

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): November 13, 2020

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 2.02 Results of Operations and Financial Condition.

The information in this Current Report on Form 8-K (this “Current Report”) is being furnished pursuant to Item 2.02 of Form 8-K and, according to general instruction B.2. thereunder, the information in this Current Report shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information in this Current Report shall not be incorporated by reference into any registration statement pursuant to the Securities Act of 1933, as amended.

On November 13, 2020, Bio-Path Holdings, Inc. (the “Company”) issued a press release announcing financial results for the quarter ended September 30, 2020. Additional information is included in the Company’s press release. A copy of the Company’s press release is attached hereto as Exhibit 99.1. The foregoing description of the press release is qualified in its entirety by reference to the attached exhibit.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated November 13, 2020

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.

BIO-PATH HOLDINGS, INC.

Dated: November 13, 2020

By: /s/ Peter H. Nielsen

Peter H. Nielsen
President and Chief Executive Officer

EXHIBIT INDEX

Exhibit
Number

Description

[99.1](#)

[Press Release dated November 13, 2020](#)



BIO-PATH HOLDINGS REPORTS THIRD QUARTER 2020 FINANCIAL RESULTS

Conference Call to be Held Today at 8:30 A.M. ET

HOUSTON—November 13, 2020 – 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 its financial results for the third quarter ended September 30, 2020 and provided an update on recent corporate developments.

“We made meaningful progress across our programs throughout the third quarter despite continued headwinds related to the COVID-19 pandemic. Importantly, enrollment continues in Stage 2 of our Phase 2 trial of prexigebersen (BP1001), a liposomal Grb2 antisense, as a combination treatment for patients suffering with acute myeloid leukemia (AML),” said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings. “We further strengthened our intellectual property portfolio with a strategic patent providing broad protection for application of prexigebersen in the treatment of a variety of cancers in combination with front-line therapies.”

“We remain on track to initiate a Phase 1 study of prexigebersen for the treatment of solid tumors by year end. This is a particularly important advancement for Bio-Path as it marks our first-in-human study in solid tumors, an area of significant need where current treatment options are often ineffective,” continued Mr. Nielsen.

Recent Corporate Highlights

- **Received Notice of Allowance for Strategic Patent for Prexigebersen in Combination with Front-Line Therapies.** In October, Bio-Path announced that the United States Patent and Trademark Office had 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. The patent provides broad protection for application of prexigebersen in the treatment of a variety of cancers in combination with front-line therapies.
- **Announced First Patient Dosed in Amended Stage 2 of the Phase 2 Clinical Trial Evaluating Prexigebersen in Acute Myeloid Leukemia.** In August, Bio-Path announced the enrollment and dosing of the first patient in the amended Stage 2 of the Phase 2 clinical study of prexigebersen for the treatment of AML in combination with front-line therapy decitabine and venetoclax.

Financial Results for the Third Quarter Ended September 30, 2020

- The Company reported a net loss of \$3.0 million, or \$0.80 per share, for the three months ended September 30, 2020, compared to a net loss of \$2.2 million, or \$0.78 per share, for the three months ended September 30, 2019.
 - Research and development expenses for the three months ended September 30, 2020 increased to \$2.0 million, compared to \$1.4 million for the three months ended September 30, 2019 primarily due to increased enrollment for our Phase 2 clinical trial of prexigebersen in AML, as well as increased preclinical study expenses.
 - General and administrative expenses for the three months ended September 30, 2020 increased to \$1.0 million, compared to \$0.9 million for the three months ended September 30, 2019 primarily due to increased franchise tax expense.
 - As of September 30, 2020, the Company had cash of \$12.1 million, compared to \$20.4 million at December 31, 2019. Net cash used in operating activities for the nine months ended September 30, 2020 was \$8.4 million compared to \$6.1 million for the comparable period in 2019. Subsequent to September 30, 2020, Bio-Path issued 850,000 shares of its common stock for gross proceeds of approximately \$4.6 million through its at-the-market offering agreement with H.C. Wainwright.
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Conference Call and Webcast Information

Bio-Path Holdings will host a conference call and webcast today at 8:30 a.m. ET to review these third quarter 2020 financial results and to provide a general update on the Company. To access the conference call please dial (844) 815-4963 (domestic) or (210) 229-8838 (international) and refer to the conference ID 5878804. A live audio webcast of the call and the archived webcast will be available in the Media section of the Company's website at www.biopathholdings.com.

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 <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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