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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): December 3, 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.

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**Item 7.01 Regulation FD Disclosure.**

On December 3, 2018, Bio-Path Holdings, Inc. (the “Company”) issued a press release titled, “Bio-Path Holdings Presents Interim Data from Phase 2 Study Evaluating Prexigebersen as a Treatment for Acute Myeloid Leukemia at the 60th Annual American Society of Hematology Annual Meeting.” 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>
<a href="#">99.1</a>	<a href="#">Press Release dated December 3, 2018</a>

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**EXHIBIT INDEX**

Exhibit  
Number

Description

[99.1](#)

[Press Release dated December 3, 2018](#)

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**Bio-Path Holdings Presents Interim Data from Phase 2 Study Evaluating Prexigebersen as a Treatment for Acute Myeloid Leukemia at the 60th Annual American Society of Hematology Annual Meeting**

**HOUSTON—December 3, 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 that previously announced interim data from the Company’s Phase 2 study evaluating prexigebersen as a treatment for acute myeloid leukemia (AML) were presented in a poster at the 2018 American Society of Hematology (ASH) Annual Meeting and Exposition, taking place from December 1-4, 2018 in San Diego, CA.

Maro Ohanian, M.D., Assistant Professor of the Department of Leukemia at The University of Texas MD Anderson Cancer Center, presented the poster titled, “Interim Safety and Efficacy of Lower Intensity Induction Therapy with Intravenous Prexigebersen (BP1001) in Patients with Untreated Acute Myeloid Leukemia (AML).” The poster reviewed interim data from the Company’s open-label Phase 2 study evaluating the efficacy and safety of prexigebersen in conjunction with low-dose cytarabine (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 what would be expected with LDAC alone in this de novo patient population.

Prexigebersen was safely administered to patients with untreated AML, who were considered unsuitable for standard chemotherapy. Of the 17 evaluable patients, there were four patients (24%) who achieved complete responses and four patients with stable disease including one patient who achieved a morphologic leukemia free state and two patients who had significantly reduced bone marrow blasts. In total, 47% of the evaluable patients showed some form of response, including stable disease, to the combination treatment. Efficacy data are encouraging in this challenging population in which the majority of patients had secondary AML or adverse-risk AML, and compares favorably to the reported CR (complete remission), CRp (complete remission with incomplete platelet recovery), and CRi (complete remission with incomplete hematologic recovery) rate with LDAC alone of 7-13%<sup>1</sup>.

“We are excited to be presenting these important data at ASH before an audience of world-leading scientists and oncologists, as they demonstrate the potential for the combination of prexigebersen and LDAC to safely and effectively treat these de novo AML patients, including doubling the complete response to treatment compared to LDAC treatment alone,” noted Peter H. Nielsen, chief executive officer of Bio-Path. “We look forward to presenting final data from this study as we expect they will provide even better results for these patients suffering with AML.”

<sup>1</sup> Heiblig, *Mediterr J Hematol* 2016; Kantarjian, *J Clin Oncol* 2012; Dohner, *Blood* 2014.

**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.

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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](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

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