

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

| <u>Exhibit<br/>Number</u>   | <u>Description</u>   |
|-----------------------------|--|
| <a href="#"><u>99.1</u></a> | <a href="#"><u>Press Release dated August 15, 2019</u></a> |

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**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: August 15, 2019

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

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**EXHIBIT INDEX**

| <u>Exhibit Number</u> | <u>Description</u>                         |
|-----------------------|--|
| <u>99.1</u>           | <u>Press Release dated August 15, 2019</u> |

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## BIO-PATH HOLDINGS REPORTS SECOND QUARTER 2019 FINANCIAL RESULTS

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

**HOUSTON—August 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 second quarter ended June 30, 2019 and provided an update on recent corporate developments.

“Throughout the second quarter we continued to execute on our clinical development plans for our innovative RNAi nanoparticle therapeutics. We are excited to begin dosing patients in the amended cohorts of our Phase 2 study of prexigebersen, which will first evaluate the safety of prexigebersen in combination with decitabine in untreated AML and high risk MDS patients and refractory/relapsed AML and high risk MDS patients, and then evaluate the efficacy of the triple combination of prexigebersen + decitabine + venetoclax in those patient groups,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings.

“We are also looking forward to completing Investigational New Drug (IND) enabling studies of BP1003, a novel liposome-incorporated STAT3 oligodeoxynucleotide inhibitor for the treatment of pancreatic cancer, and to file an IND application for a Phase 1 study of BP1003 for the treatment of pancreatic cancer in 2020. We are particularly excited to launch this program as it will be our first-in-human validation of this cutting-edge therapy in an especially challenging cancer indication that has limited treatment options,” added Mr. Nielsen.

### **Recent Corporate Highlights**

- **Presented Preclinical Data at American Association for Cancer Research Annual Meeting 2019.** In April 2019, Bio-Path presented data from preclinical studies supporting the potential of BP1003, a novel liposome-incorporated STAT3 oligodeoxynucleotide inhibitor, for the treatment of pancreatic cancer, non-small cell lung cancer (NSCLC) and acute myelogenous leukemia (AML). These data were presented in a poster at the American Association for Cancer Research (AACR) Annual Meeting 2019 in Atlanta, GA.

### **Financial Results for the Second Quarter Ended June 30, 2019**

- The Company reported a net loss of \$2.5 million, or \$0.87 per share, for the three months ended June 30, 2019, compared to a net loss of \$1.7 million, or \$2.96 per share, for the three months ended June 30, 2018.
  - Research and development expenses for the three months ended June 30, 2019 increased to \$1.5 million, compared to \$0.8 million for the three months ended June 30, 2018 primarily due to the commencement of activities related to Stage 2 of our Phase 2 clinical trial in AML to include venetoclax combination treatment with prexigebersen and two cohorts of patients.
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- General and administrative expenses for the three months ended June 30, 2019 increased to \$1.0 million, compared to \$0.9 million for the three months ended June 30, 2018 primarily due to increased legal fees and insurance costs.
- As of June 30, 2019, the Company had cash of \$17.1 million, compared to \$1.0 million at December 31, 2018. Net cash used in operating activities for the six months ended June 30, 2019 was \$4.2 million compared to \$3.4 million for the comparable period in 2018. Net cash provided by financing activities for the six months ended June 30, 2019 was \$20.3 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 second 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 3792557. 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](http://www.biopathholdings.com).

### **About Bio-Path Holdings, Inc.**

Bio-Path is a biotechnology company developing DNAbilize<sup>®</sup>, 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, 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](http://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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**Contact Information:**

**Investors**

Will O'Connor  
Stern Investor Relations, Inc.  
212-362-1200  
[will@sternir.com](mailto:will@sternir.com)

Doug Morris  
Investor Relations  
Bio-Path Holdings, Inc.  
832-742-1369

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