

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 3, 2016

BIO-PATH HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-36333

(Commission File Number)

87-0652870

(IRS Employer Identification No.)

4710 Bellaire Boulevard, Suite 210, Bellaire, Texas

(Address of principal executive offices)

77401

(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))
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Item 7.01 Regulation FD Disclosure.

On March 3, 2016, Bio-Path Holdings, Inc. (the “Company”) issued a press release titled, “Bio-Path Holdings Announces Completion of the Safety Segment of the Phase II Clinical Trial of BP1001 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated March 3, 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: March 4, 2016

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

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated March 3, 2016



Bio-Path Holdings Announces Completion of the Safety Segment of the Phase II Clinical Trial of BP1001 in Acute Myeloid Leukemia

Two patients achieved partial remission; one patient continues to receive treatment

Company working to open a multi-site Phase II clinical trial to assess efficacy

HOUSTON—March 3, 2016 – Bio-Path Holdings, Inc., (NASDAQ: BPTH) (“Bio-Path”), a biotechnology company leveraging its proprietary DNAbilize™ liposomal delivery and antisense technology to develop a portfolio of targeted nucleic acid cancer drugs, today announced positive results from the eighth and final cohort of the safety segment of Bio-Path’s Phase II trial assessing the toxicity of the Company’s lead product candidate, BP1001 (Liposomal Grb2 antisense), in combination with low-dose cytarabine (LDAC) chemotherapy in patients with advanced acute myeloid leukemia (AML).

Patients in Cohort 8 were treated with 90 mg/m² of BP1001 twice a week over a four-week period, in combination with a standard regimen of frontline LDAC. Results were consistent with those seen in previous cohorts, demonstrating BP1001 to be safe and well tolerated, with signs of anti-leukemia activity. The Company saw no adverse events attributable to BP1001 treatment. In Cohort 8, two AML patients achieved partial remission. One patient continues to receive additional treatments.

“The encouraging results from the eighth and final cohort of the safety portion of this trial are exciting not just for Bio-Path, but also for patients suffering from blood cancers like AML,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path. “These results reinforce our confidence in BP1001 as a safe and effective treatment for AML in combination with frontline chemotherapy. We look forward to assessing the efficacy of BP1001 in the Phase II clinical trial.”

With the closing of Cohort 8, the Phase II safety assessment of BP1001 in combination with low-dose cytarabine is complete. The safety assessment included two cohorts, which assessed six patients evaluated with 60 mg/m² and 90 mg/m² of BP1001 in combination with low-dose cytarabine. No toxic side effects attributable to BP1001 treatment were observed at either dose. Of the six evaluable patients included in both cohorts of the safety segment, two achieved complete remission, while two others achieved partial remission. Of the patients responding, their blood properties show improvement, suggesting BP1001’s potential efficacy as a combination therapy.

The Company is in the process of submitting these results to the U.S. Food and Drug Administration and is planning to open the efficacy portion of the Phase II trial of BP1001 in the second quarter of 2016.

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 II study for blood cancers and in preclinical studies for triple negative and inflammatory breast cancers. 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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