

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): March 17, 2015

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

**Delaware**

(State or other jurisdiction  
of incorporation)

**000-53404**

(Commission File Number)

**87-0652870**

(IRS Employer Identification No.)

**4710 Bellaire Boulevard, Suite 210, Bellaire, Texas**

(Address of principal executive offices)

**77401**

(Zip Code)

(832) 742-1357

(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 March 17, 2015, Bio-Path Holdings, Inc. (the “Company”) announced financial results for the year ended December 31, 2014. 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<br/>Number</u> | <u>Description</u>                 |
|---------------------------|------------------------------------|
| 99.1                      | Press Release dated March 17, 2015 |

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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: March 17, 2015

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

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**EXHIBIT INDEX**

Exhibit  
Number

Description

99.1

Press Release dated March 17, 2015

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**Bio-Path Holdings Reports Fiscal Year 2014  
Operational and Financial Results**

**March 17, 2015; HOUSTON, TX** – Bio-Path Holdings, Inc., (NASDAQ: 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 ended December 31, 2014.

**2014 OPERATIONAL AND FINANCIAL HIGHLIGHTS**

- 2014 Operational Highlights
    - o In the fourth quarter of 2014, Bio-Path successfully completed Cohort 6 of its Phase 1 clinical trial evaluating its lead compound, Liposomal Grb-2, in blood cancers. Three patients were evaluated in Cohort 6 and this cohort was consistent with previous cohorts in demonstrating that Liposomal Grb-2 (“BP1001”) was well tolerated with the drug showing signs of anti-leukemia activity. As a result of the safety profile of the drug, and the reduction of the target Grb-2 protein achieved in the patients tested, a maximum tolerated dose has yet to be reached.
 

A total of 34 patients, of which 21 were evaluable, enrolled into the Phase 1 clinical trial, which evaluated escalating doses of Liposomal Grb-2 (5, 10, 20, 40, 60 and 90 mg/m<sup>2</sup>). Patients were treated twice a week for four weeks, for a total of eight doses. Liposomal Grb-2 is a novel, systemic liposomal antisense treatment for blood cancers. Patients eligible for enrollment had refractory or relapsed leukemic disease and had failed other approved treatments.
    - o Subsequent to completion of Cohort 6 in the Phase 1 trial, enrollment into the safety segment of a Phase 2 study evaluating Liposomal Grb-2 in patients with acute myeloid leukemia (AML) was initiated. This segment of the study will evaluate two doses (60 mg/m<sup>2</sup> and 90 mg/m<sup>2</sup>) of Liposomal Grb-2 in combination with low dosage Ara-C therapy. Each dose cohort will include three patients with AML for a total of six patients. The endpoint of this study segment is safety of the combination of the two drugs. The clinical trial is taking place at MD Anderson Cancer Center. Bio-Path expects results of this portion of the study in the second half of 2015.
    - o Bio-Path completed preclinical testing of Liposomal Grb-2 in combination therapy with current treatments for chronic myelogenous leukemia (CML) and AML. Analysis of the results suggest that using Liposomal Grb-2 in combination with standard frontline therapies can potentially produce significant benefits in treating CML and AML patients. Treating AML cell lines with Liposomal Grb-2 and Cytarabine (“Ara-C”), a currently approved therapy, produced an additional 45 percent to 66 percent effectiveness compared to treating the AML cells with Cytarabine alone. Treating CML cell lines with Liposomal Grb-2 and Dasatinib, another front line treatment, produced an additional 18 percent to 58 percent effectiveness compared to treating the CML cells with only Dasatinib.
    - o During 2014, Bio-Path expanded its pipeline, initiating 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. The Company is working in collaboration with a leading researcher working in the MD Anderson breast cancer program. The Company expects to complete the final *in vivo* segment of the preclinical program in 2015.
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- o In the fourth quarter of 2014, Bio-Path announced that it has initiated development of its second product candidate, Liposomal Bcl-2, as a treatment for follicular lymphoma. The Company is completing a preclinical package of toxicity, tissue distribution, pharmacokinetics and efficacy studies, and anticipates filing an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) in 2015. Bio-Path expects that the favorable toxicity profile of its lead drug candidate (Liposomal Grb-2) will allow a Phase 1 clinical trial of this second drug to start at a higher dose, thus, reducing the number of patients required to complete the safety phase of the clinical trial.

Liposomal Bcl-2 (“L-Bcl-2”) is a liposomal encapsulated oligonucleotide targeted to the translation initiation site of human Bcl-2 mRNA. Bcl-2 overexpression has been associated with up to 60 percent of cancers. The antisense oligonucleotide in L-Bcl-2 used by Bio-Path Holdings is a nuclease-resistant, hydrophobic analog of phosphodiester containing the Company’s proprietary P-ethoxy backbone.

- o Bio-Path strengthened its manufacturing process in 2014, with the goal of increased capability and capacity. During the year, the Company commenced the process of bringing on two new suppliers to the drug product supply chain in order to provide increased scheduling flexibility.
- o During the year, Bio-Path occupied its new office and more fully developed its team and infrastructure. Bio-Path’s office is now located near the Houston Medical Center and closer to MD Anderson and other biopharmaceutical and research institutions. Bio-Path appointed Ulrich Mueller, Ph.D., as Chief Operating Officer and added other significant team members in all parts of the Company’s operations.
- o Bio-Path announced the appointment of Amy P. Sing, M.D. to its Board of Directors. Dr. Sing has an extensive drug development background, and notably, led the oversight of the Investigator Sponsored Trials (IST) program for the now approved breast cancer drug Avastin.
- o Bio-Path continued to increase its profile amongst the investment community and presented at the Biotech Showcase in January 2014 and the Bio Investor Forum 2014 in San Francisco in October. On October 17, 2014, Bio-Path had the honor of ringing the Closing Bell of NASDAQ.

- Financial Highlights

- o Net loss for the year 2014 was \$(4.5) million, compared to a Net Loss of \$(3.3) million for the year 2013. The increase in net loss was primarily due to an increase of approximately \$1.1 million in general and administrative expense, which resulted from an increase of \$0.9 million in organization cost, increased expense of \$0.4 million for being a NASDAQ listed company including increased legal, auditor and insurance expense and an increase of \$0.2 million in all other expenses of operation. These costs were offset to some extent by reduced stock option expense of \$0.4 million for management, officers, directors and new staff members. Research and development expense increased by \$0.1 million, due primarily to higher manufacturing development and testing expense. For the full year 2014, the Company reported a net loss per share of \$(0.05) based on 89,281,622 weighted average shares outstanding, compared to \$(0.05) per share for the year 2013.
  - o Operating expenses increased by \$1.3 million to \$4.5 million for the year 2014 compared to 2013, primarily due to increased organization expense, offset to some extent by lower stock option expense for personnel involved in administrative activities.
  - o As of December 31, 2014, the Company had cash of \$13.9 million, compared to \$3.6 million at December 31, 2013. Net cash used in operating activities for the year 2014 was \$(3.8) compared to \$(2.3) million for the year 2013. The primary reasons for the increase in net cash used in operations for the year over year period is the increased cash costs of general and administrative activities. As previously reported, the Company raised gross proceeds of an additional \$15 million during the first quarter of 2014.
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“2014 was transformational for Bio-Path. Importantly, our product pipeline advanced with our lead product candidate moving into Phase 2 development. In addition, we progressed our second product candidate toward the clinic and continued to develop our preclinical pipeline,” said Peter Nielsen, President and Chief Executive Officer. “Operationally, we strengthened our organization and upgraded our facilities. After raising \$15 million through our first institutional direct offering of common stock, Bio-Path’s shares were uplisted to the NASDAQ Capital Market and added to the Russell Global, Russell 3000® and Russell Microcap® Indexes. These accomplishments reflect the dedication of the entire Bio-Path team and we are excited by the prospects for 2015 and 2016, particularly with the on-going advancement and development of our pipeline.”

#### **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 proprietary, 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-1001 is a neutral-charge, liposome-incorporated antisense drug substance designed to inhibit Grb-2 expression.

#### **About Follicular Lymphoma**

Lymphoma is the most common blood cancer. The two main forms of lymphoma are Hodgkin lymphoma and non-Hodgkin lymphoma (NHL). Lymphoma occurs when cells of the immune system called lymphocytes, a type of white blood cell, grow and multiply uncontrollably. These cancerous lymphocytes can travel to many parts of the body, including the lymph nodes, spleen, bone marrow, blood, or other organs, and form a mass called a tumor.

#### **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 2 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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