

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): December 8, 2015

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

Delaware

(State or other jurisdiction
of incorporation)

001-36333

(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))
-

Item 7.01 Regulation FD Disclosure.

On December 8, 2015, Bio-Path Holdings, Inc. (the “Company”) issued a press release titled, “Bio-Path Holdings’ Data from Phase I and Safety Segment of Phase II Clinical Trials in Blood Cancers 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 December 8, 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: December 8, 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 December 8, 2015



Bio-Path Holdings' Data from Phase I and Safety Segment of Phase II Clinical Trials in Blood Cancers Presented at 57th American Society of Hematology (ASH) Annual Meeting

Two of the three evaluable patients achieved complete remission in safety segment of the Phase II combination therapy trial of BP1001 (Liposomal Grb2 antisense)

HOUSTON—December 8, 2015 – Bio-Path Holdings, Inc., (NASDAQ: BPTH) (“Bio-Path”), a biotechnology company leveraging its proprietary DNabilize™ liposomal delivery and antisense technology to develop a portfolio of targeted nucleic acid cancer drugs, today announced that data from the Phase I and safety segment of the Phase II clinical trials of its lead product candidate BP-100-1.01 (or BP1001, Liposomal Grb2 antisense) in the treatment of blood cancers were presented yesterday by 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, during a poster session at the 57th American Society of Hematology (ASH) Annual Meeting in Orlando, Florida.

The poster, titled “Safety, Pharmacokinetics, and Efficacy of BP-100.1.01 (Liposomal Grb2 Antisense Oligonucleotide) in Patients with Refractory or Relapsed Acute Myeloid Leukemia (AML), Philadelphia Chromosome Positive Chronic Myelogenous Leukemia (CML), Acute Lymphoid Leukemia (ALL), and Myelodysplastic Syndrome (MDS),” included data from the first seven cohorts of the study. The eighth and final cohort is ongoing.

Data from Cohorts 1 through 6 of the dose-finding monotherapy study demonstrated that BP1001 at doses up to 90 mg/m² is well tolerated and suggests possible anti-leukemia activity. Of the evaluable patients, all showed a transient drop in circulating blast percentage.

Cohort 7 was the first cohort in the safety segment of the Phase II clinical trial (also referred to as Phase Ib) and evaluated the toxicity of BP1001 at the 60 mg/m² dose level, combined with low-dose cytarabine (LDAC) chemotherapy in patients with advanced acute myeloid leukemia (AML). Bio-Path previously reported that one evaluable patient in Cohort 7 had achieved complete remission (CR) during treatment, and a second patient who demonstrated improvement in bone marrow blasts at the end of the first treatment cycle was continuing BP1001 treatment as part of an additional treatment cycle. The second patient has achieved CR after two treatment cycles and is continuing therapy in a fourth treatment cycle.

“We are thrilled that two of the three evaluable patients suffering from advanced AML in our first cohort of the safety segment of the Phase II trial have now achieved complete remission during treatment with Liposomal Grb2 combined with low-dose cytarabine,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path. “The data we have seen to date are especially encouraging because the patients evaluated in our study were refractory and treatment resistant, having been on an average of four prior therapies. We continue to make progress with the eighth cohort of the trial, which is evaluating three patients being treated with 90 mg/m² of Liposomal Grb2 antisense in combination with frontline LDAC, and look forward to successfully completing the safety portion of the Phase II clinical study.”

About BP1001

BP1001 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 DNAbilize™, its proprietary liposomal delivery and antisense 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. 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.

###

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

Media

Tony Plohoros
6 Degrees
908-591-2839
tplohoros@6degreespr.com
