Zacks Small-Cap Research

February 20, 2013
Grant Zeng, CFA
312-265-9466
gzeng@zacks.com

scr.zacks.com
111 North Canal Street, Chicago, IL 60606

Bio-Path Holdings (BPTH-OTC)

BPTH: Pipeline expanded by new indications, valuation is attractive---Outperform

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	02/11/2013
Current Price (02/19/13)	$0.35
12–Month Target Price	**$1.00**

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.

Pipeline is further expanded with the new indications of L-Grb-2. The Company will enter into Phase II clinical trials of L-Grb-2 for blood cancers.

Valuation is attractive at this point. We upgrade the Company's shares to Outperform.

SUMMARY DATA

52-Week High	**$0.42**
52-Week Low	**$0.25**
One-Year Return (%)	**2.86**
Beta	**0.78**
Average Daily Volume (sh)	**11,964**
Shares Outstanding (mil)	**62**
Market Capitalization ($mil)	**$22**
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)
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					3.50 E
2014					7.50 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.01 A	-$0.01 A	-$0.01 A	-$0.01 A	-$0.04 A
2012	-$0.01 A	-$0.01 A	-$0.01 A	-$0.01 E	-$0.05 E
2013					-$0.02 E
2014					$0.00 E

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

© Copyright 2013, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

We are upgrading Bio-Path (BPTH) shares to Outperform from Neutral based on recent developments and current valuation.

Pipeline Expanded by New Indications of Liposomal Grb-2

Recently, Bio-Path Holdings (BPTH) announced that it is initiating development of its lead cancer drug BP-100-1.01 (Liposomal Grb-2) to treat 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.

- Discussions with senior breast cancer researchers at the MD Anderson Cancer Center indicated strong scientific case that blocking Grb-2 protein using L-Grb-2 has the potential to be an effective treatment for TNBC and IBC

- 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 is to develop Liposomal Grb-2 as a tumor reduction agent **in combination with** other approved drugs in pre-operative settings;
    - 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.

- Development plan: 2013 comprised of pre-clinical development followed immediately by Phase I clinical trial;
  - The preclinical programs are expected to start in 2013 and last one year, after which time the Phase I clinical trial could begin after FDA approval to proceed;
  - Safety of L-Grb-2 established in leukemia trial can speed dosing in the TNBC/IBC trial

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.



Phase I of Liposomal Grb-2 Is Progressing Well

L-Grb-2 is the Company’s lead antisense program.

Bio-Path completed treatment of the **fourth cohort** of the **Phase I** clinical trial of Liposomal Grb-2, which is a systemic treatment for blood cancers including acute myeloid leukemia (AML), chronic myelogenous leukemia (CML), acute lymphoblastic leukemia (ALL) and myelodysplastic syndrome (MDS).

The Phase I trial is being conducted at The University of Texas MD Anderson Cancer Center. A total of three patients were enrolled and dosed in the fourth 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 40 mg/m^2 twice a week for four weeks, for a total of eight doses.

A total of three patients were enrolled and dosed in the fourth 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 40 mg/m2 twice a week for four weeks, for a total of eight doses.

Preliminary results suggest that Liposomal Grb-2, at a dose of 40 mg/m^2 is well tolerated. As was the case with the three previous cohorts, there continued to be a suggestion of possible anti-leukemia activity. One patient stabilized and qualified to receive additional treatment. Two other AML patients with more than 90 percent blast count did not receive extended treatment.

Another positive development is the fact that one patient from Cohort 3 has completed fifth treatment cycle and is continuing treatment with Liposomal Grb-2. This patient started treatment at the end of March 2012, and is reportedly in a stable condition at this time as treatment with Liposomal Grb-2 continues.

Earlier this year, Bio-Path upgraded its substance and drug supplier to meet increased demand for the drug. The step-up in the supply of Liposomal Grb-2 was necessary based upon projected treatments for patients in the clinical trial, and the increased number of patients who, in the principle investigators' opinion, stabilized from treatment with Liposomal Grb-2 and were to receive extended treatment.

Bio-Path is making significant improvement for each cohort in terms of time for completion of a cohort, number of patients enrolled and the percentage of evaluable patients that received extended treatments as the below table shows. An important measure of benefit from treatment with the drug is stabilization and being placed on extended treatment cycles. This trend is also very positive, with all three patients from cohort 3 being placed on extended treatment plans.

Summary of Grb-2 Phase I Trial Through Cohort 3						
	Time for completion	Patients			Patients on Extended Treatment	
	(weeks)	Enrolled	Evaluable	% Eval.	#	% of Eval.
Cohort 1	55	14	6	43%	2	33%
Cohort 2	26	6	3	50%	1	33%
Cohort 3	11	3	3	100%	3	100%

It is clear that the momentum of the trial has significantly changed to the better, with markedly shortened times to complete a cohort and the minimum number of patients needed. The increase in the number of patients needing drugs for extended treatments has caused Bio-Path to accelerate its plans to upgrade the capacity of drug supply chain.

We think the interim results from the first four cohorts are encouraging. The suggestion of possible anti-leukemia activity with the low doses used in the first and second cohorts is especially impressive. We continue to look forward to seeing more positive data from cohort 5 and 6 in the coming months.

Doses Increased in the Phase I Trial

To date, there has been no evidence of significant toxicity from treatment of patients with Liposomal Grb-2. This provides a significant opportunity for the Company to test higher doses in patients in order to find a dose that provides maximum potential benefit and duration of anti-leukemia effect.

Bio-Path's Phase I protocol calls for stopping testing after the final dose of 50 mg/m2 in Cohort 5. With the absence of any real toxicity barriers, the Company is able to continue to evaluate higher doses of Liposomal Grb-2.

Dosages of Liposomal Grb-2, evaluated to date, in Cohorts 1 through 4 of the clinical trial consisted of 5, 10, 20 and 40 mg/m2. The expanded protocol will continue at 50 percent increments, with the next dose for Cohort 5 being 60 mg/m2 and the following dose 90 mg/m2 for Cohort 6.

As with the previously approved protocol, dosing stops if a maximum tolerated dose (MTD) is reached; this will continue to be the case with the revised protocol. However, since it is felt among the clinical team and the Company that a MTD will likely not be reached, the Company will halt testing once an optimally biological dose is achieved. If advantageous, the Company can continue testing at a higher dose of 135 mg/m2 with 33 percent increments thereafter.

The Company has submitted the updated dosing plan to the FDA and has recently received approval from the MD Anderson Cancer Center's Institutional Review Board for the revised protocol. Enrollment of Cohort 5 will begin soon. Assuming that only two additional cohorts, testing higher doses of the drug candidate are needed, dosing in the Phase I clinical trial should be completed by mid-year 2013.

The doses increase is important. By testing additional doses, Bio-Path should be able to determine an optimal dose for response of treatment and duration of response, providing the Company with additional information in order to be more proficient in the design of future clinical trials.

Phase II Trial for Grb-2 to Be Initiated in 2013

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 2013.

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. The Company anticipates starting and completing this phase of development in 2013.

We think that 2013 will be an important year for Bio-Path. The Company will become a mid-stage (Phase II) company in 2013.

Shares Commence Trading on OTCQX

Bio-Path Holdings, Inc. (BPTH) shares began trading on the quality-controlled OTCQX on Friday, June 1, 2012.

OTCQX is the highest tier, premier trading platform for OTC companies. The trading on OTCQX means that Bio-Path is qualified for the OTCQX's high standards. The Company also announced that it has retained Roth Capital Partners to serve as the Company's Designated Advisor for Disclosure (DAD) on OTCQX, responsible for providing guidance on OTCQX requirements.

OTC Markets has 3 tiers: OTCQX, OTCQB and OTC Pink. **OTCQX** is the top tier of the OTC market. Exclusively for companies that meet the highest financial standards and undergo a qualitative review.

Investor-focused companies use the quality-controlled OTCQX platform to offer investor transparent trading, superior information and easy access through their regulated U.S. broker-dealers. The OTCQX platform offers companies and their shareholders a level of marketplace services formerly available only on a U.S. exchange.

Bio-Path's commencement of trading on the OTCQX attests to the quality of the Company's financial reporting and its technology.

VALUATION AND RECOMMENDATION

We are moving to Buy rating on Bio-Path Holdings Inc. from Neutral. Our new twelve-month price target is $1.00 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 determined by 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 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, we think Bio-Path's stock should be trading around $1.00 per share, which value the Company at about $62 million in market cap.

But Keep in Mind the Cash Burn Concern

If an appropriate partner cannot be found after the Phase I trial of Liposomal Grb-2, cash burn would be a little concern.

As of September 30, 2012, the Company had cash of $0.33 million. The Company continues to anticipate an average burn rate of approximately $290,000 per quarter. Therefore, current cash plus the proceeds from the planned financing should last through the 3Q13.

As a reminder, the Company is initiating a private placement to raise up to $4 million through the sale of shares of the Company's common stock. The offering is in progress. If successful, the Company's balance sheet will be greatly boosted.

We realize that without a partner, BPTH has to raise funds through the capital market by issuing new shares or convertible notes, which dilute existing shareholders. As the Company raises new funds in 2013, share numbers will continue to increase. BPTH will do so on a regular basis without a partner, further diluting existing shareholder base.

However, we appreciate management 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.

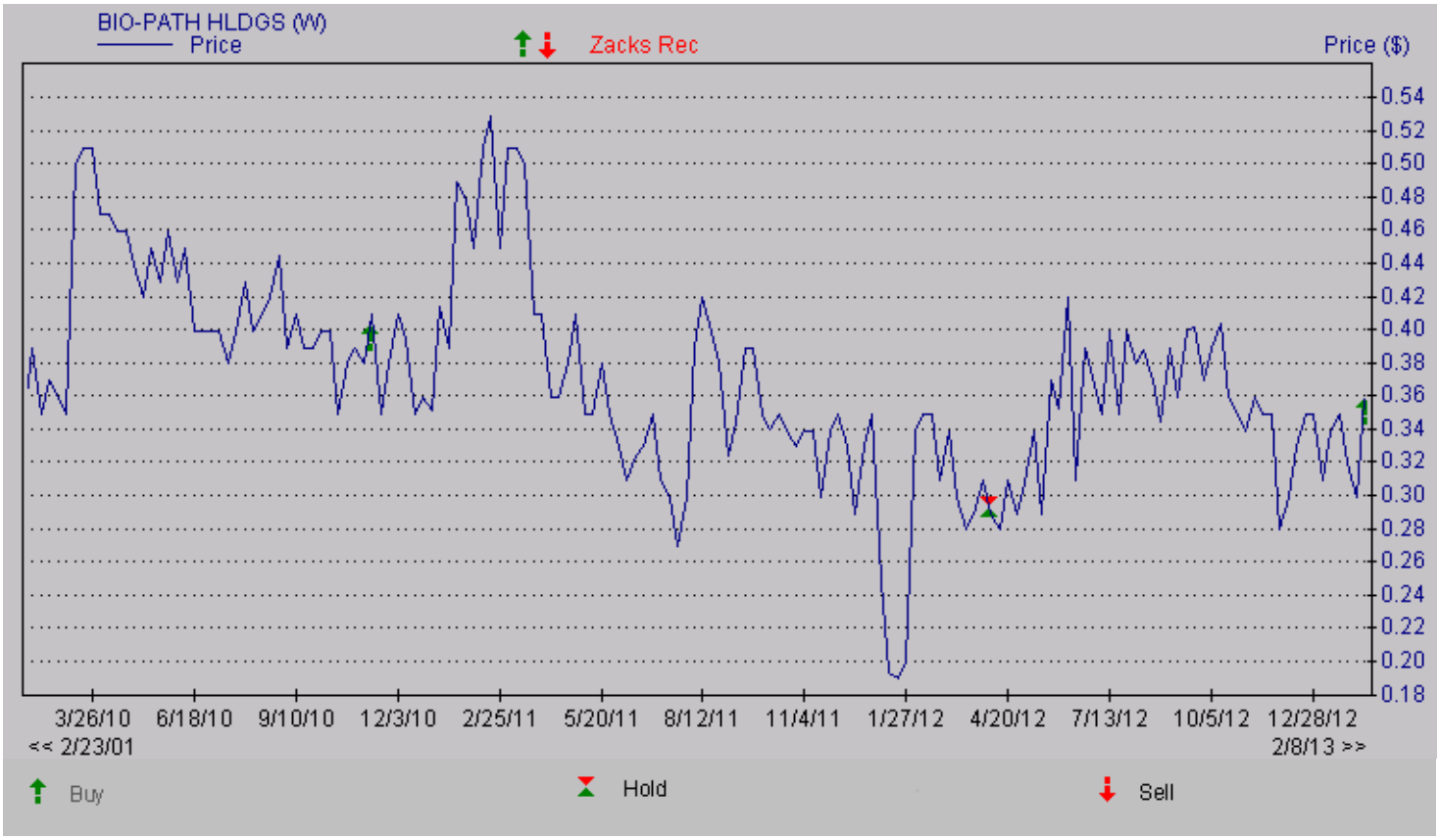
PROJECTED INCOME STATEMENT

$ in millions except for per share data	2011A (Dec)					2012E (Dec)					2013E (Dec)	2014E (Dec)	2015E (Dec)
	Q1	Q2	Q3	Q4	FYA	Q1	Q2	Q3	Q4	FYE	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**	**$3.50**	**$7.50**	**$15.00**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	*114.3%*	*100.0%*
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
Gross Income	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**3.50**	**7.50**	**15.00**
Gross Margin	-	-	-	-	-	-	-	-	-	-	*100.0%*	*100.0%*	*100.0%*
SG&A	$0.35	$0.32	$0.33	$0.22	$1.22	$0.23	$0.25	$0.25	$0.28	$1.01	$1.50	$2.50	$3.50
% SG&A	-	-	-	-	-	-	-	-	-	-	*42.9%*	*33.3%*	*23.3%*
R&D	0.24	0.14	0.18	0.58	1.14	0.29	0.54	0.59	0.60	2.02	3.50	5.00	7.00
% R&D	-	-	-	-	-	-	-	-	-	-	*100.0%*	*66.7%*	*46.7%*
Other expenses	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%*
Operating Income	**($0.59)**	**($0.46)**	**($0.50)**	**($0.80)**	**($2.37)**	**($0.52)**	**($0.79)**	**($0.84)**	**($0.88)**	**($3.03)**	**($1.50)**	**$0.00**	**$4.50**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	*0.0%*	*30.0%*
Other Net	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	($0.0)	$0.0	($0.0)	$0.0	$0.0	$0.0
Pre-Tax Income	**($0.59)**	**($0.46)**	**($0.50)**	**($0.80)**	**($2.36)**	**($0.52)**	**($0.79)**	**($0.84)**	**($0.88)**	**($3.03)**	**($1.50)**	**$0.00**	**$4.50**
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
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($0.59)**	**($0.46)**	**($0.50)**	**($0.80)**	**($2.36)**	**($0.52)**	**($0.79)**	**($0.84)**	**($0.88)**	**($3.03)**	**($1.50)**	**$0.00**	**$4.50**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Shares Out	*49.4*	*51.6*	*56.1*	*58.2*	*53.8*	*58.4*	*58.9*	*58.9*	*65.8*	*60.5*	*75.0*	*80.0*	*88.0*
Reported EPS	**($0.01)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.04)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.05)**	**($0.02)**	**$0.00**	**$0.05**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	*#DIV/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*
Non GAAP Net Income	**($0.59)**	**($0.46)**	**($0.50)**	**($0.80)**	**($2.36)**	**($0.52)**	**($0.79)**	**($0.84)**	**($0.88)**	**($3.03)**	**($1.50)**	**$0.00**	**$4.50**
Non GAAP EPS	**($0.01)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.04)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.05)**	**($0.02)**	**$0.00**	**$0.05**

Source: Company filings and Zacks estimates

© Copyright 2013, Zacks Investment Research. All Rights Reserved.

HISTORICAL ZACKS RECOMMENDATIONS



DISCLOSURES

The following disclosures relate to relationships between Zacks Investment Research ("ZIR") and Zacks Small-Cap Research ("Zacks SCR") and the issuers covered by the Zacks SCR analysts in the Small-Cap Universe.

ZIR or Zacks SCR Analysts do not hold or trade securities in the issuers which they cover. Each analyst has full discretion on the rating and price target based on their own due diligence. Analysts are paid in part based on the overall profitability of Zacks SCR. Such profitability is derived from a variety of sources and includes payments received from issuers of securities covered by Zacks SCR for non-investment banking services. No part of analyst compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in any report or blog.

ZIR and Zacks SCR do not make a market in any security nor do they act as dealers in securities. Zacks SCR has never received compensation for investment banking services on the small-cap universe. Zacks SCR does not expect received compensation for investment banking services on the small-cap universe. Zacks SCR has received compensation for non-investment banking services on the small-cap universe, and expects to receive additional compensation for non-investment banking services on the small-cap universe, paid by issuers of securities covered by Zacks SCR. Non-investment banking services include investor relations services and software, financial database analysis, advertising services, brokerage services, advisory services, investment research, and investment management.

Additional information is available upon request. Zacks SCR reports are based on data obtained from sources we believe to be reliable, but is not guaranteed as to accuracy and does not purport to be complete. Because of individual objectives, the report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed by Zacks SCR Analysts are subject to change. Reports are not to be construed as an offer or the solicitation of an offer to buy or sell the securities herein mentioned. Zacks SCR uses the following rating system for the securities it covers. 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 of Zacks Ratings is as follows on the 1011 companies covered: Buy/Outperform- 14.3%, Hold/Neutral- 78.2%, Sell/Underperform – 6.9%. Data is as of midnight on the business day immediately prior to this publication.

© Copyright 2013, Zacks Investment Research. All Rights Reserved.