

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): March 6, 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 March 6, 2020, Bio-Path Holdings, Inc. (the “Company”) issued a press release announcing financial results for the year ended December 31, 2019. 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 March 6, 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: March 6, 2020

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

EXHIBIT INDEX

Exhibit
Number

Description

[99.1](#)

[Press Release dated March 6, 2020](#)



BIO-PATH HOLDINGS REPORTS FULL YEAR 2019 FINANCIAL RESULTS

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

HOUSTON – March 6, 2020 – 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, 2019 and provided an update on recent corporate developments.

“The significant progress we made throughout 2019 has laid the foundation for Bio-Path to achieve a number of key clinical milestones in the coming year and beyond. Importantly, we strengthened our balance sheet in 2019, giving us the financial underpinning to support our clinical programs through to a number of value-creating inflection points,” stated Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings.

“We entered 2020 well positioned to execute on our clinical development strategy. Following the successful completion of the safety testing in Stage 2 of our Phase 2 Clinical Trial of prexigebersen in Acute Myeloid Leukemia (AML), we now plan to advance this program to its next stage in the first half of 2020. In addition, we filed an Investigational New Drug (IND) application for prexigebersen in the treatment of solid tumors including ovarian and endometrial cancer and expect to start that study later this year.

“We also are in the process of initiating a Phase 1 study of our second pipeline candidate, BP1002 (liposomal Bcl-2), in the first half of this year to evaluate the ability of BP1002 to treat refractory/relapsed lymphoma and chronic lymphocytic leukemia patients. Finally, we are nearing completion of IND-enabling studies of BP1003, our novel liposome-incorporated STAT3 oligodeoxynucleotide inhibitor, for the treatment of solid tumors, and expect to file an IND application for a Phase 1 study of BP1003 for the treatment of solid tumors, including pancreatic cancer, in 2020,” concluded Mr. Nielsen.

Recent Corporate Highlights

- **Raised \$8.0 Million in Registered Direct Offering.** In November 2019, Bio-Path issued and sold 808,080 shares of its common stock and warrants to purchase up to 606,060 shares of its common stock, at a combined purchase price of \$9.90 per share and associated warrant, for aggregate gross proceeds of approximately \$8.0 million.
- **Announced Clearance of Investigational New Drug Application for BP1002.** In November 2019, Bio-Path announced that the U.S. Food and Drug Administration (FDA) has reviewed and cleared the IND application for BP1002 (liposomal Bcl-2), the Company’s second drug candidate. An initial Phase 1 clinical trial will evaluate the ability of BP1002 to treat refractory/relapsed lymphoma and chronic lymphocytic leukemia patients.
- **Successfully Completed Safety Testing in Stage 2 of Phase 2 Clinical Trial in Acute Myeloid Leukemia.** In November 2019, Bio-Path announced the successful completion of the safety testing of prexigebersen in combination with decitabine in acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS) patients in Stage 2 of the Phase 2 clinical study. The safety segment of Stage 2 of the Phase 2 clinical trial comprised six evaluable patients who were treated with the combination of prexigebersen and decitabine.

Financial Results for the Full Year Ended December 31, 2019

- The Company reported a net loss of \$8.6 million, or \$3.24 per share, for the year ended December 31, 2019, compared to a net loss of \$8.6 million, or \$14.38 per share, for the year ended December 31, 2018.
 - Research and development expense for each of the years ended December 31, 2019 and December 31, 2018 was \$4.6 million.
 - General and administrative expense for the year ended December 31, 2019 increased to \$4.1 million, compared to \$3.4 million for the year ended December 31, 2018, primarily due to increased legal fees and salaries and benefits expense.
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- As of December 31, 2019, the Company had cash of \$20.4 million, compared to \$1.0 million at December 31, 2018. Net cash used in operating activities for the year ended December 31, 2019 was \$8.4 million compared to \$6.1 million for the comparable period in 2018. Net cash provided by financing activities for the year ended December 31, 2019 was \$27.8 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 2019 financial results and to provide a general update on the Company. To access the conference call, please call (844) 815-4963 (domestic) or (210) 229-8838 (international) and refer to conference ID 7152658. A live audio webcast of the call and the archived webcast will be available on 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 the treatment of blood cancers and has filed an IND for a Phase 1 clinical trial for solid tumors. The Company's second pipeline candidate BP1002, which targets the Bcl-2 protein and is planned to be evaluated for the treatment of lymphoma and chronic lymphocytic leukemia. In addition, an IND application for BP1003, a novel liposome-incorporated STAT3 antisense oligodeoxynucleotide developed by Bio-Path as a specific inhibitor of STAT3, is expected to be filed in 2020.

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, Bio-Path's ability to 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, the maintenance of intellectual property rights, that patents relating to existing for future patent applications will be issued or that any issued patents will provide meaningful protection of our drug candidates, risks relating to maintaining Bio-Path's listing on the Nasdaq Capital Market 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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