
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, 2022

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, 2022, Bio-Path Holdings, Inc. (the “Company”) issued a press release titled, “Bio-Path Holdings Presents BP1003 Data at 2022 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.

Exhibit

Number

Description

99.1

[Press Release dated April 12, 2022.](#)

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.

Dated: April 12, 2022

BIO-PATH HOLDINGS, INC.

By: /s/ Peter H. Nielsen

Peter H. Nielsen

President and Chief Executive Officer



Bio-Path Holdings Presents BP1003 Data at 2022 American Association for Cancer Research Annual Meeting

Preclinical Data Support BP1003 Combination Therapy to Treat Breast and Ovarian Cancers

HOUSTON - April 12, 2022 - 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 presented a poster highlighting preclinical BP1003 data at the 2022 American Association for Cancer Research (AACR) Annual Meeting.

The poster, titled "Targeting STAT3 with novel liposome-incorporated antisense oligonucleotide technology enhances the efficacy of paclitaxel (taxol) or 5-fluorouracil (5-FU) in breast and ovarian cancer cells," was presented by Dr. Maria Gagliardi, Research Scientist at Bio-Path Holdings.

"We are particularly pleased to have these preclinical data of BP1003 plus chemotherapy combinations against breast and ovarian cancer cells highlighted in a poster before an audience of the world's leading cancer researchers at this important scientific meeting. The data show that BP1003 enhances the efficacy of current standard of care chemotherapies in these difficult to treat solid tumor cancers," stated Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings. "We look forward to filing an Investigational New Drug (IND) application for BP1003 and to initiating a clinical study in patients with advanced solid tumors."

STAT3 is a transcription factor that regulates various tumorigenic processes, such as tumor proliferation, metastasis and drug resistance. Its overexpression and aberrant activation characterize many cancers, including breast, lung, ovarian, liver and colon cancer. Activation of the STAT3 pathway in breast and ovarian cancer cells promotes tumor initiation, migration, and taxol resistance. STAT3 also contributes to epithelial-mesenchymal transition and promotes 5-FU resistance in colorectal cancer cells. Its role in numerous malignancies made STAT3 a potential cancer therapeutic target.

BP1003, a novel liposome-incorporated STAT3 antisense oligodeoxynucleotide, efficiently reduces STAT3 expression and enhances the sensitivity of breast and ovarian cancer cells to taxol and 5-FU. These results are in line with previous work in which BP1003 plus gemcitabine displayed enhanced anti-tumor activity in pancreatic ductal adenocarcinoma. Together these results strongly suggest that BP1003 combination therapy is a novel strategy for patients with advanced solid tumors.

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>.

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, 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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