
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): March 20, 2019

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))

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 March 20, 2019, Bio-Path Holdings, Inc. (the “Company”) issued a press release announcing financial results for the year ended December 31, 2018. 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>
<u>99.1</u>	<u>Press Release dated March 20, 2019</u>

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: March 20, 2019

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

EXHIBIT INDEX

Exhibit
Number

Description

99.1

Press Release dated March 20, 2019



BIO-PATH HOLDINGS REPORTS FULL YEAR 2018 FINANCIAL RESULTS

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

HOUSTON—March 20, 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 its financial results for the full year ended December 31, 2018 and provided an update on recent corporate developments.

“Throughout 2018, we made great progress in pursuit of our mission of bringing innovative new RNAi nanoparticle therapeutics to cancer patients with high unmet medical need,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings. “This progress was highlighted by the recent updated interim analysis of our Phase 2 trial of prexigebersen in acute myeloid leukemia (AML). Of the 17 evaluable patients, 65% had a response, including 29% who achieved a complete response, one of which achieved a morphologic leukemia free state. With these interim results in hand, we are even more confident as we move this program forward in combination with venetoclax and decitabine.”

“Beyond prexigebersen, we continue to make headway across our development pipeline. We are on track to submit our Investigational New Drug application to begin a Phase 1 study of our second drug candidate, BP1002, which targets the Bcl-2 protein. This trial will seek to treat both Non-Hodgkin’s Lymphoma and chronic lymphocytic leukemia patients that have failed Venetoclax. We recently strengthened our balance sheet through a \$18.5 million registered direct offering and we now have the resources to achieve a number of key milestones that should significantly enhance shareholder value. We entered 2019 on strong footing and expect to build on that momentum throughout the balance of the year as we continue to advance these important programs,” continued Mr. Nielsen.

Recent Corporate Highlights

- **Reported Updated Interim Analysis from Phase 2 Clinical Trial of Prexigebersen for the Treatment of AML.** In March 2019, Bio-Path reported updated interim data from 17 evaluable patients showing that 11 patients (65%) had a response, including five patients (29%) who achieved CR, one of which was a morphologic leukemia free state (MLFS), and six patients achieving stable disease. Importantly, after further analysis by the principal investigators, it was observed that 68% of these patients were secondary AML patients, an extremely difficult class to treat. As a result of these updated data, Bio-Path now intends to enroll two registration-directed cohorts of the triple combination of prexigebersen + decitabine + venetoclax in untreated AML and high risk MDS patients, and refractory/relapsed AML and high risk MDS patients. In December 2018, earlier data from this program were presented in a poster at the 2018 American Society of Hematology (ASH) Annual Meeting and Exposition.
- **Raised \$18.5 Million in Registered Direct Offering.** In March 2019, Bio-Path issued 712,910 shares of its common stock at a price of \$25.95 per share, for gross proceeds of approximately \$18.5 million.

Financial Results for the Full Year Ended December 31, 2018

- The Company reported a net loss attributable to common stockholders of \$8.6 million, or \$14.38 per share, for the year ended December 31, 2018, compared to a net loss attributable to common stockholders of \$8.1 million, or \$15.99 per share, for the year ended December 31, 2017.
 - Research and development expenses for the year ended December 31, 2018 decreased to \$4.6 million, compared to \$5.5 million for the year ended December 31, 2017 primarily due to decreased salaries and benefits expense.
 - General and administrative expenses for the year ended December 31, 2018 decreased to \$3.4 million, compared to \$3.5 million for the year ended December 31, 2017 primarily due to decreased professional and consulting fees.
 - As of December 31, 2018, the Company had cash of \$1.0 million, compared to \$6.0 million at December 31, 2017. Net cash used in operating activities for the year ended December 31, 2018 was \$6.1 million compared to \$8.0 million for the comparable period in 2017. Net cash provided by financing activities for the year ended December 31, 2018 was \$1.2 million.
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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 full year 2018 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 1794629. 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 transfusion. Bio-Path's lead product candidate, prexigebersen (BP1001, targeting the Grb2 protein), is in a Phase 2 study for blood cancers and in preclinical studies for solid tumors. This is followed by BP1002, targeting the Bcl-2 protein, which the Company anticipates entering into clinical studies where it will be evaluated in Non-Hodgkin's Lymphoma and chronic lymphocytic leukemia.

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 statements regarding the offering, the intended use of proceeds and the timing of the closing of the offering, 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, 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, except as required by law.

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