

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 11, 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 11, 2024, Bio-Path Holdings, Inc. (the “Company”) issued a press release titled, “Bio-Path Holdings Outlines Rationale for Development of BP1001-A as Potential 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](#)

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[Press release dated December 11, 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 11, 2024

By: /s/ Peter H. Nielsen

Peter H. Nielsen
President and Chief Executive Officer



Bio-Path Holdings Outlines Rationale for Development of BP1001-A as Potential Treatment for Obesity in Type 2 Diabetes Patients

Extensive Scientific Evidence Supporting Growth Factor Receptor Bound Protein-2 (Grb2) as Fundamental Link in Insulin Resistance

Reallocates Resources to Metabolic Program and Discontinues Enrollment in Phase 1 Study of BP1002 to Treat Relapsed/Refractory Lymphoma and Relapsed/Refractory Chronic Lymphocytic Leukemia Due to Enrollment Challenges in Niche Patient Populations

HOUSTON—December 11, 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 outlined the growing body of scientific evidence that Bio-Path believes supports the development of BP1001-A for the treatment for obesity and related metabolic diseases in Type 2 diabetes patients.

Patients diagnosed with Type 2 diabetes are at high risk of developing life-threatening co-morbidities and often experience a poor quality of life. Lowering blood glucose levels is the principal goal in the treatment of patients with Type 2 diabetes. 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. Specifically, this cascade of events is led by decreasing insulin-induced mitogenic events and increasing insulin-induced metabolic events, thus leading to enhanced glucose internalization and storage. Bio-Path is conducting confirmatory preclinical studies to determine the effectiveness of BP1001-A in affecting insulin signaling and its potential as a therapeutic treatment for obese patients who have Type 2 diabetes.

“The rationale for initiating our development program for BP1001-A for the treatment of obesity is rooted in substantial scientific literature providing evidence that downregulating Grb2 expression affects insulin signaling, ultimately, leads to lower blood glucose levels. BP1001-A has been shown to downregulate Grb2 expression in preclinical models and has been shown to be safe and well-tolerated across a multitude of human clinical studies, giving us confidence in its potential to treat Type 2 diabetes and obesity,” said Peter H. Nielsen, President and Chief Executive Officer of Bio-Path. “We look forward to completing Investigational New Drug (IND)-enabling testing in the fourth quarter of 2024 and to advancing this important metabolic program in 2025.”

Scientific Rationale for BP1001-A for Treatment of Obesity – Patients diagnosed with Type 2 diabetes are at high risk of developing life-threatening co-morbidities and a poorer quality of life. Lowering blood glucose level is the principal goal in the treatment of patients with Type 2 diabetes. One potential method to manage Type 2 diabetes is to reduce body weight (Lingvay et al., 2022). Much success in weight loss has been reported for obese patients who are taking weight loss medication (Wilding et al., 2021; Frias et al., 2021). However, these medications are not as effective in inducing weight loss in obese patients who have Type 2 diabetes (Ghusn et al., 2022; Lingvay et al., 2022). Therefore, an alternative method of lowering blood glucose level is still needed for obese patients who have Type 2 diabetes.

Insulin lowers blood glucose level by activating the phosphoinositol-3 kinase (PI3K)/AKT pathway (Huang et al., 2018; Lee et al., 2022; Asiri et al., 2024). However, this insulin pathway is dysfunctional in obese patients who have Type 2 diabetes (Huang et al., 2018; Lee et al., 2022; Asiri et al., 2024). Literature suggests that Grb2 is an inhibitor of the insulin/PI3K/AKT pathway (Liu et al., 2009; Bhat et al., 2020; Ma et al., 2024). Upregulation of the Grb2 gene has been reported for patients with Type 2 diabetes (Bhat et al., 2020; Kumar et al., 2020; Alur et al., 2023). Knockdown of Grb2 expression enhanced insulin-induced AKT activity and glucose uptake in myoblasts and hepatoma cells (Liu et al., 2009; Shen et al., 2013). Furthermore, insulin sensitivity was restored in Grb2 heterozygous knockout mice fed on high fat-induced diet (Liu et al., 2009).

BP1001-A was designed to suppress Grb2 protein expression (Lara et al., 2020; Gagliardi and Tari Ashizawa, 2021). Bio-Path expects that by downregulating Grb2 expression, BP1001-A will lower blood glucose level by enhancing insulin-mediated AKT activation and glucose uptake and storage. Bio-Path is conducting preclinical studies to determine the effectiveness of BP1001-A in affecting insulin signaling and its potential as a therapeutic for obese patients who have Type 2 diabetes.

Resource Allocation – Separately, the Company announces its plans to reallocate resources toward its advancing metabolic program and to discontinue its Phase 1 clinical trial evaluating BP1002 as a treatment for refractory/relapsed lymphoma and refractory/relapsed chronic lymphocytic leukemia. This decision was based on enrollment challenges in these niche indications, particularly given the crowded development landscape that includes multiple competing 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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Cited Literature

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