

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 10, 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.)
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4710 Bellaire Boulevard, Suite 210, Bellaire, Texas (Address of principal executive offices)	77401 (Zip Code)
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(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:

- 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 November 10, 2016, Bio-Path Holdings, Inc. (the “Company”) announced financial results for the quarter ended September 30, 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 November 10, 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: November 10, 2016

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated November 10, 2016



BIO-PATH HOLDINGS REPORTS THIRD QUARTER 2016 FINANCIAL RESULTS

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

HOUSTON—November 10, 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 third quarter ended September 30, 2016 and also provided an update on recent corporate developments.

“Throughout the third quarter and in recent weeks, we have made meaningful progress across our clinical and corporate development programs. Earlier this month, we were pleased to announce the enrollment and dosing of the first patient in the efficacy portion of our Phase 2 clinical study of BP1001 for the treatment of acute myeloid leukemia,” said Peter Nielsen, President and CEO of Bio-Path Holdings. “Recently, the European Medicines Agency granted orphan drug designation to BP1001 for the treatment of AML, which recognizes the potential of our DNAbilize technology, underscores the significant unmet medical need in this debilitating disease, and provides regulatory provisions that can accelerate the review process and expand our market exclusivity.”

Recent Corporate Highlights

- **Announced First Patient Dosed in Phase 2 Trial Evaluating BP1001 in Acute Myeloid Leukemia.** In November, the Company announced the enrollment and dosing of the first patient in the efficacy portion of its Phase 2 clinical study of BP1001, a liposomal Grb2 antisense for the treatment of acute myeloid leukemia (AML). The primary endpoint of the study is the number of patients who achieve Complete Remission (CR), including CR with incomplete hematologic recovery (CRi) and CR with incomplete platelet recovery (CRip). Secondary endpoints assessing the safety and efficacy of BP1001 include overall survival, time to response, duration of response, and adverse events as evaluated by physical examination findings, vital signs and clinical laboratory tests.
 - **Granted Orphan Drug Designation in the European Union for BP1001 for the Treatment of AML.** In November, the Company announced that the European Medicines Agency (EMA) granted orphan drug designation to BP1001 for the treatment of AML. To receive orphan drug designation from the EMA, a therapy must be intended for the treatment of a life-threatening or chronically debilitating rare condition with a prevalence of less than five in 10,000 in the European Union. Orphan drug designation provides incentives designed to facilitate development including fee reductions for protocol assistance, scientific advice and importantly, may provide up to ten years of market exclusivity in the EU following product approval.
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Financial Results for the Third Quarter Ended September 30, 2016

The Company reported a net loss of \$1.6 million, or \$0.02 per share, for the three months ended September 30, 2016, compared to a net loss of \$1.5 million, or \$0.02 per share, for the same period last year. The increase was primarily due to the release of drug material for our Phase 2 clinical trial for BP1001 in AML and associated clinical trial costs.

Research and development expenses for the three months ended September 30, 2016 increased to \$2.3 million, compared to \$1.0 million for the same period in 2015. General and administrative expenses for the three months ended September 30, 2016 increased to \$0.7 million, compared to \$0.5 million for the three months ended September 30, 2015.

As of September 30, 2016, the Company had cash of \$11.3 million, compared to \$8.9 million at December 31, 2015. Net cash used in operating activities for the nine months ended June 30, 2016 was \$6.5 million compared to \$4.0 million for the comparable period in 2015.

Conference Call and Webcast Information

Bio-Path Holdings will host a conference call today to review these third quarter 2016 financial results, as well as to 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 12089547. A live audio webcast of the call and the archived webcast will be available in the Media 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 2 study for blood cancers and in preclinical studies for solid tumors. Bio-Path's second drug candidate, also a liposomal antisense drug, is being readied 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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