



## **Bio-Path Holdings Reports First Quarter 2014 Operational and Financial Results**

**May 16, 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 first quarter ended March 31, 2014.

### **FIRST QUARTER 2014 OPERATIONAL AND FINANCIAL HIGHLIGHTS**

- Recent Operational Highlights
  - Bio-Path is working toward completing the sixth dosage cohort of the Phase I clinical trial evaluating Bio-Path’s lead product candidate, BP-100-1.01 (Liposomal Grb-2) in blood cancers. It is anticipated that the next batch of drug will arrive in the second quarter 2014, at which point the sixth cohort should fully enroll. 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.

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.
  - Bio-Path completed initial preclinical testing of Liposomal Grb-2, in combination therapy with current treatments for Chronic myelogenous leukemia (CML) and AML. These studies provided preclinical evidence that using Liposomal Grb-2 in combination with these frontline therapies can potentially produce additional benefits in treating CML and AML patients. Currently, Bio-Path plans to evaluate Liposomal Grb-2 in Phase II clinical trials in combination therapy with frontline treatments for CML and AML. The definitive Phase II clinical trial protocol is being finalized.
  - Development of scaled-up manufacturing processes continued in the first quarter to support anticipated future requirements of Bio-Path’s liposomal antisense products.
  - During the quarter, Bio-Path started to build out its operations and team. Dr. Ulrich W. Mueller was appointed Chief Operating Officer. He brings years of clinical oncology development experience to the Company. Other strategic hires include a Director, Clinical Operations and Project Management; Controller; and

Director, IT and Data Management Systems. Bio-Path intends to add additional experienced management in the areas of manufacturing and drug supply, intellectual property and licensing. These personnel are in addition to Dr. Ana Tari, who has been serving as Director, Preclinical Operations and Research.

- In March of 2014 Bio-Path was uplisted to the NASDAQ Capital Market. Bio-Path's shares began trading on this Exchange March 10, 2014.
- In January 2014 the Company raised \$15 million in a direct offering of shares and warrants to an institutional investor, receiving net proceeds of approximately \$13.75 million.

- Financial Highlights

- The Company reported a net loss of \$504,876 for the three month period ended March 31, 2014, compared to a net loss of \$656,002 for the three month period ended March 31, 2013. The decrease was due to research and development expenses being lower in the quarter ended March 31, 2014 due to lower drug material and clinical trial expenses, offset to some extent by higher general and administrative expense. The increased general and administrative expense was primarily due to the exchange listing fee for the Company's common stock to be listed on the NASDAQ Capital Market and non-cash expense from vesting of previously granted stock options to officers, directors and management. For the first quarter 2014, the Company reported a net loss per share of \$(0.01) based on 89,237,872 weighted average shares outstanding, compared to \$(0.01) per share for the same period in 2013.
- Operating expenses of \$510,210 in the first quarter of 2014 were lower by \$145,700 compared to the first quarter of 2013 due to lower research and development expenses, offsetting higher general and administrative expense resulting from exchange listing fee and non-cash stock option expense from a grant made to officers, directors and management.
- As of March 31, 2014, the Company had cash of \$16,819,783, compared to \$3,551,832 at December 31, 2013. Net cash used in operating activities for the first three months of 2014 was \$544,422 compared to \$551,004 for the first three months of 2013. Increases in cash for working capital in the three month period ending March 31, 2014 substantially offset a lower net loss compared to the three month period ending March 31, 2013.

“The past several months have been significant for Bio-Path as the Company expands its internal capabilities in order to more efficiently progress its technology. Our balance sheet is the strongest it has ever been and gives us sufficient funding to ensure operations into 2016. We will also continue to bring experienced management into the organization in areas that are necessary to implement our clinical and business development plans,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path. “In regard to research and development, we completed

preclinical combination therapy testing of our lead drug candidate with positive results and continued manufacturing development. As drug supply issues improve, we look forward to enrolling the last patient into Cohort six of the Phase I trial. Furthermore, we are gearing up to screen new protein targets that could potentially become additional liposomal antisense drug candidates. This reflects the true potential of Bio-Path and we look forward to this next phase in the Company's development in 2014."

### 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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