



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

**November 17, 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 third quarter ended September 30, 2014.

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

- Recent Operational Highlights
  - The final patient of cohort six completed treatment in the Phase I clinical trial evaluating Bio-Path’s lead product candidate, BP-100-1.01 (Liposomal Grb-2) in blood cancers. Three patients were evaluated in Cohort 6 and this cohort was consistent with previous cohorts in demonstrating that Liposomal Grb-2 is well tolerated with the drug showing signs of anti-leukemia activity. Due to the positive safety profile of the drug, a maximum tolerated dose has yet to be reached. Bio-Path is now completing an analysis of the Phase I data and is on schedule to submit the analysis to the U.S. Food and Drug Administration (FDA) in December of 2014. In addition to an excellent safety profile, data from Cohort 6, in particular, demonstrated very encouraging results in terms of Liposomal Grb-2 inhibiting the target Grb-2 protein.

Liposomal Grb-2 is a novel, systemic liposomal antisense treatment for blood cancers. Patients eligible for enrollment into the Phase I clinical trial have refractory or relapsed disease and have failed other approved treatments; recent enrollment has focused on elderly 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 announced that the first of three Phase II clinical trials will evaluate Liposomal Grb-2 as a combination therapy in Acute Myeloid Leukemia (AML). The Company remains on track to begin its Phase II program by the end of 2014.

- Bio-Path initiated an *in vivo* testing program of Liposomal Grb-2 as a potential treatment for triple negative and inflammatory breast cancer. The Company is working in collaboration with a leading researcher working in the MD Anderson breast cancer program.

- In preparation for its Phase II clinical program, Bio-Path is qualifying a second drug product manufacturer. The manufacturer is on schedule to manufacture a cGMP batch of Liposomal Grb-2 for use in clinical development during late fourth quarter 2014 or early first quarter 2015. When qualified, this will give Bio-Path access to one drug substance manufacturer and two drug product manufacturers. Bio-Path's drug product is comprised of drug substance and lipids.
  - During the quarter, Bio-Path occupied its new office and completed the build out of its team. Bio-Path's office is now located near the Houston Medical Center and closer to MD Anderson and other biopharmaceutical and research institutions.
  - Bio-Path continued to increase its profile amongst the investment community and presented at the Bio Investor Forum 2014 in San Francisco in October. On October 17, 2014, Bio-Path had the honor of ringing the Closing Bell of NASDAQ.
  - Bio-Path announced the appointment of Amy P. Sing, M.D. to its Board of Directors. Dr. Sing has an extensive drug development background, and notably, led the oversight of the Investigator Sponsored Trials (IST) program for the now approved breast cancer drug Avastin.
- Financial Highlights
    - The Company reported a net loss of \$1,148,409 for the three months ended September 30, 2014 compared to a net loss of \$1,393,207 for the three months ended September 30, 2013. The decrease in the net loss for the three months ended September 30, 2014, compared to the three months ended September 30, 2013, was due to lower research and development and general and administrative expenses. Net loss per share, both basic and diluted, was \$0.01 per share for the three months ended September 30, 2014 and \$0.02 per share for the three months ended September 30, 2013.
    - Operating expenses of \$1,154,108 in the third quarter of 2014 were lower by \$239,620 compared to the third quarter of 2013 due to decreased research and development and general and administrative expenses. Research and development expense was \$424,521 for the three months ended September 30, 2014, a decrease of \$144,055 compared to the three months ended September 30, 2013, primarily due to a decrease of approximately \$182,000 in drug material expense for use in the clinical trial, offset to some extent by increases in manufacturing development expense of \$30,000 and \$8,000 in miscellaneous drug development expenses.

General and administrative expenses were \$713,352 for the three months ended September 30, 2014, a decrease of \$96,800 compared to the comparable period in 2013. The decrease was primarily due to a decrease of approximately \$510,000 in stock option expense, offset to some extent by an increase of \$264,000 in compensation expense for an expanded core-capabilities organization that will enable the Company to more effectively and efficiently execute its business plan; legal, audit and communications costs associated with being a public company due to higher requirements of the NASDAQ exchange listing; higher employee costs associated with a larger organization; and increased travel expense. Excluding the decrease in non-cash stock option expense for the three months ended September 30, 2014 compared to the three months ended September 30, 2013, cash costs of general and administrative expenses increased by \$413,000. The increased general and administrative expense for the comparable three month periods ending September 30, 2014 and 2013 was the result of an expanded scale of operations and listing on the NASDAQ exchange.

- As of September 30, 2014, the Company had cash of \$14,636,602, compared to \$3,551,832 at December 31, 2013. Net cash used in operating activities for the first nine months of 2014 was \$2,661,479 compared to \$1,836,311 for the first nine months of 2013. The Company raised \$13,812,373 in net funds during the first nine months of 2014 compared to \$5,403,106 in net funds raised during the first nine months of 2013.

“With Cohort 6 of our Phase I clinical trial now complete, we are focusing on the next phase of development for our lead drug candidate Liposomal Grb-2. Initial results of our analysis of the Phase I clinical trial have been very positive, with preliminary data suggesting a strong safety profile, impressive inhibition of the target Grb-2 protein, effective delivery performance of our liposomal technology and significant reductions in the cancer blast cells when patients receive treatment with Liposomal Grb-2,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path. “We are currently in the process of completing the full analysis of the Phase I trial and expect to submit this to the FDA in December. In addition, we are completing final details of the Phase II program and have a goal to begin this study before the end of 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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