

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): June 6, 2016

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

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**Delaware**

(State or other jurisdiction  
of incorporation)

**001-36333**

(Commission File Number)

**87-0652870**

(IRS Employer Identification No.)

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**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 June 6, 2016, Bio-Path Holdings, Inc. (the “Company”) issued a press release titled, “Bio-Path Holdings Reports Promising Data from Phase I and Phase II Clinical Trials of BP1001 in Blood Cancers Presented at ASCO 2016.” A copy of such press release is attached hereto as Exhibit 99.1.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| <u>Exhibit<br/>Number</u> | <u>Description</u>               |
|---------------------------|----------------------------------|
| 99.1                      | Press Release dated June 6, 2016 |

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**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: June 6, 2016

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

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**EXHIBIT INDEX**

| <u>Exhibit<br/>Number</u> | <u>Description</u>               |
|---------------------------|----------------------------------|
| 99.1                      | Press Release dated June 6, 2016 |

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**Bio-Path Holdings Reports Promising Data from Phase I and Phase II Clinical Trials of BP1001 in Blood Cancers Presented at ASCO 2016**

*Five of six evaluable patients achieved remission in safety segment of the Phase II combination therapy trial of BP1001, including three complete remissions and two partial remissions*

**HOUSTON – June 6, 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 and autoimmune drugs, today announced that data from the Phase I study of BP1001 (Liposomal Grb2 Antisense) as a treatment for acute myeloid leukemia (AML) and chronic myeloid leukemia (CML) and the safety segment of the Phase II combination therapy of BP1001 and low-dose cytarabine (LDAC) as a treatment for advanced AML were presented by Dr. Maro Ohanian, Assistant Professor at the University of Texas MD Anderson Cancer Center, during a poster presentation at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting in a poster titled, “Phase I Study of BP1001 (Liposomal Grb2 Antisense) in Patients with Hematologic Malignancies.”

“While a small dataset, we are still very excited by these robust data showing that five of six evaluable patients demonstrated activity, especially for these refractory and resistant patients. We are also encouraged by the lack of toxicity as our Phase II efficacy segment will be in de novo fragile patients, for whom the drug side effect profile is particularly important,” stated Peter H. Neilson, Chief Executive Officer of Bio-Path Holdings. “In addition, we were very pleased with BP1001’s pharmacokinetics, particularly its 30-hour half-life. The final analysis of these data, along with the demonstrated reductions in bone marrow blasts, suggests that 60 mg/m<sup>2</sup> is the appropriate dose going forward.”

The Phase I study of BP1001 comprised Cohorts 1 through 6 of the dose-finding monotherapy at doses up to 90 mg/m<sup>2</sup> in refractory/relapsed leukemia patients. The safety segment of the Phase II study evaluated the toxicity of BP1001 in Cohorts 7 and 8 in doses of 60 mg/m<sup>2</sup> and 90 mg/m<sup>2</sup>, combined with LDAC chemotherapy in refractory/relapsed patients with advanced AML.

Data from the safety segment of the Phase II combination therapy of BP1001 and LDAC showed no dose limiting toxicities. Of the six evaluable patients, four patients completed more than two cycles of treatment, three patients achieved complete remission and two patients achieved partial remission. BP1001 levels decreased bi-exponentially in plasma and the pharmacokinetics of BP1001 demonstrated a half-life at 60 mg/m<sup>2</sup> of 30 hours.

As previously reported, data from the Phase I study demonstrated that BP1001 was well tolerated in refractory/relapsed leukemia patients at doses up to 90 mg/m<sup>2</sup> with no drug related adverse events. It also decreased target Grb2 expression by an average of 50% in the 21 evaluable patients on BP1001 monotherapy. Of these patients in the Phase I study, seven patients completed more than two cycles of treatment, 10 patients had more than a 50% reduction in peripheral or bone marrow blasts and six patients had transient decline in blasts (n=3) and/or stable disease (n=3), with two patients experiencing transient improvement in leukemia cutis lesions.

**About BP1001**

BP1001 is a neutral-charge, liposome-incorporated antisense drug substance designed to inhibit Grb2 protein expression. The protein Grb2 is essential to cancer cell signaling because it is utilized by oncogenic tyrosine kinases to induce cancer progression. Suppressing the function or expression of Grb2 should interrupt its vital signaling function and have a therapeutic application in cancer.

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## **About Bio-Path Holdings, Inc.**

Bio-Path is a biotechnology company focused on developing therapeutic products utilizing DNAbilize™, its liposomal and proprietary antisense delivery 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](http://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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