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): January 10, 2025

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 January 10, 2025, Bio-Path Holdings, Inc. (the "Company") issued a press release titled, "Bio-Path Holdings Provides 2025 Clinical and Operational Update." 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 January 10, 2025.
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: January 10, 2025

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

Exhibit 99.1

Bio-Path Holdings Provides 2025 Clinical and Operational Update

Advancing Multiple Programs in Areas of Significant Unmet Medical Need

Several Milestones Across Clinical Development Pipeline Expected in 2025

HOUSTON—January 10, 2025 – 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 and obesity drugs, today provides a clinical development and operational update for 2025.

"The important work we conducted throughout 2024 has led us into what we believe is an exciting 2025 as we build off positive data generated in oncology and the addition of a new application for BP1001-A in the treatment of obesity for Type 2 Diabetes. This new application compels us to advance these studies as quickly as possible and to file for regulatory designations that could accelerate our path to approval," said Peter H. Nielsen, President and Chief Executive Officer of Bio-Path. "There is no greater challenge than the battle against cancer, and developing effective new medicines for patients suffering with few treatment options is what drives us every day. The addition of development of a potential treatment for obesity in Type 2 Diabetes patients follows this pathway as these patients need treatment beyond current weight loss drugs to support needed therapy for reducing glucose levels, which has positive impact across a number of different health-related conditions. The substantial progress we have made gives us further confidence that our DNAbilize® platform is ushering in a new path of DNA-powered medicines that can make a difference in the lives of these patients."

Clinical Program Overview

Bio-Path's clinical development program consists of one Phase 2 clinical trial, two Phase 1 or 1/1b clinical trials, and two preclinical programs. Bio-Path has developed a molecular biomarker package for its Phase 2 clinical trial in acute myeloid leukemia (AML) that was developed to identify patients that potentially have a higher propensity to respond to prexigebersen treatment. Bio-Path expects to utilize the biomarker package to accompany prexigebersen treatment in 2025 and expects to evaluate prexigebersen for the treatment of obesity. In addition, BP1001-A is in preclinical development for treatment of obesity in Type 2 Diabetes patients, which may be submitted to the U.S. Food and Drug Administration (FDA) later in the year in an Investigational New Drug (IND) application.

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 probability of success for this program. The emerging role of biomarkers has been enhancing cancer development over the past decade and has become a more common companion to many cancer development programs. Bio-Path expects to utilize the prexigebersen biomarkers in 2025 in the Phase 2 AML clinical trial and to develop additional molecular biomarker packages to accompany its new programs.

Prexigebersen Phase 2 Clinical Trial – Bio-Path's Phase 2 clinical trial for the treatment of AML is comprised of three cohorts of patients and treatments, each separately approvable by the FDA as a new 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. 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 5 to 10 months. Bio-Path also expects to utilize an advisory panel of AML experts to assist in the design of the final clinical development plans through potential FDA approval. Other significant milestones expected during 2025 include the completion of Cohort 2 and an interim analysis for Cohort 3.

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 and the first patient in the second dose cohort continued experiencing a positive response which may signal that this analog of prexigebersen has potential as a new treatment for advanced solid tumors. The patient continues to be doing well after ten months on study after failing extensive chemotherapy and surgical treatment for gynecologic cancer, demonstrating a 15% reduction in her primary tumor through nine cycles of treatment. Moreover, it appears that these positive outcomes may have contributed to allowing her to continue with rigorous exercise and improved quality of life. Completion of the second and third dosing cohorts are expected in 2025.

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 initiated in combination with gemcitabine in Stage 4 pancreatic cancer and combination therapy in breast cancer.

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. Venetoclax treats AML patients by blocking the activity of the Bcl-2 protein in AML patients. However, over time patients become resistant to venetoclax. BP1002 treats the Bcl-2 target by blocking the cell's ability to produce Bcl-2 and could provide benefit for these venetoclax resistant patients. 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/m2, the second dose cohort of 40 mg/m2 and there were no dose limiting toxicities. The third dosing cohort of 60 mg/m2 is open and enrollment closed faster than expected which Bio-Path believes reflects the need for additional treatment options.

Prexigebersen as Potential Treatment for Obesity in Type 2 Diabetes Patients – BP1001-A downregulates Grb2 expression to increase insulin sensitivity and helps lower blood glucose level in Type 2 diabetes patients. Scientific evidence suggests that by downregulating Grb2 expression, BP1001-A could help lower blood glucose levels by affecting insulin signaling. Bio-Path conducted preclinical studies that confirmed the effectiveness of BP1001-A in affecting insulin signaling and its potential efficacy as a therapeutic treatment for obese patients who have Type 2 diabetes. In 2025, Bio-Path expects to complete preclinical testing and to file an IND.

Intellectual Property Protection

Bio-Path's composition of matter patents are designed to protect encroachment from third parties on its proprietary products. These composition patents allow the Company to apply its core technology to new protein targets and receive new 20-year patents. Bio-Path's patent portfolio is as follows:

- Composition and methods of use patents issued cover DNAbilize technology, solely owned by Bio-Path.
- Seven patents issued in the U.S. with one additional application allowed; 61 foreign patents issued across 24 countries; five additional foreign patent applications allowed; three applications pending in the U.S. along with more than 30 applications pending in foreign jurisdictions.

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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