
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): April 3, 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 April 3, 2018, Bio-Path Holdings, Inc. (the “Company”) issued a press release announcing financial results for the year ended December 31, 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated April 3, 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: April 3, 2018

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

EXHIBIT INDEX

Exhibit
Number

Description

[99.1](#)

[Press Release dated April 3, 2018](#)



BIO-PATH HOLDINGS REPORTS FULL YEAR 2017 FINANCIAL RESULTS

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

HOUSTON—April 3, 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 full year ended December 31, 2017 and provided an update on recent corporate developments.

“During 2017 we made meaningful progress advancing both our clinical and corporate objectives, which has positioned us for continued growth throughout 2018 and beyond,” stated Peter Nielsen, President and Chief Executive Officer of Bio-Path. “As we move into 2018, we expect to implement the protocol amendments to our Phase 2 clinical trial of prexigebersen for the treatment of acute myeloid leukemia, to prepare for a Phase 1 clinical trial of BP1002 in lymphoma, to begin enrollment of a Phase 1 clinical trial of prexigebersen in solid tumors potentially by year-end, and to start a series of IND-enabling studies for BP1003 in pancreatic cancer. We continue to have confidence in the performance and potential of our DNabilize platform technology to produce exciting drug candidates to help patients with high unmet medical need.”

Recent Corporate Highlights

- **Reported Pre-Specified Interim Results from Phase 2 Study of Prexigebersen in Combination with LDAC to Treat AML.** Of the 17 evaluable patients, four patients achieved complete responses, one patient achieved a leukemia free, one patient had significantly reduced bone marrow blasts and three patients achieved stable disease. In total, 47% of the evaluable patients showed some form of response to the combination treatment, including four patients with complete remission (23%) and four patients with stable disease.
 - **Published Data in *The Lancet Haematology*.** In March 2018, the Company announced that data from its Phase 1/1b study of prexigebersen (BP1001) 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-centre, open-label, dose-escalation, phase 1/1b trial.”
 - **Announced Third Drug Candidate, BP1003, for Treatment of Pancreatic Cancer.** In November 2017, Bio-Path announced its third drug candidate, BP1003, entered into preclinical development for the treatment of pancreatic cancer. BP1003 targets the Stat3 protein and is currently being studied in patient-derived tumor models. Previous *ex vivo* tumor studies have shown BP1003 to successfully penetrate pancreatic tumors and enhance the efficacy of standard frontline treatments. Bio-Path expects to initiate IND-enabling studies for BP1003 in 2018.
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Upcoming Events

- **Presentation at the 2018 AACR Annual Meeting.** Bio-Path will present preclinical animal model data at the upcoming AACR Annual Meeting on Wednesday, April 18, 2018, at the Experimental and Molecular Therapeutics Session, Section 36, from 8:00 a.m. – 12:00 p.m. ET in Chicago. The abstract (#5786) is titled: “Grabbing GRB2: The use of liposome-incorporated Grb2 antisense oligonucleotides as a novel therapy in gynecologic malignancies.”

Financial Results for the Full Year Ended December 31, 2017

The Company reported a net loss attributable to common stockholders of \$8.1 million, or \$0.80 per share, for the year ended December 31, 2017, compared to a net loss attributable to common stockholders of \$6.8 million, or \$0.73 per share, for the year ended December 31, 2016. The increase was primarily due to the deemed dividend related to the warrant conversion in 2017. The per share amounts above have been adjusted to give effect to the 1-for-10 reverse stock split that occurred on February 8, 2018.

Research and development expenses were \$5.5 million for both the years ended December 31, 2017 and December 31, 2016.

General and administrative expenses for the year ended December 31, 2017 increased to \$3.5 million, compared to \$3.0 million for the year ended December 31, 2016. The increase was primarily due to increased legal and audit fees.

As of December 31, 2017, the Company had cash of \$6.0 million, compared to \$9.4 million at December 31, 2016. Net cash used in operating activities for the year ended December 31, 2017 was \$8.0 million compared to \$8.1 million for the comparable period in 2016. Net cash used in investing activities for the year ended December 31, 2017 was \$0.5 million. Net cash provided by financing activities for the year ended December 31, 2017 was \$5.1 million.

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 full year 2017 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 number 5195559. 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>.

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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