**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): May 29, 2020

# 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 May 29, 2020, Bio-Path Holdings, Inc. (the "Company") issued a press release titled, "Bio-Path Holdings Presents at 2020 American Society of Clinical Oncology Annual Meeting." 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 May 29, 2020 |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**BIO-PATH HOLDINGS, INC.**

Dated: May 29, 2020

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

**EXHIBIT INDEX**

| Exhibit Number | Description |
| --- | --- |
| 99.1 | Press Release dated May 29, 2020 |

**Exhibit 99.1**

# Bio-Path Holdings Presents at 2020 American Society of Clinical Oncology Annual Meeting

**HOUSTON – May 29, 2020** – 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 the presentation of a poster highlighting the clinical trial design of its Phase 2 study of BP1001 (prexigebersen) at the 2020 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place virtually from May 29-31, 2020.

The poster, titled, "A Phase II Study of BP1001 (liposomal Grb2 antisense oligonucleotide) in Patients with Hematologic Malignancies," was presented virtually by Dr. Maro Ohanian, Department of Leukemia, University of Texas M.D. Anderson Cancer Center. The poster describes the Phase 2 study design of BP1001 (liposomal Grb2 antisense), the Company's lead drug candidate, in combination with decitabine as a potential treatment for patients diagnosed with acute myeloid leukemia (AML) or high-risk myelodysplastic syndrome (MDS).

"This innovative trial design for BP1001 is unique in that it allowed us to adjust our treatment to include newly approved therapies that we believed would be enhanced from combination with our DNAbilize technology. We believe this robust design will provide for the best outcomes for patients and will be the most expeditious route to bringing BP1001 to market. We are delighted to have the design presented and expect that it will enhance visibility for our DNAbilize platform and its versatility among an audience dedicated to bringing new cancer treatments to patients," stated Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings.

The Phase 2 clinical trial is a multi-center, open label study with two parallel cohorts of BP1001 in combination with decitabine in untreated AML and high risk MDS patients or refractory/relapsed AML and high risk MDS patients who are ineligible or unwilling to receive intensive induction therapy. The primary objective of the study is to assess whether BP1001 in combination with decitabine provides higher response rates than decitabine alone in AML or high risk MDS patients. In addition, a six-patient safety run-in of BP1001 and decitabine was completed with no dose adjustment required.

BP1001 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. Preclinical results showed that BP1001 enhanced the inhibitory effects of cytarabine or decitabine against AML cells.

The poster also describes future development plans for BP1001 in AML. Preclinical results suggest that BP1001 plus venetoclax plus decitabine triple combination could be more efficacious than the BP1001 + decitabine combination against AML cells. Venetoclax will be added to the study, thus exploring three-drug combinations of BP1001, venetoclax and decitabine. There will be three patient cohorts in the study:

- Untreated AML patients will be treated with BP1001 plus venetoclax plus decitabine.
- Refractory/relapsed AML patients will be treated with BP1001 plus venetoclax plus decitabine.
- A third cohort of BP1001 + decitabine will be offered to refractory/relapsed AML patients who are venetoclax resistant or intolerant, or not considered by the investigator as optimal candidates for venetoclax-based therapy.

**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, is under consideration by the FDA to commence Phase 1 studies in solid tumors. This is followed by BP1002, targeting the Bcl-2 protein, where it will be evaluated in lymphoma and solid tumors clinical studies.

For more information, please visit the Company's website at http://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 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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