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, 2018

BIO-PATH HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36333**	**87-0652870**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)
4710 Bellaire Boulevard, Suite 210, Bellaire, Texas		**77401**
(Address of principal executive offices)		(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 November 15, 2018, Bio-Path Holdings, Inc. (the "Company") issued a press release announcing financial results for the quarter ended September 30, 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.

Exhibit Number	Description
99.1	Press Release dated November 15, 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: November 15, 2018

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, 2018

Exhibit 99.1

BIO-PATH HOLDINGS REPORTS THIRD QUARTER 2018 FINANCIAL RESULTS

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

HOUSTON—November 15, 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 third quarter ended September 30, 2018 and provided an update on recent corporate developments.

"Throughout the third quarter, we continued to make meaningful progress advancing and expanding our robust clinical development pipeline of RNAi nanoparticle drugs to bring innovative new treatments to cancer patients with high unmet medical need," stated Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings. "Most recently, we were delighted to report that interim data from our ongoing Phase 2 clinical trial of prexigebersen for the treatment of acute myeloid leukemia (AML) were accepted for poster presentation at the upcoming American Society of Hematology Annual Meeting (ASH) taking place in early December 2018. This is an exciting opportunity to showcase this very promising program as earlier studies showed 47% of evaluable patients demonstrated some degree of response to prexigebersen in combination with LDAC in this patient population. In addition, we were pleased to report the dosing of the first patient in Stage 2 of this Phase 2 clinical trial where, at the recommendation of the study's principal investigators, we are implementing a change in the dosing regimen administering a higher dosing of prexigebersen prior to starting treatment with LDAC. We also initiated a cohort of the Phase 2 AML trial assessing prexigebersen in combination with decitabine. We look forward to having interim results from these cohorts next year.

"We are also making progress expanding our clinical programs beyond AML. Enrollment in our global Phase 2 clinical trial of prexigebersen for the treatment of chronic myeloid leukemia (CML) continues apace and we continue to advance work on an Investigational New Drug (IND) application for prexigebersen for the treatment of solid tumors. In addition, we plan to submit an IND application by year-end to begin studies of our second drug candidate, BP1002, which targets Bcl-2 for the treatment of lymphoma and CLL. Finally, we continue our work to advance our third investigation drug candidate, BP1003, in pancreatic cancer. Toward that end, we were especially pleased to welcome Jason Fleming, MD, FACCP, to our Scientific Advisory Board (SAB). Dr. Fleming is a renowned gastrointestinal cancer specialist whose insight and guidance will be of particular value to the development of this clinical program.

"The considerable progress made in 2018 provides the foundation from which we expect to build and advance our new pathway in DNA-powered medicines into 2019 and beyond," concluded Mr. Nielsen.

Recent Corporate Highlights

- **Interim data from the ongoing Phase 2 clinical trial of prexigebersen for the treatment of AML accepted for poster presentation at ASH 2018.** In November 2018, Bio-Path announced that data from its ongoing Phase 2 clinical trial of prexigebersen will be presented at ASH 2018 by Maro Ohanian, MD, Assistant Professor of the Department of Leukemia at The University of Texas MD Anderson Cancer Center, before an audience of the world's leading blood cancer specialists.

- **Commenced Stage 2 of the Company's Phase 2 trial of prexigebersen in AML.** In August 2018, Bio-Path announced the dosing of the first patient in the open-label Phase 2 study evaluating the efficacy and safety of prexigebersen in conjunction with LDAC and a second cohort of prexigebersen and decitabine, both therapeutic regimens well established in treatment of AML patients who cannot or elect not to be treated with more intensive chemotherapy. The primary objective of the study is to determine whether these combinations with prexigebersen provides greater efficacy than what would be expected with LDAC or decitabine alone in this de novo patient population.

- **Appointed Dr. Fleming to the Company's Scientific Advisory Board.** In August 2018, Bio-Path appointed Dr. Fleming, a world-leading gastrointestinal cancer expert, to its SAB. Dr. Fleming offers substantial insight as the Company seeks to advance its lead drug candidate, prexigebersen, and its third drug candidate, BP1003, towards the clinic for the treatment of pancreatic cancer.

- **Raised $1.5 million in a registered direct offering.** In September 2018, Bio-Path issued and sold 2,261,538 shares of its common stock (or common stock equivalent) for a price of $0.65 per share, for gross proceeds of approximately $1.5 million. Additionally, in a concurrent private placement, Bio-Path issued to such investors unregistered warrants to purchase up to 2,261,538 shares of common stock with an exercise price of $0.96 per share and an exercise period commencing six (6) months following the issuance date and a term of five and one-half (5.5) years from the date of issuance.

Financial Results for Third Quarter Ended September 30, 2018

- The Company reported a net loss of $3.1 million, or $0.27 per share, for the three months ended September 30, 2018, compared to a net loss of $2.5 million, or $0.25 per share, for the three months ended September 30, 2017.

- Research and development expenses for the three months ended September 30, 2018 increased to $2.3 million, compared to $1.6 million for the three months ended September 30, 2017 primarily due to costs related to the release of drug material for our Phase 2 clinical trials for prexigebersen in AML and CML.

- General and administrative expenses for the three months ended September 30, 2018 decreased to $0.7 million, compared to $0.9 million for the three months ended September 30, 2017 primarily due to decreased legal and audit fees.

- As of September 30, 2018, the Company had cash of $2.3 million, compared to $6.0 million at December 31, 2017. Net cash used in operating activities for the nine months ended September 30, 2018 was $4.8 million compared to $5.7 million for the comparable period in 2017. Net cash provided by financing activities for the nine months ended September 30, 2018 was $1.2 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 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 8564777. 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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