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

HOUSTON—November 10, 2015 – 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 quarter ended September 30, 2015.

"The third quarter of 2015 proved to be an exciting time for Bio-Path, as we made significant progress with our lead product candidate, BP1001," said Peter Nielsen, President and Chief Executive Officer of Bio-Path. "We reported that one patient with advanced acute myeloid leukemia in our Phase Ib trial achieved complete remission, and another patient continued to steadily improve on treatment. In addition, we continued advancing our second asset, BP1002, and are preparing for it to enter the clinic to address unmet needs in patients with solid tumors and lymphomas."

Third Quarter 2015 and Recent Operational and Corporate Highlights:

- **Successful completion of Cohort 7 of Bio-Path's Phase Ib clinical trial evaluating the toxicity of its lead compound, BP1001 (Liposomal Grb2 antisense), combined with low-dose cytarabine (LDAC) chemotherapy in patients with advanced acute myeloid leukemia (AML).** Three patients were evaluated in Cohort 7, which was the first cohort of the Company's Phase Ib trial to evaluate the toxicity of BP1001 as a combination therapy. Patients were treated twice a week for four weeks with 60 mg/m^2 of BP1001, for a total of eight doses in combination with the standard regimen of LDAC. Results were consistent with previous cohorts, showing BP1001 to be safe and well tolerated. One patient in Cohort 7 achieved complete remission, and a second patient demonstrated improvement in bone marrow blasts at the end of the first treatment cycle and is continuing BP1001 treatment as part of additional treatment cycles.

- **Enrollment opened into the eighth and final cohort of the Phase Ib clinical trial, in which patients will receive dosing with 90 mg/m^2 of BP1001 in combination with the standard regimen of LDAC.** The Company is finalizing the last cohort of the safety portion for the Phase II combination therapy of BP1001 in AML.

- **Continued evaluation of BP1001 in breast cancer through a preclinical program targeting triple negative breast cancer (TNBC) and inflammatory breast cancer (IBC).** The preclinical program may be expanded to include a combination therapy evaluation.

- **Ongoing preclinical evaluation of a third DNAbilize™ product**. Bio-Path's product candidate screening and development program produced this promising product candidate,

which will diversify the Company's product pipeline. Potential indications for this new drug candidate include diffuse large B-cell lymphoma, non-small cell lung cancer, pancreatic cancer and disease candidates outside of oncology, such as autoimmune disorders.

- **Formation of 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.

- **Continued enhancement of the Company'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 and the 14th Annual BIO Investor Forum in October 2015.

- **Participation in medical meetings and congresses, showcasing the Company's proprietary technology.** Jorge Cortes, M.D., of The University of Texas MD Anderson Cancer Center and Chair of Bio-Path's inaugural Scientific Advisory Board was selected to present a poster at the 57th American Society of Hematology (ASH) Annual Meeting on December 7, 2015 in Orlando, FL. Dr. Cortes will discuss data from the Phase Ib trial of BP1001.

Expected Upcoming Milestones:

- **BP1001 in Chronic Myelogenous Leukemia (CML):** The Company is finalizing the protocol for its Phase II trial, which will evaluate the efficacy of BP1001 and frontline chemotherapy in patients with CML in blast crisis, an area of unmet medical need. The Company expects to complete preparations to initiate the toxicity portion of this Phase II trial by the end of 2015.

- **BP1001 in Acute Myeloid Leukemia (AML):** Bio-Path is planning to open a multi-center Phase II clinical trial in AML to evaluate the efficacy of treating patients with BP1001 in combination with LDAC. The combination therapy Phase II trial will enroll older AML patients who are unfit for intense treatment. This patient subset represents a major unmet need for an approach that provides a greater quality of life for patients, while offering an opportunity for clinical development of the compound. The single arm Phase II study is expected to open for enrollment in January 2016.

- **BP1002 (Liposomal Bcl2 antisense) in Follicular Lymphoma:** The Company is finalizing its Investigational New Drug (IND) Application to begin a Phase I clinical trial in follicular lymphoma with its second liposome-delivered antisense cancer drug candidate. IND filing is anticipated in early 2016.

- **BP1002 in multiple oncological and hematological indications:** This asset is ready for the clinic, and is intended to target lymphoma, breast cancer, colon cancer, prostate cancer and leukemia. The Company believes that BP1002 may have potential to treat between 40 to 60 percent of solid tumors.

Third Quarter 2015 Financial Highlights:

- The Company reported a net loss of $1.5 million for the three months ended September 30, 2015, compared to a net loss of $1.1 million for the three months ended September 30, 2014. The increase was primarily due to increased drug manufacturing and testing, an increase in drug material used and increased clinical trial expenses. The Company reported a net loss of $0.02 per share for the three months ended September 30, 2015, compared to a net loss of $0.01 per share for the three months ended September 30, 2014. Net loss for the nine months ended September 30, 2015 was $4.0 million, or $0.04 per share, compared to a net loss of $2.9 million, or $0.03 per share, for the nine months ended September 30, 2014. The increase was primarily due to increased manufacturing development, preclinical study costs and clinical trial expenses, as well as personnel costs associated with the addition of research and development support staff in the latter half of 2014.

- Research and development expenses for the three months ended September 30, 2015 increased to $1.0 million, compared to $0.4 million for the three months ended September 30, 2014. For the nine months ended September 30, 2015, research and development expenses increased to $2.1 million, compared to $1.1 million for the nine months ended September 30, 2014.

- General and administrative expenses for the three months ended September 30, 2015 decreased to $0.5 million, compared to $0.7 million for the three months ended September 30, 2014. For the nine months ended September 30, 2015, general and administrative expenses increased to $1.9 million, compared to $1.8 million for the nine months ended September 30, 2014.

- As of September 30, 2015, the Company had cash of $9.9 million**,** compared to $13.9 million at December 31, 2014. Net cash used in operating activities for the nine months ended September 30, 2015 was $4.0 million, compared to $2.7 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 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 (Grb2)

The adaptor protein Growth Receptor Bound protein-2 (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. BP1001, or Liposomal Grb2, is a neutral-charge, liposome-incorporated antisense drug substance designed to inhibit Grb2 expression.

About Bio-Path Holdings, Inc.

Bio-Path is a biotechnology company focused on developing therapeutic products utilizing DNAbilize™, its liposomal and proprietary antisense delivery 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.

# # #

Contact Information:

Investors

Kara Andress
Investor Relations
Bio-Path Holdings, Inc.

832-742-1357

Steve Silver
Rx Communications Group, LLC
917-322-2569
ssilver@rxir.com

Media

Tony Plohoros
6 Degrees
908-591-2839
tplohoros@6degreespr.com