

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 22, 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 June 22, 2021, Bio-Path Holdings, Inc. (the “Company”) issued a press release titled, “Bio-Path Granted Key Mechanism of Action U.S. Patent for BP1003.” 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>
<u>99.1</u>	<u>Press Release dated June 22, 2021</u>

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: June 22, 2021

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated June 22, 2021



Bio-Path Granted Key Mechanism of Action U.S. Patent for BP1003

Provides Protection and Highlights Novelty of BP1003 to Inhibit STAT3 Expression in a Variety of Difficult to Treat Cancers

HOUSTON— June 22, 2021 – 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, today announced that the United States Patent and Trademark Office has granted a new patent relating to the Company's BP1003 program, a novel liposome-incorporated oligodeoxynucleotide inhibitor against Signal Transduction and Activator of Transcription-3 (STAT3). The patent (U.S. Patent No. 11,041,153) is titled "P-Ethoxy Nucleic Acids for STAT3 Inhibition."

The new patent builds on earlier patents that have been granted that protect the platform technology for DNAbilize, the Company's novel RNAi nanoparticle drugs. DNAbilize is a proprietary liposomal nanoparticle delivery and antisense technology designed to systemically distribute nucleic acid drugs throughout the human body with a simple intravenous transfusion.

"Our growing intellectual property portfolio continues to be a meaningful asset for Bio-Path and the addition of this new patent further strengthens our value as we advance our newest pipeline product, BP1003," said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings. "This mechanistic patent protects our position and underscores the novelty of BP1003's ability to inhibit STAT3, a protein known to be overly expressed in a number of the most difficult to treat cancers such as pancreatic cancer (PDAC), non-small cell lung cancer (NSCLC) and acute myeloid leukemia (AML), among others. We are looking forward to advancing BP1003's development in pancreatic cancer, which we expect to begin next year."

About Signal Transducer and Activator of Transcription 3 (STAT3)

STAT3 is aberrantly active in cancer cells. The abilities of tumor cells to proliferate uncontrollably, resist apoptosis, induce vasculature formation, and invade distant organs are well-recognized hallmarks of cancer. STAT3 is a regulator of the genes involved in these cancer processes. More recently, the capability of tumors to evade immune surveillance and avoid destruction by the immune system has also gained significant acceptance in the cancer research field. STAT3, which is a point of convergence for many oncogenic pathways, has emerged as a critical mediator of tumor immune evasion at multiple levels.

Activation of STAT3 has been found in many types of cancers, including NSCLC, AML, and PDAC. Activation of STAT3 correlates with poor clinical outcome, high grade disease and metastasis, and has been linked with resistance to chemotherapy, including gemcitabine, considered a standard-of-care agent for advanced PDAC. Therefore, inhibition of STAT3 in combination with chemotherapy is expected to produce enhanced clinical benefit.

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 infusion. 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 is being evaluated in lymphoma clinical studies.

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 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 or 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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