

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): February 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 February 9, 2015, Bio-Path Holdings, Inc. (the “Company”) issued a press release titled, “Bio-Path Holdings Starts Phase II Study with Liposomal Grb-2 in AML Patients.” A copy of such press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| <u>Exhibit<br/>Number</u> | <u>Description</u>                   |
|---------------------------|--------------------------------------|
| 99.1                      | Press Release dated February 9, 2015 |

**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: February 11, 2015

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

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**EXHIBIT INDEX**

| Exhibit<br>Number | Description                          |
|-------------------|--------------------------------------|
| 99.1              | Press Release dated February 9, 2015 |

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**Bio-Path Holdings Starts Phase II Study with Liposomal Grb-2  
in AML Patients**

**HOUSTON, TX, February 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 that it has begun enrollment into the safety segment of its Phase 2 study evaluating BP-100-1.01 (Liposomal Grb-2) in patients with acute myeloid leukemia (AML).

This segment of the study will evaluate two doses (60 mg/m<sup>2</sup> and 90 mg/m<sup>2</sup>) of Liposomal Grb-2 in combination with Ara-C front line therapy. Each dose cohort will include three patients with AML for a total of six patients. The endpoint of this study segment is safety of the combination of the two drugs. The clinical trial is taking place at MD Anderson Cancer Center. Bio-Path expects results of this portion of the study in the second half of 2015.

“We are pleased to be moving Liposomal Grb-2 into the next phase of clinical development. This is a key milestone for Bio-Path and, after demonstrating a clean safety profile of the drug as a mono therapy, we are excited to evaluate the compound in its intended use in combination with an existing chemotherapeutic agent,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path. “Upon successful completion of this safety segment and review by the FDA, we would then move into a broader efficacy segment of the 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.

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

Contact Information:

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