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): November 26, 2019

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.001 per share	BPTH	The Nasdaq Capital Market

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 November 26, 2019, Bio-Path Holdings, Inc. (the "Company") issued a press release titled, "Bio-Path Holdings Announces Successful Completion of Safety Testing in Stage 2 of Phase 2 Clinical Trial 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.

Exhibit Number	Description
99.1	Press Release dated November 26, 2019

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: November 26, 2019

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated November 26, 2019

Exhibit 99.1

BIO-PATH HOLDINGS ANNOUNCES SUCCESSFUL COMPLETION OF SAFETY TESTING IN STAGE 2 OF PHASE 2 CLINICAL TRIAL IN ACUTE MYELOID LEUKEMIA

Combination of Prexigebersen and Decitabine Showed Encouraging Safety and Efficacy Results

HOUSTON – November 26, 2019 – 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 the successful completion of the safety testing of prexigebersen in combination with decitabine in acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS) patients in Stage 2 of the Phase 2 clinical study. The safety segment of Stage 2 of the Phase 2 clinical trial comprised six evaluable patients who were treated with the combination of prexigebersen and decitabine.

“We are especially pleased to have successfully completed this key safety segment of our Phase 2 study as it allows us to move forward to the next segment of this important clinical study, which is the final, efficacy portion of Stage 2 of the Phase 2 study,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings. “We are in the process of completing the documentation to submit for final approval of this last portion of Stage 2 of the Phase 2 study. These results are encouraging and give us greater confidence in the successful development of this very promising combination therapy for AML and MDS patients."

Although the treatment combination of prexigebersen and decitabine is not the treatment planned for the efficacy evaluation of Stage 2 of the Phase 2 clinical trial, the efficacy profile in this safety segment of the study was encouraging with 50% of patients having a response, including two patients (33%) showing complete responses with incomplete hematologic recovery and one patient (17%) showing partial response. For reference, in this class of AML and MDS patients, the complete response rate to treatment with decitabine alone is approximately 20%. Some patients are continuing to receive treatment.

As previously reported, Stage 1 of the Phase 2 clinical trial, which treated de novo AML patients with a combination of low dose cytarabine (LDAC) and prexigebersen, demonstrated similar safety results and efficacy compared favorably to treatment of this class of patients with LDAC alone. We believe that prexigebersen with its promising efficacy and safety profile, has the potential to be an ideal combination candidate with frontline therapy. The recent approval of the frontline therapy venetoclax provided an opportunity for adding prexigebersen to the combination of venetoclax and decitabine for the treatment of AML and MDS patients. The first step in this process was establishing the safety of combining prexigebersen and decitabine prior to proceeding to a combination treatment of prexigebersen, decitabine and venetoclax.

Bio-Path's amended Stage 2 of the Phase 2 clinical trial will have two cohorts of patients. The first cohort will include untreated AML patients as existed in the pre-amended trial but with the addition of untreated high risk MDS patients, and a second cohort will include refractory/relapsed AML patients and high risk MDS patients. Both cohorts of patients will be treated with the combination of prexigebersen, decitabine and venetoclax. The Company is finalizing amendments to add this combination treatment to Stage 2 of the Phase 2 clinical trial.

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 the treatment of blood cancers and is in the process of filing an IND for a Phase 1 clinical trial for solid tumors. The Company's second product BP1002, which targets the Bcl-2 protein, will be evaluated for the treatment of lymphoma and solid tumors. In addition, an IND is expected to be filed for BP1003, a novel liposome-incorporated STAT3 antisense oligodeoxynucleotide developed by Bio-Path as a specific inhibitor of STAT3, in 2020.

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, Bio-Path's ability to 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, the maintenance of intellectual property rights, that patents relating to existing for future patent applications will be issued or that any issued patents will provide meaningful protection of our drug candidates, risks relating to maintaining Bio-Path's listing on the Nasdaq Capital Market and such other risks which are identified in Bio-Path's most recent Annual Report on Form 10- K, in any subsequent quarterly reports on Form 10-Q and in other reports that Bio-Path files with the Securities and Exchange Commission from time to time. 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.

# # #

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