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): April 3, 2018

BIO-PATH HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36333**	**87-0652870**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4710 Bellaire Boulevard, Suite 210, Bellaire, Texas	**77401**
(Address of principal executive offices)	(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 April 3, 2018, Bio-Path Holdings, Inc. (the "Company") issued a press release titled, "Bio-Path Holdings Announces Interim Data from Phase 2 Clinical Trial of Prexigebersen in Combination with Low Dose Cytarabine (LDAC) for the Treatment of Acute Myeloid Leukemia (AML)." 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 April 3, 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: April 4, 2018

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated April 3, 2018

Exhibit 99.1

Bio-Path Holdings Announces Interim Data from Phase 2 Clinical Trial of Prexigebersen in Combination with Low Dose Cytarabine (LDAC) for the Treatment of Acute Myeloid Leukemia (AML)

Prexigebersen plus LDAC was well-tolerated and showed early anti-leukemic activity in nearly 50% of evaluable AML patients treated to date

Planned protocol amendments may provide for potential approvals in the U.S. and Europe of two prexigerbesen combination treatments

HOUSTON—April 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 announces that interim data from its Phase 2 study of prexigebersen in combination with low-dose cytarabine (LDAC) (BP1001-201) for the treatment of acute myeloid leukemia (AML) has demonstrated that the combination therapy continues to be well-tolerated and has shown early anti-leukemic activity in nearly 50% of evaluable AML patients including four patients with complete remission and four with stable disease to date in this study.

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 what would be expected with LDAC alone in this de novo patient population. The study had a pre-determined decision point at 19 evaluable patients in which the study would be terminated if less than 5 patients responded and the study would be expanded to 54 patients if five or more patients responded.

The interim analysis was performed on 17 evaluable patients instead of 19, since criteria to move to the next steps in the study had been met. Of the 17 evaluable patients, there were four patients who achieved complete responses, one patient who achieved a morphologic leukemia free state, two patients who had significantly reduced bone marrow blasts and four patients with stable disease. In total, 47% of the evaluable patients showed some form of response, including stable disease, to the combination treatment. The average age of patients in the study was 73.5 years old.

Based on the recommendations of the principal investigators of the study, the Company is amending the protocol to change the dosing schedule to that used in the Phase 1b study in relapsed and refractory AML patients in which a higher dose of prexigerbesen was administered prior to LDAC treatment starting at day 10 versus LDAC treatment starting on day four as was the case in the BP1001-201 study to date. In addition, the investigators endorse the inclusion of a decitabine cohort based on relatively new and positive data with this compound.

“We are very pleased with these encouraging interim data as they demonstrate the potential for the combination of prexigerbesen and LDAC to effectively treat these de novo AML patients. These early results are encouraging when you consider that the complete response rate in elderly AML patients greater than 65 years of age on LDAC alone have been estimated (Lin Journal of Clinical Oncology Abstract) to be only 10%[1],” noted Peter H. Nielsen, chief executive officer of Bio-Path. “We look forward to advancing the planned protocol amendments as we expect they will provide even better results for these patients suffering with AML. If successful, it will provide for approvals in the U.S. and Europe for both combination therapies.”

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.

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References

[1] Lin, T. (2016). Phase Ib/2 study of venetoclax with low-dose cytarabine in treatment-naive patients age ≥ 65 with acute myelogenous leukemia. *Journal of Clinical Oncology. 34*(15). doi: 10.1200/JCO.2016.34.15_suppl.7007

Contact Information:

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

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