



## **Bio-Path Holdings Reports Fiscal Year 2013 Operational and Financial Results**

**April 1, 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 year 2013.

### **2013 OPERATIONAL AND FINANCIAL HIGHLIGHTS**

- 2013 Operational Highlights
  - Two patients have completed treatment in 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. The Company is currently awaiting the next batch of drug, expected to arrive mid-second quarter 2014, in order to complete the sixth cohort of the clinical trial. 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. The trial is being conducted at The University of Texas MD Anderson Cancer Center (MD Anderson Cancer Center). 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 AML patients.

To date, the Company has successfully completed five cohorts of the Phase I study and has completed two-thirds of the sixth cohort. A total of 33 patients have been enrolled into the clinical trial, of which 20 have been evaluable. It is worth noting that only one additional evaluable patient is required to complete Cohort 6.

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 is expected to be available for use in that determination.

- In the fourth quarter of 2013, Bio-Path initiated 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 quarter, Bio-Path also initiated preclinical testing of Liposomal Grb-2 in combination with front-line therapies for blood cancers. This testing is being performed to provide supporting evidence for Bio-Path's Phase II clinical trial program, which is currently being planned to evaluate Liposomal Grb-2 in combination with front-line therapies.

- Dr. Jorge Cortes, deputy chair and professor of medicine in the Department of Leukemia at The University of Texas MD Anderson Cancer Center, presented results through Cohort 5 of the Phase I clinical trial at the 55th Annual Meeting of the American Society of Hematology (ASH) in New Orleans in December.
- In 2013 Bio-Path sold approximately \$6 million in shares of common stock, in two private placements that have been closed, receiving net proceeds of approximately \$5.3 million.

The accomplishments in 2013 culminated in Bio-Path uplisting to the NASDAQ Capital Market. Bio-Path's shares began trading on this Exchange March 10, 2014.

#### Additional Recent Highlights:

- Subsequent to the close of the fourth quarter, 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. As a result of this financing, the Company currently has approximately \$17 million in cash and cash equivalents.
  - Bio-Path intends to build-out the organization during 2014 in order to more fully implement its business plan. Last week, Bio-Path announced the appointment of Dr. Ulrich W. Mueller as Chief Operating Officer. Additional hires include a Director, Clinical Operations and Project Management; a Controller; and a Director, IT and Data Management Systems. These personnel are in addition to Dr. Ana Tari, who has been serving as Director, Preclinical Operations and Research.
- Financial Highlights
    - Net loss for the year 2013 was \$(3,266,013), compared to a Net Loss of \$(2,582,537) for the year 2012. The increase in net loss was due to an increase of \$648,553 in general and administrative expense, which was due to an increase in stock option expense for management, officers and directors totaling \$661,861, a non-cash expense that is based upon the Black Scholes fair value of the options grants. Research and development expense increased by \$386,173, due primarily to higher drug product expense from higher doses administered in the trial and testing, which was substantially offset by lower research and development expense – related party from technology impairment expense which occurred in

2012. Excluding the non-cash stock options expense, general and administrative expenses were lower in 2013 by \$13,308 compared to 2012. For the full year 2013, the Company reported a net loss per share of \$(0.05) based on 71,372,672 weighted average shares outstanding, compared to \$(0.04) per share for the year 2012.

- Operating expenses increased by \$686,561 to \$3,269,240 for the year 2013 compared to the year 2012, primarily due to increased stock options expense and drug material expense, offset to some extent with the absence of related party technology impairment expense during 2013.
- As of December 31, 2013, the Company had cash of \$3,551,832, compared to \$534,046 at December 31, 2012. Net cash used in operating activities for the year 2013 was \$(2,313,160) compared to \$(1,993,404) for the year 2012. The primary reasons for the increase in net cash used in operations for the year over year period is the increased cash cost of clinical trial operations, including drug material. As previously noted, the Company raised an additional \$15 million during the first quarter of 2014.

“2013 was a pivotal year for Bio-Path as the Company shored up its balance sheet, attracted institutional investor interest and achieved significant milestones on the research front, particularly confirming through an assay that Liposomal Grb-2 inhibits the disease causing protein in patients with blood cancers,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path. “We look forward to enrolling the last patient into Cohort six of the Phase I trial and going forward, expect the drug supply issues to improve. We have recently added to our management team and in 2014 look toward further building out the Company and its clinical programs.”

#### 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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