Zacks Small-Cap Research

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Bio-Path Holdings (BPTH-OTC)

BPTH: Encouraging interim Phase I data of Liposomal Grb-2, but an immediate partnership is not likely-Neutral

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	04/05/2012
Current Price (04/06/12)	$0.29
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. Enrollment is picking up momentum and full results will be available in late 2012 or early 2013.

However, finding an appropriate partner for Grb-2 after the Phase I trial may take a longer time than we expected due to the current unfavorable market environment for RNA therapeutics.

Therefore, we rate the Company's shares Neutral.

SUMMARY DATA

52-Week High	**$0.50**
52-Week Low	**$0.13**
One-Year Return (%)	**-29.27**
Beta	**0.87**
Average Daily Volume (sh)	**16,731**
Shares Outstanding (mil)	**58**
Market Capitalization ($mil)	**$17**
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 E	0.00 E	0.00 E	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 E	-$0.02 E	-$0.02 E	-$0.02 E	-$0.06 E
2013					-$0.03 E
2014					-$0.01 E

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

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WHAT'S NEW

Phase I of Liposomal Grb-2 Is Progressing Well

Enrollment is picking up steam in the **Phase I** clinical trial of **Liposomal Grb-2**. The Company has successfully completed the first two cohorts of the study, and has reported encouraging positive results. The drug has been well tolerated and possible anti-leukemia activity has been observed.

At the end of March 2012, a total of 24 patients have been enrolled in the Phase I study, of which 10 have been evaluable. The trial is now in the third cohort treating patients with the third dose level of 20 mg/m2.

Liposomal Grb-2 (BP-100-1.01) is the Company's lead drug candidate, which is a liposomal delivered **antisense** cancer drug candidate for the treatment of blood cancers including Chronic Myelogenous Leukemia (CML), Acute Myeloid Leukemia (AML), Acute Lymphoblastic Leukemia (ALL), and Myelodysplastic Syndrome (MDS).

Bio-Path (BPTH) initiated the Phase I trial in July 2010. The clinical trial is a dose-escalating study to determine the safety and tolerance of escalating doses of Liposomal Grb-2, as well as the optimal dose for further development. The trial seeks a total of 18 to 30 evaluable patients and will evaluate five doses of Liposomal Grb-2 in five cohorts with dose escalation of 5, 10, 20, 40 and 50 mg/m2. An evaluable patient is a patient who has been able to complete the four-week treatment cycle. The expected dose for treatment is 45 mg/m2 based on pre-clinical studies in animals. The clinical trial is being conducted at The University of Texas MD Anderson Cancer Center.

The Phase I trial has experienced a slow start, but it appears that the trial is progressing at a faster pace now. Possible anti-leukemia benefits in some patients may be helping in recruiting new patients. We estimate the Phase I trial will be completed in late 2012 or early 2013 which is longer than we previously expected.

Interim Data from Phase I Liposomal Grb-2 are Encouraging

Recently, BPTH reported results from first two cohorts of the Phase I clinical trial of Liposomal Grb-2.

Results from the **first dosage cohort** were reported on August 11, 2011. The drug was well tolerated with no treatment-related serious adverse events and data suggests some possible anti-leukemia activity at low dosage. Following are detailed findings from the first dosage cohort:

- A total of 14 patients were enrolled in the first cohort. All patients had failed prior therapies. Of the 14 patients, one patient withdrew prior to treatment and 13 were treated. Of the treated patients, six were evaluable and seven failed to complete a full 28-day cycle because of disease progression. Liposomal Grb-2 is systemically delivered by intravenous injection. Patients received a dose of **5 mg/m2** twice a week for four weeks, for a total of eight doses. Six evaluable patients comprised the completed first dose cohort.

- Liposomal Grb-2 at a dose of 5 mg/m2 is well tolerated. In addition, there is a suggestion of possible anti-leukemia activity, even at the low starting dose used in the first cohort.

- Of the six evaluable patients, lab parameters for blasts and bone marrow demonstrated possible anti-leukemia activity. Two patients had transient improvement and/or stable disease and received a total of five cycles each, representing five months on treatment with the drug. In addition, two patients had transient improvement on leukemia cutis lesions.

- In addition to the six evaluable patients, a patient with CML blast phase who had failed all available TKI (tyrosine kinase inhibitor) and other experimental options showed a significant reduction in blasts from 81 percent to four percent. Unfortunately, this patient discontinued study treatment due to progression of disease into the central nervous system and had to discontinue therapy.

The first cohort Phase I results was presented at the 53rd Annual Meeting of the American Society of Hematology (ASH) in December 2011 in San Diego, California.

On February 7, 2012, BPTH reported the **second dosage cohort** data. The drug was well tolerated with no treatment-related serious adverse events and data continues to suggest some possible anti-leukemia activity.

- A total of six patients were enrolled and dosed in the second cohort of the study.

- Three evaluable patients completed the 28-day treatment cycle and comprised the completed second dose cohort. Three other patients failed to complete a full 28-day cycle because of disease progression.

- Liposomal Grb-2 is systemically delivered by intravenous injection. Patients received a dose of **10 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 10 mg/m2 is well tolerated. There is also a suggestion of possible anti-leukemia activity, at the dose of 10 mg/m2.

We think the interim results from the first two cohorts are encouraging. The suggestion of possible anti-leukemia activity with the low doses used in the first and second cohorts is especially impressive.

However, A Licensing Deal May Take A Longer Time to Close

BPTH's development plan for Liposomal Grb-2 is to out-license its drug delivery technology after the Phase I trial and find a partner after a proof of concept (Phase IIa) trial. A favorable outcome of the Phase I trial will provide an opportunity for the Company to monetize its core drug delivery technology, the **neutral lipid drug delivery technology**. Bio-Path expects opportunities to negotiate non-exclusive license applications involving upfront cash payments with pharmaceutical companies developing antisense drugs that need systemic delivery technology.

However, even with encouraging interim Phase I data for Liposomal Grb-2, an appropriate licensing deal or partnership may take longer time to reach than we previously expected. We estimate the earliest time for such a deal to close will be in 2013 rather than by the end of 2012. Our assessment is based on couple of factors.

First, the completion of the Phase I trial for Liposomal Grb-2 has been delayed to late 2012 or early 2013 due to a frustratingly slow start. Although enrollment in the trial is picking up momentum due to the favorable safety profile and possible efficacy of Liposomal Grb-2, the earliest completion time for the Phase I will be by the end of 2012. If everything goes well as planned, a license deal can be reached in 2013 the earliest.

Secondly, positive results from the Phase I trial may not be sufficient to find a partner. Although we are impressed by the Phase I interim results, which has demonstrated the tolerability and possible efficacy of Liposomal Grb-2, Big Pharma and biotech companies may want to see more data after the Phase I trial. Most likely, a positive Phase II data will be needed to convince a partner that Liposomal Grb-2 and the delivery technology work in our view.

Thirdly, current market environment is not favorable for RNA therapeutics. It's still a fresh memory that only a couple of years ago, RNAi were embraced with extreme enthusiasm by the pharmaceutical community. Big pharma like Merck, Novartis, Roche, and Pfizer all jumped onto the RNAi bandwagon, hoping to find a quick fix to their internal R&D drought.

However, this momentum was rapidly reversed during 2010/2011. All major big pharma companies have terminated their RNAi programs or partnerships. This does not necessarily mean a total failure of the RNAi therapeutic platform, but it does imply some problems with this platform.

Delivery is the first and foremost challenge for RNA therapeutics. Progress has been made in the past few years, but not good enough to satisfy big pharma's thirst to quickly bulk up their clinical pipelines. Another important reason that big pharma quitted the RNA therapeutic platform is that the commercial prospect of RNA drugs is not that bright. Currently there are only two RNA drugs have been approved: Fomivirsen (Vitravene) by Isis for the treatment of cytomegalovirus retinitis (CMV), and Pegaptanib (Macugen) by Eyetech/Pfizer for the treatment of neovascular (wet) age-related macular degeneration. Both products are administered intraocularly, but neither has achieved substantial commercial success.

Based on the above analysis, we don't believe that big pharma will move back into the RNA therapeutics field any time soon until the delivery has been validated in humans and the pathway to clinical development and regulatory approval becomes more clarified. Recently Galena Biopharma, Inc. has experienced difficulties to spin off its RNAi programs in a timely manner, which further validates our assumption about the RNA therapeutics market.

Therefore, at present market environment, it may be tougher and take a longer time for BPTH to find an appropriate partner for its Liposomal Grb-2 program and the technology within. This will have an important impact on the Company's operations.

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.

At December 31, 2011, BPTH had cash of $952,252. Current cash will be sufficient to fund its operations up to June 2012. According to management, at the end of the first quarter of 2012, the Company commenced a new private placement fund raising campaign to raise up to $2 million through the sale of shares of the Company's common stock. Current cash balance plus the potential new capital inflow could expand operations into fourth quarter of 2012.

In the second quarter of 2010, the Company signed an equity purchase agreement for up to $7 million with **Lincoln Park Capital Fund**, LLC. In connection with the signing of the agreement, LPC made an initial purchase of $200,000 of common stock and warrants. The LPC financing structure puts in place a significant amount of equity capital for clinical development of Bio-Path's technology, while is expected to support clinical development of its lead products and help sustain operations through the next key milestones.

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 58 million at the end of 2011. As the Company raises new funds in second quarter of 2012, share numbers will increase further to 66 million by the end of 2012 according to our model. 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 downgrade Bio-Path Holdings Inc., from Outperform to Neutral with a new twelve-month price target of $1.00 per share. Our call is mainly based on the current unfavorable market environment for RNA therapeutics.

We believe Bio-Path's neutral lipid drug delivery platform technology has great potential to systemically deliver antisense and siRNA 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 may still take a longer time for BPTH to out license the delivery technology and to find a partner for the Liposomal Grb-2 program itself based on the current unfavorable market environment for RNA therapeutics platforms.

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 should be trading around $1.00 per share, which value the Company at about $60 million in market cap.

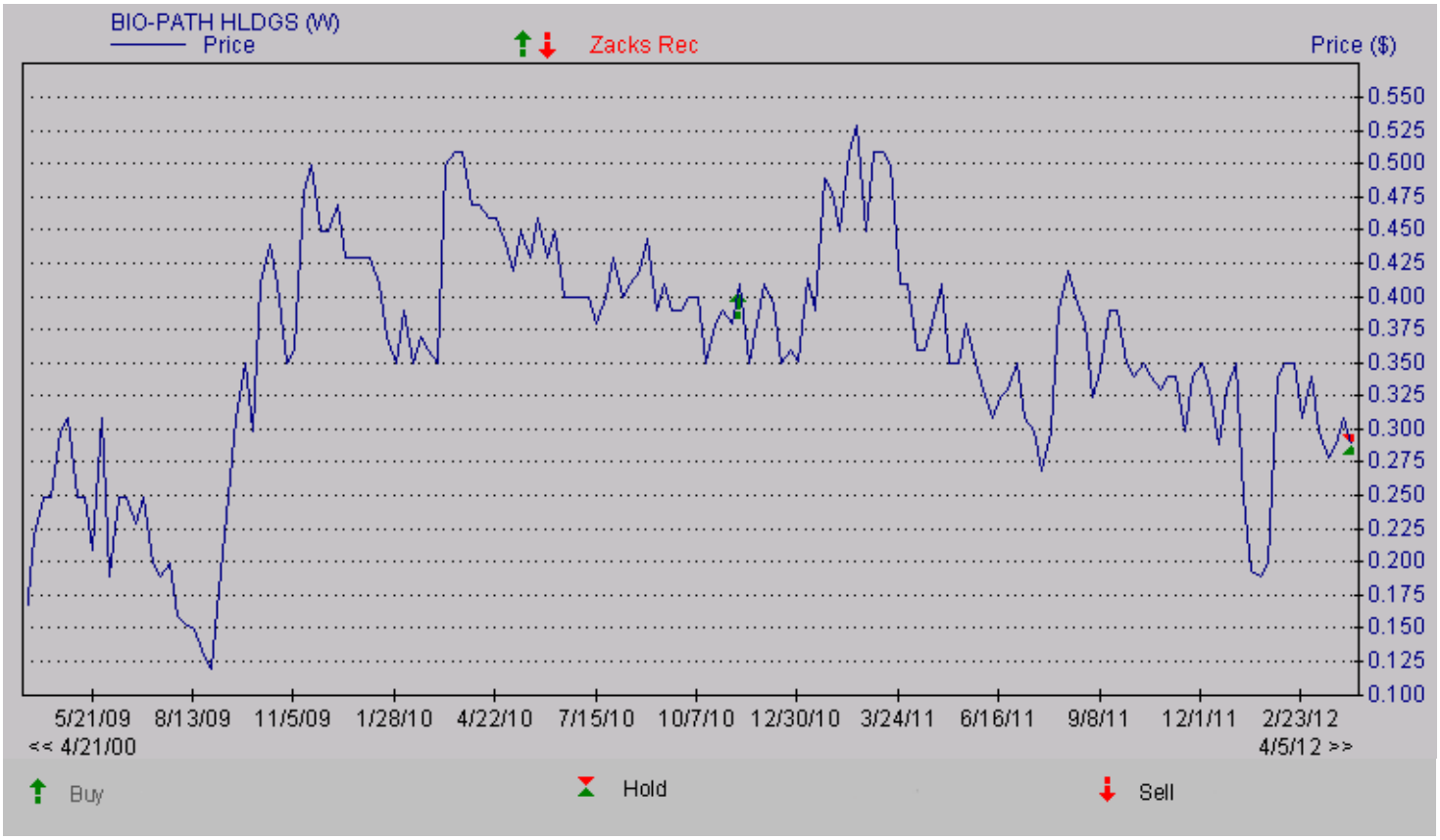
PROJECTED INCOME STATEMENT

$ 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	$0.35	$0.40	$0.48	$0.52	$1.75	$2.50	$3.00	$4.00
% SG&A	-	-	-	-	-	-	-	-	-	-	*71.4%*	*40.0%*	*26.7%*
R&D	0.24	0.14	0.18	0.58	1.14	0.50	0.55	0.60	0.60	2.25	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)**	**($0.85)**	**($0.95)**	**($1.08)**	**($1.12)**	**($4.00)**	**($2.50)**	**($0.50)**	**$4.00**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	*-6.7%*	*26.7%*
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)**	**($0.85)**	**($0.95)**	**($1.08)**	**($1.12)**	**($4.00)**	**($2.50)**	**($0.50)**	**$4.00**
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	**($0.59)**	**($0.46)**	**($0.50)**	**($0.80)**	**($2.36)**	**($0.85)**	**($0.95)**	**($1.08)**	**($1.12)**	**($4.00)**	**($2.50)**	**($0.50)**	**$4.00**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Shares Out	*49.4*	*51.6*	*56.1*	*58.2*	*53.8*	*58.3*	*61.0*	*65.3*	*65.8*	*62.6*	*75.0*	*80.0*	*88.0*
Reported EPS	**($0.01)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.04)**	**($0.01)**	**($0.02)**	**($0.02)**	**($0.02)**	**($0.06)**	**($0.03)**	**($0.01)**	**$0.05**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	*-827.3%*
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*	*$0.00*	*$0.00*
Non GAAP Net Income	**($0.59)**	**($0.46)**	**($0.50)**	**($0.80)**	**($2.36)**	**($0.85)**	**($0.95)**	**($1.08)**	**($1.12)**	**($4.00)**	**($2.50)**	**($0.50)**	**$4.00**
Non GAAP EPS	**($0.01)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.04)**	**($0.01)**	**($0.02)**	**($0.02)**	**($0.02)**	**($0.06)**	**($0.03)**	**($0.01)**	**$0.05**

Source: Company filings and Zacks estimates

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