

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): April 28, 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 April 28, 2015, Bio-Path Holdings, Inc. (the “Company”) issued a press release titled, “Bio-Path Holdings Granted Orphan Drug Designation for Liposomal Grb-2 in Acute Myeloid Leukemia.” 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 Number</u>	<u>Description</u>
99.1	Press Release dated April 28, 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: April 28, 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 April 28, 2015

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## **Bio-Path Holdings Granted Orphan Drug Designation for Liposomal Grb-2 in Acute Myeloid Leukemia**

**HOUSTON, TX, April 28, 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 they have received orphan drug designation from the U.S. Food and Drug Administration (FDA) for its lead compound Liposomal Grb-2 for the treatment of acute myeloid leukemia (AML). Orphan drug status provides Bio-Path with seven years of exclusivity after receiving formal marketing approval, as well as additional development incentives. The FDA grants this designation to certain drugs that are targeting diseases affecting fewer than 200,000 people in the United States.

“This designation from the FDA demonstrates the unmet need for an effective therapy for patients suffering from AML,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path. “It also marks a key regulatory milestone for Bio-Path and will be valuable as we continue to progress Liposomal Grb-2 through clinical trials and toward potential commercialization.”

Liposomal Grb-2 is currently in a safety segment of a Phase 2 trial in combination with Ara-C, for acute myeloid leukemia; and is being evaluated for chronic myelogenous leukemia.

Pre-clinical development is underway for triple negative and inflammatory breast cancers.

### **About Acute Myeloid Leukemia**

AML is a fast-growing cancer of the blood and bone marrow where the bone marrow makes many cancerous cells called leukemic blasts. Normal blasts develop into white blood cells that fight infection. In AML, the leukemic blasts do not develop properly and cannot fight infections. These leukemic blasts grow quickly and crowd out the bone marrow, preventing it from making the normal red blood cells, white blood cells, and platelets that the body needs. Nearly 15,000 people in the United States are diagnosed with AML each year.

### **About Growth Receptor Bound protein-2 (Grb-2)**

The adaptor protein Growth Receptor Bound protein-2 (Grb-2) is essential to cancer cell signaling because it is utilized by oncogenic tyrosine kinases to induce cancer progression. Suppressing the function or expression of Grb-2 should interrupt its vital signaling function and have a therapeutic application in cancer. BP-1001 is a neutral-charge, liposome-incorporated antisense drug substance designed to inhibit Grb-2 expression.

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## **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 2 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.*

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

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