

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): April 12, 2021

BIO-PATH HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-36333

(Commission File Number)

87-0652870

(IRS Employer Identification No.)

4710 Bellaire Boulevard, Suite 210, Bellaire, Texas

(Address of principal executive offices)

77401

(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 April 12, 2021, Bio-Path Holdings, Inc. (the “Company”) issued a press release titled, “Bio-Path Holdings Presents BP1002 Data at 2021 American Association for Cancer Research Annual Meeting.” A copy of such press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated April 12, 2021

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: April 13, 2021

By: /s/ Peter H. Nielsen

Peter H. Nielsen

President and Chief Executive Officer

EXHIBIT INDEX

Exhibit
Number

Description

[99.1](#)

[Press Release dated April 12, 2021](#)



Bio-Path Holdings Presents BP1002 Data at 2021 American Association for Cancer Research Annual Meeting

Preclinical Data Support BP1002 Combination Therapy in Venetoclax-resistant AML Patients

HOUSTON – April 12, 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 the presentation of a poster highlighting preclinical BP1002 data at the 2021 American Association for Cancer Research (AACR) Annual Meeting.

The poster, titled “The combination of liposomal Bcl-2 antisense oligonucleotide (BP1002) with decitabine is efficacious in venetoclax-resistant cells,” was presented virtually by Dr. Maria Gagliardi, Research Scientist at Bio-Path Holdings.

“We are particularly pleased to have these preclinical results of the BP1002 plus decitabine combination against venetoclax-resistant cells highlighted in a poster before an audience of the world’s leading cancer researchers at this important scientific meeting,” stated Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings. “We look forward to filing a second Investigational New Drug (IND) application for BP1002 and to initiating a clinical study in combination with decitabine in acute myeloid leukemia (AML) patients who have relapsed from venetoclax-based treatments.”

Venetoclax, an FDA-approved Bcl-2 inhibitor, is indicated for hematologic malignancies. However, venetoclax resistance among these AML patients is a growing problem. A recent study found that AML patients who had relapsed from frontline venetoclax-based treatment were also resistant to salvage therapy and had a median survival of less than 3 months¹. Thus, novel treatment approaches for these most vulnerable patients are urgently needed.

BP1002 targets the protein Bcl-2, which is responsible for driving cell survival in up to 60% of all cancers. High expression of Bcl-2 has been correlated with poor prognosis for patients diagnosed with AML. Prior preclinical studies have shown BP1002 to be a potent inhibitor against the Bcl-2 target, and the Company believes that its benign safety profile should enable BP1002 combination therapy with approved agents.

The data presented in the AACR poster show that venetoclax-resistant cells are sensitive to the inhibitory effects of BP1002 combined with decitabine, suggesting that this combination is a potential treatment for patients who have relapsed from frontline venetoclax-based therapies.

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 the treatment of 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 is being evaluated in a Phase 1 study in advanced lymphoma and chronic lymphocytic leukemia patients.

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

1) Maiti et al. Haematologica, 2021, 106(3):894-898.

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, Bio-Path's ability to raise needed additional capital on a timely basis in order for it to continue its operations, Bio-Path's ability to 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, the maintenance of intellectual property rights, that patents relating to existing for future patent applications will be issued or that any issued patents will provide meaningful protection of our drug candidates, risks relating to maintaining Bio-Path's listing on the Nasdaq Capital Market 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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