

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): January 8, 2020

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
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 January 8, 2020, Bio-Path Holdings, Inc. (the “Company”) issued a press release titled, “Bio-Path Holdings Provides Clinical Update and 2020 Business Outlook.” A copy of such press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated January 8, 2020

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: January 8, 2020

By: /s/ Peter H. Nielsen

Peter H. Nielsen

President and Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated January 8, 2020



Bio-Path Holdings Provides Clinical Update and 2020 Business Outlook

HOUSTON – January 8, 2020 – 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, today provides an update from several clinical development programs and a 2020 business overview.

“We enter 2020 with robust development plans to commence several key clinical trials that are expected to advance our DNAbilize antisense RNAi nanoparticle technology in a number of important oncology indications for which there are limited treatment options,” said Peter H. Nielsen, President and Chief Executive Officer of Bio-Path. “We are excited to initiate a number of important studies across our development pipeline and anticipate reporting key clinical datapoints from those studies later in the year.”

Phase 2 Study of Prexigebersen in Untreated and Refractory/Resistant Acute Myeloid Leukemia (AML) and High-Risk Myelodysplastic Syndrome (MDS) Patients

In March 2019, Bio-Path announced a revised strategy for the Stage 2 portion of its Phase 2 clinical trial of prexigebersen in combination with frontline chemotherapy. Bio-Path’s amended Stage 2 of the Phase 2 clinical trial will treat two cohorts of patients. The first cohort is to include untreated AML patients as existed in the pre-amended trial but with the addition of untreated, high-risk MDS patients. The second cohort is to include refractory/relapsed AML patients and high-risk MDS patients. Both cohorts of patients are planned to be treated with the combination of prexigebersen, decitabine and venetoclax. The Company is finalizing amendments to add this combination treatment to Stage 2 of the Phase 2 clinical trial.

The first step in the revised strategy involved testing the safety of the combination of prexigebersen and decitabine. In November 2019, the Company announced successful completion of this safety testing in AML and MDS patients in Stage 2 of the Phase 2 clinical study. The safety segment of Stage 2 of the Phase 2 clinical trial comprised six evaluable patients who were treated with the combination of prexigebersen and decitabine. Although the combination of prexigebersen and decitabine is not the treatment currently planned for the efficacy evaluation of Stage 2 of the Phase 2 clinical trial, the efficacy profile in this safety segment of the study was very encouraging, with 50% of patients having a response, including two patients (33%) showing complete responses with incomplete hematologic recovery and one patient (17%) showing partial response. For reference, in this class of AML and MDS patients, the complete response rate to treatment with decitabine alone is approximately 20%. Some patients are continuing to receive treatment.

The next step in this Stage 2 of the Phase 2 program will be the safety testing of prexigebersen in combination with decitabine and venetoclax in six evaluable patients drawn from either of the two cohorts of untreated AML and high-risk MDS patients or relapsed/refractory AML and high-risk MDS patients. The Company currently expects to initiate this safety testing in the second quarter of 2020. Assuming successful completion of this safety testing, the Company plans that it would then initiate the efficacy testing of this triple combination in the two cohorts of patients. In 2020, Bio-Path intends to continue its efforts to expand the number of sites, including European-based sites, to enhance patient enrollment.

The clinical design of the Stage 2 portion of the Phase 2 clinical trial calls for an interim analysis of each cohort's results after each cohort has treated 19 evaluable patients. If the results from either or both patient cohorts exceed expectations for current standard-of-care therapy, the Company expects that plans for a pivotal trial would be discussed with the FDA.

Phase 2a Study of Prexigebersen to treat Chronic Myeloid Leukemia (CML) in Tyrosine Kinase Inhibitor Failures and Accelerated and Blast Phase CML Patients

Bio-Path plans to enroll patients in a Phase 2a clinical study of prexigebersen in combination with the frontline therapy, dasatinib, for the treatment of CML in tyrosine kinase inhibitor failures and accelerated and blast phase patients in 2020. The trial is expected to be conducted at The University of Texas MD Anderson Cancer Center as a potential salvage therapy for accelerated and blast phase CML patients and will expand to other sites if feasible. Recent advances in the treatment of chronic phase CML patients with tyrosine inhibitors has limited the availability of these patients for the Bio-Path Phase 2a. As a result, the continuation of this study is being evaluated based on the potential for patient availability and clinical trial site expansion. If this Phase 2a study is advanced, it will evaluate two cohorts of three evaluable patients at two doses (60 mg/m² and 90 mg/m²) of prexigebersen in combination with dasatinib.

Phase 1 Study of Prexigebersen in Patients with Advanced Solid Tumors

In late 2019, Bio-Path filed an Investigational New Drug (IND) application to initiate a Phase 1 clinical trial of prexigebersen in patients with advanced solid tumors, including ovarian and uterine, pancreatic and breast cancer. This trial is expected to commence after the IND has been cleared by the FDA, which we currently anticipate being in 2020, at several leading cancer centers and will evaluate the safety of prexigebersen in these patients. Assuming positive Phase 1 results, the Company expects it would advance to a Phase 1b clinical trial of prexigebersen in combination with frontline therapy in these same advanced solid tumor patients.

Phase 1 Study of BP1002 in Refractory or Relapsed Lymphoma Patients and Chronic Lymphocytic Leukemia Patients

In November 2019 the FDA cleared the IND for BP1002 (liposomal Bcl-2), the Company's second drug candidate, to begin a Phase 1 clinical trial to evaluate BP1002 as a treatment for refractory/relapsed lymphoma and chronic lymphocytic leukemia patients. This study is expected to commence in the first half of 2020 and is expected to be conducted at several premier oncology centers, including the University of Texas MD Anderson Cancer Center, and is planned to evaluate the safety of BP1002 in several dose escalating cohorts to determine a maximum tolerated dose.

Preclinical Development of BP1003

The Company continues to advance its third investigational drug candidate, BP1003, for the treatment of advanced solid tumors, including pancreatic cancer. BP1003 is an antisense RNAi nanoparticle targeting the Stat3 protein.

In 2020 Bio-Path expects to complete several IND-enabling studies for BP1003. If those studies are successful, Bio-Path expects that it would file an IND in late 2020 for the first-in-humans Phase 1 study of BP1003 in patients with refractory/metastatic solid tumors including pancreatic, non-small cell lung cancer, and colorectal cancers.

BP1003 has demonstrated efficacy in combination with frontline therapies in animals against pancreatic tumors.

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 is under consideration by the FDA to commence Phase 1 studies in solid tumors. This is followed by BP1002, targeting the Bcl-2 protein, where it will be evaluated in lymphoma and solid tumors clinical studies.

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, 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 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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