

**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 2, 2013

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

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<b>Utah</b>	<b>000-53404</b>	<b>87-0652870</b>
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

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<b>2626 South Loop, Suite 180, Houston, Texas</b>	<b>77054</b>
(Address of principal executive offices)	(Zip Code)

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(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 2.02 Results of Operations and Financial Condition.**

The information in this Current Report is being furnished pursuant to Item 2.02 of Form 8-K and, according to general instruction B.2. thereunder, the information in this Current Report shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section. The information in this Current Report shall not be incorporated by reference into any registration statement pursuant to the Securities Act of 1933, as amended.

On April 2, 2013, Bio-Path Holdings, Inc. (the “Company”) announced financial results for the year ended December 31, 2012. Additional information is included in the Company’s press release dated April 2, 2013.

A copy of the Company’s press release is attached hereto as Exhibit 99.1. The foregoing description of the press release is qualified in its entirety by reference to the attached exhibit.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit</u>	<u>Number</u>	<u>Description</u>
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99.1		Press Release dated April 2, 2013
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## **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: April 4, 2013

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

## **EXHIBIT INDEX**

Exhibit Number	Description
----- 99.1	Press Release dated April 2, 2013



## Bio-Path Holdings Reports Fiscal Year 2012 Operational and Financial Results

**April 2, 2013; HOUSTON, TX** – Bio-Path Holdings, Inc., (OTCQX: BPTH) (“Bio-Path”), a biotechnology company developing a liposomal delivery technology for nucleic acid cancer drugs, today announced operational and financial results for the year 2012.

### 2012 OPERATIONAL AND FINANCIAL HIGHLIGHTS

- Recent Operational Highlights

- Enrollment continues in the Phase I clinical trial of Bio-Path’s lead antisense cancer drug product Liposomal Grb-2 (BP-100-1.01). To date, the Company has successfully completed the first four cohorts of the study and treatment of patients in the fifth cohort is currently underway at The University of Texas MD Anderson Cancer Center. The drug has been well tolerated and possible anti-leukemia has been demonstrated. Through four cohorts, a total of 27 patients have been enrolled in the study, of which 15 have been evaluable. Liposomal Grb-2 is a novel, systemic liposomal antisense treatment for blood cancers. Patients eligible for enrollment have refractory or relapsed Acute Myeloid Leukemia (AML), Philadelphia Chromosome Positive Chronic Myelogenous Leukemia (CML), Acute Lymphoblastic Leukemia (ALL), or Myelodysplastic Syndrome (MDS) and who have failed other approved treatments.

The on-going Phase I clinical trial is a dose-escalating study to determine the safety and tolerance of escalating doses of Liposomal Grb-2, as well as the optimal biologically active dose for further development. The trial seeks a total of 18 to 30 evaluable patients and will evaluate at least five doses of Liposomal Grb-2 in five cohorts. An evaluable patient is a patient who has been able to complete the four-week treatment cycle.

As previously reported, since the safety profile of Liposomal-Grb2 is quite favorable, the Company expanded the protocol for its Phase I clinical trial to evaluate higher doses of Liposomal Grb-2 than originally planned. The expanded protocol will continue at 50 percent increments, with the dose for Cohort 5 being 60 mg/m<sup>2</sup> followed by a dose of 90 mg/m<sup>2</sup> for Cohort 6. If advantageous, the Company can continue testing at a higher dose of 135 mg/m<sup>2</sup> with 33 percent increments thereafter. To date, there has been no evidence of significant toxicity from treatment with Liposomal Grb-2. This provides a significant opportunity for the Company to test higher doses in patients in order to find a dose that provides maximum potential benefit and duration of anti-leukemia effect. Importantly, it is noted that through the fourth cohort, a total of nine patients had stabilized, in the opinion of the principal investigator, and had received additional treatments with Liposomal Grb-2. The Company expects to complete the Phase I clinical trial in 2013.

The clinical trial is being conducted at The University of Texas MD Anderson Cancer Center (“MD Anderson”).

- In 2012, the Company added new suppliers for the Grb-2 drug substance and for the final drug in order to support increased dose levels being administered to patients in the Phase I trial, as well as to meet requirements for patients who were stabilized and remained on treatment with Liposomal Grb-2 for extended periods of time. Bio-Path is now well positioned to fulfill all manufacturing needs for the compound for the foreseeable future.
- Bio-Path’s common stock began trading on the OTCQX on Friday June 1, 2012. OTCQX is the highest tier, premier trading platform for OTC companies and Bio-Path is very pleased to have qualified for the OTCQX, given its high standards.

The OTCQX is a premier platform that distinguishes the best companies traded over-the-counter from the thousands of securities traded on the OTC Bulletin Board who are not required to meet any financial standards or undergo a qualitative review.

- During the second quarter of 2012, the Company launched an all-new website providing more detailed and up-to-date information on Bio-Path, its technology, product pipeline and clinical trial advancements.
- In the third quarter of 2012, the Company announced its development plans for Liposomal Grb-2 and that it expects to conduct three Phase II clinical trials of the salvage therapy in combination with current frontline therapy in three of the types of leukemias that are currently being evaluated in the Company's Phase I clinical trial. These indications include AML, CML and MDS. These clinical trials are expected to take place at four of the leading cancer centers in the U.S. in 2013. Jorge Cortes, MD, principal investigator for the Company's Phase I clinical trial, is expected to be principle investigator for the Phase II clinical trials.
- In the fourth quarter of 2012, Bio-Path expanded its Board of Directors from three to four members with the appointment of Michael Garrison to the Company's Board of Directors. Mr. Garrison, 43, is a principal and President of Body Sculpt International, LLC, which owns and operates plastic surgery clinics under the trade name Sono Bello. Prior to founding Body Sculpt International, Mr. Garrison spent 10 years in a variety of executive roles with Dell, Inc., most recently as Director of Marketing, Americas Small and Medium Business. Previously, Mr. Garrison held general management and corporate development positions with ITT Industries, a leading industrial manufacturer. Mr. Garrison holds a Master's degree in Business Administration from Harvard Business School and a Bachelor of Science in Mechanical Engineering from Purdue University.
- Focusing on its longer-term pipeline, the Company announced it is initiating development of its lead cancer drug BP-100-1.01 (Liposomal Grb-2) to treat triple negative breast cancer (TNBC) and inflammatory breast cancer (IBC), two cancers characterized by formation of aggressive tumors and relatively high mortality rates. Bio-Path's plan is to develop Liposomal Grb-2 as a targeted therapy against TNBC and IBC. Treatment goals are two-pronged: the first being to develop Liposomal Grb-2 as a tumor reduction agent in combination with other approved drugs in pre-operative settings, and the second is to develop Liposomal Grb-2 as a drug to treat and control or eliminate cancer metastasis in TNBC and IBC patients. Both of these treatment goals address high need situations for patients.

The developmental plan will be comprised of preclinical testing in cell lines to determine the inhibitory effects of Liposomal Grb-2 on cell growth and invasion followed by preclinical studies in TNBC and IBC animal models. If the preclinical studies confirm benefit, Bio-Path anticipates that it would then proceed to a Phase I clinical trial. The preclinical programs are expected to start in 2013.

- During 2012, Bio-Path continued to increase its profile and presented at three industry conferences including the Biotech Showcase™ in San Francisco, the Rodman and Renshaw Annual Global Investor Conference in New York City and the BIO Investor Forum 2012 in San Francisco. The Company also participated in two retail investor conferences, including the Southern California Investor Conference in Orange County and the BetterInvesting National Convention in Houston. Bio-Path also presented at the Biotech Showcase™ 2013 in San Francisco in January. These conferences are part of the Company's ongoing initiative to increase its visibility amongst investors.
- In 2012, Bio-Path received \$1.8 million in gross proceeds through the sale of shares of the Company's common stock. Subsequently, in the first quarter of 2013 the Company raised an additional \$2 million in cash from the sale of common stock to accredited investors.

- Financial Highlights

- Net loss for the year 2012 was \$(2,582,537), compared to a Net Loss of \$(2,363,344) for the year 2011. The increase in net loss was due to an increase of \$535,910 in research and development expense, primarily due to an approximate \$500,000 increase in expense for drug product material used in the Company's clinical trial, in addition to increased expense for clinical trial operations and advisory services. The increase in research and development expense more than offset a decrease of \$80,130 in related party research and development and a lower general and administrative expense of \$238,716,

which resulted primarily from a \$320,000 decrease in administrative and management stock option expense, offset to some extent by increased expenses associated with being a public company and travel expenses and fees related to participation in industry conferences and meetings. For the full year 2012, the Company reported a net loss per share of \$(0.04) based on 59,317,779 weighted average shares outstanding, compared to \$(0.04) per share for the year 2011.

- Operating expenses of \$2,582,679 for the year 2012 increased by \$217,064 compared to the year 2011, primarily due to increased drug material expense, offset to some extent, by reduced general and administrative expenses for management stock options.
- As of December 31, 2012, the Company had cash of \$534,046, compared to \$952,252 at December 31, 2011. Net cash used in operating activities for the year 2012 was \$(1,993,404) compared to \$(1,149,911) for the year 2011. The primary reasons for the increase in net cash used in operations for the year over year period is the increased cash cost of clinical trial operations, including drug material, as well as receipt in 2011 of a \$244,479 U.S. Government grant that was not matched in 2012. As previously noted, the Company raised an additional \$2 million during the first quarter of 2013.

“Bio-Path continued to make progress in key areas in 2012 and developed a strategic plan for its longer-term pipeline. Our lead drug candidate, Liposomal Grb-2, continued to progress through the clinic and we remain encouraged by the data,” said Peter Nielsen, President and Chief Executive Officer. “In 2012 we upgraded our supplier base drug manufacturing capacity, which is becoming more important as the trial progresses and we approach Phase II readiness. The protocol revision in 2012 expanding our dosing of Liposomal Grb-2 is an important step, as we seek to find an optimal drug dose for treating patients in a Phase II trial. Further, the plans for development of Liposomal Grb-2 into Phase II clinical trials represent a significant opportunity for the Company. We anticipate that this should take place in 2013.”

Mr. Nielsen continued, “Realizing the value of our technology, the Company decided to expand development of BP-100-1.01 into two additional breast cancer indications, IBC and TNBC, for which researchers have already made a strong scientific rationale. This further enhances our pipeline and value proposition.”

#### 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. 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. 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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