

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 15, 2013

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

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<b>Utah</b> (State or other jurisdiction of incorporation)	<b>000-53404</b> (Commission File Number)	<b>87-0652870</b> (IRS Employer Identification No.)
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<b>2626 South Loop, Suite 180, Houston, Texas</b> (Address of principal executive offices)	<b>77054</b> (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))
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**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 November 15, 2013, Bio-Path Holdings, Inc. (the “Company”) announced financial results for the third quarter ended September 30, 2013. Additional information is included in the Company’s press release.

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 Number</u>	<u>Description</u>
99.1	Press Release dated November 15, 2013

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**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: November 18, 2013

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

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**EXHIBIT INDEX**

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated November 15, 2013

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**Bio-Path Holdings Reports Third Quarter 2013  
Operational and Financial Results**

**November 15, 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 third quarter ended September 30, 2013.

**THIRD QUARTER 2013 OPERATIONAL AND FINANCIAL HIGHLIGHTS**

- Recent Operational Highlights
    - o During the quarter, two patients completed treatment in the sixth dosage cohort of Bio-Path’s Phase I clinical trial evaluating its lead product candidate, BP-100-1.01 (Liposomal Grb-2), as a systemic treatment for blood cancers including acute myeloid leukemia (AML), chronic myelogenous leukemia (CML), acute lymphoblastic leukemia (ALL) and myelodysplastic syndrome (MDS). The drug’s safety profile continues to be favorable with no treatment-related serious adverse events reported and data continues to suggest possible anti-leukemia activity. The trial is being conducted at The University of Texas MD Anderson Cancer Center (MD Anderson Cancer Center).

To date, the Company has successfully completed five cohorts of the study and has completed two-thirds of the sixth cohort. A total of 33 patients have been enrolled into the Phase I clinical trial, of which 20 have been evaluable. The Company is waiting on drug resupply to complete the sixth cohort, which is not expected to be received until the first quarter next year. Of the two patients enrolled into the sixth dosage cohort that were evaluable, both stabilized and there was sufficient drug on hand for one patient to receive an extended treatment cycle. Liposomal Grb-2 is a novel, systemic liposomal antisense treatment for blood cancers. Patients eligible for enrollment have refractory or relapsed disease and have failed other approved treatments, and recent enrollment has focused on advanced age AML patients.

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 Company intends to evaluate patient results at the end of Cohort 6 to determine if the optimal biological dose has been reached, which would bring a close to the Phase I clinical trial. The new down-regulation assay of inhibition is expected to be available for use in that determination.

    - o In the third quarter of 2013, Bio-Path announced that a scientific assay has confirmed that its lead product candidate Liposomal Grb-2 inhibits the disease-causing target protein in patients with blood cancers. The Company considers this to be a major milestone in the development of antisense therapeutics.
    - o In November 2013, Bio-Path announced that there will be a poster presentation by Dr. Jorge Cortes, deputy chair and professor of medicine in the Department of Leukemia at The University of Texas MD Anderson Cancer Center, at the 55th Annual Meeting of the American Society of Hematology (ASH) in New Orleans. The poster will highlight the aforementioned assay that was developed to measure inhibition of the disease target protein Grb-2 in patients’ peripheral blood samples from the on-going Phase I trial evaluating the Company’s lead compound, Liposomal Grb-2 antisense oligonucleotides in hematological cancers.
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- o Bio-Path initiated preclinical testing of its lead product candidate, Liposomal Grb-2, into two additional indications: triple negative breast cancer (TNBC) and inflammatory breast cancer (IBC), two cancers characterized by formation of aggressive tumors and relatively high mortality rates. During the quarter, Bio-Path also initiated preclinical testing of Liposomal Grb-2 in combination treatment with frontline therapy in blood cancers.
- o During the quarter, Bio-Path announced that it had retained Maxim Group LLC, as a financial advisor. Maxim will focus on assisting Bio-Path in its strategies for maximizing shareholder value through its full scope of investment banking services.
- o Bio-Path continued to increase its profile amongst the investment community and presented at the Bio Investor Forum 2013 in San Francisco in October.
- o In November 2013, the Company filed a shelf registration statement with the United States Securities and Exchange Commission (SEC), which has not yet been declared effective, to register the offering and sale of up to \$100 million of Bio-Path's securities. There can be no assurance that the shelf registration statement will be declared effective.
- o Bio-Path sold approximately \$3.2 million in shares of common stock, during the third quarter, in a private placement that has been closed.

- Financial Highlights

- o The Company reported a net loss of \$1,393,207 for the three month period ended September 30, 2013, compared to a net loss of \$840,552 for the three month period ended September 30, 2012. The increase was due to general and administrative expenses being higher in the quarter ended September 30, 2013 due to a non-cash expense of approximately \$595,000, resulting from a stock option grant made to officers and management. The last stock option grant to officers and management was in 2008. Excluding this expense, the net loss for the three month period ending September 30, 2013 was approximately \$42,000 lower than the comparable three month period ending September 30, 2012. For the third quarter 2013, the Company reported a net loss per share of \$(0.02) based on 75,380,214 weighted average shares outstanding, compared to \$(0.01) per share for the same period in 2012.
  - o Operating expenses of \$1,393,728 in the third quarter of 2013 were higher by \$553,239 compared to the third quarter of 2012 due to higher general and administrative expense resulting from non-cash stock option expense from a grant made to officers and management. Excluding the non-cash officer and management stock option expense, operating expenses during the three month period ending September 30, 2013 were approximately \$42,000 lower than for the comparable three month period ending September 30, 2012.
  - o As of September 30, 2013, the Company had cash of \$4,100,841, compared to \$534,046 at December 31, 2012. Net cash used in operating activities for the first nine months of 2013 was \$(1,836,311) compared to \$(1,567,536) for the first nine months of 2012. The increase in net cash used in operations between the comparable nine month periods is primarily related to an increase in cash expenses for research and development for drug material and testing; and an increase in cash used in paying down accounts payable, offset to some extent by reduced cash expenses for general and administrative expenses.
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“Bio-Path continues to build momentum in both its clinical and corporate development activities,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path. “On the corporate side, we continued to shore up our balance sheet with the completion of a private placement of common stock, resulting in currently having the highest level of cash on hand in the Company’s history. We are also excited to be working with such a successful and experienced investment banking firm as Maxim Group LLC. Through Maxim, we look forward to continue to increase shareholder value.”

Mr. Nielsen continued, “We also had success advancing our technology, although our Phase I clinical trial did slow while awaiting drug resupply. The upcoming ASH poster presentation will be the second time that data regarding our lead product candidate will be presented at this prestigious scientific conference. Unfortunately, due to drug supply issues, patients treated in the sixth cohort were not able to continue treatments beyond the clinical trial protocol, and we needed to slow enrollment into the study. In spite of these issues, we expect drug resupply in the first quarter of 2014, at which time cohort 6 should be completed fairly quickly. Importantly, regardless of the delay, Liposomal Grb-2 continues to show no signs of toxicity, while continuing to show anti-leukemia effects and potential for inhibition of AML and MDS disease in patients.”

#### 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.*

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For more information, please visit the Company's website at <http://www.biopathholdings.com>.

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