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 8, 2024

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 8.01 Other Events.

On July 8, 2024, Bio-Path Holdings, Inc. (the "Company") issued a press release titled, "Bio-Path Holdings Provides Clinical Update and Expansion Plans." 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 8, 2024.
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 10, 2024

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

Exhibit 99.1

Bio-Path Holdings Provides Clinical Update and Expansion Plans

Marks Meaningful Progress Across Key Clinical Trials in Multiple Cancer Indications

Completes Development of Oncology Molecular Biomarkers and Prepares for Preclinical Obesity Studies

HOUSTON – July 8, 2024 – 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 provides an update on the Company's clinical progress and plans for expansion.

"The Bio-Path team continues to work diligently toward advancing our important clinical work and have made meaningful progress in a number of areas critical to each program's success," said Peter H. Nielsen, President and Chief Executive Officer of Bio-Path. "With the increased clinical data that we have generated, we are now able to develop the biomarkers needed to incorporate into our oncology studies. In addition, we have completed preparations for preclinical work to support advancing prexigebersen as a potential treatment for obesity. In tandem, we are designing development plans for first-in-human clinical studies in this expansive global market for weight loss."

"The incremental advances that we are making across these programs collectively push our DNAbilize platform closer to delivering these medicines to patients. Moreover, we are continuing to see the broader potential of our platform beyond oncology and look forward to realizing its potential across multiple indications, starting with obesity," continued Mr. Nielsen.

Clinical Program Overview

Bio-Path's clinical development program consists of one Phase 2 clinical trial and three Phase 1 or 1/1b clinical trials. Bio-Path has developed a molecular biomarker package to accompany prexigebersen treatment and is currently expanding prexigebersen preclinical studies for the treatment of obesity.

Development of Molecular Biomarkers – Bio-Path has developed a molecular biomarker package to accompany prexigebersen treatment, the goal of which is to identify patients with a genetic profile more likely to respond to treatment, thereby improving the probability of success for this program. The emerging role of biomarkers has enhanced cancer development over the past decade and has become a more common companion to many oncology programs.

Prexigebersen Phase 2 Clinical Trial – Bio-Path's Phase 2 clinical trial is treating Acute Myeloid Leukemia (AML) patients. This trial is comprised of three separate cohorts of patients and treatments, each separately approvable by the FDA as a new drug indication. The first two cohorts are treating patients with the triple combination of prexigebersen, decitabine and venetoclax. The first cohort includes untreated AML patients, and the second cohort includes relapsed/refractory AML patients. Finally, the third cohort is treating relapsed/refractory AML patients, who are venetoclax-resistant or intolerant, with the two-drug combination of prexigebersen and decitabine. Based on recent interim data for safety and efficacy, the Company plans to pursue next development steps by applying molecular biomarkers to future patient selection for enrollment into the Phase 2 clinical trial. Outcomes for these older patients who are unable to receive intensive chemotherapy due to the challenging side effect profile remain suboptimal with a median survival of only five to ten months.

The study is currently paused for an interim analysis, amendment preparation and U.S. Food and Drug Administration (FDA) review. Bio-Path expects to complete enrollment in cohorts 1 and 2 of the study over the next eighteen months.

Phase 1/1b Clinical Trial in BP1001-A in Advanced Solid Tumors – A Phase 1/1b clinical trial of BP1001-A in patients with advanced or recurrent solid tumors, including ovarian and uterine, pancreatic and breast cancer, is ongoing. BP1001-A is a modified product candidate that incorporates the same drug substance as prexigebersen but has a slightly modified formulation designed to enhance nanoparticle properties. The Phase 1 study has advanced to the second, higher dose level. The Phase 1b portion of the study is expected to commence after successful completion of the three 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.

In recent months, Bio-Path advanced to dose level 2 and expects to complete enrollment in order to advance to dose level 3 by year-end.

Phase 1/1b Clinical Trial in BP1002 in Relapsed/Refractory AML – A Phase 1/1b clinical trial for BP1002 to treat relapsed/refractory AML patients, including venetoclax-resistant patients, is ongoing. BP1002 targets the protein Bcl-2, which is responsible for driving cell survival in up to 60% of all cancers. The drug venetoclax treats AML patients by blocking the activity of the Bcl-2 protein in AML patients. However, patients become resistant to venetoclax. BP1002 treats the Bcl-2 target by blocking the cell's ability to produce Bcl-2, and could have the potential to eliminate the need for venetoclax. AML patients that fail frontline venetoclax-based therapy have very poor prognosis with median overall survival of less than three months. The first dose cohort consisted of a starting dose of 20 mg/m^2, and there were no dose limiting toxicities.

Bio-Path recently completed the second dose cohort of 40 mg/m^2 and is completing an analysis of PK/PD data to be submitted to the FDA in order to advance to the next dose level. Upon submission of data and approval from FDA, Bio-Path expects to advance to dose level 3 in the fourth quarter of 2024.

Phase 1 Clinical Trial in BP1002 in Refractory/Relapsed Lymphoma and Chronic Lymphocytic Leukemia (CLL) – A Phase 1 clinical trial to evaluate the ability of BP1002 to treat refractory/relapsed lymphoma and refractory/relapsed chronic lymphocytic leukemia (CLL) patients is currently ongoing. The Phase 1 clinical trial is being conducted at the Georgia Cancer Center, The University of Texas Southwestern and New York Medical College. In January 2024, Bio-Path announced successful completion of the first dose cohort in the Phase 1 clinical trial. A total of six evaluable patients are scheduled to be treated over two dose levels with BP1002 monotherapy in a standard 3+3 design, unless there is a dose limiting toxicity which would require an additional three patients to be tested. There were no dose limiting toxicities in the first dose cohort (20 mg/m^2).

Enrollment has continued for patients in the second BP1002 dose cohort of 40 mg/m^2 and the Company expects to complete enrollment and to review these data by year-end.

Preclinical Work for BP1003 – The Company continues to advance its drug candidate, BP1003, for the treatment of advanced solid tumors, including pancreatic cancer. BP1003 is an antisense RNAi nanoparticle targeting the STAT3 protein. Plans are to conduct a Phase 1 study of BP1003 in patients with refractory, metastatic solid tumors (pancreatic, non-small cell lung cancer).

Prexigebersen as Potential Treatment for Obesity and Obesity-related Cancers – The RNAi target of prexigebersen is the Grb2 protein, which is involved in activating the RAS/ERK pathway for cell growth. By blocking the cell's ability to produce Grb2, prexigebersen treatment may limit cell growth. In obesity, two such pathways are related to leptin and insulin. Activation of leptin or insulin receptors can stimulate the RAS/ERK pathway via Grb2[i].

Bio-Path believes development of prexigebersen for the treatment for obesity and obesity-related cancers could be accelerated given the large amount of safety data from prexigebersen treatment of leukemia patients and the continued unmet medical need. The Company is preparing for preclinical development evaluating prexigebersen for the treatment of obesity and will continue thereafter to conduct additional Investigational New Drug (IND)-enabling studies with an aim to advance prexigebersen into first-in-human studies in this indication.

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 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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[i] Casado ME et al. (2023) Recent Advances in the Knowledge of the Mechanisms of Leptin Physiology and Actions in Neurological and Metabolic Pathologies. Int J Mol Sci 24(2): 1422. Published online 2023 Jan 11. doi: 10.3390/ijms24021422)