

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 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.)

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:

- 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 August 10, 2016, Bio-Path Holdings, Inc. (the “Company”) announced financial results for the quarter ended June 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 August 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: August 10, 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 August 10, 2016 |



BIO-PATH HOLDINGS REPORTS SECOND QUARTER 2016 FINANCIAL RESULTS

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

HOUSTON—August 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 second quarter ended June 30, 2016 and also provided an update on recent corporate developments.

“We made significant progress advancing our clinical development programs during the second quarter. Specifically, we were pleased to announce a sponsored research agreement with Thomas Jefferson University to investigate our DNAbilize™ technology for the development of a brain cancer immunotherapy,” said Peter Nielsen, President and CEO of Bio-Path Holdings. “In addition, we advanced preparations for the efficacy portion of our Phase II program of BP1001 for the treatment of acute myeloid leukemia (AML). We have seven leading cancer centers committed to conducting this trial and look forward to dosing patients in the near term.”

Recent Corporate Highlights

- **Entered Sponsored Research Agreement with Thomas Jefferson University.** The Company entered into a sponsored research agreement with Thomas Jefferson University to investigate Bio-Path’s DNAbilize™ antisense DNA technology for the development of a brain cancer immunotherapy that works by activating the patient’s own immune system to fight the patient’s cancer.
 - **Completed Registered Direct Public Offering.** On July 5, 2016, the Company completed the sale and issuance of 5,882,353 shares of common stock and warrants to purchase up to 2,941,177 shares of common stock in a registered direct offering with gross proceeds of approximately \$10.0 million.
 - **Presented Data at the 2016 American Society of Clinical Oncology Annual Meeting (ASCO).** Dr. Maro Ohanian, Assistant Professor at The University of Texas MD Anderson Cancer Center, presented data at the 2016 ASCO Annual Meeting. Results from the Phase I study of BP1001 for the treatment of AML and CML as well as the safety segment of the Phase II combination therapy of BP1001 in combination with low-dose cytarabine (LDAC) as a treatment for advanced AML were presented in a poster titled, “Phase I Study of BP1001 (Liposomal Grb2 Antisense) in Patients with Hematologic Malignancies.”
 - **Presented Data at the 18th Annual TIDES: Oligonucleotide and Peptides Therapeutics Conference.** In May, Dr. Ana Tari Ashizawa delivered a presentation titled, “Clinical Studies of BP1001, a drug candidate utilizing DNAbilize™ Antisense DNA Technology, in Hematologic Malignancies” at the 18th Annual TIDES: Oligonucleotide and Peptides Therapeutics Conference.
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Financial Results for the Second Quarter Ended June 30, 2016

The Company reported a net loss of \$1.9 million, or \$0.02 per share, for the three months ended June 30, 2016, compared to a net loss of \$1.1 million, or \$0.01 per share, for the same period last year. The increase was primarily due to preparations related to the Company's Phase II clinical trial for BP1001 in AML.

Research and development expenses for the three months ended June 30, 2016 increased to \$1.2 million, compared to \$0.6 million for the same period last year. General and administrative expenses for the three months ended June 30, 2016 increased to \$0.8 million, compared to \$0.6 million for the same period last year.

As of June 30, 2016, the Company had cash of \$4.2 million, compared to \$8.9 million at December 31, 2015. Net cash used in operating activities for the six months ended June 30, 2016 was \$4.6 million compared to \$2.8 million for the comparable period in 2015.

Conference Call and Webcast Information

Bio-Path Holdings will host a conference call today to review these second 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 52615237. 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 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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