
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): August 27, 2018

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 7.01 Regulation FD Disclosure.

On August 27, 2018, Bio-Path Holdings, Inc. (the “Company”) issued a press release titled, “Bio-Path Holdings Announces First Patient Dosed in Expansion of Phase 2 Trial of Prexigebersen in Acute Myeloid Leukemia.” 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>
99.1	Press Release dated August 27, 2018

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: August 27, 2018

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 August 27, 2018</u>



Bio-Path Holdings Announces First Patient Dosed in Expansion of Phase 2 Trial of Prexigebersen in Acute Myeloid Leukemia

Based on Encouraging Data, New Cohort Will Treat Patients in Combination with Decitabine

HOUSTON—August 27, 2018 – 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 it has commenced Stage 2 of the company’s Phase 2 trial of prexigebersen in acute myeloid leukemia.

The open-label Phase 2 study is evaluating the efficacy and safety of prexigebersen in conjunction with LDAC, a therapeutic regimen well established in treatment of AML patients who cannot or elect not to be treated with more intensive chemotherapy. The primary objective of the study is to determine whether the combination of prexigebersen and LDAC provides greater efficacy than would be expected with LDAC alone in this de novo patient population.

“We are delighted to announce the expansion of our ongoing Phase 2 clinical trial of prexigebersen for the treatment of acute myeloid leukemia using a dosing schedule that administers a greater amount of prexigebersen to the patient prior to commencing LDAC dosing than in the first part of the trial. Based on compelling new data, we are also including a cohort of patients who will be treated with a combination of prexigebersen and decitabine,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path. “Results from the planned interim analysis of the first part of this Phase 2 study were particularly encouraging, with 47% of treated patients demonstrating a response. Consequently, we remain enthusiastic about prexigebersen’s potential and believe these protocol changes will optimize the drug’s impact in AML cancer patients with high unmet need.”

Based on recommendations from the study’s principal investigators, the Company amended the study’s protocol to change the dosing schedule in Stage 2 to that used in the Phase 1b study in relapsed and refractory AML patients as announced in April 2018. In the Phase 1b study, a greater amount of prexigebersen was administered prior to LDAC treatment starting at day 10 versus LDAC treatment starting on day four as was the case in Stage 1 of the current Phase 2 study. Importantly, Stage 2 of the study includes a cohort of patients treated in combination with decitabine based on relatively new and positive data with this compound. Bio-Path plans to perform an interim analysis of each cohort once approximately 19 evaluable patients are reached in the cohort.

As previously announced, a planned interim analysis of Stage 1 of the study was performed on 17 evaluable patients, with four patients achieving complete responses and four patients achieving stable disease, including one patient achieving a morphologic leukemia free state and one patient who showed significantly reduced bone marrow blasts. In total, 47% of the evaluable patients showed some form of response, including stable disease, to the combination treatment. The average patient in Stage 1 of the study was 73.5 years of age.

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 lymphoma and solid tumors.

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, 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 and in any subsequent quarterly reports on Form 10-Q. 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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Contact Information:

Investors

Will O'Connor
Stern Investor Relations, Inc.
212-362-1200
will@sternir.com

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