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): August 13, 2020

BIO-PATH HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36333**	**87-0652870**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4710 Bellaire Boulevard, Suite 210, Bellaire, Texas	**77401**
(Address of principal executive offices)	(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 August 13, 2020, Bio-Path Holdings, Inc. (the "Company") issued a press release titled, "Bio-Path Holdings Announces First Patient Dosed in Amended Stage 2 of the Phase 2 Clinical Trial Evaluating Prexigebersen in Acute Myeloid Leukemia." 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 August 13, 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: August 13, 2020

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated August 13, 2020

Exhibit 99.1

Bio-Path Holdings Announces First Patient Dosed in Amended Stage 2 of the Phase 2 Clinical Trial Evaluating Prexigebersen in Acute Myeloid Leukemia

Combination of Prexigebersen, Decitabine and Venetoclax Is Expected to Have Several Potential Pathways to Registration

HOUSTON – August 13 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 announced the enrollment and dosing of the first patient in the amended Stage 2 of the Phase 2 clinical study of prexigebersen (BP1001), a liposomal Grb2 antisense, for the treatment of acute myeloid leukemia (AML), in combination with frontline therapy decitabine and venetoclax.

As previously reported, Phase 2 clinical development of prexigebersen in AML commenced with Stage 1 of the Phase 2 clinical trial, which was open label and treated de novo AML patients with a combination of prexigebersen and low dose cytarabine (LDAC). The combination of prexigebersen and LDAC was shown to be safe and more efficacious to treat this class of patients than with LDAC alone. Despite the superior combination treatment results with LDAC, the new drug decitabine was favored by oncologists. As a result, Stage 2 of the Phase 2 trial in AML dropped the combination treatment of prexigebersen and LDAC and replaced it with the combination treatment prexigebersen and decitabine. In addition, a second cohort of relapsed/refractory AML patients was added.

The recent approval of the frontline therapy venetoclax provided an opportunity for adding prexigebersen to the newly approved frontline, two-drug combination of venetoclax and decitabine for the treatment of AML patients.

Prior to finalizing plans to include prexigebersen with the frontline treatment combination of decitabine and venetoclax, the Company performed preclinical testing in AML cancer cell lines to assess prexigebersen's increased benefit to efficacy. Preclinical testing of prexigebersen with the frontline treatment of decitabine and venetoclax demonstrated the potential to enhance efficacy of the frontline treatment combination. In the studies, four AML cancer cell lines were treated with three different combinations of decitabine, venetoclax and prexigebersen (BP1001). Decrease in AML cell viability was the primary measure of efficacy. The triple combination of decitabine, venetoclax and BP1001 showed significant improvement in efficacy in three of the four AML cell lines. Based on these results, the Company believes that adding prexigebersen to the treatment combination of decitabine and venetoclax could lead to improved efficacy in AML patients.

	% Decrease in Cell Viability		
AML Cell Lines	BP1001 + decitabine	BP1001 + decitabine + venetoclax	Control[a] + decitabine + venetoclax
KG-1	64	90	46
MOLM-13	86	100	88
MV-4-11	67	95	79
Kasumi-1	33	50	47

[a] Empty liposomes control

Bio-Path's approved amended Stage 2 for this Phase 2 clinical trial has three cohorts of patients, which the Company believes provides for several potential regulatory pathways. The first two cohorts will treat patients with the triple combination of prexigebersen, decitabine and venetoclax. The first cohort will include untreated AML patients, and the second cohort will include relapsed/refractory AML patients. Finally, the third cohort will treat relapsed/refractory AML patients who are venetoclax resistant or intolerant with the two-drug combination of prexigebersen and decitabine.

The first step in establishing the amended Stage 2 of the Phase 2 trial in AML was demonstrating the safety of treating patients with the two-drug combination of prexigebersen and decitabine, which the Company previously reported has been successfully completed. Importantly, results from patients who were previously treated with the two-drug combination of prexigebersen and decitabine prior to the amendment to Stage 2 of the Phase 2 trial in AML and who meet the criteria for enrollment in the third cohort of the amended Stage 2 of the Phase 2 trial in AML can be included in the third cohort results. This represents a beneficial head-start in the third cohort enrollment. This third cohort represents a significant, unmet opportunity in clinical treatment, as options are limited for AML patients who fail frontline therapy.

The first six evaluable patients in the amended Stage 2 of the Phase 2 trial in AML will be treated with the triple combination of prexigebersen, decitabine and venetoclax to test the safety of this treatment combination. As noted previously, the enrollment and dosing of the first patient in the amended Stage 2 of the Phase 2 clinical study has occurred. This patient is in the relapsed/refractory cohort being treated with the triple combination of prexigebersen, decitabine and venetoclax.

"Despite recent advances in the field, AML continues to be a challenging malignancy with unmet medical need as most patients unfortunately eventually succumb to their disease. The potential for prexigebersen in combination with new standard of care treatments seems particularly promising. We look forward to the execution of this trial and, hopefully, to bringing another tool to bear in the fight against this deadly disease," said Jorge Cortes, M.D., Director of the Georgia Cancer Center and Chairman of the Bio-Path Scientific Advisory Board.

"We are excited to be testing prexigebersen in this promising triple combination. Given our preclinical data, which support treating AML patients with this triple combination, we believe there is strong potential for improved outcomes for patients with AML who otherwise have limited treatment options," said Peter Nielsen, President and Chief Executive Officer of BioPath Holdings.

"We believe that this unique trial design provides us with several definable registration pathways. We believe that prexigebersen, with its promising efficacy and safety profile, has the potential to be an ideal combination candidate with frontline therapy," concluded Mr. Nielsen.

Study Design

The amended Stage 2 of this Phase 2 trial in AML is an open label Phase 2, two-stage, multicenter study of prexigebersen in combination with decitabine and venetoclax in two cohorts of patients with previously untreated AML and relapsed/resistant AML. A third cohort includes treating relapsed/refractory AML patients who are venetoclax resistant or intolerant with the two-drug combination of prexigebersen and decitabine.

The full trial design-plans have approximately 54 evaluable patients for the cohort treating relapsed/refractory AML patients with the triple combination treatment of prexigebersen, decitabine and venetoclax and the cohort treating AML patients who are venetoclax resistant or intolerant with the two-drug combination of prexigebersen and decitabine, with a review of both cohorts performed after 19 evaluable patients.

The full trial design-plans have approximately 98 evaluable patients for the cohort treating untreated AML patients with the triple combination treatment of prexigebersen, decitabine and venetoclax, with a preliminary review for the cohort performed after 19 evaluable patients and a formal interim analysis after 38 evaluable patients. The higher number of patients in the full trial design for the untreated AML patient cohort is due to the higher baseline response of the frontline therapy.

The primary endpoint for this study will be the number of patients who achieve complete remission ("CR"), which includes complete remission with incomplete hematologic recovery ("CRi"), and complete remission with partial hematology recovery ("CRh").

An interim analysis will be performed on each cohort to assess the safety and efficacy of the treatment. In the event these results exceed the primary endpoint in a number of patients that meets or exceeds statistically determined thresholds, the Company plans to seek to convert the trial into a registration trial for accelerated approval.

The study is anticipated to be conducted at ten clinical sites in the U.S., and Gail J. Roboz, M.D., will be the national coordinating Principal Investigator for the Phase 2 trial. Dr. Roboz is professor of medicine and director of the Clinical and Translational Leukemia Program at the Weill Medical College of Cornell University and the New York-Presbyterian Hospital in New York City. For more information on the Phase 2 study, visit www.clinicaltrials.gov.

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 prexigebersen-A, a drug product modification of prexigebersen, 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 the impact, risks and uncertainties related to COVID-19 and actions taken by governmental authorities or others in connection therewith, 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, that patents relating to existing for future patent applications will be issued or that any issued patents will provide meaningful protection of our drug candidates, 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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