Bio-Path Holdings Reports Third Quarter 2024 Financial Results

Expands DNAbilize® Technology Beyond Oncology into Obesity

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

HOUSTON—November 15, 2024 – Bio-Path Holdings, Inc., (NASDAQ:BPTH), a biotechnology company leveraging its proprietary DNAbilize® antisense RNAi nanoparticle technology to develop a portfolio of targeted nucleic acid cancer drugs, today announced its financial results for the third quarter ended September 30, 2024 and provided an update on recent corporate developments.

"The third quarter was a particularly productive period for Bio-Path as we initiated our obesity program, which marks the first application of our DNAbilize® platform beyond oncology and highlights its broad therapeutic potential," said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings. "Importantly, we continued to advance our oncology programs and were delighted with the swift enrollment of the third cohort in our Phase 1/1b clinical trial of BP1002 in venetoclax-resistant AML patients, which was ahead of our projected timelines. We also published an article highlighting the broad anti-tumor effect of BP1003 in numerous preclinical solid tumor models, including breast, ovarian, and pancreatic cancer, in the peer-reviewed journal, *Biomedicines*."

Recent Corporate Highlights

- **Initiated BP1001-A Therapeutic Program for Treatment of Obesity.** In October, the Company announced the initiation of a therapeutic program to develop BP1001-A for the treatment of obesity and related metabolic diseases. This program marks the first application of DNAbilize® technology for development of a non-cancer application, which highlights the broad therapeutic potential of this technology. The disease pathology leading to obesity suggests that BP1001-A, which suppresses the adaptor protein Grb2, has the potential to treat insulin resistance, a major contributor to obesity, Type 2 diabetes and other related metabolic diseases. Bio-Path expects downregulating Grb2 expression with BP1001-A will enhance insulin sensitivity.

- **Completion of Enrollment for Third Dosing Cohort of Phase 1/1b Clinical Trial of BP1002 in Venetoclax-Resistant Acute Myeloid Leukemia (AML) Patients.** In October, Bio-Path announced completion of enrollment for the third dosing cohort of the Company's Phase 1/1b trial of BP1002 in venetoclax-resistant AML patients. The cohort enrolled more quickly than projected, which underscores the ongoing need for new treatment options for these relapsed/refractory patients.

- **Publication in Peer-Reviewed Journal, Biomedicines.** In September, Bio-Path published an article highlighting the therapeutic potential of BP1003 in a variety of cancer types in the peer-reviewed journal, Biomedicines. The article describes the broad anti-tumor effect of BP1003 in numerous preclinical solid tumor models including breast, ovarian, and pancreatic cancer. BP1003 is a neutral liposome incorporated with a nuclease resistant P-ethoxy antisense oligodeoxynucleotide targeting the STAT3 mRNA and its unique design enhances stability, cellular uptake, and target affinity.

- **Reported Solid Tumor Patient Response Supporting BP1001-A's Compelling Potential as Treatment for Advanced Solid Tumors.** Bio-Path's first patient in the second dose cohort in its Phase 1/1b advanced solid tumor clinical trial experiencing a positive response may signal that this analog of prexigebersen has potential as a new treatment for advanced solid tumors. The patient appears to be doing well on study after failing extensive chemotherapy and surgical treatment for gynecologic cancer, demonstrating a 15% reduction in her primary tumor through six cycles of treatment. Moreover, it appears that these positive outcomes may have contributed to allow her to continue with rigorous exercise and improved quality of life.

  The dose finding portion of the Phase 1/1b trial is comprised of BP1001-A monotherapy with no accompanying chemotherapy. This clinical trial of BP1001-A in patients with advanced or recurrent solid tumors has successfully completed the initial prescribed dose in the first cohort of 60 mg/m^2 and began enrollment in the higher dose cohort of 90 mg/m^2. The Phase 1b portion of the study is expected to commence after completion of three planned BP1001-A monotherapy dose level cohorts and is intended to assess the safety and efficacy of BP1001-A in combination with paclitaxel in patients with recurrent ovarian or endometrial tumors. Phase 1b studies are also expected to be opened in combination with gemcitabine in late-stage pancreatic cancer.

- **Closed $4.0 Million Private Placement.** In October, Bio-Path announced closing of a private placement priced at-the-market under Nasdaq rules for the issuance and sale of an aggregate of 4,597,702 shares of its common stock (or common stock equivalents in lieu thereof), series A warrants to purchase up to 6,407,657 shares of common stock and short-term series B warrants to purchase up to 6,407,657 shares of common stock at a purchase price of $0.87 per share of common stock (or per common stock equivalent in lieu thereof) and accompanying warrants in a private placement. The gross proceeds to the Company from the offering were approximately $4.0 million, before deducting the placement agent's fees and other offering expenses payable by the Company, and excluding the proceeds, if any, from the exercise of the warrants.

Financial Results for the Third Quarter Ended September 30, 2024

- The Company reported a net loss of $2.1 million, or $0.70 per share, for the three months ended September 30, 2024, compared to a net loss of $3.2 million, or $6.36 per share, for the three months ended September 30, 2023.

- Research and development expense for the three months ended September 30, 2024 decreased to $1.3 million, compared to $2.3 million for the three months ended September 30, 2023 primarily due to decreased manufacturing expenses related to drug product releases as well as a decrease in expense related to our clinical trial for BP1001 in AML due to timing of patient enrollment during the quarter.

- General and administrative expense for the three months ended September 30, 2024 increased to $1.3 million, compared to $1.0 million for the three months ended September 30, 2023 primarily due to increased legal fees and salaries and benefits expense.

- As of September 30, 2024, the Company had cash of $0.6 million, compared to $1.1 million as of December 31, 2023. Net cash used in operating activities for the nine months ended September 30, 2024 was $7.7 million compared to $9.7 million for the comparable period in 2023. Net cash provided by financing activities for the nine months ended September 30, 2024 was $7.2 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 2024 financial results and to provide a general update on the Company. To access the conference call please dial (844) 481-3014 (domestic) or (412) 317-1879 (international). 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 transfusion. Bio-Path's lead product candidate, prexigebersen (BP1001, targeting the Grb2 protein), is in a Phase 2 study for blood cancers, and BP1001-A, a drug product modification of prexigebersen, is in a Phase 1/1b study for solid tumors. The Company's second product, BP1002, which targets the Bcl-2 protein, is being evaluated for the treatment of blood cancers and solid tumors, including lymphoma and acute myeloid leukemia. 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 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 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, 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, the impact, risks and uncertainties related to global pandemics, including the COVID-19 pandemic, and actions taken by governmental authorities or others in connection therewith, 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.

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