

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 14, 2021

BIO-PATH HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

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| 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 May 14, 2021, Bio-Path Holdings, Inc. (the “Company”) issued a press release announcing financial results for the quarter ended March 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.

| <u>Exhibit Number</u> | <u>Description</u> |
|---------------------------|--|
| 99.1 | Press Release dated May 14, 2021 |

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 14, 2021

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

EXHIBIT INDEX

| Exhibit Number | Description |
|----------------------|--|
| 99.1 | Press Release dated May 14, 2021 |



Bio-Path Holdings Reports First Quarter 2021 Financial Results

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

HOUSTON—May 14, 2021 – Bio-Path Holdings, Inc., (NASDAQ:BP1H), 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 first quarter ended March 31, 2021 and provided an update on recent corporate developments.

“The start of 2021 has been marked by substantial progress across our portfolio of targeted nucleic cancer drugs which included both presented and published data in support of our DNAbilize platform,” stated Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings. “We recently announced the successful completion of the safety run-in of Stage 2 of the Phase 2 clinical study of prexigebersen for the treatment of acute myeloid leukemia (AML) in combination with frontline therapies, decitabine and venetoclax. This was particularly important as the efficacy portion of this study will include de novo fragile AML patients for whom a clean safety profile will be critical.”

“Last month, we were particularly pleased to have supportive preclinical data from our BP1002 program presented before an audience of world-leading cancer specialists at the AACR Annual Meeting and to have published an analysis highlighting the potential of prexigebersen within the oligonucleotide drug delivery landscape in the peer-reviewed journal, *Biomedicines*. This presentation and publication significantly enhanced the oncology community’s awareness of the potential for our DNAbilize platform in a variety of hard to treat cancers and we look forward to building on this momentum throughout the remainder of this year,” continued Mr. Nielsen.

Recent Corporate Highlights

- **Announced Publication in *Biomedicines*.** In April, Bio-Path announced the publication of an analysis highlighting the potential of prexigebersen (BP1001) within the antisense oligonucleotide drug delivery landscape in the peer-reviewed journal, *Biomedicines*.
 - **Presented BP1002 Data at 2021 AACR Annual Meeting.** In April, Bio-Path presented a poster highlighting preclinical BP1002 data at the 2021 American Association for Cancer Research (AACR) Annual Meeting. BP1002 targets the protein Bcl-2, which is responsible for driving cell survival in up to 60% of all cancers. High expression of Bcl-2 has been correlated with poor prognosis for patients diagnosed with AML. The data presented in the AACR poster show that venetoclax-resistant cells are sensitive to the inhibitory effects of BP1002 combined with decitabine, suggesting that this combination is a potential treatment for patients who have relapsed from frontline venetoclax-based therapies.
 - **Successfully Completed Safety Cohort of Triple Combination in Stage 2 of Phase 2 Clinical Trial in AML.** In April, Bio-Path announced the successful completion of the safety run-in of Stage 2 of the Phase 2 clinical study of prexigebersen (BP1001), a liposomal Grb2 antisense, for the treatment of acute myeloid leukemia (AML), in combination with frontline therapies, decitabine and venetoclax, in acute myeloid leukemia (AML) patients. The safety run-in of Stage 2 of the Phase 2 clinical trial was comprised of six evaluable patients who were treated with the triple combination of prexigebersen, decitabine and venetoclax.
 - **Raised \$13.0 Million in Public Offering.** In February, Bio-Path announced the closing of a public offering for 1,710,600 shares of common stock at a price of \$7.60 per share, for aggregate gross proceeds to the Company of approximately \$13.0 million, before deducting the fees and estimated offering expenses payable by the Company.
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- **Received Third U.S. Patent Grant Related to Manufacture of Platform Technology.** In February, Bio-Path announced that the United States Patent and Trademark Office granted U.S. Patent No. 10,898,506 titled, "P-ethoxy nucleic acids for liposomal formulation." The new patent builds on earlier patents granted that protect the platform technology for DNAbilize[®], the Company's novel RNAi nanoparticle drug.

Financial Results for the First Quarter Ended March 31, 2021

- The Company reported a net loss of \$2.4 million, or \$0.43 per share, for the three months ended March 31, 2021, compared to a net loss of \$3.3 million, or \$0.90 per share, for the three months ended March 31, 2020.
- Research and development expense for the three months ended March 31, 2021 decreased to \$1.3 million, compared to \$2.0 million for the three months ended March 31, 2020 primarily due to decreased preclinical expense related to timing of activities for BP1003 as well as decreased clinical trial expense due to timing of activities for our Phase 2 clinical trial of prexigebersen in AML and our Phase 1 clinical trial of BP1002 in lymphoma.
- General and administrative expense for the three months ended March 31, 2021 decreased to \$1.2 million, compared to \$1.3 million for the three months ended March 31, 2020 primarily due to decreased franchise tax expense.
- As of March 31, 2021, the Company had cash of \$30.8 million, compared to \$13.8 million as of December 31, 2020. Net cash used in operating activities for the three months ended March 31, 2021 was \$1.6 million compared to \$2.5 million for the comparable period in 2020. Net cash provided by financing activities for the three months ended March 31, 2021 was \$18.6 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 first quarter 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 5064037. 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 infusion. 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, is under consideration by the FDA to commence a Phase 1 study in solid tumors. This is followed by BP1002, targeting the Bcl-2 protein, where it is being evaluated in a Phase 1 study in advanced lymphoma and CLL patients.

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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