
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 15, 2018

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 August 15, 2018, Bio-Path Holdings, Inc. (the “Company”) issued a press release announcing financial results for the quarter ended June 30, 2018. 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 August 15, 2018.

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 15, 2018

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 August 15, 2018</u>



BIO-PATH HOLDINGS REPORTS SECOND QUARTER 2018 FINANCIAL RESULTS

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

HOUSTON—August 15, 2018 – 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 second quarter ended June 30, 2018 and provided an update on recent corporate developments.

“During the second quarter we have continued to advance our corporate mission to develop RNAi nanoparticle drugs for cancer patients with high unmet medical need. Our ongoing Phase 2 clinical trial of prexigebersen for the treatment of acute myeloid leukemia (AML) is progressing according to plan. Earlier studies showed 47% of evaluable patients demonstrated some degree of response to prexigebersen in combination with LDAC in this patient population, which is supportive of our Phase 2 clinical development program. We are also enrolling a Phase 2 clinical trial of prexigebersen for the treatment of chronic myeloid leukemia (CML).” said Peter Nielsen, President and CEO of Bio-Path Holdings.

“In addition, we expect to be submitting an IND for BP1002, our next investigational drug candidate targeting Bcl-2 for the treatment of lymphoma and CLL, in 2018. To support these exciting efforts, we continue to gather the highest-caliber team of experts in cancer and biotechnology to guide Bio-Path’s scientific and business strategy. As more of our drug candidates enter the clinic this year, we look forward to further exploring our novel therapeutics in the hope of providing better treatment options for patients most in need,” continued Mr. Nielsen.

Recent Corporate Highlights

- **Reported interim results from Phase 2 study of prexigebersen in combination with LDAC for the treatment of AML.** In April 2018, Bio-Path announced interim data from its ongoing Phase 2 clinical trial of its lead drug candidate prexigebersen. Of the 17 evaluable patients, 4 patients achieved complete responses, 1 patient achieved a leukemia free status, 1 patient had significantly reduced bone marrow blasts and 3 patients achieved stable disease. In total, 47% of the evaluable patients showed some form of response to the combination treatment, including 4 patients with complete remission (23%) and 4 patients with stable disease.
 - **Advanced Bio-Path’s preclinical program studying prexigebersen in solid tumors.** In April 2018, Bio-Path presented promising data at the American Association for Cancer Research Annual Meeting (AACR) 2018 on prexigebersen for the treatment of solid tumors in gynecologic malignancies. Prexigebersen decreased tumor burden eighty six percent (86%) and multinodular burden in mice compared to control, with no apparent toxicity. Bio-Path is currently planning to initiate clinical studies of prexigebersen in solid tumors through its current IND, which could potentially commence in 2018.
 - **Completed IND-enabling studies of BP1002 targeting Bcl-2 for the treatment of lymphoma and CLL.** In the second quarter, Bio-Path completed IND-enabling studies of BP1002, Bio-Path’s second drug candidate. This followed the completion of preclinical work showing that BP1002 decreased the viability of lymphoma cells and increased survival in mice. Bio-Path intends to file an IND in 2018 for BP1002 for the treatment of lymphoma and CLL in 2018 and is planning to initiate clinical studies in 2018.
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Financial Results for Second Quarter Ended June 30, 2018

- The Company reported a net loss attributable to common stockholders of \$1.7 million, or \$0.15 per share, for the three months ended June 30, 2018, compared to a net loss attributable to common stockholders of \$3.0 million, or \$0.31 per share, for the three months ended June 30, 2017. The decrease in net loss in 2018 was primarily due to the deemed dividend related to the warrant conversion of \$1.0 million in 2017. The Company reported a net loss attributable to common stockholders of \$3.6 million, or \$0.32 per share, for the six months ended June 30, 2018, compared to a net loss attributable to common stockholders of \$3.4 million, or \$0.35 per share, for the six months ended June 30, 2017. The increase was primarily due to total other income related to the change in fair value of the Company's warrant liability and the loss on extinguishment of the liability totaling \$1.9 million and was partially offset by the deemed dividend related to the warrant conversion of \$1.0 million in 2017.
- Research and development expenses for the three months ended June 30, 2018 decreased to \$0.8 million, compared to \$1.5 million for the three months ended June 30, 2017, primarily due to decreased clinical, manufacturing and salaries and benefits expenses. Research and development expenses for the six months ended June 30, 2018 decreased to \$1.8 million, compared to \$2.5 million for the six months ended June 30, 2017, primarily due to decreased salaries and benefits expenses.
- General and administrative expenses for the three months ended June 30, 2018 were \$0.9 million, compared to \$0.8 million for the three months ended June 30, 2017. General and administrative expenses for both the six months ended June 30, 2018 and June 30, 2017 were \$1.8 million.
- As of June 30, 2018, the Company had cash of \$2.6 million, compared to \$6.0 million at December 31, 2017. Net cash used in operating activities for the six months ended June 30, 2018 was \$3.4 million compared to \$4.2 million for the comparable period in 2017.

Conference Call and Webcast Information

Bio-Path Holdings will host a conference call and webcast today at 8:30 a.m. ET to review these second quarter 2018 financial results and to provide a general update on the Company. To access the conference call please dial (844) 815-4963 (domestic) or (210) 229-8838 (international) and refer to the conference ID 5174289. 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 Bcl-2 protein, which the company anticipates entering into clinical studies where it will be evaluated in lymphoma and solid chronic lymphocytic leukemia (CLL).

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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