



## **Bio-Path Holdings Reports Second Quarter 2013 Operational and Financial Results**

**August 15, 2013; HOUSTON, TX** – Bio-Path Holdings, Inc., (OTCQX: 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, 2013.

### **SECOND QUARTER 2013 OPERATIONAL AND FINANCIAL HIGHLIGHTS**

- **Recent Operational Highlights**

- During the quarter, Bio-Path completed treatment of the fifth dosage cohort in its Phase I clinical trial of its lead product candidate, BP-100-1.01 (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 trial is being conducted at The University of Texas MD Anderson Cancer Center (MD Anderson Cancer Center). The drug’s safety profile continues to be favorable with no treatment-related serious adverse events reported and data continues to suggest possible anti-leukemia activity.

To date, the Company has successfully completed five cohorts of the study, which has included a total of 30 patients, of which 18 have been evaluable. The Company has enrolled three patients into the sixth dosage cohort of its Phase I clinical trial. 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.

The on-going Phase I 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 biologically active dose for further development. The Company intends to evaluate patient results at the end of Cohort 6 to determine if the optimal biological dose has been reached, which would bring a close to the Phase I clinical trial. The new down-regulation assay of inhibition, featured in a company press release August 9th, of the target Grb-2 protein is expected to be available for use in that determination.

- In August of 2013, Bio-Path announced that a scientific assay has confirmed that its lead product candidate Liposomal Grb-2 inhibits the disease-causing target protein in patients with blood cancers. The assay was applied to patient samples

taken from Bio-Path's Phase I clinical trial which is evaluating Liposomal Grb-2 in blood cancers including acute myeloid leukemia (AML), chronic myelogenous leukemia (CML), acute lymphoblastic leukemia (ALL) and myelodysplastic syndrome (MDS). This discovery is a significant milestone in the development of Bio-Path's liposomal delivery technology and the specific data from this testing is planned to be reviewed at the Annual Society of Hematology (ASH) meeting in December by Jorge Cortes, M.D., Professor and Deputy Chair, Department of Leukemia, The University of Texas MD Anderson Cancer Center (MD Anderson Cancer Center).

- In July of 2013, Bio-Path announced that it was initiating preclinical testing of its lead product candidate, Liposomal Grb-2, into two additional indications: triple negative breast cancer (TNBC) and inflammatory breast cancer (IBC), two cancers characterized by formation of aggressive tumors and relatively high mortality rates.
  - During the second quarter of 2013, the Company received approximately \$2.5 million in cash from the sale of shares of common stock in a private placement and direct offering that have both been closed. The Company has since initiated a new private placement since the close of the second quarter with the goal of raising up to \$4 million from the sale of shares of its common stock.
- Financial Highlights
    - Net loss for the second quarter 2013 was \$(427,244), compared to a Net Loss of \$(787,838) for the second quarter 2012. The decrease in net loss for the second quarter 2013 was a result of a decrease in research and development expense – related party resulting from a \$345,000 technology impairment expense item that was recognized in the quarter ending June 30, 2012. For the second quarter 2013, the Company reported a net loss per share of \$(0.01) based on 66,606,105 weighted average shares outstanding, compared to \$(0.01) per share for the same period in 2012.
    - Operating expenses of \$428,646 in the second quarter of 2013 were lower by \$359,136 compared to the second quarter of 2012, primarily due to a technology impairment expense item that was recognized in the second quarter 2012, as well as lower research and development and administrative expenses for the quarter ending June 30, 2013 compared to the same period last year.
    - As of June 30, 2013, the Company had cash of \$1,927,226, compared to \$534,046 at December 31, 2012. Net cash used in operating activities for the first six months of 2013 was \$(1,122,781) compared to \$(1,029,521) for the first six months of 2012. The primary reasons for the increase in net cash used in operations between the comparable six month periods is an increase in drug development expense, increased legal and management costs, offset to some extent by lower corporate communications and costs of being a public company.

“We have made significant strides with our drug delivery technology over the past several months,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path. “As was recently announced, a scientific assay confirmed that we are inhibiting the Grb-2 protein in patients being treated with Liposomal Grb-2. This represents a significant milestone in the development of antisense therapeutics as a class of drugs. The Phase I clinical trial evaluating Liposomal Grb-2 in blood cancers continues to progress and has enrolled three patients in Cohort 6; this follows the successful completion of Cohort 5 which continued to demonstrate a clean safety profile for the drug, while showing anti-cancer activity.”

Mr. Nielsen continued, “We also expanded our pipeline during the quarter with the initiation of development of Liposomal Grb-2 into two additional indications: triple negative breast cancer and inflammatory breast cancer. Leading breast cancer experts believe Liposomal Grb-2 may be useful in treating patients with these two cancer types, for which there are few therapeutic options. We look forward to exploring this potential opportunity.”

### 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](http://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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