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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): March 11, 2022

**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:

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.

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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 March 11, 2022, Bio-Path Holdings, Inc. (the “Company”) issued a press release announcing financial results for the year ended December 31, 2021. 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 March 11, 2022.](#)

104

The cover page from this Current Report on Form 8-K, formatted in Inline XBRL (included as Exhibit 101).

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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.

Dated: March 11, 2022

**BIO-PATH HOLDINGS, INC.**

By: /s/ Peter H. Nielsen

Peter H. Nielsen

President and Chief Executive Officer

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## BIO-PATH HOLDINGS REPORTS FULL YEAR 2021 FINANCIAL RESULTS

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

**HOUSTON-March 11, 2022** - 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 year ended December 31, 2021 and provided an update on recent corporate developments.

“We continued to make steady progress throughout 2021 in pursuit of our mission to bring innovative therapies to the fight against cancer. We continue to build on the body of clinical evidence in support of our technology, were delighted to present data at the American Society of Hematology Annual Meeting in December and look forward to presenting encouraging preclinical data at the American Association for Cancer Research Annual Meeting in April,” stated Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings. “We look forward to achieving a number of value-creating milestones throughout the balance of the year as we seek to leverage the full potential of our DNabilize platform.”

### Recent Corporate Highlights

- **Presented Data from Ongoing Phase 2 Study of Prexigebersen at 2021 American Society of Hematology Annual Meeting.** In December, Bio-Path presented a poster highlighting the safety and preliminary efficacy data from its Phase 2 study of prexigebersen (BP1001) at the 2021 American Society of Hematology (ASH) Annual Meeting. The poster, titled, “Safety and Efficacy of Lower Intensity Induction Therapy with Intravenous Prexigebersen (BP1001) in Patients with High-Risk and Relapsed/Refractory Acute Myeloid Leukemia (AML),” was presented by Maro Ohanian, D.O., Department of Leukemia, University of Texas MD Anderson Cancer Center. The poster described the safety and preliminary efficacy of Bio-Path’s lead drug candidate, prexigebersen (liposomal Grb2 antisense), from a Phase 2 study in combination with decitabine or decitabine plus venetoclax as a potential treatment for patients diagnosed with AML.
- **Announced Presentation at 2022 American Association for Cancer Research (AACR) Annual Meeting.** In March, Bio-Path announced an upcoming poster presentation at the 2022 AACR Annual Meeting, taking place in Atlanta, GA. Dr. Maria Gagliardi, a Research Scientist at Bio-Path Holdings, will discuss preclinical studies of BP1003 (liposomal STAT3 antisense) in combination with paclitaxel or fluorouracil as a potential treatment against breast and ovarian cancer cells.

### Financial Results for the Year Ended December 31, 2021

- The Company reported a net loss of \$10.4 million, or \$1.55 per share, for the year ended December 31, 2021, compared to a net loss of \$10.9 million, or \$2.83 per share, for the year ended December 31, 2020.
- Research and development expense for the year ended December 31, 2021, decreased to \$5.9 million, compared to \$6.6 million for the year ended December 31, 2020, primarily due to timing of activities related to our clinical trial for prexigebersen in AML partially offset by an increase in manufacturing expenses related to drug product batch releases in the fourth quarter of 2021.
- General and administrative expense for the year ended December 31, 2021, increased to \$4.5 million, compared to \$4.3 million for the year ended December 31, 2020, primarily due to increased stock-based compensation expense.
- As of December 31, 2021, the Company had cash of \$23.8 million, compared to \$13.8 million at December 31, 2020. Net cash used in operating activities for the year ended December 31, 2021, was \$9.9 million compared to \$11.0 million for the comparable period in 2020. Net cash provided by financing activities for the year ended December 31, 2021, was \$20.0 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 2021 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 5089985. 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®, 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 prexigebersen-A, a drug product modification of prexigebersen, has been cleared by the FDA and Phase 1 studies in solid tumors are expected to commence in 2022. 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 is expected to be filed for BP1003, a novel liposome incorporated STAT3 antisense oligodeoxynucleotide developed by Bio-Path as a specific inhibitor of STAT3, in 2022.

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 the impact, risks and uncertainties related to COVID-19 and actions taken by governmental authorities or others in connection therewith, 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, 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**

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