Zacks Small-Cap Research

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Bio-Path Holdings (BPTH-OTC)

BPTH: Balance sheet boosted by new financing, on track to advance L-Grb-2 into Phase II study in 2013—maintaining Outperform rating

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	02/11/2013
Current Price (04/11/13)	$0.53
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. Cohort 5 is enrolling patients now.

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 maintain our Outperform rating on BPTH shares.

SUMMARY DATA

52-Week High	**$0.59**
52-Week Low	**$0.25**
One-Year Return (%)	**96.30**
Beta	**0.48**
Average Daily Volume (sh)	**22,877**
Shares Outstanding (mil)	**65**
Market Capitalization ($mil)	**$35**
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 A	0.00 A
2013	0.00 E	0.00 E	0.00 E	1.00 E	1.00 E
2014					5.00 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.01 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 A	-$0.04 A
2013	-$0.01 E	-$0.01 E	-$0.01 E	$0.00 E	-$0.03 E
2014					-$0.03 E

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

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WHAT'S NEW

Previously, we upgraded Bio-Path (BPTH) shares to Outperform from Neutral based on recent developments and current valuation. We still hold our Outperform rating on BPTH with price target of $1.00 per share.

Balance Sheet Boosted By New Financing

BPTH reported full year of 2012 financials on March 2, 2012 ended December 31, 2012.

There is no revenue for the year of 2012.

Operating expenses were $2.6 million for the year 2012, an increase of $0.2 million compared to the year 2011, which was primarily due to increased drug material expense.

Net loss for the year 2012 was $2.6 million, (2,582,537), compared to a net loss of $(2,363,344) for the year 2011. The increase in net loss was due to an increase of $0.5 million in research and development expense, primarily due to an approximate $0.5 million increase in expense for drug product material used in the Company's clinical trial, in addition to increased expense for clinical trial operations and advisory services.

For the full year 2012, the Company reported a net loss per share of $(0.04) based on 59,317,779 weighted average shares outstanding, compared to $(0.04) per share for the year 2011.

As of December 31, 2012, the Company had cash of $534,046. Net cash used in operating activities for the year 2012 was $2.0 million.

During the first quarter of 2013, BPTH raised an additional $2 million, which boosted the Company's balance sheet. Current cash should last into fourth quarter of 2013 according to our model.

We appreciate 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.

Enrollment in Cohort 5 of Phase I L-Grb-2 Begins

On March 7, 2013, Bio-Path Holdings (BPTH) began enrolling patients into the fifth dosage cohort in its **Phase I clinical trial** of its product candidate Liposomal Grb-2 (L-Grb-20). The Phase I study is evaluating L-Grb-2 as a systemic treatment for blood cancers, including acute myeloid leukemia (AML), chronic myelogenous leukemia (CML), acute lymphoblastic leukemia (ALL) and myelodysplastic syndrome (MDS).

L-Grb-2 is the Company's lead antisense program. The Phase I trial is being conducted at The University of Texas MD Anderson Cancer Center.

In the **fifth cohort**, patients will receive a dose of **60 mg/m^2** twice a week for four weeks, for a total of eight doses. As the Company reported in November, due to the favorable safety profile of Liposomal Grb-2, BPTH has expanded the Phase I clinical trial to include higher dosages. Following the completion of the fifth cohort, Bio-Path expects to enroll patients into a **sixth cohort** with a dosage of **90 mg/ m^2**.

We are pleased to see that BPTH initiate the enrollment of cohort 5 on schedule. The Company remains on track to complete dosing in the Phase I trial by mid-year 2013.

Previously, Bio-Path completed treatment of the **fourth cohort** of the **Phase I** clinical trial of Liposomal Grb-2.

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.

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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.

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.

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.



VALUATION AND RECOMMENDATION

We maintain our Outperform rating on BPTH shares and reiterate our twelve-month price target of $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 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 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 $65 million in market cap.

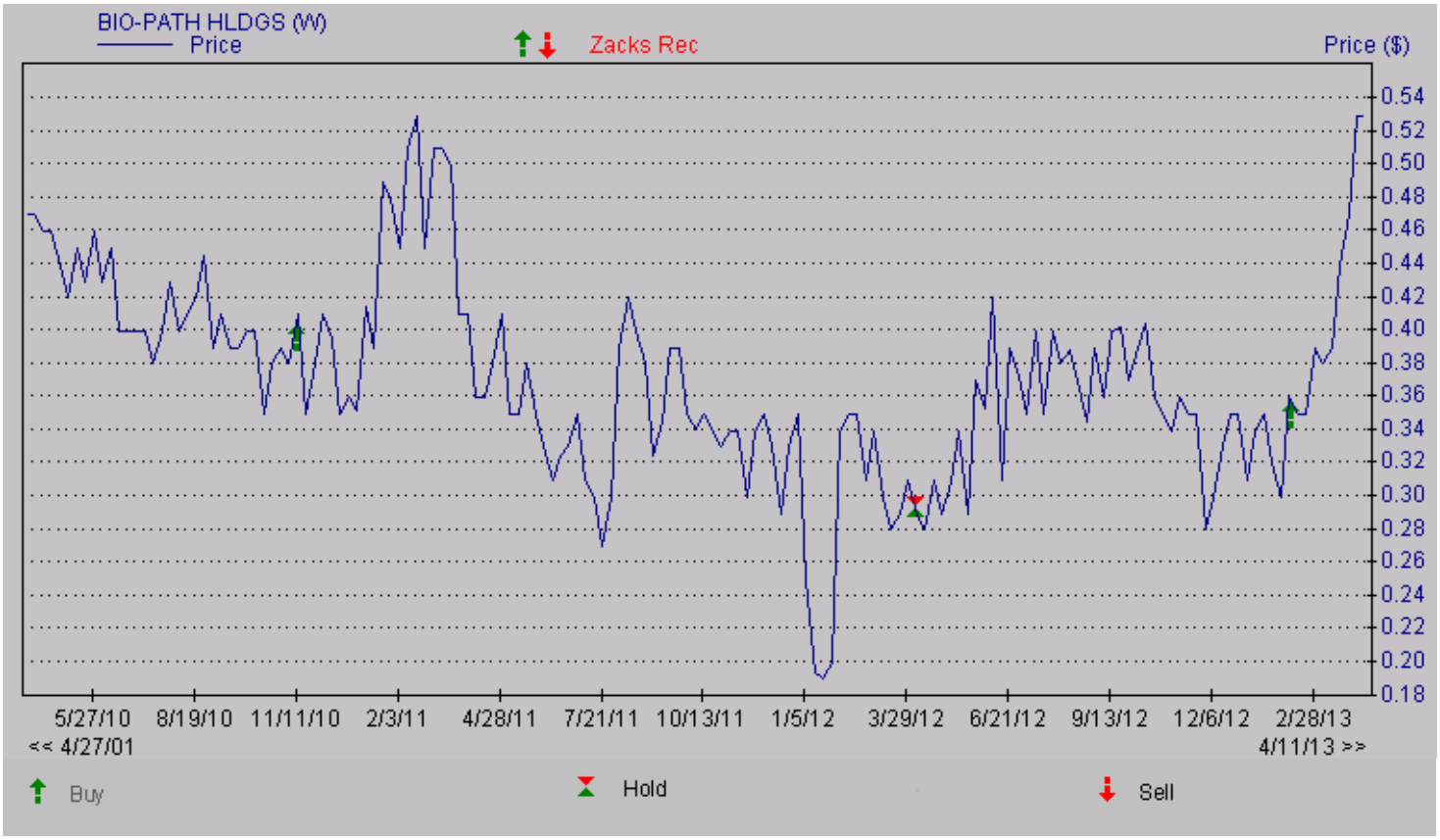
PROJECTED INCOME STATEMENT

$ in millions except for per share data	2011A (Dec)	2012A (Dec)					2013E (Dec)					2014E (Dec)	2015E (Dec)
	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**	**$1.00**	**$1.00**	**$5.00**	**$7.50**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	*400.0%*	*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
Gross Income	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**1.00**	**1.00**	**5.00**	**7.50**
Gross Margin	-	-	-	-	-	-	*0.0%*	*0.0%*	*0.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*
SG&A	$1.22	$0.23	$0.25	$0.25	$0.26	$0.99	$0.25	$0.27	$0.28	$0.29	$1.09	$2.50	$3.50
% SG&A	-	-	-	-	-	-	-	-	-	*29.0%*	*109.0%*	*50.0%*	*46.7%*
R&D	1.14	0.29	0.54	0.59	0.18	1.60	0.50	0.50	0.50	0.50	2.00	5.00	7.00
% R&D	-	-	-	-	-	-	-	-	-	*50.0%*	*200.0%*	*100.0%*	*93.3%*
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%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Operating Income	**($2.37)**	**($0.52)**	**($0.79)**	**($0.84)**	**($0.43)**	**($2.58)**	**($0.75)**	**($0.77)**	**($0.78)**	**$0.21**	**($2.09)**	**($2.50)**	**($3.00)**
Operating Margin	-	-	-	-	-	-	-	-	-	*21.0%*	-	*-50.0%*	*-40.0%*
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	**($2.36)**	**($0.52)**	**($0.79)**	**($0.84)**	**($0.43)**	**($2.58)**	**($0.75)**	**($0.77)**	**($0.78)**	**$0.21**	**($2.09)**	**($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
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($2.36)**	**($0.52)**	**($0.79)**	**($0.84)**	**($0.43)**	**($2.58)**	**($0.75)**	**($0.77)**	**($0.78)**	**$0.21**	**($2.09)**	**($2.50)**	**($3.00)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	*21.0%*	-	-	-
Shares Out	*53.8*	*58.4*	*58.9*	*58.9*	*61.1*	*59.3*	*65.0*	*70.0*	*75.0*	*80.0*	*72.5*	*90.0*	*100.0*
Reported EPS	**($0.04)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.04)**	**($0.01)**	**($0.01)**	**($0.01)**	**$0.00**	**($0.03)**	**($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*
Non GAAP Net Income	**($2.36)**	**($0.52)**	**($0.79)**	**($0.84)**	**($0.43)**	**($2.58)**	**($0.75)**	**($0.77)**	**($0.78)**	**$0.21**	**($2.09)**	**($2.50)**	**($3.00)**
Non GAAP EPS	**($0.04)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.04)**	**($0.01)**	**($0.01)**	**($0.01)**	**$0.00**	**($0.03)**	**($0.03)**	**($0.03)**

Source: Company filings and Zacks estimates

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HISTORICAL ZACKS RECOMMENDATIONS



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