
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): September 25, 2019

BIO-PATH HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or other jurisdiction of incorporation)	<u>001-36333</u> (Commission File Number)	<u>87-0652870</u> (IRS Employer Identification No.)
<u>4710 Bellaire Boulevard, Suite 210, Bellaire, Texas</u> (Address of principal executive offices)	<u>(832) 742-1357</u> (Registrant's Telephone Number, Including Area Code)	<u>77401</u> (Zip 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:

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
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 September 25, 2019, Bio-Path Holdings, Inc. (the “Company”) issued a press release titled, “Bio-Path Updates Intellectual Property Portfolio with Addition of Recently Issued Second Platform Technology Patent.” 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 September 25, 2019](#)

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: September 25, 2019

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

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
<u>99.1</u>	<u>Press Release dated September 25, 2019</u>



Bio-Path Updates Intellectual Property Portfolio with Addition of Recently Issued Second Platform Technology Patent

Leveraging Growing Patent Estate Creates Value and Strengthens Core Competency

HOUSTON— September 25, 2019 – 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 announced that the United States Patent and Trademark Office has issued a patent with claims related to the Company’s proprietary liposomal delivery and antisense technology, DNAbilize, including its use in the treatment of cancers, autoimmune diseases and infectious diseases. This is the second U.S. patent issued for the Company’s platform technology.

The new patent, United States Patent No. 10,335,428 (based on Application No. 15/657,083), titled “*P-Ethoxy Nucleic Acids for Liposomal Formulation*,” which issued July 2, 2019, provides additional claims for the broad protection previously granted in Patent No. US 9,744,187 (issued August 29, 2017) for application of the DNAbilize technology in the treatment of a variety of cancers, as well as autoimmune and infectious diseases. 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.

Bio-Path’s platform technology patents allow the Company to develop new drug product candidates using its proprietary DNAbilize technology. As new drug product candidates are developed using DNAbilize technology, new patent applications can be filed for the specific drug products incorporating DNAbilize technology.

Applying the DNAbilize technology to a protein target can result in a specific drug product for which a new DNAbilize drug product patent application can be filed. The Company anticipates that the number of DNAbilize drug product candidates will increase significantly in the coming years.

The Company believes its patented platform technology provides a powerful template with the capability to produce a large portfolio of patented drug products. The Company currently has two issued platform technology patents for DNAbilize and five pending patent applications for specific DNAbilize drug product candidates. Each of the issued technology platform patents has a life of twenty years from filing, and any issued patents for specific DNAbilize drug products will also be protected for twenty years from filing.

Consequently, the Company expects its expanding intellectual property estate for DNAbilize to be a source of both exciting breakthroughs in cancer therapy and to be an engine for out-licensing opportunities across a broad spectrum of cancer indications with currently unmet medical needs.

“Our strategy is to leverage the value of our patented DNAbilize technology by focusing on our mission to develop systemic DNAbilize treatments for hard-to-treat diseases. In doing so, we believe we can develop multiple drug products that can enhance shareholder value through partnering or licensing at various stages of drug product development. This will allow Bio-Path to focus on the front-end of the development process, while partnering out development through later stages of clinical development,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings.

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 is in the process of filing an IND for a Phase 1 clinical trial for solid tumors. The Company is also developing BP1002, which targets the Bcl-2 protein and is expected to be evaluated for the treatment of lymphoma and solid tumors. In addition, BP1003, a novel liposome-incorporated STAT3 antisense oligodeoxynucleotide developed by Bio-Path as a specific inhibitor of STAT3, is expected to enter Phase 1 studies in 2020.

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 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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