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**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, 2023

**BIO-PATH HOLDINGS, INC.**  
(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or other jurisdiction of incorporation)	<u>001-36333</u> (Commission File Number)	<u>87-0652870</u> (IRS Employer Identification No.)
<u>4710 Bellaire Boulevard, Suite 210, Bellaire, Texas</u> (Address of principal executive offices)		<u>77401</u> (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:

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
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.

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## **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, 2023, Bio-Path Holdings, Inc. (the “Company”) issued a press release announcing financial results for the quarter ended June 30, 2023. 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 August 15, 2023.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL (included as Exhibit 101).

**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, 2023

By: /s/ Peter H. Nielsen

Peter H. Nielsen

President and Chief Executive Officer



## BIO-PATH HOLDINGS REPORTS SECOND QUARTER 2023 FINANCIAL RESULTS

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

**HOUSTON—August 15, 2023** – 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 second quarter ended June 30, 2023 and provided an update on recent corporate developments.

"Our clinical progress this quarter was highlighted by the compelling interim results from Stage 2 of our Phase 2 study of prexigebersen as a treatment for acute myeloid leukemia, a blood cancer for which there are limited treatment options and for which the prognosis is grave," said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings. "The data showed prexigebersen demonstrated meaningful clinical improvement with a tolerable safety profile in these high-risk patients. On the strength of these data, we now plan to file for regulatory designations that may accelerate the pathway for bringing this potentially life-expanding therapy to patients battling this deadly hematologic cancer."

"We continue to advance our robust clinical development program across a number of important programs that leverage our innovative DNAbilize platform technology to deliver RNAi nanoparticle therapeutics directly to cancer cells. We are forging a new path in DNA-powered medicine that we believe will give patients a fighting chance to beat these difficult to treat cancers," continued Mr. Nielsen.

### **Recent Corporate Highlights**

- **Announced Positive Results from Interim Analysis of Phase 2 Clinical Trial of Prexigebersen in Acute Myeloid Leukemia.** In August, Bio-Path reported positive interim data from Stage 2 of the Company's Phase 2 study of prexigebersen in combination with decitabine and venetoclax for the treatment of acute myeloid leukemia (AML). Prexigebersen continues to be well-tolerated and has now shown compelling efficacy results in two reporting cohorts including evaluable newly diagnosed AML patients and evaluable refractory/relapsed AML patients, which exceed outcomes with combination treatment of decitabine and venetoclax.

### **Financial Results for the Second Quarter Ended June 30, 2023**

- The Company reported a net loss of \$4.2 million, or \$0.53 per share, for the three months ended June 30, 2023, compared to a net loss of \$3.0 million, or \$0.42 per share, for the three months ended June 30, 2022.
- Research and development expense for the three months ended June 30, 2023 increased to \$3.1 million, compared to \$1.9 million for the three months ended June 30, 2022 primarily due to manufacturing expenses related to drug product releases during the second quarter of 2023 and increased patient enrollment related to our Phase 2 clinical trial for prexigebersen in AML.
- General and administrative expense for both the three months ended June 30, 2023 and June 30, 2022 was \$1.2 million.
- As of June 30, 2023, the Company had cash of \$3.4 million, compared to \$10.4 million as of December 31, 2022. Net cash used in operating activities for the six months ended June 30, 2023 was \$6.9 million compared to \$6.7 million for the comparable period in 2022.

## **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 2023 financial results and to provide a general update on the Company. To access the conference call please dial (833) 630-1956 (domestic) or (412) 317-1837 (international). 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 blood cancers, and a Phase 1/1b study of BP1001-A, a drug product modification of prexigebersen, in solid tumors has commenced. The Company's second product, BP1002, which targets the Bcl-2 protein, is being evaluated for the treatment of blood cancers and solid tumors, including lymphoma and acute myeloid leukemia. In addition, an IND application is expected to be filed for BP1003, a novel liposome-incorporated STAT3 antisense oligodeoxynucleotide developed by Bio-Path as a specific inhibitor of STAT3.

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, 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 or future patent applications will be issued or that any issued patents will provide meaningful protection of our drug candidates, the impact, risks and uncertainties related to global pandemics, including the COVID-19 pandemic, and actions taken by governmental authorities or others in connection therewith, 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