

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): May 16, 2013

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

Utah

(State or other jurisdiction
of incorporation)

000-53404

(Commission File Number)

87-0652870

(IRS Employer Identification No.)

2626 South Loop, Suite 180, Houston, Texas

(Address of principal executive offices)

77054

(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 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, as amended, 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 May 16, 2013, Bio-Path Holdings, Inc. (the “Company”) announced financial results for the first quarter ended March 31, 2013. Additional information is included in the Company’s press release dated May 16, 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 Number</u>	<u>Description</u>
99.1	Press Release dated May 16, 2013

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: May 16, 2013

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated May 16, 2013



Bio-Path Holdings Reports First Quarter 2013 Operational and Financial Results

May 16, 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 first quarter ended March 31, 2013.

FIRST QUARTER 2013 OPERATIONAL AND FINANCIAL HIGHLIGHTS

- Recent Operational Highlights

- o During the quarter, Bio-Path began enrolling patients into the fifth dosage cohort of its Phase I clinical trial of its lead product candidate, BP-100-1.01 (Liposomal Grb-2), which is being evaluated 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 trial is being conducted at The University of Texas MD Anderson Cancer Center. As of May 2013, three patients have been enrolled and treated and the Company anticipates that all three will be evaluable, meeting the requirement to proceed to Cohort 6 during the second quarter 2013.

To date, the Company has successfully completed the first four cohorts of the study. 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 disease and 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.

- o Bio-Path continued to increase its profile amongst the investment community and presented at the Biotech Showcase™ in San Francisco in January.
- o In February and March of 2013, the Company sold \$346,201 of shares of its common stock in a private placement. After the close of the first quarter, the Company received an additional \$2.26 million from the completion of its private placement. Over an approximate twelve month period ending March 31, 2013 the Company sold approximately \$4 million of shares of its common stock to accredited investors in a private placement.
- o In April of 2013, the Company executed agreements to sell an additional \$550,000 of shares of its common stock in a private placement to accredited investors, of which the balance of \$102,000 is expected to be received by May 31, 2013.

- Financial Highlights

- o Net loss for the first quarter 2013 was \$(656,002), compared to a Net Loss of \$(522,227) for the first quarter 2012. The increase in net loss was due to an increase of \$121,486 in research and development expense, primarily due to an approximate \$96,110 increase in expense for drug product material used in the Company’s clinical trial, and an increase of \$20,842 in clinical trial operations expense. For the first quarter 2013, the Company reported a net loss per share of \$(0.01) based on 62,219,050 weighted average shares outstanding, compared to \$(0.01) per share for the first quarter 2012.
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- o Operating expenses of \$655,910 for the first quarter 2013 increased by \$133,283 compared to the first quarter of 2012, primarily due to increased drug material expense and clinical operation expense, in addition to small increases in research and development expense-related party and general and administrative expense.
- o As of March 31, 2013, the Company had cash of \$288,707 compared to \$534,046 at December 31, 2012. Net cash used in operating activities for the first quarter 2013 was \$(551,004) compared to \$(400,189) for the first quarter 2012. The primary reasons for the increase in net cash used in operations for the first quarter 2013 is the increased cost of clinical trial operations, including drug material used, compared to the first quarter 2012. As previously noted, the Company received an additional \$2.26 million after the close of the first quarter of 2013 and expects to receive an additional \$102,000 by May 31, 2013.

“Bio-Path had significant success over the last few months raising capital through the sale of shares of its common stock, culminating in excess of \$2 million raised. We believe this reflects investors’ positive sentiments about Bio-Path’s progress and we thank them for their continued support,” said Peter Nielsen, President and Chief Executive Officer. “On the clinical development front, our lead drug candidate, Liposomal Grb-2, continued to progress through the clinic and we remain encouraged by the data. Cohort 5 enrollment and testing moved very quickly once the latest shipment of drug supply became available from our manufacturer. Our recent patient focus has been on AML patients in advanced stages of the disease, which is a very challenging patient population that represents a significant therapeutic opportunity for the Company. We continue to anticipate that Cohort 6 could potentially be the last round of the Phase I trial.

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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