

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 15, 2020

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	BPTH	The Nasdaq Capital Market

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 15, 2020, Bio-Path Holdings, Inc. (the “Company”) issued a press release announcing financial results for the quarter ended March 31, 2020. 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 May 15, 2020

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 15, 2020

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

EXHIBIT INDEX

Exhibit
Number

Description

[99.1](#)

[Press Release dated May 15, 2020](#)



BIO-PATH HOLDINGS REPORTS FIRST QUARTER 2020 FINANCIAL RESULTS

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

HOUSTON—May 15, 2020 – 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 first quarter ended March 31, 2020 and provided an update on recent corporate developments.

“We continued to make meaningful progress throughout the first quarter across all of our promising DNAbilize clinical development programs, even in the face of challenges associated with COVID-19. During 2020, we expect to initiate safety testing of the triple combination of our lead candidate, prexigebersen, with decitabine and venetoclax as part of Stage 2 of our Phase 2 trial in patients with acute myeloid leukemia,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings. “We were also excited to present a poster at the American Association for Cancer Research Annual Meeting, which highlighted the robust clinical trial design of the planned Phase 1 study of our therapeutic candidate, BP1002, in patients with advanced lymphoid malignancies. This is an important study as we expect it will not only establish safety but may also provide insight into dosing and potential therapeutic activity. Finally, we look forward to initiating a Phase 1 study of prexigebersen-A for the treatment of solid tumors in 2020. Solid tumors represent key indications for Bio-Path to pursue as there are so few effective treatment options and they represent the vast majority of cancers.”

Recent Corporate Highlights

- **Announced Presentation at the 2020 American Society of Clinical Oncology Annual Meeting.** In May, Bio-Path announced a virtual poster presentation at the upcoming 2020 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place from May 29-31, 2020. Dr. Maro Ohanian, Department of Leukemia, University of Texas M.D. Anderson Cancer Center, will discuss the Phase 2 study design of prexigebersen (liposomal Grb2 antisense), the Company’s lead drug candidate, in combination with decitabine as a potential treatment for patients diagnosed with acute myeloid leukemia or high-risk myelodysplastic syndrome.
- **Presented a Poster at the American Association for Cancer Research Annual Meeting 2020.** In April, Bio-Path presented a poster highlighting the clinical trial design of its Phase 1 study of its therapeutic candidate BP1002 in patients with advanced lymphoid malignancies. The Phase 1 clinical trial is expected to be conducted at several leading cancer centers, including The University of Texas MD Anderson Cancer Center, the Georgia Cancer Center and the Sarah Canon Research Institute. This poster was presented at the virtual American Association for Cancer Research (AACR) Annual Meeting 2020.
- **Appointed Ernst & Young as New Auditor.** In March, the Audit Committee of Bio-Path’s Board of Directors approved the appointment of Ernst & Young LLP as the Company’s new independent registered public accounting firm.
- **Impact of COVID-19.** To date, COVID-19’s impact on operations has been limited to the inability to travel to clinical trial sites and clinical trial sites not allowing nonessential personnel on site for the purpose of monitoring activity. We anticipate COVID-19 may have an effect on patient recruiting in the near term as social distancing mandates are in effect.

Financial Results for the First Quarter Ended March 31, 2020

- The Company reported a net loss of \$3.3 million, or \$0.90 per share, for the three months ended March 31, 2020, compared to a net loss of \$1.5 million, or \$0.89 per share, for the three months ended March 31, 2019.
 - Research and development expenses for the three months ended March 31, 2020 increased to \$2.0 million, compared to \$0.4 million for the three months ended March 31, 2019 primarily due to the manufacture of drug material in preparation for our Phase 1 clinical trial of prexigebersen-A in solid tumors, an increase in clinical trial expenses related to increased enrollment in our Phase 2 clinical trial of prexigebersen in AML and start-up activities for our Phase 1 clinical trial of BP1002 in lymphoma, as well as increased preclinical study expenses.
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- General and administrative expenses for the three months ended March 31, 2020 increased to \$1.3 million, compared to \$1.1 million for the three months ended March 31, 2019 primarily due to increased franchise tax expense.
- As of March 31, 2020, the Company had cash of \$17.9 million, compared to \$20.4 million at December 31, 2019. Net cash used in operating activities for the three months ended March 31, 2020 was \$2.5 million compared to \$2.0 million for the comparable period in 2019.

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 2020 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 7973458. 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 prexigebersen-A, a drug product modification of prexigebersen, is under consideration by the FDA to commence Phase 1 studies in solid tumors. This is followed by BP1002, targeting the Bcl-2 protein, where it will be evaluated in lymphoma and solid tumors clinical studies.

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 the impact, risks and uncertainties related to COVID-19 and actions taken by governmental authorities or others in connection therewith, 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, in any subsequent quarterly reports on Form 10-Q and in other reports that Bio-Path files with the Securities and Exchange Commission from time to time. 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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