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 1, 2016

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))

Item 7.01 Regulation FD Disclosure.

On November 2, 2016, Bio-Path Holdings, Inc. (the "Company") issued a press release titled, "Bio-Path Holdings Announces First Patient Dosed in Phase 2 Trial Evaluating BP1001 in Acute Myeloid Leukemia." A copy of such press release is attached hereto as Exhibit 99.1.

On November 3, 2016, the Company issued a press release titled, "Bio-Path Announces Orphan Drug Designation in the European Union for BP1001 for the Treatment of Acute Myeloid Leukemia." A copy of such press release is attached hereto as Exhibit 99.2.

On November 4, 2016, the Company issued a press release titled, "Bio-Path Holdings to Present Data at the 2016 ASH Annual Meeting." A copy of such press release is attached hereto as Exhibit 99.3.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated November 2, 2016
99.2	Press Release dated November 3, 2016
99.3	Press Release dated November 4, 2016

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 4, 2016

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated November 2, 2016
99.2	Press Release dated November 3, 2016
99.3	Press Release dated November 4, 2016

Exhibit 99.1

Bio-Path Holdings Announces First Patient Dosed in Phase 2 Trial Evaluating BP1001 in Acute Myeloid Leukemia

HOUSTON—November 2, 2016 – Bio-Path Holdings, Inc., (NASDAQ: BPTH), a biotechnology company leveraging its proprietary DNAbilize™ liposomal delivery and antisense technology to develop a portfolio of targeted nucleic acid cancer drugs, today announced the enrollment and dosing of the first patient in the efficacy portion of its Phase 2 clinical study of BP1001, a liposomal Grb2 antisense for the treatment of acute myeloid leukemia (AML). The objective of the Phase 2 study is to further assess the efficacy and safety of BP1001, Bio-Path's lead development candidate.

The Phase 2 clinical trial is a multicenter study of BP1001 in combination with low dose cytarabine (LDAC) in patients with previously untreated AML who are not otherwise eligible for standard or high-intensity chemotherapy regimens or who have elected a low-intensity regimen.

The trial is a single arm, open label, two-stage design to assess the safety profile, pharmacokinetics, pharmacodynamics, and efficacy of 60 mg/m^2 of BP1001 in combination with LDAC compared to historical response rates documented for LDAC alone. Evaluable patients will receive an initial dose intravenous (IV) infusion of BP1001 over 60 minutes and every three days thereafter, as eight doses per 28-day cycle of 60 mg/m^2 BP1001, and will be administered LDAC as a subcutaneous (SQ) injection, twice daily for 20 consecutive doses per 28-day cycle.

The primary endpoint of the study is the number of patients who achieve Complete Remission (CR), including CR with incomplete hematologic recovery (CRi) and CR with incomplete platelet recovery (CRip). Secondary endpoints assessing the safety and efficacy of BP1001 include overall survival, time to response, duration of response, and adverse events as evaluated by physical examination findings, vital signs and clinical laboratory tests.

The full trial design includes approximately 54 evaluable patients with an interim analysis performed after 19 patients. In the event the interim results exceed the primary endpoint in a number of patients that meets or exceeds statistically determined thresholds, the Company may seek to convert the trial into a registration trial for accelerated approval.

Among the sites registered to conduct the study are Weill Medical College of Cornell University, Baylor Scott & White Health, The University of Kansas and The University of Texas MD Anderson Cancer Center.

"This is an exciting milestone for Bio-Path as it will be the first study to confirm the efficacy of BP1001 as a treatment for AML and to validate our DNAbilize™ platform," said Peter H. Nielsen, Chief Executive Officer of Bio-Path Holdings. "We are particularly pleased with the Phase 2 trial design, which has a built-in interim analysis that offers a pathway to an accelerated approval should the efficacy results for the first 19 evaluable patients demonstrate the high response rate seen in the safety segment of our Phase 2 trial. We look forward to the completion of this study and expect its results to replicate these very promising early data," added Mr. Nielsen.

Patients in the safety segment of the trial treated with 60 mg/m^2 and 90 mg/m^2 of BP1001 twice a week over a four-week period, in combination with a standard regimen of frontline low-dose cytarabine (LDAC), showed BP1001 to be safe and well tolerated, with signs of significant anti-leukemia activity. Of the six evaluable patients included in both cohorts of the safety segment, three achieved complete remissions, while two others achieved partial remission. There were no attributable adverse events reported.

As previously reported, BP1001's pharmacokinetics at a dose of 60 mg/m^2 had a 30-hour half-life, significantly better than the half-life with a dose of 90 mg/m^2. The final analysis of these data, along with the demonstrated reductions in bone marrow blasts, suggested that 60 mg/m^2 is the appropriate dose for use in the Phase 2 trial. Administratively, this required Bio-Path to reformat documents for the Phase 2 trial with the 60 mg/m^2 dose and resubmit for approvals with the U.S. Food and Drug Administration (FDA) and site Institutional Review Boards, requiring additional time prior to starting the Phase 2 trial.

About Bio-Path Holdings, Inc.

Bio-Path is a biotechnology company focused on developing therapeutic products utilizing DNAbilize™, its proprietary liposomal delivery and antisense technology, to systemically distribute nucleic acid drugs throughout the human body with a simple intravenous transfusion. Bio-Path's lead product candidate, BP1001 (Liposomal Grb2 antisense), is in a Phase 2 study for blood cancers and in preclinical studies for solid tumors. Bio-Path's second drug candidate, also a liposomal antisense drug, is ready for the clinic where it will be evaluated in lymphoma and solid tumors.

For more information, please visit the Company's website at http://www.biopathholdings.com.

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 the Company'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. 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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Bio-Path Holdings, Inc.
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Exhibit 99.2

Bio-Path Announces Orphan Drug Designation in the European Union for BP1001 for the Treatment of Acute Myeloid Leukemia

HOUSTON—November 3, 2016 – Bio-Path Holdings, Inc., (NASDAQ: BPTH), a biotechnology company leveraging its proprietary DNAbilize™ liposomal delivery and antisense technology to develop a portfolio of targeted nucleic acid cancer drugs, today announced that the European Medicines Agency (EMA) granted orphan drug designation to BP1001 for the treatment of acute myeloid leukemia (AML).

"We are pleased that BP1001 has received orphan drug designation from the EMA, recognizing the urgent need for an effective treatment for AML and the potential of BP1001 to improve outcomes for patients facing this debilitating disease," stated Peter H. Nielsen, Chief Executive Officer of Bio-Path Holdings. "This marks an important regulatory milestone for Bio-Path now that we have entered the efficacy portion of our Phase 2 trial of BP1001 for the treatment of AML."

To receive orphan drug designation from the EMA, a therapy must be intended for the treatment of a life-threatening or chronically debilitating rare condition with a prevalence of less than five in 10,000 in the European Union. Orphan drug designation provides incentives designed to facilitate development including fee reductions for protocol assistance, scientific advice and importantly, may provide up to ten years of market exclusivity in the EU following product approval.

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Bio-Path Holdings to Present Data at the 2016 ASH Annual Meeting

HOUSTON—November 4, 2016 – Bio-Path Holdings, Inc., (NASDAQ: BPTH), a biotechnology company leveraging its proprietary DNAbilize™ liposomal delivery and antisense technology to develop a portfolio of targeted nucleic acid cancer drugs, today announced an upcoming poster presentation at the 2016 American Society of Hematology (ASH) Annual Meeting, taking place from December 3-6, 2016 in San Diego, CA.
Dr. Ana Tari Ashizawa, Director of Research at Bio-Path, will present preclinical and clinical data of BP1001 (Liposomal Grb2 antisense) for the treatment of chronic myeloid leukemia (CML).

Details for the poster presentation are as follows:

Date: Monday, December 5, 2016
Presentation Time: 6:00 pm – 8:00 pm Pacific Time
Location: San Diego Convention Center, Hall GH
Session: Chronic Myeloid Leukemia: Biology and Pathophysiology, excluding Therapy
Abstract: 4293
Title: "BP1001, a Novel Therapeutic for Chronic Myelogenous Leukemia" (Link to abstract)

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