
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 16, 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 May 16, 2018, Bio-Path Holdings, Inc. (the “Company”) issued a press release announcing financial results for the quarter ended March 31, 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.

<u>Exhibit Number</u>	<u>Description</u>
<u>99.1</u>	<u>Press Release dated May 16, 2018</u>

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 16, 2018

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

EXHIBIT INDEX

Exhibit Number	Description
<u>99.1</u>	<u>Press Release dated May 16, 2018</u>



BIO-PATH HOLDINGS REPORTS FIRST QUARTER 2018 FINANCIAL RESULTS

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

HOUSTON—May 16, 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 first quarter ended March 31, 2018 and provided an update on recent corporate developments.

“Throughout the first quarter of 2018, we made major strides advancing our RNAi nanoparticle drugs for the treatment of a variety of cancers with limited treatment options. Specifically, we were delighted to publish and present data in support of our DNabilize[®] technology in both peer-viewed journal articles and at key oncology medical meetings. In particular, we were delighted with the interim results from our ongoing Phase 2 clinical trial of prexigebersen for the treatment of AML, which showed 47% of evaluable patients demonstrated some degree of response to prexigebersen in combination with LDAC, representing a significant advance for de-novo patients previously untreated for AML who are not otherwise eligible for standard or high-intensity chemotherapy regimens or who have elected a low intensity regimen,” said Peter Nielsen, President and CEO of Bio-Path Holdings.

“Moving forward, we continue to leverage our DNabilize[®] RNAi nanoparticle technology to develop treatments for other cancers with high unmet medical need. To that end, we have gathered a team of leading cancer and biotechnology experts to guide our current and future clinical programs. We remain committed to our mission of advancing novel treatments for oncology patients with limited treatment options and will continue to drive the advancement of Bio-Path’s exciting drug candidates,” 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.
 - **Presented preclinical data on prexigebersen at the American Association for Cancer Research Annual Meeting (AACR).** In April 2018, Bio-Path presented promising data at 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.
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- **Published data in *The Lancet Haematology*.** In March 2018, Bio-Path announced that data from its Phase 1/1b study of prexigebersen as a treatment for hematological malignancies was published in *The Lancet Haematology* in an article titled, “Liposomal Grb2 antisense oligodeoxynucleotide (BP1001) in patients with refractory or relapsed haematological malignancies: a single-center, open-label, dose-escalation, phase 1/1b trial.”
- **Strengthened the Scientific Advisory Board (SAB) with the addition of Anas Younes, MD.** In May 2018, Bio-Path announced the appointment of Dr. Anas Younes to the SAB. Dr. Younes is a Professor and Chief of Lymphoma Service at Memorial Sloan Kettering Cancer Center, and one of the world’s leading lymphoma experts. His expertise will be especially invaluable in guiding Bio-Path’s BP1002 through the clinic for lymphoma and solid tumors.
- **Enhanced leadership with the appointment of Paul Aubert to Board of Directors.** In February 2018, Bio-Path announced the appointment of Paul Aubert to the Company’s Board of Directors. Paul Aubert is the sole shareholder at Paul Aubert PLC and was previously General Counsel at a specialty pharmaceutical company. His transactional experience and expertise in corporate law will provide valuable insight to the Bio-Path team.

Financial Results for First Quarter Ended March 31, 2018

- The Company reported a net loss of \$1.9 million, or \$0.17 per share, for the three months ended March 31, 2018, compared to a net loss of \$0.4 million, or \$0.04 per share, for the three months ended March 31, 2017. The increase in net loss in 2018 was primarily due to other income of \$1.6 million recognized in 2017 related to the change in the fair value of the Company’s warrant liability.
- Research and development expenses for the three months ended March 31, 2018 decreased to \$0.9 million, compared to \$1.0 million for the three months ended March 31, 2017 primarily due to decreased stock-based compensation expense.
- General and administrative expenses for both the three months ended March 31, 2018 and March 31, 2017, were \$1.0 million.
- As of March 31, 2018, the Company had cash of \$4.3 million, compared to \$6.0 million at December 31, 2017. Net cash used in operating activities for the three months ended March 31, 2018 was \$1.7 million compared to \$1.8 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 first 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 1096178. 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 tumors.

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

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Contact Information:

Investors

Will O'Connor
Stern Investor Relations, Inc.
212-362-1200
will@sternir.com

Doug Morris
Investor Relations
Bio-Path Holdings, Inc.
832-742-1369
