

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 18, 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 7.01 Regulation FD Disclosure.

On March 18, 2025, Bio-Path Holdings, Inc. (the “Company”) issued a press release titled, “Bio-Path Holdings Announces Pre-Clinical Results Signaling Increased Potential for BP1001-A as Treatment for Obesity in Type 2 Diabetes Patients.” 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](#)

[Press release dated March 18, 2025.](#)

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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 19, 2025

By: /s/ Peter H. Nielsen

Peter H. Nielsen

President and Chief Executive Officer



Bio-Path Holdings Announces Pre-Clinical Results Signaling Increased Potential for BP1001-A as Treatment for Obesity in Type 2 Diabetes Patients

Recent Pre-Clinical Studies Showed BP1001-A Attenuated Fatty Acid-Induced Insulin Resistance and Restored Insulin Sensitivity in Muscle Progenitor and Skeletal Muscle Fiber Cell Models

HOUSTON—March 18, 2025 – Bio-Path Holdings, Inc., (OTCQB:BPTH), a biotechnology company leveraging its proprietary DNAbilize® liposomal delivery and antisense technology to develop a portfolio of targeted nucleic acid cancer and obesity drugs, today reported results from recent preclinical studies of BP1001-A that support its potential as a treatment for obesity. In these studies, BP1001-A attenuated fatty acid-induced insulin resistance and restored insulin sensitivity in muscle progenitor and skeletal muscle fiber cell models, which signal increased potential for BP1001-A as a treatment for obesity and related metabolic diseases in Type 2 diabetes patients.

“The important work we conducted throughout 2024 has led us into what we believe is an exciting 2025 as we build off positive data generated in oncology and the addition of a new application for BP1001-A in the treatment of obesity for Type 2 Diabetes. This new application compels us to advance these studies as quickly as possible and to file for regulatory designations that could accelerate our path to approval,” said Peter H. Nielsen, President and Chief Executive Officer of Bio-Path. “There is no greater challenge than the battle against cancer, and developing effective new medicines for patients suffering with few treatment options is what drives us every day. The addition of development of a potential treatment for obesity in Type 2 Diabetes patients follows this pathway as these patients need treatment beyond current weight loss drugs to support needed therapy for reducing glucose levels, which has positive impact across a number of different health-related conditions. The substantial progress we have made gives us further confidence that our DNAbilize® platform is ushering in a new path of DNA-powered medicines that can make a difference in the lives of these patients.”

Updated results from BP1001-A obesity and Type 2 diabetes testing from the second stage of pre-clinical testing are as follows:

- Previously, Bio-Path reported BP1001-A increased insulin sensitivity in myoblast cells (muscle progenitor cells). Skeletal muscle fiber cell models now confirm BP1001-A also increases insulin sensitivity in C2C12 myotubes.
- High fat diet rich in saturated fatty acids can lead to insulin resistance. Palmitic acid, the most common saturated fatty acid in a high fat diet, has been shown to impair insulin signaling. Recent pre-clinical work showed that BP1001-A attenuated palmitic acid-induced insulin resistance and restored insulin sensitivity in C2C12 myoblasts and myotubes.

These data show BP1001-A has increased potential as a treatment for obese patients who have Type 2 diabetes. In the final step of pre-clinical testing, Bio-Path will use a mouse model to assess the impact of BP1001-A on animal weight and its effect on insulin sensitivity and glucose tolerance. If successful, Bio-Path anticipates filing an Investigational New Drug (IND) application in 2025 to initiate a first-in-human Phase 1 clinical trial to further validate safety, measure pharmacokinetics and establish dosing for potential pivotal trials.

“These encouraging pre-clinical results demonstrate BP1001-A’s ability to restore insulin sensitivity in muscle progenitor and skeletal muscle fiber cell models and add to the growing body of evidence supporting this mechanism of action and its potential as a treatment for obesity in Type 2 diabetes patients. The failure of currently available medications to induce weight loss in obese patients who have Type 2 diabetes has created 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. We look forward to initiating our final pre-clinical mouse model study in the first half of 2025 and to filing an IND by year-end.”

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 is conducting preclinical studies to investigate 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.

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.

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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