of the diseases: AML, CML and MDS, is planned to have 25 to 30 patients per indication. The trials will be conducted at four of the leading cancer centers in the nation, including the MD Anderson Cancer Center. Dr. Jorge Cortes will continue in his role as Principal Investigator for the Phase II clinical trials. The primary endpoint for the study is contemplated to be **duration of response**.

It is expected that there will be only one combination dose administered to each patient in their respective Phase II trial, and consequently, there will not be any time-consuming dose escalation steps. Each patient will receive a full treatment cycle, consisting of two doses per week for four weeks. Utilizing the expertise of four leading cancer centers in the Phase II program should allow the trial to proceed at a good pace. Ideally, once the Phase II portion of the trial is opened it should be possible for dosing to be completed within six months.

Bio-Path's Liposomal Delivery Technology Achieves Major Milestone

On August 9, 2013, Bio-Path Holdings, Inc. (BPTH) announced that a scientific assay has confirmed that its lead product candidate BP-100-1.01 (**Liposomal Grb-2)** inhibits the disease-causing target protein in patients with blood cancers. The assay was applied to patient samples taken from Bio-Path's **Phase I** clinical trial which is evaluating Liposomal Grb-2 in blood cancers including acute myeloid leukemia (AML), chronic myelogenous leukemia (CML), acute lymphoblastic leukemia (ALL) and myelodysplastic syndrome (MDS).

The data confirm that L-Grb-2 blocks the production of its **target protein Grb-2** in clinical trial patient samples. L-Grb-2 was designed to block the protein production of Growth factor Receptor Bound protein-2 (Grb-2), and disrupt the activity (i.e. phosphorylation) of its downstream effector extracellular signals regulated kinases 1,2 (ERK1,2). To verify that L-Grb-2 decreases Grb-2 protein production and ERK1,2 phosphorylation, flow cytometric analysis was performed on the samples. Fluorescent-labeled antibodies for Grb-2 and phosphorylated ERK1,2 were purchased from commercial suppliers which have previously demonstrated the reactivity and specificity of these antibodies. Leukemic cell lines as well as peripheral blood samples from healthy volunteers and diseased patients were used to validate the precision and the reproducibility of the flow cytometry protocol. Peripheral blood samples were obtained from patients prior to study initiation (baseline) and during the course of therapy. The medium fluorescence of Grb-2 and the median fluorescence of phosphorylated ERK1,2 on CD33-expressing leukemic cells were compared to baseline to assess inhibition of the target proteins. The testing was performed by a third party certified Good Laboratory Practice (GLP) testing laboratory.

The specific data from this testing is planned to be reviewed at the Annual Society of Hematology (ASH) meeting in December by Jorge Cortes, M.D., Professor and Deputy Chair, Department of Leukemia, The University of Texas MD Anderson Cancer Center (MD Anderson Cancer Center).

We think this discovery is a significant milestone in the development of Bio-Path's liposomal delivery technology. The significance of this testing is that it confirms Bio-Path's delivery technology value proposition. Bio-Path's product candidates are administered to the patient by simple intravenous transfusion and are perfused throughout the body via blood flow. As evidenced to date in the Company's clinical trial, the liposomal drug product produces no toxic side effects, and safely transports the antisense drug substance throughout the body to reach the diseased cell for insertion across the cell membrane. Success of Bio-Path's delivery technology affirmed through testing opens several avenues to maximize growth in the value of the Company.

Inhibition of the disease-causing protein has the effect of down regulating the disease. This will allow for Liposomal Grb-2 to be used potentially in combination with current frontline treatments. This discovery also points to the potential use of a liposomal antisense treatment as a standalone treatment to transform and manage a disease, which has a disease-causing protein, as a chronic disorder.

Further, the scientific proof of principle for the drug delivery technology may lead to licensing and business development opportunities for Bio-Path.

Pipeline Expanded by New Indications of Liposomal Grb-2

On July 22, 2013, Bio-Path announced that it is initiating **preclinical testing** of its lead product candidate Liposomal Grb-2 into two additional indications: triple negative breast cancer **(TNBC)** and inflammatory

breast cancer **(IBC),** two cancers characterized by formation of aggressive tumors and relatively high mortality rates.

Liposomal Grb-2 (L-Grb-2) is the Company's lead drug candidate currently in a **Phase I** clinical trial. L-Grb-2 is a liposomal delivered **antisense** cancer drug that targets **an multibillion dollar annual market** for Chronic Myelogenous Leukemia (CML), Acute Myeloid Leukemia (AML), Acute Lymphoblastic Leukemia (ALL), and Myelodysplastic Syndrome (MDS).
Grb-2 (growth factor-bound protein-2) is an adaptor protein which is essential to cancer cell signaling because it is utilized by oncogenic tyrosine kinases to induce cancer progression. Suppressing the function or expression of Grb-2 should interrupt its vital signaling function and have a therapeutic application in cancer. L-Grb-2 is a neutral-charge, liposome-incorporated antisense drug substance designed to inhibit Grb-2 expression.

Bio-Path's plan is to develop Liposomal Grb-2 as a targeted therapy against TNBC and IBC. Treatment goals are two-pronged:

- the first being to develop Liposomal Grb-2 as a tumor reduction agent in combination with other approved drugs in pre-operative settings;

- and the second is to develop Liposomal Grb-2 as a drug to treat and control or eliminate cancer metastasis in TNBC and IBC patients.

- Both of these treatment goals address high need situations for patients. Following successful completion of the preclinical studies, Bio-Path expects to start a **Phase I** clinical trial in TNBC and IBC **in 2014.**

We think the development of Liposomal Grb-2 for the treatment of TNBC and IBC is a major milestone for Bio-Path that has the opportunity to produce substantial value for the Company. Successful development of these applications will be of great benefit to TNBC and IBC patients. Further, the treatment goal for tumor inhibition and reduction in a pre-operative setting provides a potential pathway for rapid approval by the FDA of Liposomal Grb-2, while the longer term effects of controlling or eliminating metastasis will build long term use of our drug.

The new development of L-Grb-2 also expands Bio-Path's pipeline.

Market for TNBC and IBC is Rather Large

Triple negative breast cancer (TNBC) tumors do not express estrogen receptors, progesterone receptors, and low HER2. These negative results mean that the growth of the cancer is not supported by the hormones estrogen and progesterone, or by the presence of too many HER2 receptors. Therefore, TNBC does not respond to hormonal therapy or therapies that target HER2 receptors. In addition, TNBC tumors are very aggressive. Approximately 15 to 20 percent of breast cancers are triple-negative.

Inflammatory breast cancer (IBC) is a rare and very aggressive disease in which cancer cells block lymph vessels in the skin of the breast. This type of breast cancer is called "inflammatory" because the breast often looks swollen and red, or "inflamed." IBC accounts for two to five percent of all breast cancers. IBC tumors are very aggressive and are frequently hormone receptor negative, which means hormone therapies may not be effective. Five year survival rate for IBC is 40 percent versus 87 percent for all breast cancers combined, making IBC a priority area for development of new treatments.

The combined market for TNBC and IBC is very large in our view due to the huge market for breast cancer in our view. Together with the CML, AML and MDS, L-Grb-2 is targeting a multibillion dollar market.

Norvatis' Gleevec gives a vivid example. Gleevec generated $4.7 billion in sales in 2011. The initial clinical target for L-Grb-2 is Gleevec-resistant **CML**. There are approximately 40,000 patients in the U.S. with CML. Currently most patients are treated with Gleevec, an inhibitor of the tyrosine kinase bcr-abl, the causative agent of CML. Gleevec is quite effective at treating CML but many patients develop resistance to Gleevec and, consequently, recurrence of their disease.

In addition to CML, L-Grb-2 also targets AML and MDS as well as the TNBC and IBC, each has a significant market.



Valuation Is Still Very Attractive

We maintain our Outperform rating on BPTH shares and raise our twelve-month price target to $3.50 per share.

Our call is based on recent progress the Company has made and current valuation of the Company's shares.

We believe Bio-Path's **neutral lipid drug delivery platform technology** has great potential to systemically deliver antisense drug candidates in human bodies. Its pipeline has been expanded by new indications and can be easily expanded into other therapeutic areas if the delivery platform technology proves successful for current cancer indications.

Obviously, Bio-Path's success will be dependent on the neutral lipid drug delivery technology. Antisense and siRNA currently are two most promising targeted therapies. However, the biggest challenge for antisense and siRNA therapeutics is their systemic delivery into targeted disease areas. Most conventional delivery methods have failed to do so. Bio-Path's unique neutral lipid delivery technology may have potential to be successful. Testing of this delivery technology in animals has demonstrated a 10-30 fold increase in tumor cell uptake with this technology compared to other delivery methods without any evidence of toxicity.

We are encouraged by the progress BPTH has made with its lead drug candidate Liposomal Grb-2. We are impressed by the interim results, which have demonstrated the safety and potential efficacy of the candidate. We are especially impressed by the suggestion of possible anti-leukemia activity at the very low dosage, which was an unexpected and very positive result. We are also pleased to see the Company is expanding its pipeline by developing new indications of its lead compound L-Grb-2.

In terms of valuation, we think Bio-Path shares are extremely undervalued at this point. By comparing to its peers in the biotech industry and considering the potential of its drug delivery technology and

progresses the Company has made in the past few months. Our price target of $3.5 per share values the Company at about $264 million in market cap based on 75.4 million outstanding shares.

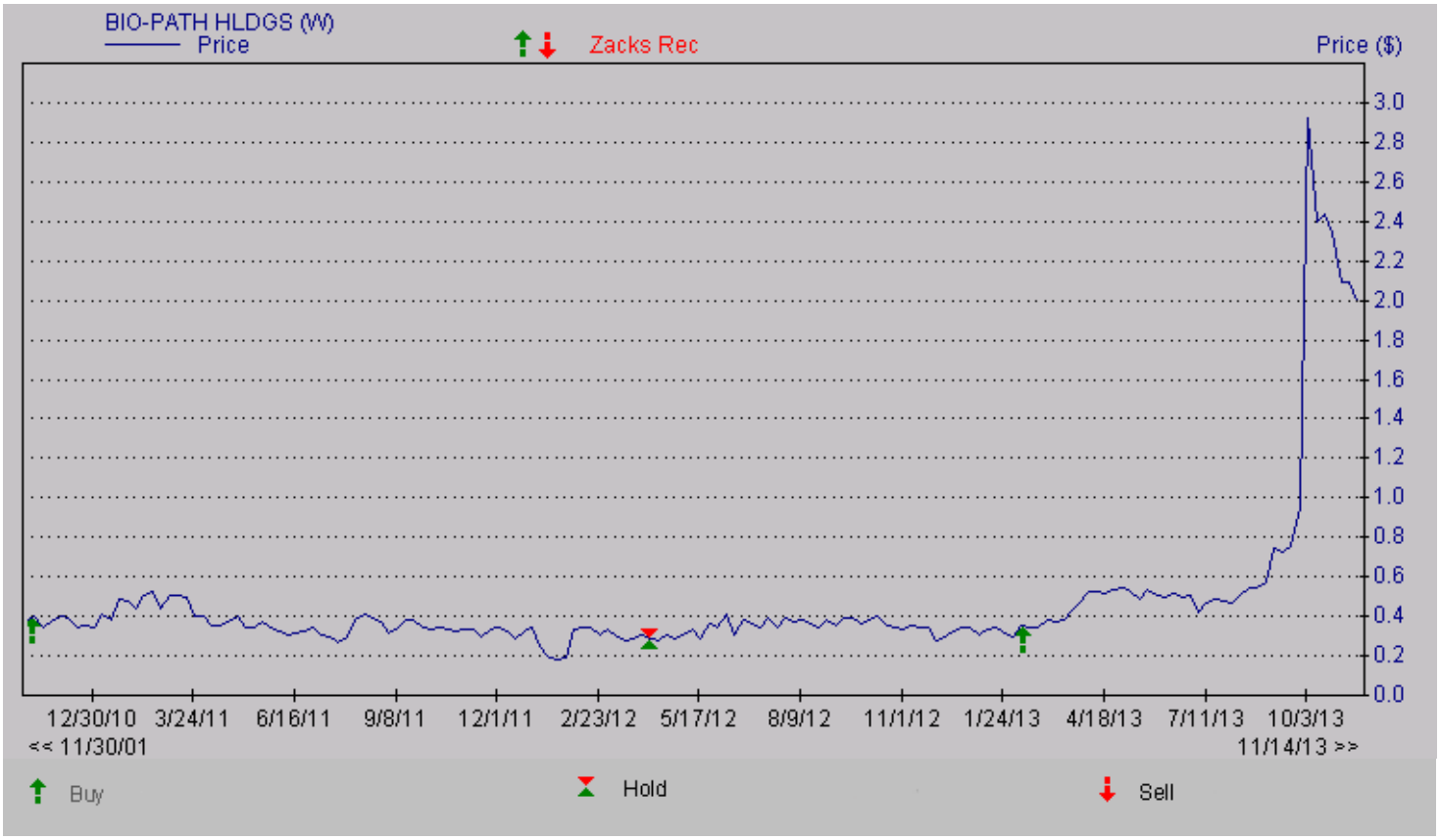
PROJECTED INCOME STATEMENT

$ in millions except for per share data	2010A	2011A	2012A (Dec)					2013E (Dec)					2014E (Dec)	2015E (Dec)
	FYA	FYA	Q1	Q2	Q3	Q4	FYA	Q1	Q2	Q3	Q4	FYE	FYE	FYE
Total Revenues	**$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**	**$7.50**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	*50.0%*
CoGS	$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
Gross Income	**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**	**7.50**
Gross Margin	-	-	-	-	-	-	-	*0.0%*	*0.0%*	*0.0%*	-	-	*100.0%*	*100.0%*
SG&A	$0.70	$1.22	$0.23	$0.25	$0.25	$0.26	$0.99	$0.24	$0.24	$0.81	$0.35	$1.64	$2.50	$3.50
% SG&A	-	-	-	-	-	-	-	-	-	-	-	-	*50.0%*	*46.7%*
R&D	1.14	1.14	0.29	0.54	0.59	0.18	1.60	0.42	0.19	0.58	0.50	1.69	5.00	7.00
% R&D	-	-	-	-	-	-	-	-	-	-	-	-	*100.0%*	*93.3%*
Other expenses	0.48	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	-	-	-	-	-	-	-	*0.0%*	*0.0%*	*0.0%*	*0.0%*	-	*0.0%*	*0.0%*
Operating Income	**($2.33)**	**($2.37)**	**($0.52)**	**($0.79)**	**($0.84)**	**($0.43)**	**($2.58)**	**($0.66)**	**($0.43)**	**($1.39)**	**($0.85)**	**($3.33)**	**($2.50)**	**($3.00)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	*-50.0%*	*-40.0%*
Other Net	$0.2	$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
Pre-Tax Income	**($2.08)**	**($2.36)**	**($0.52)**	**($0.79)**	**($0.84)**	**($0.43)**	**($2.58)**	**($0.66)**	**($0.43)**	**($1.39)**	**($0.85)**	**($3.33)**	**($2.50)**	**($3.00)**
Taxes (benefits)	$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	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($2.08)**	**($2.36)**	**($0.52)**	**($0.79)**	**($0.84)**	**($0.43)**	**($2.58)**	**($0.66)**	**($0.43)**	**($1.39)**	**($0.85)**	**($3.33)**	**($2.50)**	**($3.00)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Shares Out	*48.2*	*53.8*	*58.4*	*58.9*	*58.9*	*61.1*	*59.3*	*62.2*	*66.6*	*75.4*	*80.0*	*71.1*	*90.0*	*100.0*
Reported EPS	**($0.04)**	**($0.04)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.04)**	**($0.01)**	**($0.01)**	**($0.02)**	**($0.01)**	**($0.05)**	**($0.03)**	**($0.03)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	*8.0%*
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	**($2.08)**	**($2.36)**	**($0.52)**	**($0.79)**	**($0.84)**	**($0.43)**	**($2.58)**	**($0.66)**	**($0.43)**	**($1.39)**	**($0.85)**	**($3.33)**	**($2.50)**	**($3.00)**
Non GAAP EPS	**($0.04)**	**($0.04)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.04)**	**($0.01)**	**($0.01)**	**($0.02)**	**($0.01)**	**($0.05)**	**($0.03)**	**($0.03)**

Source: Company filings and Zacks estimates

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HISTORICAL ZACKS RECOMMENDATIONS



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