

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 9, 2013

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

**Utah**

**000-53404**

**87-0652870**

(State or other jurisdiction  
of incorporation)

(Commission File Number)

(IRS Employer Identification No.)

**2626 South Loop, Suite 180, Houston, Texas**

**77054**

(Address of principal executive offices)

(Zip Code)

(832) 971-6616

(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 8.01 Other Events.**

On December 9, 2013, Bio-Path Holdings, Inc. issued a press release titled “Preliminary Results from Bio-Path Holdings’ Phase I Clinical Trial Presented at the Annual Meeting of the American Society of Hematology (ASH) in New Orleans.”

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 December 9, 2013

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**BIO-PATH HOLDINGS, INC.**

Dated: December 9, 2013

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

**EXHIBIT INDEX**

Exhibit Number -----	Description -----
99.1	Press Release dated December 9, 2013



## **Preliminary Results from Bio-Path Holdings' Phase I Clinical Trial Presented at the Annual Meeting of the American Society of Hematology (ASH) in New Orleans**

**December 9, 2013; HOUSTON, TX** – Bio-Path Holdings, Inc., (OTCQX: BPTH) (“Bio-Path”), a biotechnology company developing a liposomal delivery technology for nucleic acid cancer drugs, announced that Dr. Jorge Cortes, deputy chair and professor of medicine in the Department of Leukemia at The University of Texas MD Anderson Cancer Center, presented Phase I data from Bio-Path’s clinical trial evaluating its lead product candidate, Liposomal Grb-2 (BP-100.1.01), in hematological cancers at the 55th Annual Meeting of the American Society of Hematology (ASH) in New Orleans.

The study titled “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)” included the first five cohorts of the study. The sixth cohort of the study is on-going and Bio-Path expects to have enrollment completed in the first quarter of 2014.

The clinical trial was a standard dose-finding study. The starting dose was 5 mg/m<sup>2</sup> twice weekly intravenously (IV) over two to three hours for 28 days and proceeded through doses of 10, 20, 40, and 60 mg/m<sup>2</sup>. A total of 28 patients who had failed other therapies were included in the study (19 AML, 4 MDS and 5 CML), and 18 patients were evaluable. Ten patients failed to complete the full 28-day treatment cycle due to disease progression with no toxicity.

Data from the Phase I trial demonstrated:

- Among 18 evaluable patients, nine experienced at least a 50 percent reduction in peripheral or bone marrow blasts from baseline.
- Five patients demonstrated transient improvement and/or stable disease, three of whom received a total of five cycles each.
- Two patients, in addition to achieving marked blast percentage declines, also experienced transient improvement in leukemia cutis lesions.

### *Disease Stabilization in MDS and AML*

- Two patients with MDS, a 53-year old male and a 72-year old female, both achieved disease stabilization and continued therapy for five cycles before disease progression.
- A 54-year old HIV positive male with AML achieved stable disease and marked reduction in peripheral blasts, continuing therapy for five cycles before disease progression.

### *Experience in CML-Blast Phase*

- Patient with myeloid blast crisis of CML
- Prior therapies consist of: imatinib, dasatinib, nilotinib, DCC-2036, Cytarabine + Fludarabine + Dasatinib + Gemtuzumab, PHA-739358, Clofarabine + Dasatinib
- Upon start of BP-100-1.01 patient showed a significant reduction in blasts from 81 percent to 5 percent but due to leptomeningeal disease progression discontinued therapy before full cycle.

### *Inhibition of Target Grb-2 Protein*

- Grb-2 levels were compared to baseline prior to treatment.
- On day 15, BP-100-1.01 decreased Grb-2 in five of eight samples tested (average reduction 55 percent)
- End of treatment day15, BP-100-1.01 decreased Grb-2 levels in eight out of nine patients (average reduction 45 percent)

### *Conclusions*

- Preliminary results suggest that BP-100-1.01, at doses up to 60 mg/m<sup>2</sup> is well tolerated and there is suggestion of anti-leukemia activity.
- Of the evaluable patients, all showed a transient drop in circulating or bone marrow blast percentage.
- Doses administered in Cohorts 1-5 expected to be below Optimal Biological Dose.
- As the study progresses it is anticipated that clearer signs of activity will be noted.

### About Bio-Path's Delivery Technology

Bio-Path's drug delivery technology involves microscopic-sized liposome particles that distribute nucleic acid drugs systemically and safely throughout the human body, via simple intravenous infusion. The delivery technology is applied to single stranded (antisense) nucleic acid compounds with the potential to revolutionize the treatment of cancer and other diseases where drugable targets of disease are well characterized. The Company is currently focused on developing liposomal antisense drug candidates. Bio-Path also anticipates developing liposome tumor targeting technology, representing next-generation enhancements to the Company's core liposome delivery technology.

### 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-100.1.01 is a neutral-charge, liposome-incorporated antisense drug substance designed to inhibit Grb-2 expression.

### 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 I 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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