

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 14, 2012

**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 2.02 Results of Operations and Financial Condition.**

The information in this Item 2.02 of 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 Item 2.02 of 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 Item 2.02 of this Current Report shall not be incorporated by reference into any registration statement pursuant to the Securities Act of 1933, as amended.

On November 16, 2012, Bio-Path Holdings, Inc. (the “Company”) announced financial results for the third quarter ended September 30, 2012. Additional information is included in the Company’s press release.

A copy of such press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

## **Item 8.01 Other Events.**

On November 14, 2012, the Company issued a press release titled “Bio-Path Holdings Successfully Completes Fourth Cohort in Phase I Clinical Trial of Lead Product Candidate Liposomal Grb-2 in Leukemia.”

A copy of such press release is attached hereto as Exhibit 99.2 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 November 16, 2012
99.2	Press Release dated November 14, 2012

**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: November 16, 2012

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

## EXHIBIT INDEX

Exhibit Number	Description
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99.1	Press Release dated November 16, 2012
99.2	Press Release dated November 14, 2012



## **Bio-Path Holdings Reports Third Quarter 2012 Operational and Financial Results**

**November 16, 2012; 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 quarter ended September 30, 2012.

### **THIRD QUARTER 2012 OPERATIONAL AND FINANCIAL HIGHLIGHTS**

- Recent Operational Highlights
  - Bio-Path completed treatment of the fourth cohort in the Company’s Phase I clinical trial of its lead product candidate, BP-100-1.01 (Liposomal Grb-2), which is a systemic treatment for blood cancers including acute myeloid leukemia (AML), chronic myelogenous leukemia (CML), acute lymphoblastic leukemia (ALL) and myelodysplastic syndrome (MDS). The trial is being conducted at The University of Texas MD Anderson Cancer Center. A total of three patients were enrolled and dosed in the fourth cohort of the study. All three patients completed the 28-day treatment cycle and were evaluable. Liposomal Grb-2 is systemically delivered by intravenous injection. Patients received a dose of 40 mg/m<sup>2</sup> twice a week for four weeks, for a total of eight doses. Preliminary results suggest that Liposomal Grb-2, at a dose of 40 mg/m<sup>2</sup> is well tolerated. As was the case with the three previous cohorts, there continued to be a suggestion of possible anti-leukemia activity. One patient stabilized and qualified to receive additional treatment.

Another positive development is the fact that one patient from Cohort 3 is continuing treatment with Liposomal Grb-2, and is currently in a fourth treatment cycle. This patient started treatment seven months ago at the end of March 2012, and is reportedly in a stable condition at this time as treatment with Liposomal Grb-2 continues.

- As previously reported, the Company is expanding the protocol for its Phase I clinical trial to evaluate higher doses of Liposomal Grb-2. The expanded protocol will continue at 50 percent increments, with the next dose for Cohort 5 being 60 mg/m<sup>2</sup> and the following dose 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 of patients 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.

- The Company announced its development plans for Liposomal Grb-2 and expects to conduct three Phase II clinical trials of Liposomal Grb-2 salvage therapy in combination with the frontline therapy in three of the types of leukemia 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.
  
  - Bio-Path continued to increase its profile amongst the investment community and made a Company presentation at the Rodman & Renshaw investor conference in New York City and at the 11<sup>th</sup> Annual BIO Investor Forum in San Francisco. An archive of these presentations may be found at the Company's website: [www.biopathholdings.com](http://www.biopathholdings.com). 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 is scheduled to present at Biotech Showcase 2013 in January.
  
  - Bio-Path continued raising capital through a private placement, initiated in the second quarter, to raise up to \$2 million through the sale of shares of the Company's common stock to accredited investors. Commitments for approximately \$1.7 million have been received, and through September, sales of approximately \$945,000 of common stock have been finalized including approximately \$800,000 in the third quarter. The balance of funds raised is in various stages of documentation and finalization. Subsequently, in October, the Company amended the offering to allow up to \$4 million of common stock to be sold through December 2012.
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- Financial Highlights
    - Net loss for the third quarter 2012 was \$(840,552), compared to a Net Loss of \$(503,819) in the third quarter 2011. The increase in net loss was due to an increase in research and development expense from a higher cost of drug material, which more than offset a decrease in general administrative expense during the same periods. For the third quarter of 2012, the Company reported a net loss per share of \$(0.01) based on 58,902,046 weighted average shares outstanding, compared to \$(0.01) per share for the same period last year.
  
    - Operating expenses of \$840,489 in the third quarter of 2012 increased by \$336,000 compared to the third quarter 2011, primarily due to increased drug material expense, offset to some extent, by reduced administrative expenses for management stock options.
  
    - As of September 30, 2012, the Company had cash of \$332,862, compared to \$952,252 at December 31, 2011. Net cash used in operating activities for the first nine months of 2012 was \$(1,567,536) compared to \$(726,157) for the first nine months of 2011. The primary reasons for the increase in net cash used in operations between the comparable nine month period is the increased 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 is currently conducting a private placement, which has raised \$945,000 to date. The Company has received additional commitments for up to \$700,000, which are in various stages of being finalized.

“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. “We have begun to put into place a protocol to expand our clinical development of Liposomal Grb-2 into Phase II clinical trials and anticipate that this should take place in 2013. We look forward to continuing to work with the renowned University of Texas MD Anderson Cancer Center, as well as expand our trial sites into three additional prominent cancer centers in the U.S.”

### 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](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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## **Bio-Path Holdings Successfully Completes Fourth Cohort in Phase I Clinical Trial of Lead Product Candidate Liposomal Grb-2 in Leukemia**

- *Drug Well-Tolerated and Possible Anti-Leukemia Activity Continues to be Demonstrated -*
- *Positive Safety Data Allows for Testing Higher Doses in Phase I -*
- *Company to Expand Clinical Program to Include Three Phase II Trials in Three Hematologic Cancer Indications -*

### **FOR IMMEDIATE RELEASE**

**November 14, 2012 HOUSTON, TX** – Bio-Path Holdings, Inc., (OTCQX: BPTH) (“Bio-Path”), a biotechnology company developing a liposomal delivery technology for nucleic acid antisense cancer drugs, today announced that it has completed treatment of the fourth dosage cohort in its Phase I clinical trial of its lead product candidate, BP-100-1.01 (Liposomal Grb-2), which is a systemic treatment for blood cancers including acute myeloid leukemia (AML), chronic myelogenous leukemia (CML), acute lymphoblastic leukemia (ALL) and myelodysplastic syndrome (MDS). The trial is being conducted at The University of Texas MD Anderson Cancer Center (MD Anderson Cancer Center). The drug’s safety profile continues to be favorable with no treatment-related serious adverse events reported and data continues to suggest some possible anti-leukemia activity. Due to the favorable safety profile of Liposomal Grb-2 demonstrated to date, Bio-Path announced plans to integrate higher dosing into the Phase I clinical trial.

Separately, Bio-Path provided an update on clinical development of Liposomal Grb-2 announcing its intent to conduct three Phase II clinical trials of Liposomal Grb-2 salvage therapy in combination with frontline therapy in three different leukemia disease types.

#### *Completion of Cohort 4*

A total of three patients were enrolled and dosed in the fourth cohort of the study. All three patients completed the 28-day treatment cycle and were evaluable. Liposomal Grb-2 is systemically delivered by intravenous injection. Patients received a dose of 40 mg/m<sup>2</sup> twice a week for four weeks, for a total of eight doses. Preliminary results suggest that Liposomal Grb-2, at a dose of 40 mg/m<sup>2</sup> is well tolerated. The protocol for the clinical trial includes dose escalation of 5, 10, 20, 40 and 50 mg/m<sup>2</sup>. The expected dose for treatment is 45 mg/m<sup>2</sup> based on pre-clinical studies in animals.

As was the case with the three previous cohorts, there continued to be a suggestion of possible anti-

leukemia activity. One patient stabilized and qualified to receive additional treatment. Two other AML patients with more than 90 percent blast count did not receive extended treatment.

Another positive development is the fact that one patient from Cohort 3 is continuing treatment with Liposomal Grb-2, and is currently in a fourth treatment cycle. This patient started treatment seven months ago at the end of March 2012, and is reportedly in a stable condition at this time as treatment with Liposomal Grb-2 continues.

“The data from Cohort 4 continues to be consistent with earlier cohorts of the trial, demonstrating consistent safety, as well as a continuation of possible anti-leukemia activity related to the drug,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path. “We continue to be very encouraged as the trial continues, particularly as it is important to remember that patients in our clinical trial are refractory or relapsed to current therapies and have failed other approved treatments. These patients have very advanced stages of disease, and are often in very poor condition. Although fewer patients in Cohort 4 qualified for extended treatment, it is interesting to note that the two who did not qualify for extended treatment were both AML patients with more than 90 percent blast count. It may be that there just was not enough drug administered at the Cohort 4 dose level for stabilization to occur in these severely ill patients.”

#### *Testing of Higher Doses in the Phase I Clinical Trial*

To date, there has been no evidence of significant toxicity from treatment of patients 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. Bio-Path’s Phase I protocol calls for stopping testing after the final dose of 50 mg/m<sup>2</sup> in Cohort 5. The Principal Investigator for the clinical trial, in consultation with Bio-Path’s Board of Directors, determined that with the absence of any real toxicity barriers, the Company should continue to evaluate higher doses of Liposomal Grb-2.

Dosages of Liposomal Grb-2, evaluated to date, in Cohorts 1 through 4 of the clinical trial consisted of 5, 10, 20 and 40 mg/m<sup>2</sup>. The expanded protocol will continue at 50 percent increments, with the next dose for Cohort 5 being 60 mg/m<sup>2</sup> and the following dose 90 mg/m<sup>2</sup> for Cohort 6. As with the previously approved protocol, dosing stops if a maximum tolerated dose (MTD) is reached; this will continue to be the case with the revised protocol. However, since it is felt among the clinical team and the Company that a MTD will likely not be reached, the Company will halt testing once an optimally biological dose is achieved. If advantageous, the Company can continue testing at a higher dose of 135 mg/m<sup>2</sup> with 33 percent increments thereafter.

The Company has submitted the updated dosing plan to the U.S. Food and Drug Administration (FDA) and has just recently received approval from the MD Anderson Cancer Center’s Institutional Review Board for the revised protocol. All necessary steps to proceed with the new Cohort 5 dosing are expected to be completed by the end of December 2012. Assuming that only two additional cohorts, testing higher doses of the drug candidate are needed, dosing in the Phase I clinical trial should be completed by mid-year 2013.

“We are extremely fortunate that the safety profile of our drug candidate Liposomal Grb-2 allows us to continue dosing at higher levels. By testing additional doses, we should be able to determine an optimal dose for response of treatment and duration of response, providing us with additional information in order to be more proficient in the design of future clinical trials, positioning us for

likelier success, said Mr. Nielsen.”

### *Phase II Clinical Trials of Liposomal Grb-2 Combination Salvage Therapy in Three Separate Types of Leukemia*

Separately, Bio-Path today announced plans to further progress Liposomal Grb-2 into Phase II development. Following discussions with the Principal Investigator for the Clinical Trial and Bio-Path’s Board of Directors, the Company plans to conduct three Phase II clinical trials of Liposomal Grb-2 salvage therapy in three of the types of leukemia that are currently being evaluated in the Company’s Phase I clinical trial. These indications include AML, CML and MDS.

While not yet finalized, the outline of the proposed clinical program for Liposomal Grb-2 is to evaluate the compound in a Phase I/II clinical trial in combination with the frontline therapy for each of the leukemia types: AML, CML and MDS. The Phase I portion of the trial will be a single cohort in three patients to test for any potential negative synergies of using the two drugs together. After successfully passing that test, the clinical trial would immediately proceed into a Phase II trial.

The Phase II trial in each of the diseases: AML, CML and MDS, is planned to have 25 to 30 patients per indication. The trials will be conducted at four of the leading cancer centers in the nation, including the MD Anderson Cancer Center. Dr. Jorge Cortes will continue in his role as Principal Investigator for the Phase II clinical trials. The primary endpoint for the study is contemplated to be duration of response. It is expected that there will be only one combination dose administered to each patient in their respective Phase II trial, and consequently, there will not be any time-consuming dose escalation steps. Each patient will receive a full treatment cycle, consisting of two doses per week for four weeks. Utilizing the expertise of four leading cancer centers in the Phase II program should allow the trial to proceed at a good pace. Ideally, once the Phase II portion of the trial is opened it should be possible for dosing to be completed within six months. The Company anticipates starting and completing this phase of development in 2013.

Lastly, in commenting on the Phase II clinical trials, Mr. Nielsen said, “The plans to develop Liposomal Grb-2 as combination salvage therapy treatment for advanced stage patients with AML, CML and MDS is an extremely important development for Bio-Path. The opportunity for three drug approvals in a relatively moderate time frame is a potentially significant opportunity for Bio-Path’s shareholders. Down regulation of the Grb-2 protein acts like a light switch in shutting down the leukemia cancers being studied. Liposomal Grb-2 in combination with frontline therapies has the potential to extend effectiveness of frontline therapies indefinitely in these patients, which would be a major therapeutic milestone for patients.”

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