
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 31, 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.

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 31, 2023, Bio-Path Holdings, Inc. (the “Company”) issued a press release announcing financial results for the year ended December 31, 2022. 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 31, 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: March 31, 2023

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



BIO-PATH HOLDINGS REPORTS FULL YEAR 2022 FINANCIAL RESULTS

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

HOUSTON—March 31, 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 year ended December 31, 2022 and provided an update on recent corporate developments.

“We entered 2023 from a position of strength and will continue to build on the momentum generated last year to advance our important clinical programs in hard-to-treat cancers,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings. “We see continued enthusiasm from clinical investigators and patients alike and hope to make even more progress toward completing these key studies. We have an exciting year ahead as we look forward to reporting data from a number of clinical trials evaluating our DNAbilize platform across solid tumors and acute myeloid leukemia, all cancers with limited treatment options.”

Recent Corporate Highlights

- **Announced First Patient Dosed in Phase 1/1b Clinical Trial of BP1001-A in Solid Tumors.** In December, Bio-Path announced the enrollment and dosing of the first patient in a Phase 1/1b clinical trial of BP1001-A (liposomal Grb2) in patients with solid tumors, including ovarian, endometrial, pancreatic and breast cancer.

Important Near-Term Clinical Milestones

BP1001-A Phase 1/1b Clinical Trial in Solid Tumors

- Important trial with advanced or recurrent solid tumors, including ovarian and uterine, pancreatic and breast cancer with initial cohort completion and data readout expected before mid-year.

BP1002 Phase 1/1b Clinical Trial in Relapsed/Refractory AML

- Focus on patients who relapsed on venetoclax treatment with initial cohort completion and readout expected in the second quarter of 2023.

Prexigebersen (BP1001) Phase 2 Clinical Trial in AML

- Two of the three cohorts in the clinical trial already exceed the minimum efficacy required for enrollment expansion.
- Assess safety and efficacy of each cohort treatment combination therapy with potential to qualify for expedited program status after cohort’s initial interim analysis, which are expected to commence by cohort in the second quarter of 2023.

Financial Results for the Year Ended December 31, 2022

- The Company reported a net loss of \$13.9 million, or \$1.91 per share, for the year ended December 31, 2022, compared to a net loss of \$10.4 million, or \$1.55 per share, for the year ended December 31, 2021.
 - Research and development expense for the year ended December 31, 2022, increased to \$9.2 million, compared to \$5.9 million for the year ended December 31, 2021, primarily due to manufacturing expenses related to drug product releases in 2022, increased enrollment in our Phase 2 clinical trial for prexigebersen in AML and start-up costs related to our Phase 1 clinical trial for BP1002 in refractory/relapsed AML patients.
 - General and administrative expense for the year ended December 31, 2022, increased to \$4.7 million, compared to \$4.5 million for the year ended December 31, 2021, primarily due to increased legal fees.
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- As of December 31, 2022, the Company had cash of \$10.4 million, compared to \$23.8 million at December 31, 2021. Net cash used in operating activities for the year ended December 31, 2022, was \$15.1 million compared to \$9.9 million for the comparable period in 2021. Net cash provided by financing activities for the year ended December 31, 2022, was \$1.7 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 2022 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.

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 a Phase 1 study 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 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 2023.

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. 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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