



Bio-Path Holdings Reports Third Quarter 2021 Financial Results

Conference Call to be Held Today at 8:30 A.M. ET

HOUSTON—November 12, 2021 – Bio-Path Holdings, Inc., (NASDAQ:BPTH), a biotechnology company leveraging its proprietary DNabilize® liposomal delivery and antisense technology to develop a portfolio of targeted nucleic acid cancer drugs, today announced its financial results for the third quarter ended September 30, 2021 and provided an update on recent corporate developments.

“The clinical and regulatory advances made during the third quarter position us to initiate two key trials with prexigebersen-A in solid tumors and BP1002 in relapsed/refractory acute myeloid leukemia (AML) patients,” stated Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings. “Looking to the balance of the year, we look forward to presenting safety and preliminary efficacy data from our ongoing Phase 2 trial of prexigebersen for the treatment of AML before an audience of world-leading oncologists at the American Society for Hematology Annual Meeting. Collectively, the progress we are making throughout 2021 is bringing us one step closer to achieving our goal of bringing new medicines to the fight against cancer.”

Recent Corporate Highlights

- **Clearance of IND Application for Phase 1/1b Clinical Trial of Prexigebersen-A.** In October, Bio-Path announced that the U.S. Food and Drug Administration (FDA) had reviewed and cleared the Investigational New Drug (IND) application to initiate a Phase 1/1b clinical trial of prexigebersen-A (liposomal Grb2-A or BP1001-A) in patients with solid tumors, including ovarian, endometrial, pancreatic and triple negative breast cancer. Prexigebersen-A is a modified drug product with the same drug substance as prexigebersen but includes formulation enhancements to produce smaller drug nanoparticles.
- **Clearance of IND Application for BP1002.** In August, the Company announced that the FDA had reviewed and cleared the IND application for BP1002 (liposomal Bcl-2), the Company’s second drug candidate, for an initial Phase 1/1b clinical trial that will evaluate the ability of BP1002 to treat refractory/relapsed AML patients.

Financial Results for the Third Quarter Ended September 30, 2021

- The Company reported a net loss of \$2.1 million, or \$0.29 per share, for the three months ended September 30, 2021, compared to a net loss of \$3.0 million, or \$0.80 per share, for the three months ended September 30, 2020.

- Research and development expense for the three months ended September 30, 2021 decreased to \$1.0 million, compared to \$2.0 million for the three months ended September 30, 2020, primarily due to timing of activities related to our clinical trial for prexigebersen in AML and timing of drug material manufacturing and shipping activities.
- General and administrative expense for the three months ended September 30, 2021 increased to \$1.1 million, compared to \$1.0 million for the three months ended September 30, 2020, primarily due to increased stock-based compensation expense.
- As of September 30, 2021, the Company had cash of \$26.6 million, compared to \$13.8 million at December 31, 2020. Net cash used in operating activities for the nine months ended September 30, 2021 was \$7.1 million, compared to \$8.4 million for the comparable period in 2020. Net cash provided by financing activities for the nine months ended September 30, 2021 was \$20.0 million.

Conference Call and Webcast Information

Bio-Path Holdings will host a conference call and webcast today at 8:30 a.m. ET to review these third quarter 2021 financial results and to provide a general update on the Company. To access the conference call please dial (844) 815-4963 (domestic) or (210) 229-8838 (international) and refer to the conference ID 6684508. A live audio webcast of the call and the archived webcast will be available in the Media section of the Company's website at www.biopathholdings.com.

About Bio-Path Holdings, Inc.

Bio-Path is a biotechnology company developing DNAbilize®, a novel technology that has yielded a pipeline of RNAi nanoparticle drugs that can be administered with a simple intravenous infusion. Bio-Path's lead product candidate, prexigebersen (BP1001, targeting the Grb2 protein), is in a Phase 2 study for blood cancers, and prexigebersen-A, a drug product modification of prexigebersen, has been cleared by the FDA to commence a Phase 1/1b study in solid tumors. This is followed by BP1002, targeting the Bcl-2 protein, which is being evaluated in a Phase 1 study in advanced lymphoma and CLL patients and has been cleared by the FDA for a Phase 1/1b study in refractory/relapsed AML patients. In addition, an IND is expected to be filed for BP1003, a novel liposome-incorporated STAT3 antisense oligodeoxynucleotide developed by Bio-Path as a specific inhibitor of STAT3.

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

Forward-Looking Statements

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws. These statements are based on management's current expectations and accordingly are subject to uncertainty and changes in circumstances. Any express or implied statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Any statements that are not historical facts contained in this release are forward-looking statements that involve risks and uncertainties, including the impact, risks and uncertainties related to COVID-19 and actions taken by governmental authorities or others in connection therewith, Bio-Path's ability to raise needed additional capital on a timely basis in order for it to continue its operations, Bio-Path's ability to 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, the maintenance of intellectual property rights, that patents relating to existing or future patent applications will be issued or that any issued patents will provide meaningful protection of our drug candidates, and such other risks which are identified in Bio-Path's most recent Annual Report on Form 10-K, in any subsequent quarterly reports on Form 10-Q and in other reports that Bio-Path files with the Securities and Exchange Commission from time to time. 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

Will O'Connor
Stern Investor Relations, Inc.
212-362-1200
will@sternir.com

Doug Morris
Investor Relations
Bio-Path Holdings, Inc.
832-742-1369