Zacks Small-Cap Research

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Bio-Path Holdings (BPTH-OTC)

BPTH: Unique drug delivery technology with great potential-Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	11/11/2010
Current Price (11/14/11)	$0.34
12 –Month Target Price	**$2.50**

OUTLOOK

Bio-Path is a development stage drug delivery biotech company. We are optimistic about the great potential of the Company's neutral lipid drug delivery technology and ligand-enhanced lipid tumor targeting technology, which enable systemic delivery of antisense, RNAi and siRNA drug candidates. Bio-Path's pipeline targets the multi-billion dollar cancer market and the Company has moved its lead drug candidate liposomal-Grb-2 into a Phase I trial. The Company's good working relationship with the MD Anderson Cancer Center and its out-license oriented strategy should build shareholder value in a rapid and cost-effective way. We rate the Company's shares Outperform.

SUMMARY DATA

52-Week High	**$0.55**
52-Week Low	**$0.26**
One-Year Return (%)	**-17.07**
Beta	**0.84**
Average Daily Volume (sh)	**6,572**
Shares Outstanding (mil)	**56**
Market Capitalization ($mil)	**$19**
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)
2009	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2010	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2011	0.00 A	0.00 A	0.00 A	0.00 E	0.00 E
2012					1.50 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2009	-$0.01 A	-$0.01 A	-$0.01 A	-$0.01 A	-$0.05 A
2010	-$0.01 A	-$0.01 A	-$0.01 A	-$0.01 A	-$0.04 A
2011	-$0.01 A	-$0.01 A	-$0.01 A	-$0.02 E	-$0.05 E
2012					-$0.05 E

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

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WHAT'S NEW

Bio-Path Reports Third Quarter 2011 Financial Results

There was no revenue for the quarter ended September 30, 2011.

Research and development expense was $127,109 for the three months ended September 30, 2011; a decrease of $108,237 over the three months ended September 30, 2010. The year to date decrease in research and development expense results primarily from lower drug development testing and supply expense and stock options expense offset by lesser increases in clinical trial and amortization expense. Research and development expense – related party is higher for the quarter and year to date versus prior year due to greater clinical trial patient expense accrued or paid to MD Anderson.

General and administrative expenses were $327,380 for the three months ended September 30, 2011; an increase of $61,438 over the three months ended September 30, 2010. The increase in general and administrative expenses results from the increased operating expenses relating to legal and accounting expense, increased participation in industry conferences and general expenses related to being a public company.

Net loss was $503,819 for the three months ended September 30, 2011, compared to a loss of $501,337 for the three months ended September 30, 2010. Net loss per share, both basic and diluted was the same for the respective three month periods. The increase in year to date net loss for 2011 compared to 2010 was due to higher general and administrative and research and development – related party expense offset to a lesser degree by lower research and development expense.

At September 30, 2011, Bio-Path had cash of $983,286 compared to $238,565 at December 31, 2010. The increase in the nine month period is primarily from the sale of common stock through the private placement offering and the exercise of the warrants for cash.

Net cash used in operations during the nine months ended September 30, 2011 was $726,157 compared to $995,584 for the nine months ended September 30, 2010.

Management believes that available cash will be sufficient to fund liquidity and capital expenditure requirements up to June 2012. The Company anticipates raising approximately an additional $8,600,000 in net proceeds to completely implement its business plan. Currently, the Company has several discussions underway with potential investors at this time which could result in sufficient capital inflow to extend operations beyond June of 2012 and possibly even 2013.

Apparently, earnings report is not important for Bio-Path at this point. Investors should be focused on the company's pipeline advancement and clinical development. In this regard, we think Bio-Path has made great progress so far this year.

Encouraging Interim Phase I Results Were Reported

On August 11, 2011, Bio-Path Holdings, Inc.(BPTH) announced that it has completed treatment of the first dosage cohort in the Company's **Phase I** clinical trial of its lead product candidate, BP-100-1.01 (Liposomal Grb-2).

As a reminder, Liposomal Grb-2 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 Company commenced its Phase I clinical trial to study L-Grb-2 in human patients in July of 2010. The trial is being conducted at the MD Anderson Cancer Center.

The drug was well tolerated with no treatment-related serious adverse events reported 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 of the study. 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.

- Preliminary results suggest that 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. The protocol for the clinical trial includes dose escalation of 5, 10, 20, 40 and 50 mg/m2.

- 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 Phase I results has been accepted for a poster presentation at the 53rd Annual Meeting of the American Society of Hematology (ASH) to be held December 10 to13, 2011 in San Diego, California. The ASH Annual Meeting is the premier event for physicians and healthcare researchers involved in hematology to meet to learn about the latest developments to treat blood diseases.

We are impressed by the interim results which are very encouraging. 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. In contrast, efficacy studies of Liposomal Grb-2 in animals used dose of 45 mg/m2. The Company is proceeding through the next cohorts of the clinical trial to determine if higher doses of the drug will increase favorable anti-leukemia effects on patients.

The Principal Investigator for the clinical trial is preparing, with the assistance of the Company, an abstract for submission to the American Hematology Society Annual Meeting later this year in San Diego and potential other important scientific conferences later in the year. The study continues to accrue patients and Cohort 2 is open with dosing at 10 mg/m2.

We think Bio-Path is on track to execute its plan in terms of clinical advancement and business development. We are optimistic about Bio-Path' **neutral lipid drug delivery technology** and related **liposome tumor targeting technology.** The Company has established a decent pipeline based on the above technologies and has moved its lead drug candidate Liposomal Grb-2 (L-Grb-2 or BP-100-1.01) into a Phase I clinical trial. L-Grb-2 is a liposomal delivered antisense cancer drug that targets an estimated $1 billion annual market for Chronic Myelogenous Leukemia (CML), Acute Myeloid Leukemia (AML), Acute Lymphoblastic Leukemia (ALL), and Myelodysplastic Syndrome (MDS). We expect to see positive results for the cohort 2 studies.

A favorable outcome of the Phase I trial will provide an opportunity for the Company to monetize its core 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.

We continue to rate Bio-Path Outperform and reiterate our twelve month price target of $3 per share.

KEY POINTS

- We maintain our Outperform rating for Bio-Path Holdings Inc. and reiterate our twelve month price target of $2.5 per share.

- We are optimistic about Bio-Path's neutral lipid drug delivery technology and related ligand-enhanced lipid tumor targeting technology, which enable systemic delivery of antisense and siRNA drug candidates. Antisense and siRNA are two of the most promising targeted therapeutics, but are challenged by their systemic delivery and distribution into diseased areas in humans. Bio-Path's two platform technologies have great potential to achieve this goal.

- Bio-Path's pipeline targets the multi-billion dollar cancer market. The Company has advanced its lead antisense cancer drug candidate liposomal-Grb-2 (L-Grb-2) into Phase I clinical trials using its neutral lipid drug delivery technology. The Company's two other cancer drug candidates liposomal-Bcl-2 (L-Bcl-2, antisense) and liposomal-FAK (L-FAK, siRNA) are at the pre-clinical stage and the Company plans to bring them into clinic soon as funding levels permit.

- With a good working relationship with the prestigious MD Anderson Cancer Center, combined with its two drug delivery platform technologies, the Company's pipeline could be easily expanded into other therapeutic areas in a rapid and cost-effective way.

- We think Bio-Path's out-license oriented growth strategy is highly workable in the current pharmaceutical/biotech environment. We believe current market environment is favorable for small biotech companies in terms of out-licensing to and partnering with big pharma/biotech companies. This strategy will greatly reduce the risks associated with drug development and help to build shareholder value rapidly.

- We think Bio-Path's shares are undervalued based on the Company's fundamentals. We understand the Street discounts the Company's value because of its early stage pipeline and the uncertainty of its drug delivery technology. But we have a different opinion. Investors should also consider the great potential of the Company's platform technology and pipeline. For investors with high risk tolerance, Bio-Path should be considered as a component of the portfolio.

OVERVIEW

Bio-Path Holdings, Inc., through its wholly-owned subsidiary Bio-Path Inc., is a development stage biotech company. The Company was founded with technology from The University of Texas, MD Anderson Cancer Center dedicated to developing novel cancer drugs under an exclusive license arrangement. Since its inception, the Company has acquired three exclusive licenses from MD Anderson Cancer Center for three lead products and related nucleic acid drug delivery technology, including tumor targeting technology.

The Company's key technology licensed from MD Anderson is **neutral lipid drug delivery technology** (neutral liposome). The liposomal technology enables systemic delivery of antisense, small interfering RNA (siRNA) and hydrophobic small molecules for treatment of cancer. Bio-Path recently licensed new

liposome tumor targeting technology, which has the potential to be applied to augment the Company's current delivery technology to further improve the effectiveness of its antisense and siRNA drugs under development as well as other future liposome-based drugs. The liposome technology is already in clinical test and tumor targeting technology is still in the research and development stage

Bio-Path's lead drug candidate **liposomal Grb-2** (L-Grb-2, BP-100-1.01) is an antisense drug candidate currently in a Phase I clinical trial. Bio-Path's pipeline also includes **liposomal Bcl-2** (L-Bcl-2, BP-100-1.02), a liposome delivered antisense cancer drug that targets the lymphoma and certain solid tumor markets, and **liposomal FAK** (L-FAK, BP-100-2.01), a liposomal delivered siRNA drug candidate. While liposomal FAK is still in pre-clinical development, a pre-IND package for liposomal Bcl-2 has been filed with the FDA which could lead to this drug candidate receiving an IND next year to commence a clinical trial.

In addition to its existing technology and drug candidates under license, the Company has a close working relationship with key members of the MD Anderson's staff, which should provide Bio-Path with the opportunity to license promising new drug candidates in the future. Bio-Path expects the working relationship with MD Anderson to enable the Company to broaden its technology to include cancer drugs other than antisense and siRNA.

Bio-Path's business plan is to act efficiently as an intermediary in the process of translating newly discovered drug technologies into authentic therapeutic drug candidates. Its strategy is to selectively license potential drug candidates for certain cancers, and to advance these candidates through proof of concept into a safety study (Phase I), and human efficacy trials (Phase IIA), and then potentially out-license individual successful drug candidates to a pharmaceutical company.

The Company was founded in May of 2007 as a Utah corporation. In February of 2008, Bio-Path completed a reverse merger with Ogden Golf Co. Corporation, a public company traded over the counter that had no current operations. The name of Ogden Golf was changed to Bio-Path Holdings, Inc. and the directors and officers of Bio-Path, Inc. became the directors and officers of Bio-Path Holdings, Inc. Bio-Path has become a publicly traded company as a result of this merger.

Bio-Path is headquartered in Houston, TX.

INVESTMENT THESES

Two Unique Platform Technologies Constitute the Core Competency

Bio-Path currently holds intellectual property of two unique drug delivery platform technologies which are the keys to the Company's success.

The Company's core technology is **neutral lipid drug delivery technology** (neutral liposome) which was licensed from the MD Anderson Cancer Center. The liposomal technology enables systemic delivery of antisense, RNA interference (RNAi), small interfering RNA (siRNA) and hydrophobic small molecules for treatment of various diseases. The systemic delivery of antisense (single stranded) and siRNA (double stranded) has great potential for therapeutic drugs having little or no toxicity. Small interfering RNA (siRNA) is also of great importance in drug development as a research tool for identifying specific protein activity.

The Nobel prize winning discovery of RNA interference (RNAi) is a revolution in biology, representing a breakthrough in understanding how genes are turned on and off in cells, and a completely new approach to drug discovery and development. RNAi is a natural process of gene silencing. By harnessing the natural biological process of RNAi occurring in human cells, the creation of a major new class of

medicines, known as RNAi therapeutics, is on the horizon. RNAi therapeutics target the 'root' genetic cause of diseases by potently silencing specific messenger RNA, thereby preventing the disease-causing proteins from being made.

Small interfering RNAs (siRNAs) are short double stranded nucleic acid molecules that mediate RNAi and interfere with the process of producing proteins inside cells.

Antisense RNAs are small, chemically modified strands of DNA that interfere with messenger RNA (mRNA). These drugs (oligonucleotides) are engineered in a sequence that is exactly opposite (hence, anti) to the coding (sense) sequence of mRNA. Upon binding with the mRNA, a duplex is formed. This duplex inhibits the production of the intended protein.

Antisense and siRNA may offer some advantages over conventional therapies. The antisense complex can be synthesized chemically in a lab and then introduced into the cell. Once introduced, antisense can target virtually any protein synthesized by the body. This is a significant advantage over small molecule or antibody drug candidates that target only specific classes of proteins. With knowledge of the sequenced human genome, scientists should be able to develop antisense compounds for each and every gene/mRNA. Additionally, the antisense identification and subsequent production process is more straightforward than the traditional small molecule or antibody drug discovery platform. Scientists only need to identify the specific gene worth testing, and then synthesize the antisense oligonucleotide. This offers a significant time and cost of discovery advantage. Although siRNA therapeutics are more recent to the pharmaceutical industry than antisense, the structures are similar with siRNA being a double stranded nucleic acid complex compared to the single stranded antisense oligonucleotide. As a result, the above mentioned advantages of antisense over conventional therapies are also expected to apply to siRNA.

Antisense and siRNA are two of the most promising fields of targeted therapy. Development of antisense and siRNA, however, has been limited by the lack of a suitable method to deliver these drugs to the diseased cells with high uptake into the cell and without causing toxicity. Bio-Path's neutral-lipid based liposome technology is designed to accomplish this goal.

The neutral lipid drug delivery technology solves this problem by employing DOPC neutral lipid formulations to incorporate the antisense/siRNA into liposomes. These liposomes are inert in the body, incorporate the antisense/siRNA with high efficiency and form microscopic to nano-sized particles that can migrate inside tumors. Testing of Bio-Path's delivery technology in animals has demonstrated a 10-30 fold increase in tumor cell uptake compared to other delivery methods.

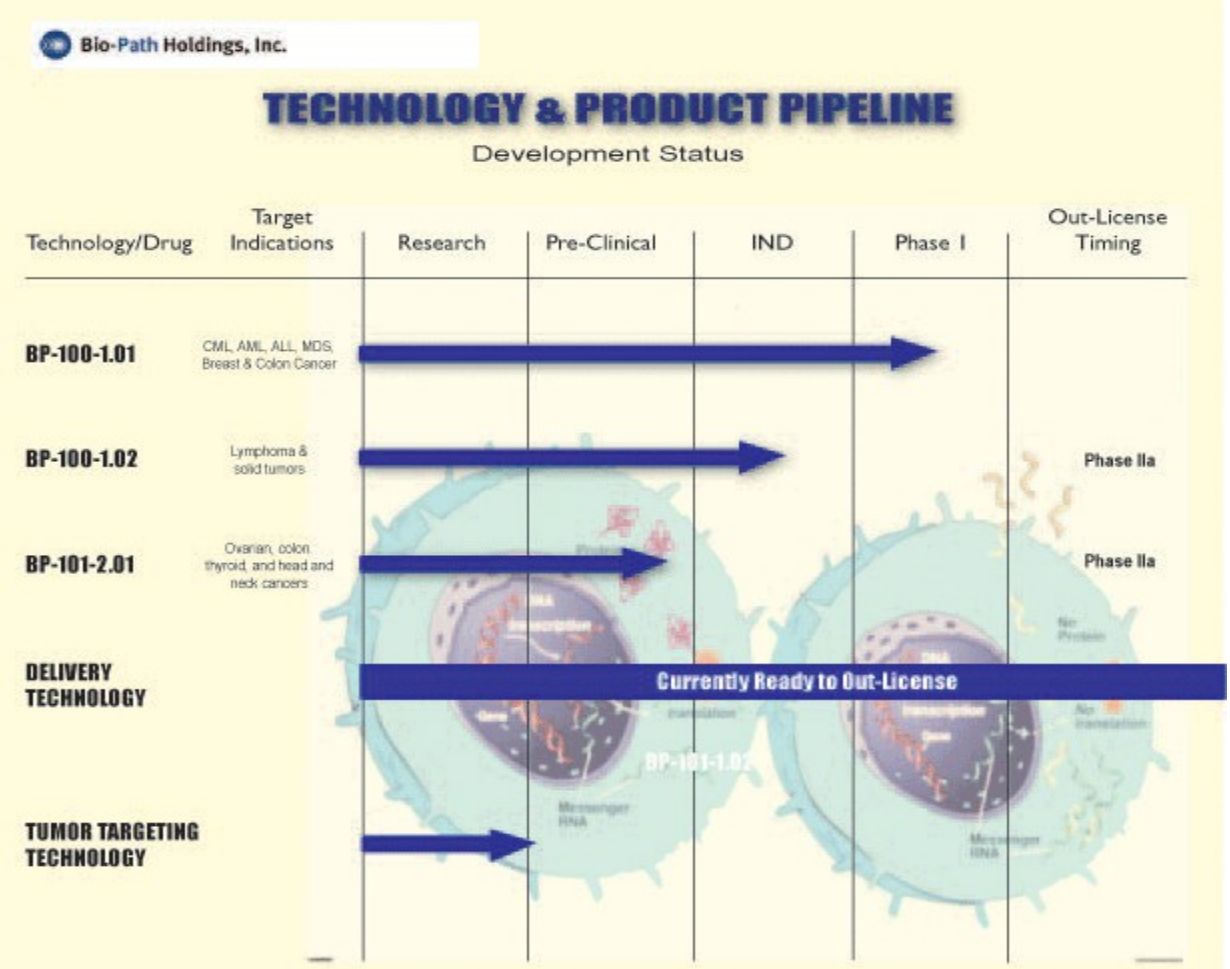
In addition to the neutral lipid drug delivery technology, Bio-Path recently licensed from MD Anderson a new **liposome tumor targeting technology**, which has the potential to be applied to augment the Company's current delivery technology to further improve the effectiveness of its antisense and siRNA drugs under development as well as other future liposome-based drugs. Tumor targeting will enhance the Company's liposome delivery technology by coating the liposome with ligands targeted to a receptor that is specifically over-expressed on a majority of solid and hematological tumors and on eighty percent (80%) of metastatic epithelial tumors. This liposome tumor-targeting technology could be a highly promising strategy for treating primary and metastatic cancers.

The new liposome tumor targeting technology will be developed as an extension of the Company's current delivery technology, with a goal towards a more potent and focused delivery of the antisense and siRNA cancer treatments to the tumor tissue. Adding a ligand to the liposome that targets a receptor that is highly expressed on the surface of tumor cells is expected to drive uptake of the liposomes into the tumor tissue, enhancing relative deposition in the target tumor tissue. In animal studies conducted at MD Anderson Cancer Center, researchers demonstrated targeted neutral lipid-based liposomes increased siRNA uptake 5 to 8-fold higher into cancer cells compared to those of non-targeted liposomes and controls. These efficiencies are in addition to the delivery efficiencies noted above from the core neutral lipid-based liposome delivery technology.

The core liposome technology is already in a clinical trial while tumor targeting technology is still at the research and development stage. This technology has the potential to revolutionize the treatment of cancer and other diseases where the targets of disease are well characterized. The reason is because the neutral lipid delivery capability enables systemic delivery of nucleic acid drugs to diseased cells with little or no toxicity, something no other technology has been able to do.

Pipeline Has Advanced into Clinic, Targeting Multi-billion Dollar Cancer Market

Bio-Path's core technology, if successful, will enable it to be at the center of emerging genetic and molecular target-based therapeutics that require systemic delivery of DNA and RNA-like materials. The Company is currently using its neutral lipid drug delivery platform testing three drug candidates for the treatment of various hematologic cancers. If successful, these drug candidates could potentially be used in treating many other indications of cancer.



Source: Bio-Path Holdings Inc.

Liposomal Grb-2 (L-Grb-2 or BP-100-1.01) 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 estimated $1 billion annual market for Chronic Myelogenous Leukemia (CML), Acute Myeloid Leukemia (AML), Acute Lymphoblastic Leukemia (ALL), and Myelodysplastic Syndrome (MDS).

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 tyrosine kinase inhibitors including

Gleevec (from Novartis), 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.

Grb-2 (growth factor-bound protein-2) is an adaptor protein that links tyrosine kinases such as bcr-abl with their downstream signaling molecules, including RAS. RAS is a critical regulator of cellular proliferation. The Company's collaborators have demonstrated that L-Grb-2 is effective in inhibiting the growth of human CML cells in animal models. And L-Grb-2 has a relatively safety profile.

L-Grb-2 is currently in a **Phase I** clinical trial. In March of 2010, Bio-Path received written notification from the FDA that its application for Investigational New Drug (IND) status for L-Grb-2 had been granted. This enabled the Company to commence its Phase I clinical trial to study L-Grb-2 in human patients, which began in July of 2010.

The Phase I clinical trial is a dose-escalating study to determine the safety and tolerance of escalating doses of L-Grb-2. The study will also determine the optimal biologically active dose for further development. The pharmacokinetics of L-Grb-2 in patients will be studied, making it possible to investigate whether the delivery technology performs as expected based on pre-clinical studies in animals. The trial will evaluate five doses of L-Grb-2 and 15 to 18 patients may be accrued into the study. The clinical trial is being conducted at The University of Texas MD Anderson Cancer Center.

An important outcome for the Phase I clinical trial is the ability to assess for the first time the performance of the Company's neutral lipid delivery technology platform in human patients. Being platform technology, a successful demonstration of the delivery technology in this study will allow the Company to immediately begin expanding its drug candidates by simply applying the delivery technology template to multiple new drug product targets. In this manner, Bio-Path can quickly build an attractive drug product pipeline with multiple drug product candidates for treating cancer as well as treating other important diseases including diabetes, cardiovascular conditions and neuromuscular disorders.

A favorable outcome of the Phase I trial will also provide an opportunity for the Company to monetize this core 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.

In early November 2010, Bio-Path received a grant of $244,479 from the US Government's Qualifying Therapeutic Discover Project Program (QTDP) to help fund the Company's Phase I clinical trial of L-Grb-2. The amount of funds awarded were the maximum allocation allowed under the program. The grant program was very competitive and being selected is a strong validation of the Company's technology.

The Company expects the Phase I clinical trial to continue for approximately twelve additional months, primarily depending on the rate of enrollment of patients into the trial. L-Grb-2 for CML has been granted Orphan Drug status in the US.

Another potential clinical target for L-Grb-2 is **breast cancer** where it has been shown that down regulation of Grb-2 leads to inhibition of growth in breast cancer cells that express high levels of the EGFR or ErbB-2 (another member of the EGFR gene family) tyrosine kinases.

Liposomal Bcl-2 (L-Bcl-2, BP-100-1.02) is Bio-Path's co-lead compound. L-Bcl-2 is a liposome delivered **antisense** cancer drug that targets the lymphoma and certain solid tumor markets. These markets collectively represent more than $2 billion of potential product sales for the Company's drug product.

Bcl-2 is a protein that is involved in regulating apoptosis or programmed cell death. Apoptosis is a physiologic mechanism of cell turnover by which cells actively commit suicide in response to aberrant external signals. Over-expression of Bcl-2 prevents the induction of apoptosis in response to cellular insults such as treatment with chemotherapeutic agents. Bcl-2 is over-expressed in more than 90% of

follicular B-cell non-Hodgkins lymphoma due to a chromosomal rearrangement and is the key factor in the initiation of this malignancy. Bcl-2 is also overexpressed in a wide variety of solid tumors (it is estimated to be over-expressed in 40 percent of cancers). For example, Bcl-2 over-expression has been associated with the progression of prostate cancer from hormone dependence to hormone independence and may contribute to the relative drug resistant phenotype typically observed in hormone independent prostate cancer.

L-Bcl-2 is similar to Genta Corp's Genasense. Both drug candidates are antisense RNA therapeutics targeting the Bcl-2 protein. The difference between Bio-Path's L-Bcl-2 and Genta's Genasense is that L-Bcl-2 is a liposomal antisense drug candidate and Genasense is a naked antisense drug candidate. In clinical trials, Genasense, either as a single agent or as a combination therapy, has demonstrated great anticancer efficacy. The major problem with Genasense is that it has an unfavorable safety profile compared to standard treatments due to its unique phosphorothioate chemical composition. Genasense also has increased side effects when it is used in combination with other drugs. That's one of the reasons the FDA has not yet approved Genasense. L-Bcl-2, on the other hand, may have a favorable safety profile due to the targeted delivery by liposome, plus it is expected that efficacy will be increased due to the ability of the liposomes to increase cellular uptake of the antisense.

Clinical targets for L-Bcl-2 include lymphoma, breast cancer, colon cancer, prostate cancer, leukemia and melanoma. A pre-IND package for L-Bcl-2 has been filed with the FDA and it is ready for a clinical trial after receiving an **IND** from the FDA.

Liposomal FAK (L-FAK, BP-100-2.01) is Bio-Path's lead siRNA drug candidate, a third cancer drug candidate currently in pre-clinical development.

Focal-adhesion kinase (FAK) is an important mediator of growth-factor signaling, cell proliferation, cell survival and cell migration. FAK is overexpressed in ovarian cancer and is predictive of poor clinical outcome. FAK is also overexpressed in a large number of other human tumors including colon, breast, thyroid, and head and neck cancers. This makes FAK a potentially important new therapeutic target.

L-FAK has demonstrated anti-tumor activity in preliminary ovarian cancer xenograft mouse models. L-FAK will be clinically tested for validation as a novel, targeted ovarian cancer therapeutic agent. The Company prepared a review package of the testing material for this drug product and reviewed the information with the FDA. Based on this review and feedback, the Company plans to perform additional pre-clinical work including two toxicity studies in mice and primates before filing for an IND for L-FAK.

A Clear Growth Strategy is in Place, Execution is Key

Bio-Path's initial plan is and continues to be, the acquisition of licenses for drug technologies from MD Anderson Cancer Center, funding clinical and other trials for such technologies and to commercialize such technologies.

The Company's strategy is to selectively license potential drug candidates for certain cancers, to advance these candidates through proof of concept into a safety study (Phase I), to human efficacy trials (Phase IIA), and then out-license each individual potential drug to a pharmaceutical company for final development and commercialization.

Bio-Path's **out-license oriented growth strategy** is highly workable in current pharmaceutical/biotech environment in our view. We believe current market environment is favorable for small biotech companies in terms of out-licensing to and partnering with big pharma/biotech companies.

We believe specters long haunting the pharmaceutical industry will continue to exist for a relatively long time. Big pharma/biotech companies are facing a series of problems: patent expiration cliff in the next few years, low R&D productivity, generic competition, and even a more conservative health authority. The bottom line is ever declining drug sales. Simply put, big pharma has large, expensive drug channels that

need patented drug products. In order to offset these declining sales, big pharma/biotech companies are turning attention into smaller biotech companies for solution. Forming partnerships through licensing with smaller biotech companies can significantly boost big pharma/biotech's pipeline. This is more efficient and cost-effective than in-house R&D. We have seen numerous licensing/partnership programs established in the recent past.

In addition to increased licensing/partnership programs, we are also seeing increased M&A activities throughout the pharmaceutical/biotech industry. Direct buyout of smaller biotech firms by big pharma companies leads to an establishment of an internal biotech center in the pharma company. This is particularly important and an effective way to do so when more and more pharmaceutical companies are adopting the biotech R&D model.

We expect a continued uptrend in licensing/partnership and M&A activities in the next few years throughout the pharmaceutical/biotech industry. As long as the challenges still exist in the pharmaceutical industry, the licensing/partnership with and buyout of smaller biotech companies by big Pharma/biotech companies will continue to make sense. From a financial perspective, the licensing/partnership and M&A also make sense since currently there are tons of cash sitting in the balance sheets of big pharma/biotech companies.

We believe there is a great deal of opportunities for Bio-Path at current market and industry environment. The Company holds two platform drug delivery technologies which can systemically deliver antisense and siRNA drug candidates in humans. This should be more attractive to big pharma/biotech companies. Once Bio-Path can demonstrate positive results from its first human Phase I trial of its lead antisense drug candidate L-Grb-2, we should see a lot of interest not only for the drug itself but the delivery platform technology in particular.

In addition to out-license, Bio-Path may also choose to advance one or more of its own drug candidates and commercialize the drugs on their own after approval. They plan to do so, because there are certain cancers that are primarily treated only in a comprehensive cancer center; of which there are approximately forty in the US and perhaps two hundred throughout the world. In such a case, marketing and distribution will become a realistic possibility for select products. These candidates may be eligible for Orphan Drug Status which provides additional incentives in terms of market exclusivities and non-dilutive grant funding for clinical trials.

With an experienced management team and scientific advisory board, we believe the growth strategy will be well executed in the coming years. Actually, management has indicated that they have initiated the process of monetizing its platform technology. This should bring in the first revenue for the Company if successful.

Strong Intellectual Property and the MD Anderson Advantage

Bio-Path was founded to focus on bringing the capital and expertise needed to translate drug candidates developed at MD Anderson into real treatment therapies for cancer patients. All drug candidates and related delivery technology of the Company were licensed from MD Anderson. The three drug candidates are: liposomal Grb-2 (antisense), liposomal Bcl-2 (antisense) and liposomal FAK (siRNA). The two drug delivery platform technologies are: neutral lipid drug delivery technology and its extension of vector-enhanced neutral lipid tumor targeting technology. These licenses specifically provide drug delivery platform technologies with composition of matter intellectual property that enable systemic delivery of antisense, small interfering RNA (siRNA) and potentially hydrophobic small molecules for the treatment of cancer.

In addition to its existing technologies under license, the Company has a close working relationship with key members of the MD Anderson's staff, which should provide Bio-Path with a strong pipeline of promising drug candidates in the future. Bio-Path expects the working relationship with MD Anderson to

provide the opportunity for the Company to broaden its technology to include cancer drugs other than antisense and siRNA.

MD Anderson is one of the largest and most widely recognized cancer centers in the world. U.S. News & World Report's America's Best Hospitals" survey has ranked MD Anderson as one of the two best cancer hospitals for 16 consecutive years. MD Anderson treats more than 100,000 patients each year, of which approximately 11,000 will participate in therapeutic clinical research exploring novel treatments which is the largest such program in the nation. MD Anderson employs more than 15,000 people including more than 1,000 M. D. clinicians and Ph.D. researchers, and is routinely conducting more than 700 clinical trials at any one time.

Over the past several years MD Anderson has augmented its clinical and research prominence through the establishment of the Pharmaceutical Development Center (PDC). The PDC was formed for the sole purpose of helping researchers at MD Anderson prepare their newly discovered compounds for clinical trials. It has a full-time staff of professionals and the capability to complete all of the studies required to characterize a compound for the filing of an Investigational New Drug Application (IND).

The good working relationship will give Bio-Path the following advantages:

- give Bio-Path ongoing access to MD Anderson's Pharmaceutical Development Center for drug development;
- provide rapid communication to Bio-Path of new drug candidate disclosures in the Technology Transfer Office;
- standardize clinical trial programs sponsored by Bio-Path;
- standardize sponsored research under a master agreement addressing intellectual property sharing.

The good working relationship with MD Anderson should allow Bio-Path to leverage the Center's pre-clinical and clinical development capabilities, including using the PDC for pre-clinical studies as well as clinical pharmacokinetics and pharmacodynamics and the institution's world-renowned clinics, particularly for early clinical trials. This should allow the Company to develop its drug candidates with experienced professional staff at a reduced cost compared to using external contract laboratories. This should also allow the Company to operate in an essentially virtual fashion, thereby avoiding the expense of setting up and operating laboratory facilities, without losing control over timing or quality or IP contamination.

Experienced Management, Scientific Advisors and Founders

Scientific advisors and founders are comprised of leaders in developing cancer therapeutics:

Ana M. Tari, Ph.D. is lead researcher for the development of L-Grb-2 and scientific co-founder of Bio-Path. Dr. Tari has been instrumental in transferring licensed technology from MD Anderson to the Company and currently works to support manufacturing of the L-Grb-2 drug product and clinical trial operations. Dr. Tari will shortly be increasing her role with the Company by taking the role of Director of Research and Pre-clinical Operations. Dr. Tari previously was an Associate Professor at The University of Texas MD Anderson Cancer Center and is currently Associate Professor at the University of Florida at Gainsville.

Gabriel Lopez-Berestein, M.D. is scientific co-founder of Bio-Path; Professor of Medicine and Internist, Director, Cancer Therapeutics Discovery Program. Gabriel is the chief of Section of Immunobiology and Drug Carriers, MD Anderson. Has brought seven drugs from R&D into the clinic and has had two public companies previously formed from his research.

Anil Sood, MD – Scientific co-founder of Bio-Path. Dr Sood is Professor, Gynecologic Oncology and a surgeon at MD Anderson. Dr. Sood was recently recognized as one of the most published and accomplished new scientists/clinicians at MD Anderson.

A Scientific Advisory Board (SAB) comprised of leading edge scientists and drug developers is expected to be formed after additional funding is secured. The mission of the SAB will be to develop strategies for the Company to rapidly expand its technology to other promising protein expression drug targets. In addition to outside scientists and drug developers, a Chief Scientific Officer consultant and Medical Officer will eventually be added to the Scientific Advisory Board as funding permits.

Peter Nielsen is a co-founder of Bio-Path, serving as its President and Chief Executive Officer, and has been a director of the Company since its founding. He also currently serves as CFO until an additional person is added at a later date. Peter has developed a close working relationship over the last five years with key individuals at MD Anderson and suppliers of the Company's lead drug product while coordinating pre-clinical and manufacturing development of Bio-Path's lead product. He has also worked with several other biotech companies in a senior management capacity and as a Director, developing and executing on strategies for growth. Mr. Nielsen has a broad management background in senior management and has significant negotiating experience. He has engineering and MBA degrees from U.C. Berkeley.

Douglas P. Morris is a co-founder of Bio-Path serving as its Vice President of Corporate Development, Secretary and a Director. Since 1993, Mr. Morris has been an officer and director of Celtic Investment, Inc., a financial services company that owns Celtic Bank. Since 1990, Mr. Morris owns and operates Hyacinth Resources, LLC, a privately held business consulting firm. Mr. Morris has recently formed Sycamore Ventures, LLC, a privately-held consulting firm. Mr. Morris has a BA from Brigham Young University and a Masters in Public Administration from the University of Southern California.

Gillian C. Ivers-Read serves as a Director of and a senior advisor to Bio-Path for drug development operations. Ms. Ivers-Read is currently Executive Vice President, Development Operations since April 2009 for Clovis Oncology. Previously, Ms. Ivers-Read was a founder and Executive Vice President of Pharmion Corp, being a member of the team that took the company from a start-up in 2002 to selling the company to Celgene in 2009 for approximately $3 billion. From 1996 to 2001, Ms. Ivers-Read held various regulatory positions with Hoechst Marion Roussel and its successor Aventis Pharmaceuticals, Inc., where she most recently held the position of Vice President, Global Regulatory Affairs. From 1994 to 1996, Ms. Ivers-Read was Vice President, Development and Regulatory Affairs for Argus Pharmaceuticals and from 1984 to 1994 she served as a regulatory affairs director for Marion Merrell Dow.

Bio-Path utilizes a team of outside consultants and scientists to augment drug development operations. As additional funding becomes available to support contemporaneous clinical trials of additional drug products, the plan is that Bio-Path will add full-time individuals to its organization to perform these duties.

INDUSTRY OUTLOOK

Our Outlook for the Biotech Industry is Positive in General

We believe there are a number of strong secular growth drivers that still power the biotech industry-namely, an aging population and an enormous research and development (R&D) effort to bring new, better drugs to market. People are living longer, and many have prescription pharmaceuticals to thank for it. Recent breakthroughs in oncology, neurology, and cardiology offer sizable market opportunities. Biotechnology research is finally starting to deliver. Expanded knowledge of genomics and proteomics is attracting significant attention from some of the industry's larger players. Drug companies are finding ways to reformulate and enhance current products. This is clearly a positive for the biotech industry. Demand for innovative medicines remains strong and biotechnology should deliver the next wave of pharmaceutical products to the market. This should allow the group to outperform the broader sector.

Licensing/partnership are the lifeline of biotech industry. We expect to see continued partnership and in-licensing/out-licensing activities for biotech companies in the next few years.

We also expect further consolidation throughout the industry because we believe that current market environment in the Pharma/Biotech industry is favorable for M&A activities. The big pharmaceutical companies have long been faced with big challenges such as patent expiration for blockbusters, low research and development productivity, and generic competition. Platform technology and efficient R&D efforts in smaller biotech companies may be part of the solution to the challenges faced by big Pharma companies. As long as the challenges still exist in the pharmaceutical industry, the buyout of smaller biotech companies by big Pharma/giant biotech companies will continue to make sense.

For individual biotech companies, we think companies with one or more of the following fundamentals will be attractive.

- With approved products on the market which can generate cash for the company;
- With a strong balance sheet and low cash burn rate; huge amount of cash will be needed to provide funds for drug development before it can reach the market;
- With platform technologies with deep, diversified pipeline (from early to late stage drug candidates); platform technology can produce series drug candidates, and is usually worth more than a single drug candidate program. When a drug candidate is moving closer to market, it usually reduces development risks.

We are especially optimistic about the drug delivery companies, a subgroup of biotech industry. Drug delivery technology is an integral part of drug development process. Drug delivery methods have made great progress in the past decade due to the breakthrough of general technology and its application in life science. Innovative drug delivery technologies are keys to innovative medicines in some aspects. Big pharma/biotech companies are particularly interested in smaller biotech ones with unique drug delivery technologies. We see great potential for partnering and/or straight buyout for such drug delivery companies.

Investors should pay attention to those large profitable biotechnology stocks, as well as small-cap biotechnology stocks with promising pipelines.

RECOMMENDATION AND VALUATION

We maintain our Outperform rating for Bio-Path Holdings Inc. and reiterate our twelve month price target of $2.5 per share.

Our call is based on the Company's fundamentals. 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 targets the multi-billion dollar cancer market 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 big 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 be the solution. 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. Based

on the pre-clinical results, there will be a high probability the technology will work in humans. Therefore, all eyes will be on the Phase I clinical results for the Company's lead antisense drug candidate L-Grb-2, which is expected to be available in the middle of next year subject to the rate of patient enrollment.

Bio-Path's good working relationship with MD Anderson not only helps the Company establish a promising pipeline, but also reduces its development cost and preserves shareholder value.

We believe Bio-Path's strategy to out-license its drug candidates after successful proof-of-concept Phase IIa clinical trials is workable. By doing so, the risks associated with drug development will be reduced greatly. With an appropriate growth strategy in place, the Company is well positioned to deliver shareholder value in the next few quarters.

Unlike many biotechnology companies, Bio-Path is also limiting its expenditures in the short term to its proof-of-concept clinical trial in order to preserve shareholder value. The labor force is primarily contracted on an hourly basis in order to keep costs down, while the burn rate remains very reasonable. The Company plans to scale up as clinical development accelerates, however management remains focused on controlling spending.

Although it's always difficult to value a development stage biotech company like Bio-Path, we think Bio-Path's shares are undervalued based on the Company's fundamentals. Currently, the Company shares are trading at about $0.40 per share which values the Company at about $20 million. This is certainly a huge discount compared to its peers.

We understand that the Street discounts Bio-Path because of the early stage of its pipeline and the uncertainty of the Company's drug delivery technology. But we have a different opinion. We think the Company's Phase I clinical study of its lead antisense drug candidate L-Grb-2 delivered by the neutral lipid drug delivery technology has a high probability to succeed based on its strong positive pre-clinical results.

Once the Phase I delivers positive results, the Company will have an opportunity to monetize this drug delivery technology and this will bring in the first revenue for the Company. Our long term model shows that the Company will become profitable in fiscal 2015. We think Bio-Path should be valued at least $150 million at current stage which translate into a share price of about $2.5 per share. Apparently, this is a high risk Company, but return should also be high. Investors with high risk tolerance and relatively long investment horizon may consider Bio-Path as a component of their portfolio.

RISKS

Early Stage Development Poses Higher Risks

Although antisense and siRNA are two most promising targeted therapies, and Bio-Path's neutral lipid drug delivery technology has the potential to provide systemic delivery of the above two RNA therapeutics, data collected so fare are limited, and only come from pre-clinical trials. We remind investors that risks associated with drug development and related delivery technologies are high, especially for early stage of drug candidates.

Even the Company's most advanced drug candidate Liposomal Grb-2 is only in Phase I clinical trial. Both clinical and regulatory hurdles are difficult to overcome at this point. However, investors' concern should be partly relieved by the Company's growth strategy, namely out-licensing its drug candidates when the Company finishes proof-of-concept clinical trials (Phase IIa). This will help reduce the development risks.

A Relatively Weak Balance Sheet

Bio-Path has no revenue so far.

At September 30, 2011, Bio-Path had cash of $983,286. We believe the available cash will be sufficient to fund its operations up to June 2012.

Currently, the Company has several discussions underway with potential investors which could result in sufficient capital inflow to extend operations beyond June of 2012 and possibly even 2013.

Management indicated that cash burn rate will be roughly at $0.3 million each quarter and 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 minimizes dilution of early-stage investors.

Cash burn concern should be relieved by the Lincoln Park Capital Fund agreement.

In December of 2009, Bio-Path anticipated that the Company needed to raise an additional $10 million to enable it to complete all projected clinical trials for its product candidates and conduct certain additional clinical trials in other Bio-Path drug candidates. In the second quarter of 2010, the Company signed an equity purchase agreement for up to $7 million with Lincoln Park Capital Fund, LLC, a Chicago-based institutional investor. 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 allowing the Company to draw on it only as needed, in an effort to minimize shareholder dilution.

The completion of the LPC Purchase Agreement provides the Company with up to $7 million in new capital. This amount of funding is expected to support clinical development of its lead products and help sustain operations through the next key milestones.

The Company may need to tap the capital market regularly. Equity financing will result in a dilution to existing shareholders.

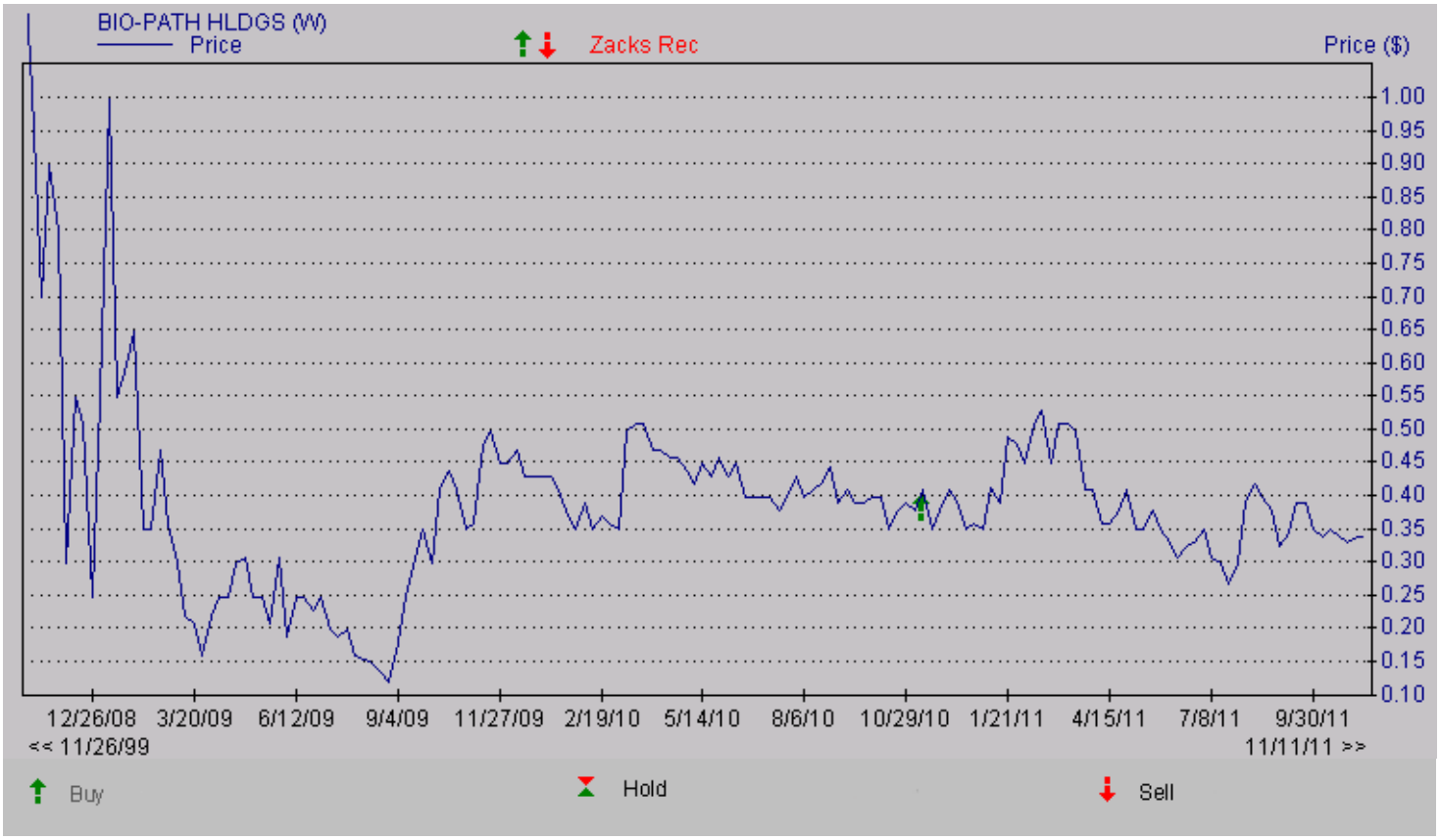
PROJECTED INCOME STATEMENT

$ in millions except for per share data	2010E (Dec)					2011E (Dec)					2012E (Dec)	2013E (Dec)	2014E (Dec)	2015E (Dec)
	Q1A	Q2A	Q3	Q4A	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**	**$0.00**	**$0.00**	**$0.00**	**$1.50**	**$3.50**	**$7.50**	**$15.00**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	*133.3%*	*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	$0.0
Gross Income	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**1.50**	**3.50**	**7.50**	**15.00**
Gross Margin	-	-	-	-	-	-	-	-	-	-	-	*100.0%*	*100.0%*	*100.0%*
SG&A	$0.16	$0.19	$0.16	$0.19	$0.70	$0.35	$0.32	$0.33	$0.45	$1.45	$2.00	$2.50	$3.00	$4.00
% SG&A	-	-	-	-	-	-	-	-	-	-	-	*71.4%*	*40.0%*	*26.7%*
R&D	0.14	0.05	0.15	0.81	1.14	0.24	0.14	0.18	0.75	1.31	2.50	3.50	5.00	7.00
% R&D	-	-	-	-	-	-	-	-	-	-	-	*100.0%*	*66.7%*	*46.7%*
Other expenses	0.19	0.19	0.19	-0.10	0.48	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	**($0.49)**	**($0.43)**	**($0.50)**	**($0.91)**	**($2.33)**	**($0.59)**	**($0.46)**	**($0.50)**	**($1.20)**	**($2.76)**	**($3.00)**	**($2.50)**	**($0.50)**	**$4.00**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	*-6.7%*	*26.7%*
Other Net	$0.0	$0.0	($0.0)	$0.2	$0.2	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	**($0.49)**	**($0.43)**	**($0.50)**	**($0.66)**	**($2.08)**	**($0.59)**	**($0.46)**	**($0.50)**	**($1.20)**	**($2.76)**	**($3.00)**	**($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	$0.0
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($0.49)**	**($0.43)**	**($0.50)**	**($0.66)**	**($2.08)**	**($0.59)**	**($0.46)**	**($0.50)**	**($1.20)**	**($2.76)**	**($3.00)**	**($2.50)**	**($0.50)**	**$4.00**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Shares Out	*46.6*	*47.6*	*49.1*	*49.4*	*48.2*	*49.4*	*51.6*	*56.1*	*53.0*	*52.5*	*55.0*	*60.0*	*65.0*	*70.0*
Reported EPS	**($0.01)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.04)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.02)**	**($0.05)**	**($0.05)**	**($0.04)**	**($0.01)**	**$0.06**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	*-842.9%*
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*	*$0.00*
Non GAAP Net Income	**($0.49)**	**($0.43)**	**($0.50)**	**($0.66)**	**($2.08)**	**($0.59)**	**($0.46)**	**($0.50)**	**($1.20)**	**($2.76)**	**($3.00)**	**($2.50)**	**($0.50)**	**$4.00**
Non GAAP EPS	**($0.01)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.04)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.02)**	**($0.05)**	**($0.05)**	**($0.04)**	**($0.01)**	**$0.06**

Source: Company filings and Zacks estimates

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HISTORICAL ZACKS RECOMMENDATIONS



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