

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 5, 2016

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:

- 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 December 5, 2016, Bio-Path Holdings, Inc. (the “Company”) issued a press release titled, “Bio-Path Holdings Presents Clinical Data Evaluating BP1001 as a Treatment for Chronic Myelogenous Leukemia at the 58th Annual American Society of Hematology 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 5, 2016

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 6, 2016

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 6, 2016



Bio-Path Holdings Presents Clinical Data Evaluating BP1001 as a Treatment for Chronic Myelogenous Leukemia at the 58th Annual American Society of Hematology Annual Meeting

–Results Support Planned Phase 2 Clinical Trial in CML–

HOUSTON—December 5, 2016 – Bio-Path Holdings, Inc., (NASDAQ: BPTH), 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 a review of BP1001 data as a treatment for chronic myelogenous leukemia (CML) was presented in a poster at the 58th Annual American Society of Hematology (ASH) Annual Meeting taking place from December 3-6, 2016 in San Diego, CA.

Ana Tari Ashizawa, Ph.D., Bio-Path’s director of research, presented the poster titled “BP1001, a Novel Therapeutic for Chronic Myelogenous Leukemia.” The results demonstrated that BP1001 decreased the proliferation of Gleevec® (imatinib)-resistant CML cells in a dose-dependent manner. In addition, BP1001 pretreatment enhanced the inhibitory effects of Sprycel® (dasatinib) in CML cells, leading to cell death. Five CML blast phase patients were enrolled in the first cohort (5 mg/m² BP1001) of the Phase 1 BP1001 clinical study. Two CML patients, who had T315I mutation, showed significant reductions in circulating blasts during treatment. One patient’s blasts were reduced from 89% to 12%, while another patient’s blasts were reduced from 24% to 7%.

“These patient data, supported by previous *in vivo* and *in vitro* results, suggest that BP1001 has the potential to treat the 33% of CML patients who are resistant to Gleevec, the current standard of care. Sprycel is a second-generation tyrosine kinase inhibitor that is often used for Gleevec resistant patients. We are pleased that our preclinical results showed that BP1001 can enhance Sprycel activity in CML cells. These positive data give us confidence that BP1001 could play a valuable role in treating this patient population and encourage us to move forward with the initiation of our safety segment of the Phase 2 trial in patients with CML,” said Peter Nielsen, chief executive officer of Bio-Path Holdings.

About BP1001

BP1001 (Liposomal Grb2 antisense) is Bio-Path’s lead product candidate, a neutral-charge, liposome-incorporated antisense drug designed to inhibit protein synthesis of Grb2 (growth factor receptor bound protein 2). Grb2 plays an essential role in cancer cell activation via the RAS pathway. Grb2 is an adapter protein that bridges signals between activated and mutated tyrosine kinases, such as Flt3, c-Kit, and Bcr-Abl, and the Ras pathway, leading to activation of the ERK and AKT proteins. Inhibition of Grb2 by BP1001 represents a significant advance in treating cancers with activated tyrosine kinases using a target not druggable with antibodies or kinase inhibitors. Inhibition of Grb2 has been demonstrated to halt cell proliferation and enhance cell killing by chemotherapeutic agents without added toxicity.

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 2 study for blood cancers and in preclinical studies for solid tumors. 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 www.biopathholdings.com.

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