

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 22, 2014

**BIO-PATH HOLDINGS, INC.**  
(Exact name of registrant as specified in its charter)

**Utah**

(State or other jurisdiction  
of incorporation)

**000-53404**

(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 (see General Instruction A.2. below):

- 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))
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**Item 7.01 Regulation FD Disclosure.**

On December 22, 2014, Bio-Path Holdings, Inc. issued a press release titled “Bio-Path Holdings to Initiate Development of Liposomal Bcl-2 in Follicular Lymphoma.”

A copy of such press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated December 22, 2014

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**BIO-PATH HOLDINGS, INC.**

Dated: December 22, 2014

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

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**EXHIBIT INDEX**

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated December 22, 2014

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## Bio-Path Holdings to Initiate Development of Liposomal Bcl-2 in Follicular Lymphoma

### - Company Broadening its Pipeline with Second Product Candidate -

**December 22, 2014; HOUSTON, TX** – Bio-Path Holdings, Inc., (NASDAQ: BPTH) (“Bio-Path”), a biotechnology company developing a liposomal delivery technology for nucleic acid cancer drugs, today announced that it has initiated development of Liposomal Bcl-2 as a treatment for follicular lymphoma. Bio-Path has a completed preclinical package of toxicity, tissue distribution, pharmacokinetics and efficacy studies. The Company plans to file an Investigational New Drug application (IND) in the first half of 2015.

Liposomal Bcl-2 (“L-Bcl-2”) is a liposomal encapsulated oligonucleotide targeted to the translation initiation site of human Bcl-2 mRNA. The antisense oligonucleotide in L-Bcl-2 used by Bio-Path Holdings is a nuclease-resistant, hydrophobic analog of phosphodiester containing the Company’s proprietary P-ethoxy backbone. The main advantage of this structure is the lack of a sulfur moiety, which has been associated with bleeding diathesis. Bcl-2 overexpression has been associated with up to 60 percent of cancers.

Bio-Path’s L-Bcl-2 demonstrated excellent toxicity and efficacy in preclinical studies. The *in vivo* studies of follicular lymphoma in SCID mice demonstrated a 60 percent survival rate, with the treated mice remaining alive while continuing to receive on-going treatment with the compound.

The Company expects that the Phase I clinical trial design will use a standard 3+3 dose escalation design, with 50 percent dose escalation with each round. The Company anticipates that the favorable toxicity profile of its lead drug candidate Liposomal Grb-2 currently in clinical trials, will allow it to start this Phase I clinical trial at a higher dose. On this basis, the Company is planning a Phase I clinical trial for Liposomal Bcl-2 that will require five cohorts and only 15 patients.

Peter Nielsen, President and Chief Executive Officer of Bio-Path, commented, “Initiating development of our second compound is an important step for the Company as it broadens Bio-Path’s pipeline and opportunities. Bcl-2 overexpression is reported to be involved in a large number of cancer indications. Due to the low toxicity demonstrated in Bio-Path’s product candidates, Liposomal Bcl-2 has the unique potential to be used in higher doses that could potentially enable it to knock down resistance of tumors to chemotherapy.”

Mr. Nielsen continued, “There is tremendous potential for Bio-Path’s Liposomal Bcl-2 to make significant contributions to the treatment of a large number of cancers. Furthermore, with the knowledge gained from our first product candidate; importantly, the toxicity profile of the compound, we estimate that this clinical trial will be conducted more quickly and at a lower cost. Our proprietary platform provides us with a strategic advantage for building a pipeline of opportunities that share similar characteristics and manufacturing techniques, allowing for an efficient and focused development program.”

#### About Follicular Lymphoma

Lymphoma is the most common blood cancer. The two main forms of lymphoma are Hodgkin lymphoma and non-Hodgkin lymphoma (NHL). Lymphoma occurs when cells of the immune system called lymphocytes, a type of white blood cell, grow and multiply uncontrollably. These cancerous lymphocytes can travel to many parts of the body, including the lymph nodes, spleen, bone marrow, blood, or other organs, and form a mass called a tumor.

#### About Bio-Path’s Delivery Technology

Bio-Path’s drug delivery technology involves microscopic-sized liposome particles that distribute nucleic acid drugs systemically and safely throughout the human body, via simple intravenous infusion. The delivery technology is applied to single stranded (antisense) nucleic acid compounds with the potential to revolutionize the treatment of cancer and other diseases where drugable targets of disease are well characterized. The Company is currently focused on developing liposomal antisense drug candidates. Bio-Path also anticipates developing liposome tumor targeting technology, representing next-generation enhancements to the Company’s core liposome delivery technology.

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## **About Bio-Path Holdings, Inc.**

Bio-Path is a biotechnology company focused on developing therapeutic products utilizing its proprietary liposomal delivery technology designed to systemically distribute nucleic acid drugs throughout the human body with a simple intravenous transfusion. Bio-Path's lead product candidate, Liposomal Grb-2, is in a Phase I study for blood cancers and in preclinical studies for triple negative and inflammatory breast cancers. Bio-Path's second drug candidate, also a liposomal antisense drug, is ready for the clinic where it will be evaluated in lymphoma and solid tumors.

*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 and 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, and such other risks which are identified in the Company's most recent Annual Report on Form 10-K and in any subsequent quarterly reports on Form 10-Q. 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.*

For more information, please visit the Company's website at <http://www.biopathholdings.com>.

### Contact Information:

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