**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): December 13, 2021

# 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 December 13, 2021, Bio-Path Holdings, Inc. (the "Company") issued a press release titled, "Bio-Path Holdings Presents Data from Ongoing Phase 2 Study of Prexigebersen at 2021 American Society of Hematology Annual Meeting." A copy of such press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release dated December 13, 2021. |
| 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: December 13, 2021

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 Study of Prexigebersen at 2021 American Society of Hematology Annual Meeting

*Preliminary Prexigebersen Data Show Signs of Safety and Efficacy in High Risk AML Patients*

**HOUSTON - December 13, 2021** - 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 announces a poster highlighting the safety and preliminary efficacy data of its Phase 2 study of prexigebersen (BP1001) was presented at the 2021 American Society of Hematology (ASH) Annual Meeting, taking place from December 11-14, 2021.

The poster, titled, "Safety and Efficacy of Lower Intensity Induction Therapy with Intravenous Prexigebersen (BP1001) in Patients with High-Risk and Relapsed/Refractory Acute Myeloid Leukemia (AML)," was presented by Maro Ohanian, D.O., Department of Leukemia, University of Texas MD Anderson Cancer Center. The poster described the safety and preliminary efficacy of Bio-Path's lead drug candidate, prexigebersen (liposomal Grb2 antisense), from a Phase 2 study in combination with decitabine or decitabine plus venetoclax as a potential treatment for patients diagnosed with AML.

"Our study's novel clinical trial protocol was designed to adjust for the inclusion of newly approved therapies that we believed would be enhanced from combination with our DNAbilize technology," said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings. "This robust design provided for early evaluation of various combinations of prexigebersen to optimize the best potential outcomes for patients and allows for the most expeditious pathway to market. We are delighted to have these safety and preliminary efficacy data presented among an audience dedicated to bringing new cancer treatments to patients."

The Phase 2 clinical trial is a multi-center, open label study with three patient cohorts:

- Untreated AML patients treated with prexigebersen in combination with decitabine plus venetoclax;
- Refractory/relapsed AML patients treated with prexigebersen in combination with decitabine plus venetoclax; and
- Refractory/relapsed AML patients, resistant or intolerant to venetoclax, treated with prexigebersen in combination with decitabine.

The primary objective of the study is to assess whether prexigebersen in combination with decitabine plus venetoclax provides higher response rates than decitabine plus venetoclax in AML patients and whether prexigebersen in combination with decitabine provides higher response rates than decitabine alone in AML patients. The study was amended to obtain safety run-in data for patients treated with prexigebersen + decitabine first before proceeding to safety run-in for patients treated with prexigebersen + decitabine + venetoclax. In the Poster we report the safety run-in and efficacy data of AML patients treated with prexigebersen + decitabine or prexigebersen + decitabine + venetoclax.

**Data Highlights**

Six patients, including four patients (67%) with de novo AML and two secondary AML patients (33%), were treated with at least one cycle of prexigebersen + decitabine combination therapy. All patients in this cohort (median age 72 years) were considered high risk due to having either adverse risk status by ELN (n=5) or treated secondary AML (n=1). Data showed that adverse events (AEs) were generally consistent with those expected with decitabine and/or AML. Three of the six patients (50%) had a response, including two de novo patients (33%) who achieved a CRi (complete remission with incomplete blood count recovery) and one secondary AML patient (17%) who achieved a partial remission (PR). Patients with these conditions generally have a less than 20% CR/CRi response rate.

Six patients were treated with at least one cycle of prexigebersen + decitabine + venetoclax combination therapy. Of the six patients, two (33%) had de novo AML and four (67%) were relapsed/refractory. All patients in this cohort were adverse-risk by ELN (n=2) or relapsed/refractory (n=4). AEs were generally consistent with decitabine and venetoclax treatment and/or for AML. Four patients (67%) achieved a complete remission (CR)/CRi/morphological leukemia free state (MLFS) (n=1/2/1) and one (17%) achieved a PR. Of these five patients, three were relapsed/refractory (75% of relapsed/refractory patients) (1 CR/1 CRi/1 MLFS) and two were de novo (1 CRi/1 PR) (100% of the de novo patients). CR rates to combination treatment with decitabine and venetoclax for relapsed/refractory AML patients are 42-52%[1,2] and 0-39%[1,2] for relapsed/refractory secondary AML patients.

The preliminary efficacy data are compelling and show that prexigebersen -based combination therapy was not only safely administered to high-risk and relapsed/refractory AML patients considered unsuitable for standard chemotherapy, but also

demonstrated encouraging efficacy signals. This is particularly encouraging as relapsed/refractory patients are a challenging population in which current treatment options are suboptimal.

**About Prexigebersen (BP1001)**

Prexigebersen is a neutral liposome incorporated with nuclease-resistant, hydrophobic P-ethoxy antisense oligodeoxynucleotides targeted to Grb2 mRNA. Grb2 is an adaptor protein that links oncogenic tyrosine kinases with downstream kinases, such as ERK and AKT, which are critical to cell proliferation and survival.

**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 prexigebersen-A, a drug product modification of prexigebersen, has been cleared by the FDA and Phase 1 studies in solid tumors will commence in 2022. 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, in 2022.

For more information, please visit the Company's website at http://www.biopathholdings.com.

1) DiNardo et al. Lancet Haematology, 2020, Oct;7(10):e724-e736.
2) Aldoss et al. Haematol, 2018, 103:e404-e407.

**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 the impact, risks and uncertainties related to COVID-19 and actions taken by governmental authorities or others in connection therewith, BioPath'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 and 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, 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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