

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): November 5, 2015

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

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| Delaware (State or other jurisdiction of incorporation) | 000-53404 (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 (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 November 5, 2015, Bio-Path Holdings, Inc. (the “Company”) issued a press release titled, “Bio-Path Holdings’ Data to be Presented at 57th American Society of Hematology (ASH) Annual Meeting.” 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 November 5, 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: November 5, 2015

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 November 5, 2015 |



Bio-Path Holdings' Data to be Presented at 57th American Society of Hematology (ASH) Annual Meeting

Jorge Cortes, M.D., of MD Anderson Cancer Center to present poster with data from Phase I and Ib clinical trials of BP-100-1.01 (Liposomal Grb-2 antisense) in blood cancers

Patient in Phase Ib combination therapy trial achieved complete remission

HOUSTON—November 5, 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 Dr. Jorge Cortes, Deputy Chair of the Department of Leukemia at the University of Texas MD Anderson Cancer Center and Chair of Bio-Path’s Scientific Advisory Board, will present data from Bio-Path’s Phase I and Ib clinical trials of its lead product candidate BP-100-1.01 (Liposomal Grb-2 antisense) in the treatment of blood cancers during a poster session at the 57th American Society of Hematology (ASH) Annual Meeting in Orlando, Florida.

Details for the poster presentation are as follows:

Title: “Safety, Pharmacokinetics, and Efficacy of BP-100-1.01 (Liposomal Grb-2 Antisense Oligonucleotide) in Patients with Refractory or Relapsed Acute Myeloid Leukemia (AML), Philadelphia Chromosome Positive Chronic Myelogenous Leukemia (CML), Acute Lymphoblastic Leukemia (ALL), and Myelodysplastic Syndrome (MDS)”

Session Name: 616. Acute Myeloid Leukemia: Novel Therapy, excluding Transplantation: Poster III

Date: Monday, December 7, 2015

Presentation Time: 6:00 p.m. - 8:00 p.m. Eastern Time

Location: Hall A, Orange County Convention Center

The poster will highlight results from Bio-Path’s Phase I and Ib clinical trials in patients with blood cancers, notably the complete remission (CR) of one patient with advanced acute myeloid leukemia (AML) who was treated with BP-100-1.01 in combination with low-dose cytarabine (LDAC) chemotherapy and another patient with chronic myelogenous leukemia (CML) who showed significant reduction (81 percent to 5 percent) in bone marrow blasts. The results suggest possible disease inhibition with BP-100-1.01 treatment.

The full abstract can be found at <https://ash.confex.com/ash/2015/webprogram/Paper84781.html>.

For more information on the ASH Annual Meeting, visit <http://www.hematology.org/Annual-Meeting/>.

About BP-100-1.01

BP-100-1.01 is a neutral-charge, liposome-incorporated antisense drug substance designed to inhibit Grb-2 protein expression. The protein 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.

About Bio-Path Holdings, Inc.

Bio-Path is a biotechnology company focused on developing therapeutic products utilizing its proprietary liposomal delivery technology, DNAbilize™, to systemically distribute nucleic acid drugs throughout the human body with a simple intravenous transfusion. Bio-Path's lead product candidate, BP-100-1.01, 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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