**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): August 21, 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 7.01 Regulation FD Disclosure.**

On August 21, 2024, Bio-Path Holdings, Inc. (the "Company") issued a press release titled, "Bio-Path Holdings Reports Solid Tumor Patient Response Supporting BP1001-A's Compelling Potential as Treatment for Advanced 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 August 21, 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: August 21, 2024

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

**Exhibit 99.1**

**Bio-Path Holdings Reports Solid Tumor Patient Response Supporting BP1001-A's Compelling Potential as Treatment for Advanced Solid Tumors**

*First Solid Tumor Patient Treated with Second, Higher Dose in Phase 1/1b BP1001-A Clinical Trial Experienced Tumor Reduction and Continued Stable Disease*

*Reports Continued Patient Progress from Phase 2 Triple Combination Study of Prexigebersen in Acute Myeloid Leukemia (AML)*

*Supportive Safety and Efficacy Data from Two Assets Validate Potential of DNAbilize® Platform Technology to Treat Most Vulnerable Cancer Patients*

**HOUSTON – August 21, 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 from the Company's ongoing Phase 1/1b clinical trial of BP1001-A in solid tumor patients and reports continued patient progress from the Company's ongoing Phase 2 triple combination study of prexigebersen in Acute Myeloid Leukemia (AML).

"These positive responses mark a significant milestone for Bio-Path as they suggest our DNAbilize platform technology has the potential to produce multiple drug candidates capable of target-specific protein inhibition for over-expressed, disease-causing gene products," said Peter H. Nielsen, President and Chief Executive Officer of Bio-Path. "We were thrilled to see that our first patient treated with the higher dose (90 mg/m2) in our Phase 1/1b study of BP1001-A has shown tumor regression and stable disease. We believe this is significant, particularly considering the heavily pretreated and fragile patient population involved."

"This elderly female patient with gynecologic cancer had previously been treated with multiple lines of chemotherapy along with multiple surgeries for her disease, and only now is showing positive clinical results with BP1001-A treatment. Importantly, we are not seeing the onerous side effects typically seen in patients with advanced solid tumors being treated with standard frontline therapies," continued Mr. Nielsen.

"In addition, we observed extended treatment durability in two elderly patients in our Phase 2 triple combination study of prexigebersen, venetoclax and decitabine in AML patients. These ongoing positive outcomes underscore the potential for prexigebersen to treat fragile AML patients for extended periods. We are particularly pleased with these results, as AML patients are typically unable to tolerate intensive chemotherapy and thus experience very poor clinical outcomes," concluded Mr. Nielsen.

*Bio-Path's DNAbilize Technology Platform* – Bio-Path's DNAbilize platform is a novel technology that achieves systemic delivery for target-specific protein inhibition for any gene product that is over-expressed in disease. The Company's drug delivery and antisense technology uses P-ethoxy, which is a deoxyribonucleic acid (DNA) backbone modification intended to protect the DNA from destruction by the body's enzymes when circulating in vivo, incorporated inside of a lipid bilayer having neutral charge. Bio-Path believes this combination allows for high efficiency loading of antisense DNA into non-toxic, cell-membrane-like structures for delivery of the antisense drug substance into cells. In vivo, DNAbilize delivered antisense drug substances are systemically distributed throughout the body to allow for reduction or elimination of target proteins in blood diseases and solid tumors. Through testing in numerous animal studies and dosing in clinical trials, the Company's DNAbilize drug candidates have demonstrated a promising safety and efficacy profile. Bio-Path currently has four DNAbilize drug product candidates in development.

*Solid Tumor Patient Response in Second, Higher Dose Cohort* – 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/m2 and began enrollment in the higher dose cohort of 90 mg/m2. 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

*AML Patients Demonstrate Extended Treatment Durability* – During the Company's recent pause for an interim analysis of results for Bio-Path's Phase 2 clinical trial treating AML patients, attention focused on two elderly patients who demonstrated continued treatment durability. The first patient is an elderly female who has received 16 cycles of treatment over 21 months and continues in complete remission. The second patient is an elderly male who is completing his twelfth cycle of treatment over fourteen months and continues in complete remission. The clinical trial investigator treating these two patients indicated that they are both doing very well on treatment. Both patients are being treated with the triple combination of prexigebersen, decitabine and venetoclax.

**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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