



Bio-Path Holdings Reports Second Quarter 2014 Operational and Financial Results

August 18, 2014; HOUSTON, TX – Bio-Path Holdings, Inc., (NASDAQ: BPTH) (“Bio-Path”), a biotechnology company developing a liposomal delivery technology for nucleic acid cancer drugs, today announced operational and financial results for the second quarter ended June 30, 2014.

SECOND QUARTER 2014 OPERATIONAL AND FINANCIAL HIGHLIGHTS

- Recent Operational Highlights
 - The final patient of cohort six is currently being treated in the Phase I clinical trial evaluating Bio-Path’s lead product candidate, BP-100-1.01 (Liposomal Grb-2) in blood cancers. Assuming this patient successfully completes the treatment cycle, we anticipate concluding the sixth cohort of the study by the end of the third quarter.
 - Initial analysis of the data from the Phase I clinical trial are encouraging at the dose levels previously administered to patients, including patients treated in Cohort 6. The Company intends to complete its evaluation of patient results at the end of Cohort 6 to determine if an optimal biological dose has been reached, which could bring a close to the Phase I clinical trial.
 - Bio-Path laid out its strategy regarding next steps in the clinical development of Liposomal Grb-2. Specifically, there are encouraging indications from the data that an optimal biological dose has been reached, which the Company would use to move Liposomal Grb-2 immediately into a Phase II clinical trial. Additionally, because there is no evidence of drug related toxicity, the current Phase I trial could concurrently be extended with a Cohort 7, treating patients with a higher dose of 135 mg/m². This strategy has been discussed with regulatory experts and no substantive issues have been identified that would block this path, assuming the final analysis of the data continues to be supportive.

Liposomal Grb-2 is a novel, systemic liposomal antisense treatment for blood cancers. Patients eligible for enrollment have refractory or relapsed disease and have failed other approved treatments, and recent enrollment has focused on older age acute myelogenous leukemia (AML) patients. The clinical trial is being conducted at The University of Texas MD Anderson Cancer Center (MD Anderson).

- Bio-Path previously reported that it has completed preclinical testing of Liposomal Grb-2 in combination therapy with current treatments for chronic myelogenous leukemia (CML) and AML. Analysis of the results suggest that using Liposomal Grb-2 in combination with standard frontline therapies can potentially produce significant benefits in treating CML and AML patients. Treating AML cell lines with Liposomal Grb-2 and Cytarabine, a currently approved therapy, produced an additional 45 percent to 66 percent effectiveness compared to treating the AML cells with Cytarabine alone. Treating CML cell lines with Liposomal Grb-2 and Dasatinib, another front line treatment, produced an additional 18 percent to 58 percent effectiveness compared to treating the CML cells with only Dasatinib. Currently, Bio-Path plans to evaluate Liposomal Grb-2 in Phase II clinical trials in combination therapy with frontline treatments for CML and AML. Phase II clinical trial protocols are being finalized.
 - In collaboration with a leading researcher working in the MD Anderson breast cancer program, Bio-Path will initiate *in vivo* testing of Liposomal Grb-2 as a potential treatment for triple negative and inflammatory breast cancer. With a successful outcome, the Company will proceed to submit an Investigational New Drug (IND) application for Phase I clinical trials in triple negative and inflammatory breast cancers.
 - Bio-Path has taken steps to qualify another drug product manufacturer, which will provide increased capacity and added flexibility to meet demand for product. Development of scaled-up manufacturing processes continued in the second quarter to support anticipated future requirements of Bio-Path's liposomal antisense products.
 - During the quarter, Bio-Path continued to build out its operations and team. This initiative is expected to be completed by the end of the third quarter 2014.
- Financial Highlights
 - The Company reported a net loss of \$1,268,777 for the three months ended June 30, 2014 compared to a net loss of \$427,244 for the three months ended June 30, 2013. The increase in the net loss for the three months ended June 30, 2014, compared to the three months ended June 30, 2013, was primarily due to higher research and development expense and higher general and administrative expenses. Earlier this year, the Company raised a significant amount of capital, which allowed it to significantly increase operations, and achieve a listing of its common stock on the NASDAQ Capital Market exchange, which required significant legal, audit and listing fees. Net loss per share, both basic and diluted, was \$0.01 per share for the three months ended June 30, 2014 and \$0.01 per share for the three months ended June 30, 2013.
 - Operating expenses of \$1,274,801 in the second quarter of 2014 were higher by \$846,155 compared to the second quarter of 2013 due to increased research and development expenses and increased general and administrative expense. Research and development expense was \$517,040 for the three months ended

June 30, 2014, an increase of \$361,004 compared to the three months ended June 30, 2013, primarily due to an increase of \$233,985 in drug material expense for use in the clinical trial, and increases of \$35,860 for clinical trial expense and development of a patient data system, \$89,360 for drug manufacturing development expense and \$12,190 for stock option expense for employees involved in research and development activities.

General and administrative expenses were \$754,548 for the three months ended June 30, 2014, an increase of \$514,005 compared to the three months ended June 30, 2013. The increase was due to significant corporate development activities, including filing a shelf registration statement with the U.S. Securities and Exchange Commission (SEC), completion of a \$15 million registered direct offering of shares of our common stock and warrants and the listing of Bio-Path shares on the NASDAQ Capital Market, all resulting in the step-up in operations as Bio-Path builds an increased core-capabilities organization that will enable the Company to better and more effectively execute its business plan. These actions resulted in an increase in general and administrative expense for the three months ended June 30, 2014, compared to the three months ended June 30, 2013, of \$85,417 for legal and auditor services, \$50,383 in expenses for listing and filing fees and directors and officers insurance, \$44,883 for expenses of starting up an expanded Houston office operation, \$218,528 for organization costs including healthcare, wages and bonus accrual, \$97,065 in non-cash stock option expense for employees involved in administrative activities and \$17,729 for various other items.

- As of June 30, 2014, the Company had cash of \$15,721,128 compared to \$3,551,832 at December 31, 2013, and to \$16,819,783 at the end of the first quarter 2014. Net cash used in operating activities for the first six months of 2014 was \$1,643,077 compared to \$1,122,781 for the first six months of 2013. The Company raised \$13,812,373 in net funds during the first six months of 2014 compared to \$2,515,961 in net funds raised during the first six months of 2013.

“Our focus this quarter continued to be on moving our lead product candidate, Liposomal Grb-2, through testing. Enrollment resumed in Cohort 6 of the Phase I clinical trial following the arrival of additional drug supply. We only require one more patient to complete the treatment cycle in order to conclude Cohort 6. That patient has been enrolled and it is anticipated will complete treatment in the next few weeks,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path. “Furthermore, we have built a patient data base that has enabled us to take a systematic look at all of the clinical trial data compiled to date. A preliminary review suggests that we may have achieved an optimal biological dose. Based on this, we developed a strategy to address the apparent lack of toxicity in our drug, which is a positive result, but creates an interest to continue the Phase I testing at higher doses, while there is a desire and need to move Liposomal Grb-2 into more advanced development. Our strategy of moving into the Phase II clinical trial while continuing with the Phase I is unique, but it is not often that you have a drug that doesn’t appear to have a toxicity profile.”

Mr. Nielsen continued, “While moving Liposomal Grb-2 forward in hematological cancers, we also continued to pursue development of the drug for triple negative and inflammatory breast cancers. We look forward to moving into the next animal phase of testing in these indications, which represent very real, high need situations for breast cancer patients. With a strong balance sheet, an expanded management team and research and development programs that are progressing, Bio-Path continues to meet its strategic goals. ”

About Bio-Path’s Delivery Technology

Bio-Path’s drug delivery technology involves microscopic-sized liposome particles that distribute nucleic acid drugs systemically and safely throughout the human body, via simple intravenous infusion. The delivery technology is applied to single stranded (antisense) nucleic acid compounds with the potential to revolutionize the treatment of cancer and other diseases where drugable targets of disease are well characterized. The Company is currently focused on developing liposomal antisense drug candidates. Bio-Path also anticipates developing liposome tumor targeting technology, representing next-generation enhancements to the Company’s core liposome delivery technology.

About Growth Receptor Bound protein-2 (Grb-2)

The adaptor protein Growth Receptor Bound protein-2 (Grb-2) is essential to cancer cell signaling because it is utilized by oncogenic tyrosine kinases to induce cancer progression. Suppressing the function or expression of Grb-2 should interrupt its vital signaling function and have a therapeutic application in cancer. BP-100.1.01 is a neutral-charge, liposome-incorporated antisense drug substance designed to inhibit Grb-2 expression.

About Bio-Path Holdings, Inc.

Bio-Path is a biotechnology company focused on developing therapeutic products utilizing its proprietary liposomal delivery technology designed to systemically distribute nucleic acid drugs throughout the human body with a simple intravenous transfusion. Bio-Path’s lead product candidate, Liposomal Grb-2, is in a Phase I study for blood cancers and in preclinical studies for triple negative and inflammatory breast cancers. Bio-Path’s second drug candidate, also a liposomal antisense drug, is ready for the clinic where it will be evaluated in lymphoma and solid tumors.

Any statements that are not historical facts contained in this release are forward-looking statements that involve risks and uncertainties, including Bio-Path’s ability to raise needed additional capital on a timely basis in order for it to continue its operations, have success in the clinical development of its technologies, the timing of enrollment and release of data in such clinical studies and the accuracy of such data, limited patient populations of early stage clinical studies and the possibility that results from later stage clinical trials with much larger patient populations may not be consistent with earlier stage clinical trials, and such other risks which are identified in the Company’s most recent Annual Report on Form 10-K and in any subsequent quarterly reports on Form 10-Q. These documents are available on request from Bio-Path Holdings or at www.sec.gov. Bio-Path disclaims any intention or obligation to

update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

For more information, please visit the Company's website at <http://www.biopathholdings.com>.

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