
**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): May 15, 2024

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:

<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 May 15, 2024, Bio-Path Holdings, Inc. (the “Company”) issued a press release announcing financial results for the quarter ended March 31, 2024. 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 May 15, 2024.

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: May 15, 2024

By: /s/ Peter H. Nielsen

Peter H. Nielsen

President and Chief Executive Officer



Bio-Path Holdings Reports First Quarter 2024 Financial Results

Marks Progress Across Key Clinical and Corporate Goals

Strengthened Balance Sheet with \$3.5 Million

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

HOUSTON—May 15, 2024 – 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 first quarter ended March 31, 2024 and provided an update on recent corporate developments.

“The multiple milestones achieved throughout the first quarter and in recent weeks are creating momentum to help advance our goal to deliver a better path for cancer patients,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings, Inc. “We made meaningful progress across all areas of the business, which include important clinical milestones, expanding our global patent portfolio and strengthening the balance sheet. These achievements leave us well positioned for continued progress throughout the balance of the year.”

Recent Corporate Highlights

- **Expanded Global Patent Portfolio.** In April, Bio-Path announced the receipt of newly issued patents in Mexico, Australia and Japan, and updated investors on the extent of its global intellectual property portfolio. Bio-Path expanded its intellectual property portfolio by filing patent applications applicable to its technology and business strategy. Bio-Path’s patent portfolio currently includes five issued patents in the U.S. and 54 issued patents in foreign jurisdictions, providing protection in 21 countries.
- **Successfully Completed Higher Dose Second Cohort in Phase 1/1b Clinical Trial of BP1002 in Refractory/Relapsed Acute Myeloid Leukemia (AML) Patients.** In April, the Company announced completion of the second dose cohort of the dose escalation portion of its Phase 1/1b clinical trial of BP1002 evaluating the ability of BP1002 to treat refractory/relapsed acute myeloid leukemia (AML) patients, including venetoclax-resistant patients. The dose escalation portion calls for a total of six evaluable patients to be treated with BP1002 monotherapy over two dose levels in a standard 3+3 design, with a starting dose of 20 mg/m² and the second dose of 40 mg/m². The testing of these two dose levels is now complete and the clinical trial will pause for a brief data review by the FDA, and then Bio-Path expects dose testing will continue at the next planned higher dose of 60 mg/m². The approved treatment cycle is two doses per week over four weeks, resulting in eight doses administered over twenty-eight days. The Phase 1b portion of the study is expected to commence after completion of BP1002 monotherapy cohorts and will assess the safety and efficacy of BP1002 in combination with decitabine in refractory/relapsed AML patients.
- **Completed \$1.2 Million Registered Direct Offering and \$2.3 Million Through At-The-Market (ATM) Financing.** In April, Bio-Path entered into a definitive agreement with certain institutional investors for the sale and issuance of 375,000 shares of its common stock at a purchase price per share of \$3.225 in a registered direct offering priced at-the-market under Nasdaq rules. The gross proceeds to Bio-Path from the offering were approximately \$1.2 million, before deducting the placement agent’s fees and other offering expenses payable by Bio-Path. Bio-Path intends to use the net proceeds from the offering for working capital and general corporate purposes. In addition, Bio-Path sold \$2.3 million shares of common stock under its At-The-Market Offering Agreement, bringing funds raised to \$3.5 million.
- **Completed First Dose Cohort in Phase 1 Clinical Trial Evaluating BP1002 to Treat Refractory/Relapsed Lymphoma and Refractory/Relapsed Chronic Lymphocytic Leukemia Patients.** In January, Bio-Path announced completion of the first dose cohort of the dose escalation portion of its Phase 1 clinical trial of BP1002 evaluating the

ability of BP1002 for the treatment of refractory/relapsed lymphoma and refractory/relapsed chronic lymphocytic leukemia (CLL) patients.

Financial Results for the First Quarter Ended March 31, 2024

- The Company reported a net loss of \$3.2 million, or \$4.88 per share, for the three months ended March 31, 2024, compared to a net loss of \$5.3 million, or \$13.25 per share, for the three months ended March 31, 2023.
- Research and development expense for the three months ended March 31, 2024 decreased to \$2.3 million, compared to \$4.0 million for the three months ended March 31, 2023 primarily due to decreased manufacturing expenses related to drug product releases partially offset by an increase in expense related to our clinical trial for BP1002 in lymphoma due to increased patient enrollment in the first quarter of 2024.
- General and administrative expense for the three months ended March 31, 2024 increased to \$1.4 million, compared to \$1.3 million for the three months ended March 31, 2023 primarily due to increased legal fees.
- As of March 31, 2024, the Company had cash of \$0.2 million, compared to \$1.1 million as of December 31, 2023. Net cash used in operating activities for the three months ended March 31, 2024 was \$1.0 million compared to \$3.7 million for the three months ended March 31, 2023. Subsequent to March 31, 2024, the Company received gross proceeds of \$3.5 million through sales of shares of common stock under the At-The-Market Offering Agreement and the April 2024 Registered Direct Offering.

Conference Call and Webcast Information

Bio-Path will host a conference call and webcast today at 8:30 a.m. ET to review these first quarter 2024 financial results and to provide a general update on the Company. To access the conference call please dial (844) 481-3014 (domestic) or (412) 317-1879 (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 BP1001-A, a drug product modification of prexigebersen, is in a Phase 1/1b study for solid tumors. 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.

For more information, please visit the Company's website at 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 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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