
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): April 3, 2019

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

Delaware (State or other jurisdiction of incorporation)	001-36333 (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:

- 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))

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 April 3, 2019, Bio-Path Holdings, Inc. (the “Company”) issued a press release titled, “Bio-Path Holdings Presents Preclinical Data at American Association for Cancer Research Annual Meeting 2019.” 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 April 3, 2019](#)

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: April 3, 2019

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

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
<u>99.1</u>	<u>Press Release dated April 3, 2019</u>



Bio-Path Holdings Presents Preclinical Data at American Association for Cancer Research Annual Meeting 2019

Highlighting Important Cancer Gene, STAT3, Therapeutic Strategy in Pancreatic, Non-Small Cell Lung Cancers and Acute Myelogenous Leukemia

HOUSTON—April 3, 2019 – Bio-Path Holdings, Inc., (NASDAQ: BPTH), a biotechnology company leveraging its proprietary DNAbilize® antisense RNAi nanoparticle technology to develop a portfolio of targeted nucleic acid cancer drugs, announced that data from pre-clinical studies supporting the potential of BP1003, a novel liposome-incorporated STAT3 oligodeoxynucleotide inhibitor, for the treatment of pancreatic cancer, non-small cell lung cancer (NSCLC) and acute myelogenous leukemia (AML) were presented in a poster at the American Association for Cancer Research (AACR) Annual Meeting 2019 today in Atlanta, GA.

The poster, entitled “*BP1003, a Novel Liposome-Incorporated STAT3 Antisense Oligodeoxynucleotide Inhibitor,*” was presented by Ana Tari Ashizawa, Ph.D., Vice President of Research and Development at Bio-Path.

The poster highlights four antisense oligo sequences directed against STAT3 mRNA identified by Bio-Path and manufactured using DNAbilize® antisense RNAi nanoparticle technology. Cell viability tests and Western blots were conducted to determine the inhibitory effects of liposome-incorporated STAT3 antisense oligo on NSCLC and AML cells. An *ex vivo* live tissue sensitivity assay (LTSA) was performed with a panel of 20 pancreatic ductal adenocarcinoma (PDAC) patient-derived xenografts (PDX) to study the overall activity of BP1003 alone, and in combination with gemcitabine. Using previously defined criteria, tissue slice viability inhibition greater than 30% and with a $p < 0.05$ was considered to be a response. For validation of *ex vivo* results, PDAC PDX tumor bearing mice were administered BP1003 and gemcitabine twice a week for 28 days. Tumor volumes were monitored for up to 49 days.

The most potent liposome-incorporated STAT3 antisense sequence in decreasing NSCLC cell viability was selected as the drug candidate BP1003. Further validation in AML cells demonstrated that BP1003 inhibited cell viability and STAT3 protein expression. In the *ex vivo* LTSA assay, BP1003 at a dose of 10 μM significantly inhibited the tissue slice viability in 9 out of 18 PDAC PDXs by more than 30% ($p < 0.05$). The combination of BP1003 and gemcitabine further enhanced *ex vivo* efficacy of BP1003 in a subset of PDXs. In the *in vivo* study with PDAC PDX models, a combination of BP1003 and gemcitabine caused tumor regression during the 28-day drug treatment period. This anti-cancer activity was maintained for another 21 days, even when drug treatment had ceased.

Preclinical pancreatic cancer models demonstrated that BP1003 successfully penetrated the stroma into pancreatic tumors. As previously reported, Bio-Path’s lead drug candidate, prexigebersen, has been tested in the above-described *ex vivo* pancreatic cancer preclinical model, and the results also demonstrated that prexigebersen penetrated the pancreatic tumors. Finally, the results in pancreatic cancer showed that BP1003 inhibited tumor slice viability in 9 of 18 PDAC PDXs.

“We believe these data suggest that between our two drug candidates, BP1003 and prexigebersen, Bio-Path will be able to treat human pancreatic tumors. The Company expects to initiate a Phase I study of prexigebersen for the treatment of solid tumors in 2019, including a cohort of metastatic pancreatic cancer patients. We plan to complete Investigational New Drug (IND) enabling studies in 2019 and to file an IND application for a Phase I study of BP1003 for the treatment of pancreatic cancer in 2020,” stated Peter Nielsen, Chief Executive Officer of Bio-Path.

“We developed BP1003, a novel liposome-incorporated STAT3 antisense oligodeoxynucleotide, as a specific inhibitor of STAT3 as it is thought to be one of the most important genes involved with a variety of cancers. STAT3 is considered to be an undruggable target, which has hampered the development of a therapy for it. Inhibition of STAT3 requires a systemic RNAi solution, such as DNAbilize, in order to exert its anti-cancer activity,” noted Dr. Tari Ashizawa.

“These data are very encouraging and suggest that our two drug candidates, BP1003 and prexigebersen, are active against pancreatic cancer which is often treatment refractory and lethal. As with prexigebersen, studies to date have shown BP1003 to be generally safe and well-tolerated in preclinical models. We believe there is a great potential for the additional development of BP1003 as a treatment for NSCLC, AML and a variety of metastatic cancers,” added Mr. Nielsen.

About Signal Transducer and Activator of Transcription 3 (STAT3)

Signal Transduction and Activator of Transcription-3 (STAT3), though typically inactive in normal cells, is aberrantly active in cancer cells. The abilities of tumor cells to proliferate uncontrollably, resist apoptosis, induce vasculature formation, and invade distant organs are well-recognized hallmarks of cancer. STAT3 is a regulator of the genes involved in these cancer processes. More recently, the capability of tumors to evade immune surveillance and avoid destruction by the immune system has also gained significant acceptance in the cancer research field. STAT3, which is a point of convergence for many oncogenic pathways, has emerged as a critical mediator of tumor immune evasion at multiple levels.

Activation of STAT3 has been found in many types of cancers, including NSCLC, AML, and PDAC. Activation of STAT3 correlates with poor clinical outcome, high grade disease and metastasis, and has been linked with resistance to chemotherapy, including gemcitabine, considered a standard-of-care agent for advanced PDAC. Therefore, inhibition of STAT3 in combination with chemotherapy is expected to produce enhanced clinical benefit.

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 the treatment of blood cancers and in preclinical studies for solid tumors. The Company is also developing BP1002, which targets the Bcl-2 protein and is expected to be evaluated for the treatment of lymphoma and solid tumors. In addition, BP1003, a novel liposome-incorporated STAT3 antisense oligodeoxynucleotide developed by Bio-Path as a specific inhibitor of STAT3, is expected to enter Phase 1 studies in 2020.

For more information, please visit the Company's website at <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, Bio-Path's ability to 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, the maintenance of intellectual property rights, risks relating to maintaining Bio-Path's listing on the Nasdaq Capital Market 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. 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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