

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 28, 2025

**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	N/A

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 28, 2025, Bio-Path Holdings, Inc. (the “Company”) issued a press release announcing financial results for the year ended December 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 March 28, 2025.](#)

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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.

**BIO-PATH HOLDINGS, INC.**

Dated: March 28, 2025

By: /s/ Peter H. Nielsen

Peter H. Nielsen  
President and Chief Executive Officer

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## Bio-Path Holdings Reports Full Year 2024 Financial Results

*Reports Continued Progress Across Both Obesity and Oncology Franchises*

**HOUSTON—March 28, 2025** – Bio-Path Holdings, Inc., (OTCQB:BP1001), a biotechnology company leveraging its proprietary DNAbilize® antisense RNAi nanoparticle technology to develop a portfolio of targeted nucleic acid cancer and obesity drugs, today announced its financial results for the year ended December 31, 2024 and provided an update on recent corporate developments.

“We are merely touching the tip of the iceberg in terms of realizing the potential of our DNAbilize® platform to change the treatment paradigm in both obesity and oncology,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings. “Throughout the last year, we built on the body of scientific evidence in support of our powerful platform technologies’ therapeutic effects and fortified our intellectual property to protect it from potential competitors. We continue to advance our clinical studies for BP1001-A as a treatment for obesity in Type 2 diabetes patients, where we have shown restored insulin sensitivity in cell models. Beyond this, our ongoing oncology studies continue to advance, and we are reporting ever improving outcomes for the most vulnerable patients battling these life-threatening cancers.”

### Recent Corporate Highlights

- **Announced Pre-Clinical Results Signaling Increased Potential for BP1001-A as Treatment for Obesity in Type 2 Diabetes Patients.** Scientific evidence suggests that by downregulating growth factor receptor-bound protein 2 (Grb2) expression, BP1001-A could help lower blood glucose level by affecting insulin signaling. In December 2024, Bio-Path reported results from preclinical studies of BP1001-A for obesity demonstrating enhanced insulin sensitivity in myoblast and hepatoma cells. Furthermore, in March 2025, Bio-Path reported preclinical results that BP1001-A attenuated fatty acid-induced insulin resistance and restored insulin sensitivity in muscle progenitor and skeletal muscle fiber cell models. Together these studies signal increased potential for BP1001-A as a treatment for obesity and related metabolic diseases in Type 2 diabetes patients.
- **Expanded Global Patent Portfolio.** In February 2025, Bio-Path announced the receipt of newly issued patents in the United States and New Zealand, and updated investors on the extent of its global intellectual property portfolio. Bio-Path received Notice of Allowance from the United States Patent and Trademark Office for U.S. Patent No. 17/339,366 titled, "P-ethoxy nucleic acids for STAT3 inhibition." The New Zealand Intellectual Property Office has granted Patent No. 741793 titled, "P-ethoxy nucleic acids for liposomal formulation." These new patents build on earlier patents granted that protect the DNAbilize® platform technology and the Company’s novel RNAi nanoparticle drugs.

Bio-Path continues to expand its intellectual property portfolio by filing patent applications that are applicable to its technology and business strategy. Bio-Path’s patent portfolio currently includes seven issued patents in the U.S. and 61 issued patents in foreign jurisdictions, providing protection in 26 countries. The Company has three additional pending patent applications in the U.S. and five additional allowed patent applications in foreign jurisdictions.

- **Provided Update from Phase 1/1b Clinical Trial of BP1002 for Treatment of Refractory/Relapsed Acute Myeloid Leukemia.** In February 2025, the Company provided an update from the ongoing Phase 1/1b clinical trial evaluating BP1002 for the treatment of refractory/relapsed acute myeloid leukemia (AML), including venetoclax-resistant patients. The Company announced a meaningful patient response to treatment and that the study has progressed to the fourth, higher dose cohort of 90 mg/m<sup>2</sup>.

### Financial Results for the Year Ended December 31, 2024

- The Company reported a net loss of \$9.9 million, or \$4.12 per share, for the year ended December 31, 2024, compared to a net loss of \$16.1 million, or \$33.63 per share, for the year ended December 31, 2023.

- Research and development expense for the year ended December 31, 2024 decreased to \$7.3 million, compared to \$11.6 million for the year ended December 31, 2023 primarily due to decreased manufacturing expenses related to drug product releases in 2024 compared to 2023.
- General and administrative expense for the year ended December 31, 2024 increased to \$4.7 million, compared to \$4.2 million for the year ended December 31, 2023 primarily due to increased salaries and benefits expense as well as expenses related to our special shareholder meeting in 2024.
- Change in fair value of the Company's warrant liability for the year ended December 31, 2024 resulted in a non-cash income of \$2.1 million compared to a non-cash loss of \$0.3 million for the year ended December 31, 2023.
- As of December 31, 2024, the Company had cash of \$1.2 million, compared to \$1.1 million as of December 31, 2023. Net cash used in operating activities for the year ended December 31, 2024 was \$10.6 million compared to \$11.5 million for the comparable period in 2023. Net cash provided by financing activities for the year ended December 31, 2024 was \$10.7 million.

#### **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 BP1001-A, a drug product modification of prexigebersen, is in a Phase 1/1b study for solid tumors. BP1001-A is also being evaluated as a treatment for obesity and related metabolic diseases in Type 2 diabetes patients. 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 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 [www.biopathholdings.com](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**

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