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): July 17, 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 July 17, 2023, Bio-Path Holdings, Inc. (the "Company") issued a press release titled, "Bio-Path Holdings Announces Successful Completion of First Dose Cohort in Phase 1/1b Clinical Trial of BP1001-A in Solid Tumors." 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 July 17, 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: July 17, 2023

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

Exhibit 99.1

Bio-Path Holdings Announces Successful Completion of First Dose Cohort in Phase 1/1b Clinical Trial of BP1001-A in Solid Tumors

Advancing to Second Cohort of Phase 1/1b Clinical Trial Evaluating BP1001-A to Treat Patients with Solid Tumors, Including Ovarian, Endometrial, Pancreatic and Breast Cancer

HOUSTON – July 17, 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 BP1001-A (liposomal Grb2) in patients with solid tumors, including ovarian, endometrial, pancreatic and breast cancer.

"We are delighted to have completed the first cohort of this first-in-human Phase 1/1b study of BP1001-A as it further demonstrated the drug's favorable safety profile, which is critical for the treatment of these very vulnerable cancer patients," said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings. "Importantly, this achievement enables us to advance to the second cohort of this important study in solid tumor cancers, for which we hope to complete enrollment by year end 2023."

The dose escalation portion of the Phase 1/1b clinical trial is ongoing at more than eight leading cancer centers in the United States, including The University of Texas MD Anderson Cancer Center, The Mary Crowley Cancer Research Center, and Karmanos Cancer Center. Initially, a total of nine evaluable patients are scheduled to be treated with BP1001-A monotherapy in a standard 3+3 design, with a starting dose of 60 mg/m^2 and continuing with 90 mg/m^2 and 135 mg/m^2. The approved treatment cycle is two doses per week over four weeks, resulting in eight doses administered over twenty-eight days. The Phase 1b portion of the study will commence after successful completion of BP1001-A monotherapy cohorts and will assess the safety and efficacy of BP1001-A in combination with paclitaxel in patients with recurrent ovarian or endometrial tumors, and BP1001-A with gemcitabine in patients with metastatic pancreatic tumors.

Three patients were enrolled into the first dose cohort of BP1001-A at 60 mg/m^2 at three different centers in the study, including one patient with hepatic lesions (and lung metastases) and two with advanced gynecologic lesions. All three patients had undergone extensive previous chemotherapies and/or surgeries for their disease prior to enrollment in this Phase 1 study. No patient experienced any treatment related adverse events or any adverse events deemed related to the study drug.

About BP1001-A

BP1001-A is a modified drug product with the same drug substance as Bio-Path's lead drug candidate, prexigebersen, but includes formulation enhancements to produce smaller drug nanoparticles. The goal of this product enhancement is to produce smaller drug nanoparticles that can pass through vasculature pore spaces, thereby enabling release of the drug product into the interior of the tumor to enhance drug effectiveness. In pre-clinical testing in mice, results clearly demonstrated that the reduced size formulation produced a reduction in tumor burden, evidence that the drug product effectiveness was improved with the smaller drug product nanoparticles.

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 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 application is expected to be filed for BP1003, a novel liposome-incorporated STAT3 antisense oligodeoxynucleotide developed by Bio-Path as a specific inhibitor of STAT3, in 2023.

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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