

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): November 15, 2019

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 November 15, 2019, Bio-Path Holdings, Inc. (the “Company”) issued a press release announcing financial results for the quarter ended September 30, 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.

Exhibit

Number

Description

[99.1](#)

[Press Release dated November 15, 2019](#)

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: November 15, 2019

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

EXHIBIT INDEX

Exhibit
Number

Description

[99.1](#)

[Press Release dated November 15, 2019](#)



BIO-PATH HOLDINGS REPORTS THIRD QUARTER 2019 FINANCIAL RESULTS

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

HOUSTON – November 15, 2019 – 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 third quarter ended September 30, 2019 and provided an update on recent corporate developments.

“Throughout the third quarter we continued to make progress across all of our innovative RNAi nanoparticle therapeutic programs. Importantly, we continued treating patients and are nearing completion of the safety portion of the Phase 2 clinical study of prexigebersen in combination with decitabine in untreated AML and high risk MDS patients and refractory/relapsed AML and high risk MDS patients. Upon completion of this key milestone, we expect to begin the study of prexigebersen with decitabine plus venetoclax,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings. “Additionally, we filed an Investigational New Drug (IND) application for our second pipeline candidate, BP1002, and further strengthened and expanded our patent portfolio with the addition of a key new patent that protects our DNAbilize[®] platform and underscores its novelty. In addition, an IND for prexigebersen in the treatment of solid tumors starting with ovarian and endometrial cancer is being finalized for filing. Patients diagnosed with recurrent ovarian or endometrial cancer often have poor outcomes and it is our hope that prexigebersen may provide clinical benefit for such patients.”

“We are working toward completing IND enabling studies of BP1003, a 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. Pancreatic cancer patients have extremely limited treatment options, consequently, we are dedicated to moving this therapy forward as quickly as possible,” added Mr. Nielsen.

Recent Corporate Highlights

- **Appointed Martina Molsbergen to the Board of Directors.** In October 2019, Bio-Path announced the appointment of Martina Molsbergen, Chief Executive Officer of C14 Consulting, to its Board of Directors. Her considerable experience in business development will be invaluable as Bio-Path seeks a variety of partnerships and collaborations in order to advance the Company’s DNAbilize platform technology.
 - **Updated Intellectual Property Portfolio with Addition of Recently Issued Second Platform Technology Patent.** In September 2019, Bio-Path announced that the United States Patent and Trademark Office issued a patent with claims related to the Company’s proprietary liposomal delivery and antisense technology, DNAbilize[®], including its use in the treatment of cancers, autoimmune diseases and infectious diseases. This is the second U.S. patent issued for the Company’s platform technology.
 - **Dosed Patient in Amended Phase 2 Prexigebersen Trial in Acute Myeloid Leukemia.** In August 2019, Bio-Path announced patient dosing in the amended Phase 2 trial of prexigebersen for the treatment of acute myeloid leukemia (AML), which was updated to include patients with high risk myelodysplastic syndrome (MDS) and refractory/relapsed AML patients. Bio-Path continues treating patients and is nearing completion of the safety portion of the amended Phase 2 study, which is evaluating prexigebersen in combination with decitabine. Upon successful completion of this safety assessment, the Company plans to add venetoclax to the prexigebersen/decitabine combination treatment.
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Financial Results for the Third Quarter Ended September 30, 2019

- The Company reported a net loss of \$2.2 million, or \$0.78 per share, for the three months ended September 30, 2019, compared to a net loss of \$3.1 million, or \$5.38 per share, for the three months ended September 30, 2018.
- Research and development expenses for the three months ended September 30, 2019 decreased to \$1.4 million, compared to \$2.3 million for the three months ended September 30, 2018 primarily due to lower expenses in 2019 related to drug material releases for the Company's Phase 2 clinical trials for prexigebersen in AML and CML.
- General and administrative expenses for the three months ended September 30, 2019 increased to \$0.9 million, compared to \$0.7 million for the three months ended September 30, 2018 primarily due to increased legal fees and insurance costs.
- As of September 30, 2019, the Company had cash of \$15.4 million, compared to \$1.0 million at December 31, 2018. Net cash used in operating activities for the nine months ended September 30, 2019 was \$6.1 million compared to \$4.8 million for the comparable period in 2018. Net cash provided by financing activities for the nine months ended September 30, 2019 was \$20.5 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 third quarter 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 2095674. 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 is in the process of filing an IND for a Phase 1 clinical trial for solid tumors. The Company is also developing BP1002, which targets the Bcl-2 protein and is expected to be evaluated for the treatment of lymphoma and solid tumors. In addition, BP1003, a novel liposome-incorporated STAT3 antisense oligodeoxynucleotide developed by Bio-Path as a specific inhibitor of STAT3, is expected to enter Phase 1 studies 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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