

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 11, 2016

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

Delaware

(State or other jurisdiction
of incorporation)

001-36333

(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 on Form 8-K (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 11, 2016, Bio-Path Holdings, Inc. (the “Company”) announced financial results for the quarter ended March 31, 2016. 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 May 11, 2016

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Company has duly caused this Current Report to be signed on its behalf by the undersigned hereunto duly authorized.

BIO-PATH HOLDINGS, INC.

Dated: May 11, 2016

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 May 11, 2016



BIO-PATH HOLDINGS REPORTS FIRST QUARTER 2016 FINANCIAL RESULTS

Conference Call to be Held Today at 8:30 A.M. ET

HOUSTON—May 11, 2016 – Bio-Path Holdings, Inc., (NASDAQ: BPTH), a biotechnology company leveraging its proprietary DNAbilize™ liposomal delivery and antisense technology to develop a portfolio of targeted nucleic acid cancer drugs, today announced its financial results for the first quarter ended March 31, 2016 and also provided an update on recent corporate developments.

“2016 is already proving to be a truly pivotal year for Bio-Path as we advanced our clinical programs and further validated our DNAbilize™ technology with two important research collaborations,” said Peter Nielsen, President and CEO of Bio-Path Holdings. “We were pleased to announce the completion of the safety segment of our Phase II trial of BP1001 in acute myeloid leukemia. These results are encouraging and allow us to move forward with the efficacy portion of the study. In addition, we continue to develop a broader preclinical solid tumor testing program, which will evaluate our DNAbilize™ platform to treat advanced ovarian cancer and triple negative and inflammatory breast cancers and may be expanded to include combination therapies. We look forward to continued progress throughout the year and to advancing our clinical programs to the benefit of cancer patients.”

Recent Corporate Highlights

- **Announced Completion of the Safety Segment of the Phase II Trial of BP1001 in Acute Myeloid Leukemia.** Patients treated with 90 mg/m² of BP1001 twice a week over a four-week period, in combination with a standard regimen of frontline low-dose cytarabine (LDAC), showed results consistent with those seen in previous cohorts, demonstrating BP1001 to be safe and well tolerated, with signs of anti-leukemia activity. Of the six evaluable patients included in both cohorts of the safety segment, two achieved complete remissions, while two others achieved partial remission. There were no attributable adverse events reported. Based upon this safety data, the U.S. Food and Drug Administration (FDA) approved the study’s advancement to the efficacy segment and the Company is currently recruiting patients into this portion of the trial.
 - **Entered Sponsored Research Agreement with The University of Texas MD Anderson Cancer Center.** The University of Texas MD Anderson Cancer Center will evaluate Bio-Path’s DNAbilize™ technology platform to assess its ability to modulate pancreatic cancer, including the Company’s next drug candidate. Testing will be performed in xenografts derived from malignant pancreatic tumors removed from patients at MD Anderson.
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- **Announced Sponsored Research Agreement with The University of Texas Southwestern Medical Center.** The Company entered into a sponsored research agreement with The University of Texas Southwestern Medical Center (UT Southwestern) to evaluate Bio-Path's DNabilize™ technology platform to assess its efficacy to down-regulate immune response in a systemic lupus erythematosus (SLE) model. SLE is a chronic autoimmune disorder that presents an array of symptoms, including skin lesions, heart inflammation, joint pain, kidney failure and neuropsychiatric disorders. Included in the evaluation will be BP1001 (Liposomal Grb2 antisense), Bio-Path's lead product candidate, which is currently in a Phase II study to treat blood cancers.

Financial Results for the First Quarter Ended March 31, 2016

The Company reported a net loss of \$1.9 million for the quarter, as compared with a net loss of \$1.4 million in the same period last year. This increase was primarily due to preparation activities related to our Phase II clinical trial for BP1001 in AML. Basic and diluted net loss per share was \$0.02 for the three month period ended March 31, 2016, as compared with a basic and diluted net income per share of \$0.02 in the same period last year.

Research and development expense for the quarter increased to \$1.0 million compared with \$0.6 million in the same period last year. General and administrative expense for the quarter was \$0.8 million, consistent with the same period in 2015.

As of March 31, 2016, the Company had cash of \$6.5 million, compared with \$8.9 million at December 31, 2015. Net cash used in operating activities for the quarter was \$2.4 million compared with \$1.4 million in the same period last year.

Conference Call and Webcast Information

Bio-Path Holdings will host a conference call today to review these first quarter 2016 financial results, as well as provide a general update on the Company, via a webcast and conference call at 8:30 a.m. ET. To access the conference call please dial (844) 260-6671 (domestic) or (508) 915-0912 (international) and refer to the conference ID number 5580108. A live audio webcast of the call and the archived webcast will be available in the Investors section of the Company's website at www.biopathholdings.com.

About Bio-Path Holdings, Inc.

Bio-Path is a biotechnology company focused on developing therapeutic products utilizing DNAbilize™, its proprietary liposomal delivery and antisense technology, to systemically distribute nucleic acid drugs throughout the human body with a simple intravenous transfusion. Bio-Path's lead product candidate, BP1001 (Liposomal Grb2 antisense), is in a Phase II 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.

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

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