

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): October 22, 2020

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

<b>Delaware</b> (State or other jurisdiction of incorporation)	<b>001-36333</b> (Commission File Number)	<b>87-0652870</b> (IRS Employer Identification No.)
<b>4710 Bellaire Boulevard, Suite 210, Bellaire, Texas</b> (Address of principal executive offices)	<b>77401</b> (Zip Code)	
	<b>(832) 742-1357</b> (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 October 22, 2020, Bio-Path Holdings, Inc. (the “Company”) issued a press release titled, “Bio-Path Receives Notice of Allowance for Strategic Patent for Prexigebersen in Combination with Front Line Cytidine Analogues or Bcr-Abl Tyrosine Kinase Inhibitors in a Variety of Cancers.” 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 October 22, 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: October 22, 2020

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

---

## EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
<a href="#">99.1</a>	<a href="#">Press Release dated October 22, 2020</a>

---



**Bio-Path Receives Notice of Allowance for Strategic Patent for Prexigebersen in Combination with Front Line Cytidine Analogues or Bcr-Abl Tyrosine Kinase Inhibitors in a Variety of Cancers**

*Growing Patent Estate Creates Value and Supports Key Combination Therapies*

**HOUSTON— October 22, 2020** – Bio-Path Holdings, Inc., (NASDAQ:BPTH), a biotechnology company leveraging its proprietary DNAbilize<sup>®</sup> 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 issued a notice of allowance for claims related to the Company’s lead product candidate, prexigebersen, in combination with either a cytidine analogue, such as decitabine, or the Bcr-Abl tyrosine kinase inhibitors dasatinib and nilotinib. Prexigebersen is a liposomal formulation containing the antisense oligodeoxynucleotide targeting growth factor receptor-bound protein 2 (Grb2).

The new patent, titled, “*Combination Therapy with Liposomal Antisense Oligonucleotides*,” (based on Application No. 16/333,221), will provide broad protection for application of prexigebersen in the treatment of a variety of cancers in combination with front-line therapies.

“This further strengthens our intellectual property portfolio and complements already granted patents. Our growing patent estate continues to be a valuable asset for Bio-Path as it provides protection not only for our core product portfolio and research efforts but now also offers broad protection in combination with established front-line therapies,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings.

“Bio-Path is currently in an ongoing Phase 2 clinical trial of prexigebersen in combination with decitabine as a treatment for acute myeloid leukemia (AML), and this new patent protects the unique therapy combination and supports our ongoing investment in this program to bring a new treatment option to patients with AML who have limited treatment options,” added Mr. Nielsen.

**About Bio-Path Holdings, Inc.**

Bio-Path is a biotechnology company developing DNAbilize<sup>®</sup>, 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 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 and chronic lymphocytic leukemia (CLL). A third product, BP1001-A, is finalizing an IND to be evaluated in solid tumor clinical studies.

For more information, please visit the Company's website at [www.biopathholdings.com](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, 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](http://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.

###

## **Contact Information:**

### **Investors**

Will O'Connor  
Stern Investor Relations, Inc.  
212-362-1200  
[will@sternir.com](mailto:will@sternir.com)

Doug Morris  
Investor Relations  
Bio-Path Holdings, Inc.  
832-742-1369

---