Zacks Small-Cap Research

August 19, 2014
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Bio-Path Holdings (BPTH-OTC)

BPTH: to advance L-Grb-2 into Phase II study in 2H2014 while continuing to test higher dose in Phase I trial—maintaining Outperform rating

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	02/11/2013
Current Price (08/18/14)	$2.36
12–Month Target Price	**$7.00**

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 2H14 when drug supply is available.

Pipeline is further expanded with the new indications of L-Grb-2. Balance sheet has been boosted by recent $15 million financing.

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

SUMMARY DATA

52-Week High	**$4.94**
52-Week Low	**$0.47**
One-Year Return (%)	**308.76**
Beta	**1.22**
Average Daily Volume (sh)	**249,682**
Shares Outstanding (mil)	**89**
Market Capitalization ($mil)	**$200**
Short Interest Ratio (days)	**3.54**
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)
2013	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2014	0.00 A	0.00 A	0.00 E	0.00 E	0.00 E
2015					5.00 E
2016					5.00 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.01 A	-$0.01 A	-$0.02 A	$0.01 A	-$0.05 A
2014	-$0.01 A	-$0.01 A	-$0.01 E	$0.01 E	-$0.05 E
2015					-$0.01 E
2016					-$0.02 E

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

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WHAT'S NEW

- ***BPTH reports 2Q14 financials with a strong balance sheet;***
- ***Positive interim L-Grb-2 Phase I data reported, Phase II trial expected to begin in 2H14;***
- ***New IND applications for triple negative and inflammatory breast cancer will be filed;***
- ***Outperform rating maintained, reiterating PT of $7.00 per share.***

Bio-Path Reports 2Q2014 Financials

On August 18, Bio-Path Holdings (BPTH) announced operational and financial results for the second quarter ended June 30, 2014.

There was no revenue recorded for the second quarter of 2014.

R&D expenses were $0.52 million for 2Q14, compared to $0.19 million for 2Q13, an increase of $361,004 primarily due to an increase of $233,985 in drug material expense for use in the clinical trial, and increases of $35,860 for clinical trial expense and development of a patient data system, $89,360 for drug manufacturing development expense and $12,190 for stock option expense for employees involved in research and development activities.

SG&A expenses were $0.75 million for 2Q14, compared to $0.24 million for 2Q13, an increase of $514,005. The increase was due to significant corporate development activities.

Total operating expenses were $1.3 million for 2Q14, compared to $0.43 million for 2Q13 due to increased research and development expenses and increased general and administrative expense.

Net loss was $1.27 million for the three months ended June 30, 2014 compared to a net loss of $0.43 million for the three months ended June 30, 2013.

Net loss per share was $0.01 per share for the three months ended June 30, 2014 and $0.01 per share for the three months ended June 30, 2013.

Balance Sheet Remains Strong

As of June 30, 2014, the Company had cash of $15.7 million, compared to $3.6 million at December 31, 2013, and to $16.8 million at the end of the first quarter 2014.

On January 16, Bio-Path (BPTH) announced that it is raising approximately $10.0 million in a registered direct offering at a price of $3.00 per unit. And on Jan 20, the offering was upsized to **$15 million**.

The entire offering is being sold to two dedicated healthcare funds that are managed by Sabby Management. Each Unit consists of one share of Bio-Path common stock, and a warrant to purchase one half (0.5) of a share of Bio-Path common stock. The common stock and warrants is immediately separable. The warrants will be exercisable immediately, have a term of five years and an exercise price of $4.74 per share of common stock.

After placement agent fees and estimated offering expenses, the Company received net proceeds of approximately **$13.8 million**. The offering was closed on January 21, 2014.

Although the new financing dilutes existing shareholder base by issuing 5 million new common shares plus the options to buy additional 2.5 million shares, we think it is positive to Bio-Path **in the following aspects:**

First, this new financing further strengthens the company's balance sheet. According to our model, current cash on hand will be sufficient to fund its operations through the end of 2016.

Secondly, with increased cash balance, Bio-Path should be able to accelerate the advancement of its clinical programs especially the initiation of **Phase II** clinical trial of its lead program liposomal Grb-2 (L-Grb-2) in 1Q14.

Thirdly, the new financing further validates Bio-Path's RNA delivery technology and clinical data. The two healthcare funds providing the financing are sophisticated institutional investors. Their confidence in Bio-Path should have reflected their positive sentiments about Bio-Path's delivery technology and progress made in clinical development.

With all these in mind, we think this new financing should create value for shareholders both immediately and in the long run.

Interim Data of L-Grb-2 Phase I Presented and Enrollment Continues

The ongoing **Phase I** clinical trial is a standard dose-finding study. The starting dose was 5 mg/m^2 twice weekly intravenously (IV) over two to three hours for 28 days and proceeded through doses of 10, 20, 40, 60, and 90 mg/m^2.

Bio-Path presented interim **Phase I** data of L-Grb-2 in hematological cancers at the 55th Annual Meeting of the American Society of Hematology (ASH) in New Orleans in December, 2013. This presentation included the **first five cohorts** of the study.

A total of 28 patients who had failed other therapies were included in the study (19 AML, 4 MDS and 5 CML), and 18 patients were evaluable. Ten patients failed to complete the full 28-day treatment cycle due to disease progression with no toxicity.

Data from the first five cohorts of the Phase I trial demonstrated:

- L-Grb-2 was safe and well tolerated.
- Among 18 evaluable patients, nine experienced at least a 50 percent reduction in peripheral or bone marrow blasts from baseline.
- Five patients demonstrated transient improvement and/or stable disease, three of whom received a total of five cycles each.
- Two patients, in addition to achieving marked blast percentage declines, also experienced transient improvement in leukemia cutis lesions.

Disease Stabilization in MDS and AML

- Two patients with MDS achieved disease stabilization and continued therapy for five cycles before disease progression.
- A 54-year-old HIV positive male with AML achieved stable disease and marked reduction in peripheral blasts, continuing therapy for five cycles before disease progression.

Experience in CML-Blast Phase

- One patient with myeloid blast crisis of CML with 8 prior therapies.
- Upon start of L-Grb-2 patient showed a significant reduction in blasts from 81 percent to 5 percent but due to leptomeningeal disease progression discontinued therapy before full cycle.

Inhibition of Target Grb-2 Protein

- On day 15, L-Grb-2 decreased Grb-2 in five of eight samples tested (average reduction 55 percent).
- End of treatment day 15, L-Grb-2 decreased Grb-2 levels in eight out of nine patients (average reduction 45 percent).

Enrollment and treatment of cohort 6 (**90 mg/m^2**) is ongoing. Two patients have completed treatment in the sixth dosage cohort. Sufficient drug quantities are now in place to complete Cohort 6 of the trial. The trial requires three evaluable patients per cohort. The third patient has been enrolled and it is anticipated to complete treatment in the next few weeks. The Company intends to evaluate patient results at the end of Cohort 6 to determine if the optimal biological dose has been reached, which would bring a close to the Phase I clinical trial.

Importantly, Bio-Path has built a patient data base that has enabled the company to take a systematic look at all of the clinical trial data compiled to date. A preliminary review suggests that Bio-path may have achieved an optimal biological dose. Based on this, the company has developed a strategy to address the apparent lack of toxicity in the drug, which is a positive result, but creates an interest to continue the Phase I testing at higher doses, while there is a desire and need to move Liposomal Grb-2 into more advanced development. The strategy of moving into the Phase II clinical trial while continuing with the Phase I is unique. The current Phase I trial could concurrently be extended with a **Cohort 7**, treating patients with a higher dose of **135 mg/m^2.**

The inhibition of Grb-2 protein is a significant milestone in the development of Bio-Path's liposomal delivery technology. The significance of this finding 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 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.

Phase II Trial for Grb-2 to Be Initiated in 2H2014

Bio-Path 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 2H2014**.

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.

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.

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.**

In collaboration with a leading researcher working in the MD Anderson breast cancer program, Bio-Path will initiate in vivo testing of Liposomal Grb-2 as a potential treatment for triple negative and inflammatory breast cancer. With a successful outcome, the Company will proceed to submit an IND application for **Phase I** clinical trials in triple negative and inflammatory breast cancers.

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 Still Attractive

We maintain our Outperform rating on BPTH shares and reiterate our twelve-month price target of $7.00 per share.

We are impressed with recent progress the Company has made. Balance sheet has been boosted with recent $15 million new financing. Positive data from Phase I of L-Grb-2 was presented at ASH. Bio-Path is on track to initiate Phase II of L-Grb-2 in 2H2014 while continuing to test higher dose in the ongoing Phase I trial.

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.

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 still attractive at this point. By comparing to its peers in the RNA therapeutics space and considering the potential of its drug delivery technology and

progresses the Company has made in the past few quarters, there is still plenty of room for further price appreciation in our view.

Our price target of $7.00 per share values the Company at about $620 million in market cap based on 89 million outstanding shares.

Recent deal between **Alnylam** and **Sanofi/Genzyme** makes up believe that BPTH could be a candidate for buyout or license with its RNA delivery technology. The initiation of the Phase II trial of L-Grb-2 and positive data from the Phase II will increase the likelihood of potential negotiations.

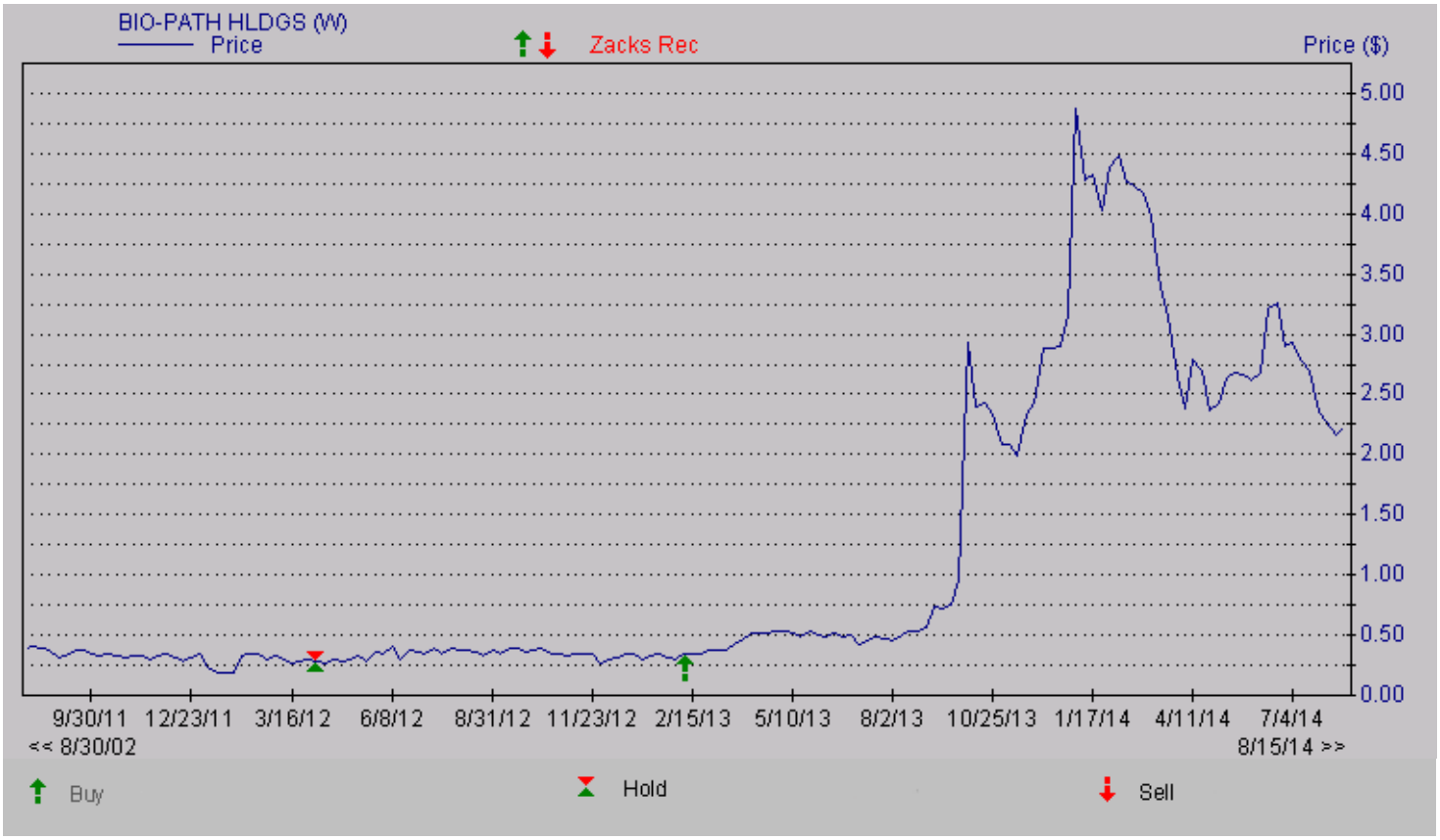
PROJECTED INCOME STATEMENT

$ in millions except for per share data	2012A (Dec)	2013A (Dec)	2014E (Dec)					2015E (Dec)	2016E (Dec)	2017E (Dec)	2018E (Dec)
	FYA	FYA	Q1	Q2	Q3	Q4	FYE	FYE	FYE	FYE	FYE
Total Revenues	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$5.00**	**$5.00**	**$7.50**	**$10.00**
YOY Growth	-	-	-	-	-	-	-	-	*0.0%*	*50.0%*	*33.3%*
CoGS	$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**	**5.00**	**5.00**	**7.50**	**10.00**
Gross Margin	-	-	-	-	-	-	-	*100.0%*	*100.0%*	*100.0%*	*100.0%*
SG&A	$0.99	$1.63	$0.38	$0.75	$0.45	$0.50	$2.09	$2.20	$2.80	$3.40	$4.50
% SG&A	-	-	-	-	-	-	-	*44.0%*	*56.0%*	*45.3%*	*45.0%*
R&D	1.60	1.63	0.13	0.52	0.75	0.85	2.25	3.50	4.50	5.50	6.50
% R&D	-	-	-	-	-	-	-	*70.0%*	*90.0%*	*73.3%*	*65.0%*
Other expenses	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	**($2.58)**	**($3.27)**	**($0.51)**	**($1.27)**	**($1.20)**	**($1.35)**	**($4.34)**	**($0.70)**	**($2.30)**	**($1.40)**	**($1.00)**
Operating Margin	-	-	-	-	-	-	-	*-14.0%*	*-46.0%*	*-18.7%*	*-10.0%*
Other Net	$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	**($2.58)**	**($3.26)**	**($0.50)**	**($1.27)**	**($1.20)**	**($1.35)**	**($4.32)**	**($0.70)**	**($2.30)**	**($1.40)**	**($1.00)**
Taxes (benefits)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($2.58)**	**($3.26)**	**($0.50)**	**($1.27)**	**($1.20)**	**($1.35)**	**($4.32)**	**($0.70)**	**($2.30)**	**($1.40)**	**($1.00)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-
Shares Out	*59.3*	*71.4*	*89.2*	*89.2*	*90.0*	*91.0*	*89.9*	*95.0*	*98.0*	*100.0*	*104.0*
Reported EPS	**($0.04)**	**($0.05)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.05)**	**($0.01)**	**($0.02)**	**($0.01)**	**($0.01)**
YOY Growth	-	-	-	-	-	-	-	*-84.7%*	*218.5%*	*-40.3%*	*-31.3%*
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*
Non GAAP Net Income	**($2.58)**	**($3.26)**	**($0.50)**	**($1.27)**	**($1.20)**	**($1.35)**	**($4.32)**	**($0.70)**	**($2.30)**	**($1.40)**	**($1.00)**
Non GAAP EPS	**($0.04)**	**($0.05)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.05)**	**($0.01)**	**($0.02)**	**($0.01)**	**($0.01)**

Source: Company filings and Zacks estimates

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HISTORICAL ZACKS RECOMMENDATIONS



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