Bio-Path Holdings Reports Fiscal Year 2015 Operational and Financial Results

HOUSTON—March 16, 2016 – Bio-Path Holdings, Inc., (NASDAQ: BPTH) ("Bio-Path"), a biotechnology company leveraging its proprietary DNAbilize™ liposomal delivery technology to develop a portfolio of targeted nucleic acid cancer drugs, today announced operational and financial results for the year ended December 31, 2015.

"2015 was a year of significant progress for Bio-Path," said Peter Nielsen, President and Chief Executive Officer of Bio-Path. "With two full remissions achieved in the safety segment of our Phase II trial of lead candidate BP1001 in advanced AML patients, the formation of an inaugural Scientific Advisory Board, and receiving orphan drug designation for BP1001 in AML, we are looking forward to a successful 2016."

2015 Operational Highlights:

- **Finalized the data package for the monotherapy portion of the Phase I clinical trial of Bio-Path's lead product candidate, BP1001 (Liposomal Grb2 antisense), in blood cancers during the fourth quarter of 2015.** BP1001 was well tolerated and showed signs of anti-leukemia activity and no drug-related toxicities. Among 21 evaluable patients, more than half experienced at least a 50 percent reduction in peripheral or bone marrow blasts from baseline. Additionally, several patients demonstrated transient improvement and/or stable disease. Notably, one patient with chronic myelogenous leukemia (CML) blast phase showed a significant reduction in blasts. Patient data from the Phase I clinical trial also demonstrated significant reductions in the target Grb2 protein and its downstream proteins, providing positive evidence that Bio-Path's DNAbilize™ neutral lipid delivery with proprietary antisense technology successfully delivers an antisense drug substance to a diseased cell to knock down the target protein.

- **Received orphan drug designation from the U.S. Food and Drug Administration (FDA) for BP1001 for the treatment of acute myeloid leukemia (AML) in the second quarter of 2015.** Orphan drug status provides Bio-Path with seven years of exclusivity after receiving formal marketing approval, as well as additional development incentives.

- **Performed preclinical testing of BP1001 in 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.** Bio-Path is rolling this initiative into a broader solid tumor testing program, including advanced ovarian cancer. The preclinical program may be expanded to include combination therapy evaluations.

- **Added a second drug manufacturer, strengthening Bio-Path's manufacturing process while increasing capability and capacity.**

- **Continued preclinical evaluation of a third DNAbilize™ product.** Bio-Path's product candidate screening and development program has validated the next promising candidate, which will diversify the Company's product pipeline. Potential indications include diffuse large B-cell lymphoma, non-small cell lung cancer, pancreatic cancer and disease candidates outside of oncology, such as autoimmune disorders.

- **Formed a Scientific Advisory Board to support the advancement of Bio-Path's clinical and preclinical therapeutic candidates.** Jorge Cortes, M.D., renowned leukemia expert from The University of Texas MD Anderson Cancer Center, joined as Chairman. Amy P. Sing, M.D., a member of Bio-Path's board of directors and Senior Director of Medical Affairs at Genomic Health, Inc., joined as a founding member.

- **Presented Bio-Path's proprietary technology and clinical trial results at an international meeting.** Jorge Cortes, M.D. of The University of Texas MD Anderson Cancer Center and Chair of Bio-Path's Scientific Advisory Board presented a poster at the 57th American Society of Hematology (ASH) Annual Meeting on December 7, 2015 in Orlando, FL. Dr. Cortes discussed data from the Phase I and safety segment of the Phase II clinical trials of BP1001 in blood cancers. These data included the complete remission of two evaluable patients receiving BP1001 in combination with low-dose cytarabine (LDAC) chemotherapy.

- **Presented to the medical and scientific community at the IBC's 17th Annual TIDES: Oligonucleotide and Peptide Therapeutics Conference in San Diego.** The presentation featured Bio-Path's DNAbilize™ technology for delivering liposome/antisense drugs and highlighted BP1001. The TIDES Summit is prominently known as the premier conference for the oligonucleotide and peptide discovery, development and manufacturing industries.

- **Continued enhancement of Bio-Path's public profile within the investment community and biopharmaceutical industry.** Chief Executive Officer Peter Nielsen delivered company presentations at the 17th Annual Rodman & Renshaw Global Investment Conference in September 2015, the 14th Annual BIO Investor Forum in October 2015, Biotech Showcase™ 2015 Conference in San Francisco, CA in January 2016 and the 18th Annual BIO CEO & Investor Conference in New York City in February 2016.

- **Established an "at-the-market" ("ATM") program during the second quarter of 2015, through which it may offer and sell up to $25 million of common stock from time to time, at Bio-Path's discretion, through an investment banker, acting as sales agent.** Sales of Bio-Path common stock under the ATM program may be made directly on or through the Nasdaq Capital Market, among other methods. As of December 31, 2015, the Company has not offered or sold any shares of common stock under the ATM program.

Recent / First Quarter 2016 Operational Highlights:

- **Completed the safety segment of the Phase II clinical trial of BP1001, in combination with low-dose cytarabine (LDAC) chemotherapy, in patients with advanced AML.** Of the six evaluable patients, two had a complete response and two had a partial response, with one patient continuing treatment. Bio-Path saw no adverse events attributable to BP1001 treatment.

- **Entered into a sponsored research agreement with The University of Texas MD Anderson Cancer Center to evaluate Bio-Path's clinical pipeline for its ability to modulate pancreatic cancer.**

Expected Upcoming Milestones:

- **BP1001 in Acute Myeloid Leukemia (AML):** Bio-Path is finalizing steps to commence a multi-site Phase II clinical trial assessing the efficacy of BP1001 in combination with low-dose cytarabine (LDAC) chemotherapy, which is expected to commence in the second quarter of 2016.

- **BP1001 in Chronic Myelogenous Leukemia (CML):** Bio-Path commenced development of a protocol for a Phase II clinical trial evaluating BP1001 in combination with frontline chemotherapy in CML patients in blast crisis, an area of unmet medical need. This clinical trial is expected to start in the second quarter of 2016.

- **BP1002 (Liposomal Bcl2; L-Bcl2):** Bio-Path is finalizing a preclinical package of toxicity, tissue distribution, pharmacokinetics and efficacy studies for its second product candidate, BP1002. An Investigational New Drug (IND) application will be filed with the FDA upon finalizing drug batch required for the Chemistry, Manufacturing and Controls section of the IND. Bio-Path expects that the favorable toxicity profile of BP1001 will allow for a Phase I clinical trial of BP1002 to begin at a higher dose, thus reducing the number of patients required to complete the safety phase of the trial.

2015 Financial Highlights:

- Bio-Path reported a net loss of $5.5 million for the year ended December 31, 2015, compared to a net loss of $4.5 million for the year ended December 31, 2014. The increase was primarily due to increased clinical trial expenses, manufacturing development, preclinical study costs and personnel costs associated with the addition of research and development support staff in the second half of 2014. The Company reported a net loss of $0.06 per share for the year ended December 31, 2015, compared to a net loss of $0.05 per share for the year ended December 31, 2014.

- Research and development expenses for the year ended December 31, 2015 increased to $3.0 million, compared to $1.8 million for the year ended December 31, 2014.

- General and administrative expenses for the year ended December 31, 2015 decreased to $2.5 million, compared to $2.7 million for the year ended December 31, 2014.

- As of December 31, 2015, the Company had a cash balance of $8.9 million**,** compared to $13.9 million at December 31, 2014. Net cash used in operating activities for the year ended December 31, 2015 was $5.0 million, compared to $3.8 million for the comparable period in 2014.

About Bio-Path's Delivery Technology

Bio-Path's drug delivery technology, called DNAbilize™, 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 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 BP1001 (Liposomal Grb2 antisense)

BP1001 (Liposomal Grb2 antisense) is a neutral-charge, liposome-incorporated antisense drug substance designed to inhibit Grb2 protein expression. The protein Grb2 is essential to cancer cell signaling because it is utilized by oncogenic tyrosine kinases to induce cancer progression. Suppressing the function or expression of Grb2 should interrupt its vital signaling function and have a therapeutic application in cancer.

About Bio-Path Holdings, Inc.

Bio-Path is a biotechnology company focused on developing therapeutic products utilizing DNAbilize™, its proprietary liposomal delivery and antisense technology, to systemically distribute nucleic acid drugs throughout the human body with a simple intravenous transfusion. Bio-Path's lead product candidate, BP1001 (Liposomal Grb2 antisense), is in a Phase II 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.

For more information, please visit the Company's website at http://www.biopathholdings.com.

Forward-Looking Statements

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.

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