
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 9, 2017

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 9, 2017, Bio-Path Holdings, Inc. (the “Company”) announced financial results for the quarter ended September 30, 2017. 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.

Exhibit

Number Description

[99.1](#) [Press Release dated November 9, 2017.](#)

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 9, 2017

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

EXHIBIT INDEX

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------------|---|
| <u>99.1</u> | <u>Press Release dated November 9, 2017</u> |



BIO-PATH HOLDINGS REPORTS THIRD QUARTER 2017 FINANCIAL RESULTS

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

HOUSTON – November 9, 2017 – Bio-Path Holdings, Inc. (NASDAQ: BPTH), a biotechnology company leveraging its proprietary DNAbilize[®] antisense RNAi nanoparticle technology to develop a portfolio of targeted nucleic acid cancer drugs, today announced its financial results for the third quarter ended September 30, 2017 and provided an update on recent corporate developments.

“The third quarter was marked by growth and progress as we continue to advance our clinical and preclinical pipeline candidates. Following our recent financing, we are well-positioned to achieve several important milestones, including an interim update from our Phase 2 clinical trial of prexigebersen for the treatment of acute myeloid leukemia,” said Peter Nielsen, President and CEO of Bio-Path Holdings. “In addition, the selection of BP1003 as a new drug candidate for the treatment of pancreatic cancer highlights the exciting and expansive potential of our DNAbilize[®] technology platform to produce targeted drug candidates that can address many different diseases with high unmet need.”

Recent Corporate Highlights

- **Completed Registered Direct Public Offering.** On November 3, 2017, Bio-Path agreed to the sale and issuance of 13,333,332 shares of common stock and warrants to purchase up to 6,666,666 shares of common stock to healthcare focused institutional investors in a registered direct offering with gross proceeds of approximately \$4.0 million. The offering closed on November 6, 2017.
 - **Selected Third Drug Candidate, BP1003, for Treatment of Pancreatic Cancer.** In November, Bio-Path announced that BP1003, which targets the Stat3 protein, has been moved into preclinical development for the treatment of pancreatic cancer. The candidate is currently being studied in a patient-derived tumor model, and previous models have shown it to successfully penetrate pancreatic tumors and enhance the efficacy of standard frontline treatments.
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- **Demonstrated Promising Preclinical Results for Prexigebersen in Solid Tumors.** In November, Bio-Path announced that prexigebersen, targeting the Grb2 protein, showed ovarian tumor penetration in recently completed preclinical studies. Bio-Path plans to initiate a Phase 1 trial of prexigebersen in several solid tumor types in 2018. Prexigebersen is currently in Phase 2 development for the treatment of blood cancers and has demonstrated clinical benefit as a monotherapy and in combination with standard frontline treatments in both acute myeloid leukemia and chronic myeloid leukemia.
- **Announced Encouraging Preclinical Results for BP1002.** In November, Bio-Path announced that, BP1002, targeting the Bcl2 protein, demonstrated strong anti-non-Hodgkin's lymphoma activity in cell lines and in an animal model. The Company intends to initiate a Phase 1 trial of BP1002 in lymphoma in 2018.

Financial Results for the Third Quarter Ended September 30, 2017

The Company reported a net loss attributable to common stockholders of \$2.5 million, or \$0.02 per share, for the three months ended September 30, 2017, compared to a net loss attributable to common stockholders of \$1.6 million, or \$0.02 per share, for the three months ended September 30, 2016. The increase was primarily due to the benefit received from the change in fair value of the warrant liability in 2016. The Company reported a net loss attributable to common stockholders of \$5.9 million, or \$0.06 per share, for the nine months ended September 30, 2017, compared to a net loss attributable to common stockholders of \$5.4 million, or \$0.06 per share, for the nine months ended September 30, 2016. The increase was primarily due to the deemed dividend related to the warrant conversion of \$1.0 million during the period.

Research and development expenses for the three months ended September 30, 2017 decreased to \$1.6 million, compared to \$2.3 million for the three months ended September 30, 2016. For the nine months ended September 30, 2017, research and development expenses decreased to \$4.1 million, compared to \$4.5 million for the nine months ended September 30, 2016. The decreases were primarily due to the release of drug material for our Phase 2 clinical trial for prexigebersen in AML in 2016.

General and administrative expenses for the three months ended September 30, 2017 increased to \$0.9 million, compared to \$0.7 million for the three months ended September 30, 2016. For the nine months ended September 30, 2017, general and administrative expenses increased to \$2.7 million, compared to \$2.3 million for the nine months ended September 30, 2016.

As of September 30, 2017, the Company had cash of \$4.6 million, compared to \$9.4 million at December 31, 2016. Net cash used in operating activities for the nine months ended September 30, 2017 was \$5.7 million compared to \$6.5 million for the comparable period in 2016. Net cash used in investing activities for the nine months ended September 30, 2017 was \$0.5 million. Net cash provided by financing activities for the nine months ended September 30, 2017 was \$1.5 million.

Conference Call and Webcast Information

Bio-Path Holdings will host a conference call tomorrow to review these third quarter 2017 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) 815-4963 (domestic) or (210) 229- 8838 (international) and refer to the conference ID number 3166609. 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 developing DNabilize[®], a novel technology that has yielded a pipeline of RNAi nanoparticle drugs that can be administered with a simple intravenous transfusion. Bio-Path's lead product candidate, prexigebersen (BP1001, targeting the Grb2 protein), is in a Phase 2 study for blood cancers and in preclinical studies for solid tumors. This is followed by BP1002, targeting the Bcl2 protein, which the company anticipates entering into clinical studies where it will be evaluated in lymphoma and solid tumors.

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

Forward-Looking Statements

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws. These statements are based on management's current expectations and accordingly are subject to uncertainty and changes in circumstances. Any express or implied statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. 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 Bio-Path'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.

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