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): June 14, 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 June 14, 2024, Bio-Path Holdings, Inc. (the "Company") issued a press release titled, "Bio-Path Holdings Presents Data from Ongoing Phase 2 Combination Study of Prexigebersen for Treatment of Acute Myeloid Leukemia at European Hematology Association Congress." 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 June 14, 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: June 14, 2024

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

Exhibit 99.1

Bio-Path Holdings Presents Data from Ongoing Phase 2 Combination Study of Prexigebersen for Treatment of Acute Myeloid Leukemia at European Hematology Association Congress

Encore Presentation Highlights Positive Results from Interim Analysis Demonstrating Significant Clinical Improvement and Tolerable Safety Profile for Prexigebersen Combination in High-Risk Patients

HOUSTON—June 14, 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, presented interim results from the Company's Phase 2 study of prexigebersen (BP1001) in combination with decitabine and venetoclax for the treatment of acute myeloid leukemia (AML) in a poster presentation at 2024 European Hematology Association (EHA) Congress, on June 14, 2024 in Madrid, Spain.

Jorge Cortes, M.D., Director of the Georgia Cancer Center, presented data showing prexigebersen continues to be well-tolerated and has now demonstrated compelling efficacy results in two reporting cohorts including evaluable newly diagnosed AML patients and evaluable refractory/relapsed AML patients, both of which exceeded outcomes with frontline therapy.

"It was a pleasure to present these compelling data to an audience of European oncologists who treat AML patients and understand the continued great need for new therapeutic options," said Peter Nielsen, Chief Executive Officer of Bio-Path. "Given that our study is being conducted in the U.S., this encore presentation is an important step towards educating global oncology leaders on the benefits of prexigebersen and its potential to be another tool in their fight against AML."

Data Highlights

In Cohort 1, 31 newly diagnosed patients were enrolled; 20 evaluable patients (9 male: 45%) with a median age of 75 years (range, 69 - 84), treated with at least one cycle of prexigebersen, decitabine and venetoclax, had adverse-risk (n=12, 2017 ELN guidelines) or secondary AML (sAML; n=7) evolved from myelodysplastic syndromes (n=4), chronic myelomonocytic leukemia (n=1) or treatment-related AML (n=2). Fifteen patients (75% of evaluable; 54% of enrolled) achieved complete remission (CR), CRh (CR with partial recovery of peripheral blood counts), or CRi (CR with incomplete hematologic recovery); two patients achieved partial remission (PR) and two patients achieved stable disease (SD).

In Cohort 2, 38 relapsed/refractory patients were enrolled; 23 evaluable patients (13 male: 57%) with a median age of 63 years (range, 24 - 89), treated with at least one cycle of prexigebersen, decitabine and venetoclax, had adverse-risk (n=13) or sAML (n=5). Twelve patients (55% of evaluable; 32% of enrolled) achieved CR/CRi/CRh; one patient achieved PR, eight patients achieved SD and one patient had treatment failure.

Among the evaluable patients of both cohorts, adverse events were consistent with those expected with decitabine and venetoclax and/or AML, including fatigue (72%), anemia (60%) and neutropenia (49%), while the most frequent severe adverse events were febrile neutropenia (26%) and sepsis (5%). Given these promising interim results, Bio-Path expects to continue enrollment of up to 98 and 54 evaluable patients for Cohorts 1 and 2, respectively.

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.

# # #

Contact Information:

Investors

Will O'Connor
Stern Investor Relations, Inc.
212-362-1200
will@sternir.com

Doug Morris
Investor Relations
Bio-Path Holdings, Inc.
832-742-1369