

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): August 11, 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, 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 August 11, 2015, Bio-Path Holdings, Inc. (the “Company”) announced financial results for the quarter ended June 30, 2015. 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 August 11, 2015

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: August 12, 2015

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

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated August 11, 2015



**Bio-Path Holdings Reports Second Quarter 2015
Operational and Financial Results**

August 11, 2015; HOUSTON, TX – Bio-Path Holdings, Inc., (NASDAQ: BPTH) (“Bio-Path”), a biotechnology company leveraging its proprietary liposomal delivery technology to develop a portfolio of targeted nucleic acid cancer drugs, today announced operational and financial results for the quarter ended June 30, 2015.

SECOND QUARTER 2015 AND RECENT OPERATIONAL AND FINANCIAL HIGHLIGHTS

- o The data package for the monotherapy portion of the Phase 1 clinical trial of Bio-Path’s lead compound, Liposomal Grb-2 (“BP-1001”), in blood cancers was finalized during the quarter. Liposomal Grb-2 was well tolerated with the drug showing signs of anti-leukemia activity and no drug related toxicities. Among 21 evaluable patients, more than half experienced at least a fifty percent (50%) reduction in peripheral or bone marrow blasts from baseline. Additionally, several patients demonstrated transient improvement and/or stable disease. Notably, one patient with Chronic Myelogenous Leukemia (CML) blast phase showed a significant reduction in blasts. The patient data from the Phase I clinical trial also demonstrated significant reductions in the target Grb-2 protein and its downstream proteins, providing positive evidence that Bio-Path’s DNAbilize™ neutral lipid delivery with proprietary antisense technology successfully delivers an antisense drug substance to a diseased cell to knock down the target protein, which is an industry-first for antisense systemic therapeutics.
- o Enrollment continues into the safety portion of the Phase 2 combination trial evaluating Liposomal Grb-2 and low dose Ara-C frontline therapy in patients with Acute Myeloid Leukemia (AML). The safety portion of the Phase 2 trial is designed to assess two cohorts with three patients each: 60 mg/m² of Liposomal Grb-2 and frontline Ara-C and 90 mg/m² of Liposomal Grb-2 and frontline Ara-C in its intended use in combination with an existing chemotherapeutic agent. Bio-Path expects this portion of the program will be completed in the second half of 2015.

The Phase 2 combination trial will target older AML patients who are unfit for intense treatment. The average age of diagnosis for AML is 66 years old. However, older patients do not tolerate intense chemotherapy well and treatment related mortality is a major concern among AML patients greater than 65 years old, representing approximately sixty percent (60%) of AML patients. This patient segment represents an unmet need for an approach that provides quality of life and provides an excellent opportunity for clinical development of Liposomal Grb-2.

- o An abstract has been submitted by Jorge Cortes, M.D., Professor and Deputy Chair, Department of Leukemia, The University of Texas MD Anderson Cancer Center (MD Anderson Cancer Center) and staff for presentation of the specific data from the Phase 1 clinical trial monotherapy testing of Liposomal Grb-2, which is planned to be reviewed at the Annual Society of Hematology (ASH) meeting in December. In addition, the available data from the safety portion of the Phase 2 trial combination therapy evaluating Liposomal Grb-2 and low dose Ara-C frontline therapy in patients with AML is also to be included in the data package for presentation at the ASH meeting.
 - o Bio-Path commenced development during the quarter of a protocol for a Phase 2 clinical trial evaluating Liposomal Grb-2 and frontline therapy in patients with CML in blast crisis, which is an unmet need. The Company expects to complete preparations to initiate the toxicity portion of this Phase 2 trial by the end of 2015.
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- o Product candidate vetting and development continued during the quarter to support efforts to broaden the Company's product pipeline. These product candidates include opportunities in the cancer area as well as candidates outside of cancer such as autoimmune disease.
 - o Preclinical testing of its lead product candidate, Liposomal Grb-2, is continuing, into two additional indications: triple negative breast cancer (TNBC) and inflammatory breast cancer (IBC), two cancers characterized by the formation of aggressive tumors and relatively high mortality rates. The Company is working in collaboration with a leading researcher working in the The University of Texas MD Anderson Cancer Center (MD Anderson) breast cancer program. The Company completed testing of a monotherapy *in vivo* segment of the preclinical program and is evaluating the results. The preclinical program may be expanded to include a combination therapy evaluation.
 - o Bio-Path has retained a public relations firm specializing in biotech and large pharmaceutical company public relations. Key among the goals will be increasing industry and investor awareness of Bio-Path's DNAbilize™ neutral lipid delivery of p-ethoxy antisense technology and Bio-Path as a multi-product candidate company.
 - o Bio-Path established an "at-the-market" ("ATM") program during the quarter through which it may offer and sell up to \$25 million of common stock from time to time, at Bio-Path's discretion, through an investment banker, acting as sales agent. Sales of Bio-Path common stock under the ATM program may be made directly on or through the Nasdaq Capital Market, among other methods.
- Second Quarter 2015 Financial Highlights
 - o The Company reported a net loss of \$1.1 million for the three months ended June 30, 2015, compared to a net loss of \$1.3 million for the three months ended June 30, 2014. The decrease was primarily due to decreased management and administrative personnel costs. The Company reported a net loss per share of \$0.01 for both the three months ended June 30, 2015 and June 30, 2014. Net loss for the six months ended June 30, 2015 was \$2.5 million, or \$0.03 per share, compared to a net loss of \$1.8 million, or \$0.02 per share, for the six months ended June 30, 2014. The increase was primarily due to increased manufacturing development and preclinical study costs as well as personnel costs associated with the addition of research and development support staff in the latter half of 2014.
 - o Research and development expenses for the three months ended June 30, 2015 increased to \$0.6 million compared to \$0.5 million for the three months ended June 30, 2014. For the six months ended June 30, 2015, research and development expenses increased to \$1.2 million compared to \$0.6 million for the six months ended June 30, 2014.
 - o General and administrative expenses for the three months ended June 30, 2015 decreased to \$0.6 million compared to \$0.8 million for the three months ended June 30, 2014. For the six months ended June 30, 2015, general and administrative expenses increased to \$1.4 million compared to \$1.1 million for the six months ended June 30, 2014.
 - o As of June 30, 2015, the Company had cash of \$11.1 million, compared to \$13.9 million at December 31, 2014. Net cash used in operating activities for the six months ended June 30, 2015 was \$2.8 million compared to \$1.6 million for the comparable period in 2014.

"Completion of the data package for the monotherapy portion of the Phase 1 trial of Liposomal Grb-2 in blood cancers was a significant milestone in wrapping up that portion of the trial," said Peter Nielsen, President and Chief Executive Officer of Bio-Path. "The data demonstrates that Liposomal Grb-2 is a targeted therapy treatment that does not have treatment side effects, which greatly enhances its potential for combination therapy with other frontline treatments. The safety portion of our Phase 2 combination therapy trial is gaining momentum. The submission of the abstract to the ASH meeting for a presentation of both the monotherapy portion of the Phase 1 plus the early cohorts from the Phase 2 combination therapy trial presents an early opportunity to highlight the potential of Liposomal Grb-2 combination therapy with Ara-C to treat an important, unmet need of the AML population. We believe development of Liposomal Grb-2 with AML fragile patient population is an exciting development opportunity. We continue to make significant progress in building a solid pipeline of cancer therapies, which is a key goal for Bio-Path. We recently initiated plans and development for a Phase 2 trial of Liposomal Grb-2 combination therapy in CML blast crisis patients. This is another unmet patient area with a high priority. Preparation of the Liposomal Bcl-2 package to initiate a trial in follicular lymphoma is also on track. Development of our preclinical pipeline has increased, adding product candidate opportunities outside of cancer that could benefit from our unique delivery technology."

Mr. Nielsen continued, “Operationally, the retention of a top firm to work with Bio-Path to build and implement a comprehensive public relations program is an important corporate development step. Bio-Path’s technology, clinical development and organization have progressed far enough now that we expect this be a very effective communications and media program. Our balance sheet continues to be strong, with sufficient cash to continue our development programs through 2015 and into 2016. In addition, the establishment of a \$25 million ATM financing program provides us the ability to raise additional capital in the short term if needed.”

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 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. 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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