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 29, 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 March 29, 2018, Bio-Path Holdings, Inc. (the "Company") issued a press release titled, "Bio-Path Holdings Announces Publication in *The Lancet Haematology*." 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 March 29, 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: March 29, 2018

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated March 29, 2018

Exhibit 99.1

Bio-Path Holdings Announces Publication in *The Lancet Haematology*

Prexigebersen was well tolerated and showed early anti-leukemic activity in combination with cytarabine in relapsed or refractory hematologic malignancies

HOUSTON—March 29, 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 data from its Phase 1 study of prexigebersen (BP1001) as a treatment for haematological malignancies was published in the online edition of *The Lancet Haematology* in an article titled, "Liposomal Grb2 antisense oligodeoxynucleotide (BP1001) in patients with refractory or relapsed haematological malignancies: a single-centre, open-label, dose-escalation, phase 1/1b trial."

The single-center, open-label, dose-escalation phase 1/1b trial enrolled and treated 39 subjects (aged ≥18 years) with refractory or relapsed hematologic malignancies at MD Anderson Cancer Center in Houston. The objectives of this study were to establish the toxicity and tolerance of escalating doses of BP1001 monotherapy in patients with refractory or relapsed leukemia, to assess the maximum tolerated dose of BP1001, and to determine the optimal biologically active dose of BP1001, defined as a 50% reduction in Grb2 expression in circulating leukemia cells. The study also assessed the in-vivo pharmacokinetics of BP1001 and tumor response.

The study employed a 3+3 dose escalation strategy, with at least three patients enrolled at each dose level. BP1001 was administered intravenously, twice weekly for 28 days with a starting dose in cohort 1 of 5 mg/m², cohort 2 (10 mg/m²), cohort 3 (20 mg/m²), cohort 4 (40 mg/m²), cohort 5 (60 mg/m²), or cohort 6 (90 mg/m²). Following completion of monotherapy, the safety and toxicity of BP1001 (60 or 90 mg/m²) in combination with 20 mg low-dose cytarabine (twice-daily subcutaneous injections) was evaluated in a phase 1b study in patients with refractory or relapsed acute myeloid leukemia (i.e., those patients who were refractory to at least one previous therapy regimen and no more than one previous salvage regimen).

The study results showed that BP1001 was well tolerated, with early evidence of anti-leukaemic activity in combination with low-dose cytarabine. To further explore this anti-leukaemic activity, BP1001 in combination with low-dose cytarabine combination is being studied in an ongoing phase 2 clinical trial in patients with previously untreated acute myeloid leukaemia who are ineligible for intensive induction therapy.

In addition to the publication of the study results, the article was selected for commentary by Xavier Thomas, MD and Etienne Paubelle, MD, PhD, Department of Hematology, Lyon-Sud Hospital, Pierre Bénite, France. In their view, "Much improvement is still needed in the treatment of these high-risk patients. Because of their specific mechanism of action and their good tolerance, liposome-incorporated antisense oligodeoxynucleotides might be an effective new therapeutic strategy."

"We are delighted to have these very favorable data published in *The Lancet Haematology* and to have the formal commentary of Drs. Thomas and Paubelle, two recognized international hematologists," noted Peter H. Nielsen, Chief Executive Officer of Bio-Path. "We continue to enroll our Phase 2 study of prexigebersen in patients with untreated acute myeloid leukemia and these anti-leukemic data are especially encouraging."

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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