Zacks Small-Cap Research

November 20, 2012
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Bio-Path Holdings (BPTH-OTC)

BPTH: Doses increased in Phase I trial of Liposomal Grb-2, balance sheet will be boosted by new financing-Neutral

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	04/05/2012
Current Price (11/16/12)	$0.35
12–Month Target Price	**$0.75**

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.

However, further financing is needed. If an appropriate partner for Grb-2 after the Phase I trial cannot be found, existing shareholder base will be diluted.

Therefore, we rate the Company's shares Neutral.

SUMMARY DATA

52-Week High	**$0.42**
52-Week Low	**$0.13**
One-Year Return (%)	**16.67**
Beta	**0.86**
Average Daily Volume (sh)	**29,550**
Shares Outstanding (mil)	**59**
Market Capitalization ($mil)	**$21**
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**

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WHAT'S NEW

BPTH Reports Third Quarter Financials

No revenue was recorded for the 2Q12.

R&D expense was $0.59 million for 3Q12 compared to $0.18 million for the 3Q11. SG&A expense was $0.25 million for 3Q12 compared to $0.33 million for 3Q11.

Operating expenses were $0.84 million in the third quarter of 2012, an increase of $0.34 million compared to the third quarter 2011, primarily due to increased drug material expense, offset to some extent, by reduced administrative expenses for management stock options

Net loss for the third quarter 2012 was $0.84 million, compared to a net loss of $0.50 million in the third quarter 2011. The increase in net loss was due to an increase in research and development expense from a higher cost of drug material, which more than offset a decrease in general administrative expense during the same periods.

For the third quarter of 2012, the Company reported a net loss per share of $(0.01) based on 58.9 million weighted average shares outstanding, compared to $(0.01) per share for the same period last year.

As of September 30, 2012, the Company had cash of $0.33 million compared to $0.95 million at December 31, 2011. Net cash used in operating activities for the first nine months of 2012 was $1.6 million compared to $0.73 million for the first nine months of 2011. The primary reasons for the increase in net cash used in operations between the comparable nine month period is the increased cost of clinical trial operations, including drug material, as well as receipt in 2011 of a $244,479 U.S. Government grant that was not matched in 2012.

As a reminder, at the end of first quarter of 2012, the Company has initiated a private placement to raise up to $2 million through the sale of shares of the Company's common stock. The offering is in progress and the Company has raised $945,000 to date. The Company has received additional commitments for up to $700,000, which are in various stages of being finalized.

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.

Phase I of Liposomal Grb-2 Is Progressing Well

Bio-Path recently abandoned its RNAi program **Liposomal FAK** (L-FAK, BP-100-2.01) due to unfavorable market environment. Right now, the Company is focused on its lead antisense program Liposomal Grb-2.

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 is continuing treatment with Liposomal Grb-2, and is currently in a fourth treatment cycle. This patient started treatment seven months ago 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

	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. All necessary steps to proceed with the new Cohort 5 dosing are expected to be completed by the end of December 2012. 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.

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.

Cash Burn Is a Concern without a Partner

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, at the end of first quarter of 2012, the Company has initiated a private placement to raise up to $2 million through the sale of shares of the Company's common stock. The offering is in progress and the Company has raised $945,000 to date. The Company has received additional commitments for up to $700,000, which are in various stages of being finalized.

Without a partner, BPTH has to raise funds through the capital market by issuing new shares or convertible notes, which dilute existing shareholders. We have noticed that share numbers have increased from 48 million at the end of 2010 to 59 million at the end of 3Q2012. 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.

RECOMMENDATION AND VALUATION

We maintain our Neutral rating on Bio-Path Holdings Inc. with a twelve-month price target of $0.75 per share.

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 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 program. We are impressed by the interim results, which have demonstrated the safety and possible 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.

Although interim data from the Phase I clinical trial of Liposomal Grb-2 are encouraging with favorable safety profile and possible anti-leukemia benefits, it remains uncertain that when BPTH can find a partner to continue to develop Liposomal Grb-2 program in Phase III trials.

Further financing is needed if an appropriate partner for Grb-2 after the Phase I trial cannot be found. Equity financing will dilute existing shareholder base.

By comparing to its peers in the biotech industry and considering the early stage of its pipeline and the uncertainty of the Company's drug delivery technology, we think in the next 12-month period of time, Bio-Path's stock should be trading around $0.75 per share, which value the Company at about $45 million in market cap.

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

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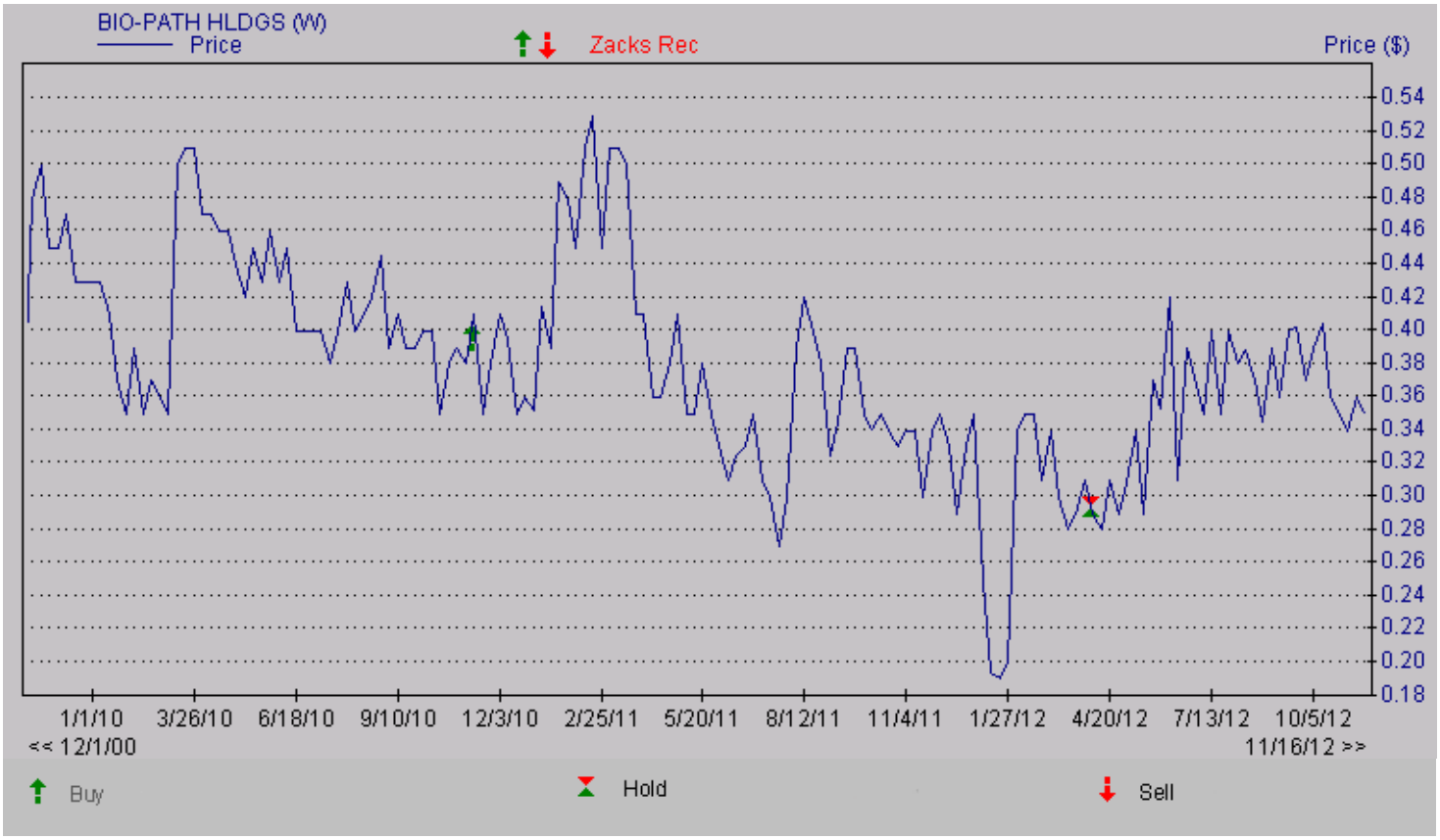
HISTORICAL ZACKS RECOMMENDATIONS



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