

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): December 19, 2024

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 7.01 Regulation FD Disclosure.

On December 19, 2024, Bio-Path Holdings, Inc. (the “Company”) issued a press release titled, “Bio-Path Holdings Announces Preclinical Testing of BP1001-A as Potential Treatment for Obesity in Type 2 Diabetes Patients Enhances Insulin Sensitivity.” A copy of such press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit
Number

Description

[99.1](#)
104

[Press release dated December 19, 2024.](#)

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: December 19, 2024

By: /s/ Peter H. Nielsen

Peter H. Nielsen
President and Chief Executive Officer



Bio-Path Holdings Announces Preclinical Testing of BP1001-A as Potential Treatment for Obesity in Type 2 Diabetes Patients Enhances Insulin Sensitivity

Preclinical Studies Confirmed BP1001-A Mechanism of Action and Therapeutic Potential in Obesity and Type 2 Diabetes

HOUSTON—December 19, 2024 – Bio-Path Holdings, Inc., (NASDAQ:BP1001), a biotechnology company leveraging its proprietary DNAbilize® liposomal delivery and antisense technology to develop a portfolio of targeted nucleic acid cancer drugs, today reported that results from preclinical studies of BP1001-A for obesity demonstrated enhanced insulin sensitivity, confirming BP1001-A as a potential treatment for obesity and related metabolic diseases in Type 2 diabetes patients.

BP1001-A downregulates growth factor receptor-bound protein 2 (Grb2) expression to increase insulin sensitivity and helps lower blood glucose level in Type 2 diabetes patients. Scientific evidence suggests that by downregulating Grb2 expression, BP1001-A could help lower blood glucose level by affecting insulin signaling. Bio-Path conducted preclinical studies that confirmed the effectiveness of BP1001-A in affecting insulin signaling and its potential efficacy as a therapeutic treatment for obese patients who have Type 2 diabetes. The study results showed:

- BP1001-A reduced Grb2 protein expression in myoblast cells
- BP1001-A increased the levels of phosphorylated AKT and phosphorylated FOXO-1 in myoblast and hepatoma cells in the presence of insulin

These initial data confirmed that by downregulating Grb2 expression, BP1001-A could enhance insulin-induced metabolic events by affecting the insulin/phosphoinositol-3 kinase (PI3K)/AKT pathway and increase insulin sensitivity.

“The success of our initial preclinical testing, which supports the mechanism of action and highlights the efficacy of BP1001-A to enhance insulin sensitivity, further validates BP1001-A as a potential treatment for obesity in Type 2 diabetes patients. The failure of leading weight loss medications to induce weight loss in obese patients who have Type 2 diabetes creates a compelling need for an alternative method of lowering blood glucose in obese patients who have Type 2 diabetes,” said Peter H. Nielsen, President and Chief Executive Officer of Bio-Path. “We are excited by the rapid progress we have made advancing BP1001-A as a potential treatment for obesity and related metabolic diseases in Type 2 diabetes patients based on previous BP1001-A preclinical studies as they support our continued and rapid development of this promising program.”

Bio-Path has initiated animal studies to confirm the efficacy of BP1001-A as a potential treatment for obesity and related metabolic diseases in Type 2 diabetes patients. If successful, Bio-Path anticipates initiating a first-in-human Phase 1 clinical trial in 2025 to further validate safety, measure pharmacokinetics and establish dosing for potential pivotal trials.

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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