UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT PURSUANT
TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): December 14, 2023

BIO-PATH HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36333**	**87-0652870**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4710 Bellaire Boulevard, Suite 210, Bellaire, Texas	**77401**
(Address of principal executive offices)	(Zip Code)

(832) 742-1357
(Registrant's Telephone Number, Including Area Code)

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.001 per share	BPTH	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On December 14, 2023, Bio-Path Holdings, Inc. (the "Company") issued a press release titled, "Bio-Path Holdings Successfully Completes First Dose Cohort of Phase 1/1b Clinical Trial of BP1002 in Refractory/Relapsed Acute Myeloid Leukemia." A copy of such press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release dated December 14, 2023.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL (included as Exhibit 101).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Company has duly caused this Current Report to be signed on its behalf by the undersigned hereunto duly authorized.

BIO-PATH HOLDINGS, INC.

Dated: December 14, 2023

By:/s/ Peter H. Nielsen
Peter H. Nielsen
President and Chief Executive Officer

Exhibit 99.1

Bio-Path Holdings Successfully Completes First Dose Cohort of Phase 1/1b Clinical Trial of BP1002 in Refractory/Relapsed Acute Myeloid Leukemia

BP1002 Offers Unique Opportunity for Venetoclax-Resistant Patients by Utilizing RNAi to Limit Cells' Ability to Produce Bcl-2 Protein

HOUSTON – December 14, 2023 – 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 completion of the first dose cohort of the dose escalation portion of its Phase 1/1b clinical trial of BP1002 evaluating the ability of BP1002 to treat refractory/relapsed acute myeloid leukemia (AML) patients including venetoclax-resistant patients.

"We are delighted to safely complete this first dose cohort and to advance BP1002 into the next cohort as it brings us one step closer to providing access to this very promising treatment for the most vulnerable patients who have limited therapeutic options," said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings. "We look forward to advancing this study in higher doses with the hope that increased levels of BP1002 will prove even more efficacious and safe in these sickest of sick patients."

A total of three evaluable patients per dosing cohort are scheduled to be treated with BP1002 monotherapy in a standard 3+3 design, unless there is a dose limiting toxicity which would require an additional three patients tested. The first dose cohort consisted of a starting dose of 20 mg/m^2, and there were no dose limiting toxicities. The approved treatment cycle is two doses per week over four weeks for a total of eight doses administered over twenty-eight days. The Phase 1b portion of the study is expected to commence after completion of BP1002 monotherapy cohorts and will assess the safety and efficacy of BP1002 in combination with decitabine in refractory/relapsed AML patients.

Gail J. Roboz, M.D., is the National Principal Investigator for the Phase 1/1b trial. Dr. Roboz is a professor of medicine and director of the Clinical and Translational Leukemia Program at the Weill Medical College of Cornell University and the New York-Presbyterian Hospital in New York City. Gary Schiller, M.D., The University of California at Los Angeles Cancer Center, Maro Ohanian, D.O., Department of Leukemia, University of Texas MD Anderson Cancer Center, and David Hermel, M.D., Scripps Health, are each serving as principal investigators.

About BP1002

BP1002 targets the protein Bcl-2, which is responsible for driving cell survival in up to 60% of all cancers. The current standard of care for patients with AML not eligible for intensive chemotherapy is venetoclax, an oral Bcl-2 inhibitor that targets the BH3 domain of the Bcl-2 protein, in combination with a hypomethylating agent or with low-dose cytarabine. Unfortunately, many patients become resistant to venetoclax treatment. A published study found that AML patients who had relapsed from frontline venetoclax-based treatment were refractory to salvage therapy and had a median survival of less than 3 months. By targeting Bcl-2 at the mRNA level rather than the protein, BP1002 may overcome and prevent some of the mechanisms of resistance that affect venetoclax treatment. Published preclinical studies have shown BP1002 to be a potent inhibitor against the Bcl-2 target and its benign safety profile should enable effective BP1002 combination therapy with approved agents, such as decitabine.

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 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 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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