UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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): October 6, 2020

CORBUS PHARMACEUTICALS HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-37348**	**46-4348039**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

500 River Ridge Drive, Norwood, MA	**02062**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 963-0100

Not Applicable
(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))

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	CRBP	The Nasdaq Global 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.

On October 6, 2020, Corbus Pharmaceuticals Holdings, Inc. (the "Company") issued a press release announcing results from its Phase 2b study of lenabasum in patients with cystic fibrosis ("CF"). A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Current Report on Form 8-K under Item 7.01, including the information contained in Exhibit 99.1, is being furnished to the Securities and Exchange Commission, and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by a specific reference in such filing.

Item 8.01 Other Information.

On October 6, 2020, the Company announced results from its Phase 2b study of lenabasum in patients with CF.The CF-002 Phase 2b trial did not meet the primary endpoint of a statistically significant reduction in rate of new pulmonary exacerbations ("PEx") per subject per 28 weeks.

CF-002 was a multinational Phase 2b study evaluating the efficacy and safety of lenabasum in CF. This was a double-blind, randomized, placebo-controlled study, with dosing of lenabasum at 5 mg twice per day, lenabasum 20 mg twice per day or placebo twice per day for 28 weeks, with 4 weeks safety follow-up off active treatment. The primary efficacy endpoint was the event rate of new PEx per subject per 28 weeks, when the primary definition of new PEx was physician diagnosis of PEx, prescription of new antibiotics for that PEx starting more than 28 days after completion of the last antibiotic course for any previous PEx, with 4 out of 12 Fuch's criteria present in the subject.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description.
99.1	Press Release, dated October 6, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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

CORBUS PHARMACEUTICALS HOLDINGS, INC.

Dated: October 6, 2020

By: */s/ Yuval Cohen*
Name: Yuval Cohen, PhD
Title: Chief Executive Officer

Exhibit 99.1

Corbus Pharmaceuticals Announces Phase 2b Study of Lenabasum for Treatment of Cystic Fibrosis Did Not Meet Primary Endpoint

- Study did not meet primary endpoint of reducing rate of pulmonary exacerbations
- Lenabasum treatment had a favorable safety profile and was well-tolerated
- Data to be presented at the upcoming North American Cystic Fibrosis Conference Oct. 7-23

Norwood, MA, October 6, 2020 —Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) ("Corbus" or the "Company"), a clinical-stage drug development company pioneering transformative medicines that target the endocannabinoid system, today announced topline results from its 28-week Phase 2b study of lenabasum in patients with cystic fibrosis (CF). The study enrolled patients in the U.S., Canada and Europe at high risk for recurrent pulmonary exacerbations (PEx). Subjects received lenabasum or placebo added to their background treatments for CF.

The CF-002 Phase 2b trial did not meet the primary endpoint of a statistically significant reduction in rate of new PEx per subject per 28 weeks. Lenabasum treatment had a favorable safety profile and was well-tolerated.

The topline data will be presented at the upcoming virtual North American Cystic Fibrosis Conference (NACFC), taking place October 7-23, 2020.

Barbara White, M.D., Chief Medical Officer and Head of Research of Corbus, said, "We are very disappointed that the study did not meet the primary endpoint. We look forward to providing more details of study results starting tomorrow at NACFC. We thank the participants, the staff at study sites, the Cystic Fibrosis Foundation, and the European Cystic Fibrosis Society Clinical Trials for their support and partnership throughout this study."

Yuval Cohen, Ph.D., Chief Executive Officer of Corbus, said, "We are immensely grateful to the Cystic Fibrosis Foundation for their invaluable support of this program from its inception. It has been a privilege to work with the CF community throughout this development program."

Phase 2b CF-002 Trial Design

CF-002 was a multinational Phase 2b study evaluating the efficacy and safety of lenabasum in CF. This was a double-blind, randomized, placebo-controlled study, with dosing of lenabasum at 5 mg twice per day, lenabasum 20 mg twice per day or placebo twice per day for 28 weeks, with 4 weeks safety follow-up off active treatment. The primary efficacy endpoint was the event rate of new PEx per subject per 28 weeks, when the primary definition of new PEx was physician diagnosis of PEx, prescription of new antibiotics for that PEx starting more than 28 days after completion of the last antibiotic course for any previous PEx, with 4 out of 12 Fuch's criteria present in the subject. The Phase 2b CF study was funded in part by a Development Award for up to $25 Million from the Cystic Fibrosis Foundation.

About Lenabasum

Lenabasum is a novel, oral, small molecule that selectively binds as an agonist to the cannabinoid receptor type 2 (CB2) and resolves inflammation and limits fibrosis in animal and human models of disease. CB2 is preferentially expressed on activated immune cells and on fibroblasts, muscle cells, and endothelial cells. Lenabasum has demonstrated acceptable safety and tolerability profiles in clinical studies to date.

About Corbus

Corbus Pharmaceuticals Holdings, Inc. is a clinical-stage company focused on the development and commercialization of novel medicines designed to target the endocannabinoid system. The Company's lead product candidate, lenabasum, is a novel, oral, selective cannabinoid receptor type 2 (CB2) agonist that resolves chronic inflammation and limits fibrosis in animal and human models. Lenabasum is currently being evaluated in dermatomyositis and systemic lupus erythematosus. Corbus is also developing a pipeline of other drug candidates from its endocannabinoid system platform.

Lenabasum is not approved for the treatment of any indication. For more information on Corbus' clinical programs, please visit here.

For more information, visit www.CorbusPharma.com, and connect with us on Twitter, LinkedIn, and Facebook.

Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's trial results, product development, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors, including the potential impact of the recent COVID-19 pandemic and the potential impact of sustained social distancing efforts, on our operations, clinical development plans and timelines, which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

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