



Bio-Path Holdings Reports First Quarter 2015 Operational and Financial Results

May 12, 2015; 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 quarter ended March 31, 2015.

FIRST QUARTER 2015 AND RECENT OPERATIONAL AND FINANCIAL HIGHLIGHTS

- Enrollment continues into the safety portion of the Phase 2 combination trial evaluating Liposomal Grb-2 and low dose Ara-C frontline therapy in patients with acute myeloid leukemia (AML). The safety portion of the Phase 2 trial is designed to assess two cohorts: 60 mg/m² of Liposomal Grb-2 and frontline Ara-C and 90 mg/m² of Liposomal Grb-2 and frontline Ara-C in its intended use in combination with an existing chemotherapeutic agent.
- Bio-Path received orphan drug designation from the U.S. Food and Drug Administration (FDA) for its lead compound Liposomal Grb-2 for the treatment of AML. Orphan drug status provides Bio-Path with seven years of exclusivity after receiving formal marketing approval, as well as additional development incentives.
- Preclinical testing of its lead product candidate, Liposomal Grb-2, is continuing, 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. The Company is working in collaboration with a leading researcher working in the MD Anderson breast cancer program. The Company expects to complete the final *in vivo* segment of the preclinical program in 2015.
- Bio-Path is completing a preclinical package of toxicity, tissue distribution, pharmacokinetics and efficacy studies for its second product candidate, Liposomal Bcl-2 (L-Bcl-2), and anticipates filing an Investigational New Drug (IND) application with the FDA in 2015. Bio-Path expects that the favorable toxicity profile of its lead drug candidate (Liposomal Grb-2) will allow for a Phase 1 clinical trial of this second drug to start at a higher dose, thus, reducing the number of patients required to complete the safety phase of the clinical trial.

Liposomal Bcl-2 is a liposomal encapsulated oligonucleotide targeted to the translation initiation site of human Bcl-2 mRNA. Bcl-2 overexpression has been

associated with up to 60 percent of cancers. The antisense oligonucleotide in L-Bcl-2 used by Bio-Path is a nuclease-resistant, hydrophobic analog of phosphodiester containing the Company's proprietary P-ethoxy backbone.

- Bio-Path continued qualification of a second drug manufacturer, with the goal of strengthening its manufacturing process and increasing capability and capacity.
 - Bio-Path continued efforts to broaden its product pipeline and is vetting potential new product candidates for future development in the cancer area.
 - Bio-Path initiated efforts to increase its profile amongst the medical and scientific community and presented last week at the IBC's 17th Annual TIDES: Oligonucleotide and Peptide Therapeutics Conference in San Diego. The presentation featured Bio-Path's DNabilizeTM technology for delivering liposome/antisense drugs and also highlighted the Company's lead product candidate, Liposomal Grb-2. The TIDES Summit is prominently known as the premier conference for the oligonucleotide and peptide discovery, development and manufacturing industries.
 - Tara Sadeghi joined Bio-Path as Director of Clinical Operations. Reporting to Dr. Ulrich Mueller, Chief Operating Officer, she will be responsible for all clinical activities surrounding the Company's drug development programs. Ms. Sadeghi previously was employed with The University of Texas MD Anderson Cancer Center.
- First Quarter 2015 Financial Highlights
 - The Company reported a net loss of \$1.4 million for the three months ended March 31, 2015, compared to a net loss of \$0.5 million for the three months ended March 31, 2014. The increase was due to higher professional fees, increased preclinical activity, manufacturing development expenses and personnel costs. The Company reported a net loss per share of \$0.02 for the three months ended March 31, 2015, based on 89,762,872 weighted average shares outstanding, compared to a net loss of \$0.01 per share for the same period in 2014.
 - Operating expenses of \$1.4 million in the first quarter of 2015 were higher by approximately \$0.9 million compared to the first quarter of 2014 due to increased research and development expenses related to increased preclinical activity, manufacturing development and personnel costs associated with further building the organization in the latter half of 2014. Additionally, general and administrative expenses increased due to higher professional fees and personnel costs.
 - As of March 31, 2015, the Company had cash of \$12.5 million, compared to \$13.9 million at December 31, 2014. Net cash used in operating activities for the

three months ended March 31, 2015 was \$1.4 million compared to \$0.5 million for the comparable period in 2014.

“While stock market dynamics don’t necessarily reflect the progress being made at Bio-Path, this first quarter included several important achievements for the Company,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path. “Receipt of orphan drug designation from the FDA for our lead candidate Liposomal Grb-2 demonstrates the unmet need for an effective therapy for patients suffering from AML. It also marks a key regulatory milestone for Bio-Path which will be valuable as we continue to progress Liposomal Grb-2 through clinical trials and toward potential commercialization. Advancing and building a solid pipeline of cancer therapies is a key goal for Bio-Path and we have made definitive progress in this area. Our lead product candidate is now in the first segment of a Phase 2 trial while our second product candidate progresses toward the clinic. We also continue development of our preclinical pipeline while identifying additional product candidates that could benefit from our unique delivery technology.”

Mr. Nielsen continued, “Operationally, presenting at the Tides Conference was an important step for Bio-Path in the process of increasing awareness in the scientific community of the progress we’ve made advancing our oligonucleotide delivery technology, with the potential for developing collaborations for future new development. Our balance sheet continues to be strong, with sufficient cash to continue our development programs through 2015 and into 2016.”

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 proprietary, 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-1001 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 2 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. 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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