



Bio-Path Holdings, Inc.

Bio-Path Holdings Reports Third Quarter 2012 Operational and Financial Results

November 16, 2012; 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 quarter ended September 30, 2012.

THIRD QUARTER 2012 OPERATIONAL AND FINANCIAL HIGHLIGHTS

- Recent Operational Highlights
 - Bio-Path completed treatment of the fourth cohort in the Company’s 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. A total of three patients were enrolled and dosed in the fourth cohort of the study. All three patients completed the 28-day treatment cycle and were evaluable. Liposomal Grb-2 is systemically delivered by intravenous injection. Patients received a dose of 40 mg/m² twice a week for four weeks, for a total of eight doses. Preliminary results suggest that Liposomal Grb-2, at a dose of 40 mg/m² is well tolerated. As was the case with the three previous cohorts, there continued to be a suggestion of possible anti-leukemia activity. One patient stabilized and qualified to receive additional treatment.

Another positive development is the fact that one patient from Cohort 3 is continuing treatment with Liposomal Grb-2, and is currently in a fourth treatment cycle. This patient started treatment seven months ago at the end of March 2012, and is reportedly in a stable condition at this time as treatment with Liposomal Grb-2 continues.

- As previously reported, the Company is expanding the protocol for its Phase I clinical trial to evaluate higher doses of Liposomal Grb-2. The expanded protocol will continue at 50 percent increments, with the next dose for Cohort 5 being 60 mg/m² and the following dose 90 mg/m² for Cohort 6. If advantageous, the Company can continue testing at a higher dose of 135 mg/m² with 33 percent increments thereafter. To date, there has been no evidence of significant toxicity from treatment of patients with Liposomal Grb-2. This provides a significant opportunity for the Company to test higher doses in patients in order to find a dose that provides maximum potential benefit and duration of anti-leukemia effect.

- The Company announced its development plans for Liposomal Grb-2 and expects to conduct three Phase II clinical trials of Liposomal Grb-2 salvage therapy in combination with the frontline therapy in three of the types of leukemia that are currently being evaluated in the Company's Phase I clinical trial. These indications include AML, CML and MDS. These clinical trials are expected to take place at four of the leading cancer centers in the U.S. in 2013.
- Bio-Path continued to increase its profile amongst the investment community and made a Company presentation at the Rodman & Renshaw investor conference in New York City and at the 11th Annual BIO Investor Forum in San Francisco. An archive of these presentations may be found at the Company's website: www.biopathholdings.com. The Company also participated in two retail investor conferences, including the Southern California Investor Conference in Orange County and the BetterInvesting National Convention in Houston. Bio-Path is scheduled to present at Biotech Showcase 2013 in January.
- Bio-Path continued raising capital through a private placement, initiated in the second quarter, to raise up to \$2 million through the sale of shares of the Company's common stock to accredited investors. Commitments for approximately \$1.7 million have been received, and through September, sales of approximately \$945,000 of common stock have been finalized including approximately \$800,000 in the third quarter. The balance of funds raised is in various stages of documentation and finalization. Subsequently, in October, the Company amended the offering to allow up to \$4 million of common stock to be sold through December 2012.

- Financial Highlights

- Net loss for the third quarter 2012 was \$(840,552), compared to a Net Loss of \$(503,819) in the third quarter 2011. The increase in net loss was due to an increase in research and development expense from a higher cost of drug material, which more than offset a decrease in general administrative expense during the same periods. For the third quarter of 2012, the Company reported a net loss per share of \$(0.01) based on 58,902,046 weighted average shares outstanding, compared to \$(0.01) per share for the same period last year.
- Operating expenses of \$840,489 in the third quarter of 2012 increased by \$336,000 compared to the third quarter 2011, primarily due to increased drug material expense, offset to some extent, by reduced administrative expenses for management stock options.
- As of September 30, 2012, the Company had cash of \$332,862, compared to \$952,252 at December 31, 2011. Net cash used in operating activities for the first nine months of 2012 was \$(1,567,536) compared to \$(726,157) for the first nine months of 2011. The primary reasons for the increase in net cash used in operations between the comparable nine month period is the increased cost of clinical trial operations, including drug material, as well as receipt in 2011 of a \$244,479 U.S. Government grant that was not matched in 2012. As previously noted, the Company is currently conducting a private

placement, which has raised \$945,000 to date. The Company has received additional commitments for up to \$700,000, which are in various stages of being finalized.

“Our lead drug candidate, Liposomal Grb-2, continued to progress through the clinic and we remain encouraged by the data,” said Peter Nielsen, President and Chief Executive Officer. “We have begun to put into place a protocol to expand our clinical development of Liposomal Grb-2 into Phase II clinical trials and anticipate that this should take place in 2013. We look forward to continuing to work with the renowned University of Texas MD Anderson Cancer Center, as well as expand our trial sites into three additional prominent cancer centers in the U.S.”

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 druggable 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. 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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