

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): October 9, 2015

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

**Delaware**

(State or other jurisdiction  
of incorporation)

**000-53404**

(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 (see General Instruction A.2. below):

- 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 October 9, 2015, Bio-Path Holdings, Inc. (the “Company”) issued a press release titled, “Bio-Path Holdings Announces Successful Completion of Cohort 7 of Phase Ib Clinical Trial Evaluating Liposomal Grb-2 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 October 9, 2015

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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: October 9, 2015

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

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**EXHIBIT INDEX**

Exhibit  
Number

Description

99.1

Press Release dated October 9, 2015

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**Bio-Path Holdings Announces Successful Completion of Cohort 7 of Phase Ib  
Clinical Trial Evaluating Liposomal Grb-2 in Acute Myeloid Leukemia**

*One of two patients evaluated achieved complete remission; second patient shows continued improvement*

*Company opens enrollment into eighth and final cohort of Phase Ib clinical trial*

**HOUSTON—October 9, 2015** – Bio-Path Holdings, Inc., (NASDAQ: BPTH) (“Bio-Path”), a biotechnology company developing a liposomal delivery technology for nucleic acid cancer drugs, today announced the successful completion of Cohort 7 of its Phase Ib clinical trial evaluating the toxicity of its lead compound, Liposomal Grb-2, combined with low-dose cytarabine (LDAC) chemotherapy in patients with advanced Acute Myeloid Leukemia (AML). Bio-Path has opened enrollment into Cohort 8, which will complete the Company’s Phase Ib study of Liposomal Grb-2.

Three patients were evaluated in Cohort 7, which was the first cohort of the Company’s Phase Ib trial to evaluate the toxicity of Liposomal Grb-2 as a combination therapy. Patients were treated twice a week for four weeks with 60 mg/m<sup>2</sup> of Liposomal Grb-2, for a total of eight doses in combination with the standard regimen of LDAC. Results were consistent with previous cohorts, showing Liposomal Grb-2 to be safe and well tolerated.

Furthermore, one patient achieved complete remission during treatment. A second patient demonstrated improvement in bone marrow blasts at the end of the first treatment cycle and is continuing Liposomal Grb-2 treatment as part of an additional treatment cycle. The third evaluable patient completed the treatment cycle, but did not show improvement. One patient ended the study early due to disease progression, and therefore was not evaluated in this cohort.

“I am highly encouraged to see that a patient suffering from advanced AML who was treated with Liposomal Grb-2 has achieved complete remission, and that another patient is continuing to improve,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path. “Complete remission in a patient with refractory and treatment-resistant AML is an exciting milestone for Bio-Path and blood cancer patients, suggesting that Liposomal Grb-2 might have the potential to improve survival rates in combination with frontline chemotherapy. We anticipate that these positive results will support rapid enrollment into Cohort 8, and look forward to continuing the development of Liposomal Grb-2.”

Bio-Path has opened Cohort 8 for patients to be treated with 90 mg/m<sup>2</sup> of Liposomal Grb-2, in combination with frontline LDAC. Upon successfully completing the evaluation of three patients in Cohort 8, the Company will finalize the Phase Ib clinical study.

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

Bio-Path is a biotechnology company focused on developing therapeutic products utilizing its proprietary liposomal delivery technology designed to systemically distribute nucleic acid drugs throughout the human body with a simple intravenous transfusion. Bio-Path’s lead product candidate, Liposomal Grb-2, 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>.

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## **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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## **Contact Information:**

### **Investors**

Kara Andress  
Investor Relations  
Bio-Path Holdings, Inc.  
832-742-1357

Steve Silver  
Rx Communications Group, LLC  
917-322-2569  
[ssilver@rxir.com](mailto:ssilver@rxir.com)

### **Media**

Tony Plohoros  
6 Degrees  
908-591-2839  
[tplohoros@6degreespr.com](mailto:tplohoros@6degreespr.com)

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