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 29, 2017

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 December 29, 2017, Bio-Path Holdings, Inc. (the "Company") issued a press release titled, "Bio-Path Holdings Provides Clinical Update and 2018 Business Outlook." 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 December 29, 2017

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: January 2, 2018

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated December 29, 2017

Exhibit 99.1

Bio-Path Holdings Provides Clinical Update and 2018 Business Outlook

HOUSTON – December 29, 2017 – 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 provided an update from several clinical programs and provided a 2018 business overview.

"We are very excited about the potential for Bio-Path as we enter 2018. The year ahead is expected to be highlighted by a variety of value-creating milestones across a number of important clinical development programs aimed at further validating our DNAbilize platform as a potential treatment for a variety of oncology indications," stated Peter H. Nielsen, chief executive officer of Bio-Path Holdings. "We continue to advance our unique platform technology to address a number of cancers that remain unresponsive to current treatment paradigms."

"We are very encouraged about the potential for our DNAbilize technology, which is supported by compelling earlier data that show prexigebersen to be safe and efficacious against a wide range of cancer indications and are hopeful that these positive data will be replicated in our ongoing late-stage clinical trials," continued Mr. Nielsen.

Phase 2 Study of Prexigebersen in De Novo AML Patients

Bio-Path is conducting a Phase 2 clinical trial of its lead drug candidate, prexigebersen, in combination with frontline therapy low dose cytarabine (LDAC) in de novo acute myeloid leukemia (AML) patients who are ineligible or unwilling to undergo intensive induction therapy. The single arm trial is designed for up to 54 evaluable patients with an interim analysis performed after 19 patients.

To-date in this study, over 50 potential patients have been pre-screened, 26 patients have been screened, 23 patients have been enrolled and 17 patients have been deemed evaluable with 6 additional patients currently undergoing treatment. Bio-Path expects the 19 patient pre-specified analysis to be completed in early 2018, at which time the assessment of these patients will be addressed by Bio-Path.

Plans for a pivotal trial will be discussed with the FDA if these results exceed expectations for current standard of care therapy.

Phase 2a Study of Prexigebersen in Accelerated and Blast Phase CML Patients

Bio-Path today announces the initiation of its Phase 2a clinical study of prexigebersen for the treatment of chronic myeloid leukemia (CML) in accelerated and blast phase patients. The trial is being conducted at The University of Texas MD Anderson Cancer Center as a potential salvage therapy for accelerated and blast phase CML patients.

Two cohorts of three evaluable patients each will be enrolled to evaluate two doses (60 mg/m2 and 90 mg/m2) of prexigebersen in combination with the front-line treatment dasatinib.

Phase 1 Study of BP1002 in Refractory or Relapsed Lymphoma Patients

In 2018, Bio-Path intends to initiate a Phase 1 clinical trial of BP1002, an antisense RNAi nanoparticle targeting the Bcl-2 protein, in refractory or relapsed lymphoma patients. The clinical trial would evaluate the safety of BP1002 in several dose escalating cohorts to determine a maximum tolerated dose and/or optimal biologically active dose.

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 Bcl2 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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Contact Information:

Investors

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

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