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): September 8, 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 September 8, 2020, Corbus Pharmaceuticals Holdings, Inc. (the "Company") issued a press release announcing results from its Phase 3 RESOLVE-1 study of lenabasum in patients with diffuse cutaneous systemic sclerosis. 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 September 8, 2020, the Company announced results from its Phase 3 RESOLVE-1 study of lenabasum in patients with diffuse cutaneous systemic sclerosis ("SSc").

The RESOLVE-1 study tested the efficacy and safety of lenabasum in 365 patients with diffuse cutaneous SSc in a multi-national, double-blind, randomized, placebo-controlled study, with dosing of lenabasum at 20 mg twice daily, lenabasum at 5 mg twice daily, or placebo twice daily for 52 weeks. The primary endpoint of the RESOLVE-1 study was the American College of Rheumatology Combined Response Index for Systemic Sclerosis ("ACR CRISS") score, a composite endpoint that reflects the probability of patient improvement. Topline data showed no significant differences in the primary and secondary endpoints when comparing lenabasum to placebo, both added to background drug therapy. For the primary endpoint at Week 52, median ACR CRISS scores were 0.887 in the placebo arm and 0.888 in the lenabasum 20 mg twice daily arm. The maximum achievable ACR CRISS score is 1.0.

Similar proportions of placebo-treated and lenabasum-treated subjects had at least one treatment emergent adverse event ("AEs"), 86.2% in the placebo arm and 91.7% in the lenabasum 20 mg twice daily arm. Serious AEs occurred in 14.6% of subjects in the control arm and 9.2% of subjects in the lenabasum 20 mg twice daily arm. Severe adverse events occurred in 13% of subjects in the control arm and 5.8% of subjects in the lenabasum arm. No subjects receiving lenabasum withdrew from the study because of an AE related to study drug. Lenabasum treatment was well-tolerated in this study. No evidence of lenabasum-related immunosuppression or new safety signals for lenabasum were observed.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description.
99.1	Press Release, dated September 8, 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: September 8, 2020

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

Exhibit 99.1

Corbus Pharmaceuticals Announces Topline Results from RESOLVE-1 Phase 3 Study of Lenabasum for Treatment of Systemic Sclerosis

- Topline data showed no significant differences in the primary and secondary endpoints when comparing lenabasum to placebo, both added to background drug therapy
- Unprecedented improvement was observed in subjects on placebo added to background drug therapy, achieving median ACR CRISS score of 0.887
- 84% of enrolled subjects were receiving background immunosuppressive drugs, reflecting recent trends in clinical practice
- Lenabasum treatment was safe and well-tolerated in this study with no new safety signals observed
- Further analyses of data are underway, and results will be presented at upcoming medical conferences
- Lenabasum clinical trials in cystic fibrosis, dermatomyositis and systemic lupus erythematosus are ongoing
- Company to host conference call and webcast today, September 8, 2020 at 8:30 a.m. ET

Norwood, MA, September 8, 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 the 52-week Phase 3 RESOLVE-1 study of lenabasum in patients with diffuse cutaneous systemic sclerosis (SSc). SSc is a rare and life-threatening multi-system autoimmune disease for which there are currently no U.S. Food and Drug Administration (FDA)-approved treatments for overall disease.

Topline data showed no significant differences in the primary and secondary endpoints when comparing lenabasum to placebo, both added to background drug therapy.

For the primary endpoint, the median American College of Rheumatology Combined Response Index for Systemic Sclerosis (ACR CRISS) scores at Week 52 were 0.887 in the placebo arm and 0.888 in the lenabasum 20 mg twice daily arm. ACR CRISS is a composite endpoint that reflects the probability of patient improvement. The maximum achievable ACR CRISS score is 1.0.

RESOLVE-1 is the first 52-week, randomized, placebo-controlled Phase 3 trial that tested the efficacy and safety of lenabasum in 365 patients with diffuse cutaneous SSc in a multinational, double-blind, randomized, placebo-controlled study, with dosing of lenabasum at 20 mg twice daily, lenabasum at 5 mg twice daily, or placebo twice daily for 52 weeks. The majority of enrolled patients (84%) were receiving background immunosuppressive drugs, reflecting recent trends in clinical practice.

Similar proportions of placebo-treated and lenabasum-treated subjects had at least one treatment emergent adverse event (AEs), 86.2% in the placebo arm and 91.7% in the lenabasum 20 mg twice daily arm. Serious AEs occurred in 14.6% of subjects in the control arm and 9.2% of subjects in the lenabasum 20 mg twice daily arm. Severe AEs occurred in 13% of subjects in the control arm and 5.8% of subjects in the lenabasum arm. No subjects receiving lenabasum withdrew from the study because of an AE-related to study drug. Lenabasum treatment was well-tolerated in this study. No evidence of lenabasum-related immunosuppression or new safety signals for lenabasum were observed.

Further analyses of these data are underway, and once Corbus has a fuller understanding of the data, the Company would like to engage with the FDA to determine potential next steps in this clinical development program. The data will be presented at upcoming medical conferences.

Yuval Cohen, Ph.D., Chief Executive Officer of Corbus said, “We are surprised and deeply disappointed that the RESOLVE-1 trial did not meet its primary endpoint. I would like to extend my gratitude to the participants in the study and the clinical staff at the study sites, as well as to the Corbus employees, for their hard work and dedication. We now look forward to upcoming topline results from our study of lenabasum in patients with cystic fibrosis.”

Robert Spiera, M.D., Co-Principal Investigator on RESOLVE-1 and Director of the Scleroderma, Vasculitis, and Myositis Program at the Hospital for Special Surgery, Weill Cornell Medical College in New York City said, “I am genuinely surprised by these results. Immunosuppressive drugs, alone or in combination, are increasingly becoming a mainstay of treatment for patients with early diffuse cutaneous SSc. However, the impact of these drugs on disease has not previously been studied systematically and clearly was underappreciated by the community of SSc experts. The high degree of efficacy of background drug therapy in the control arm is well beyond what was expected.”

Professor Christopher Denton, PhD, FRCP, Co-Principal Investigator on RESOLVE-1 and Professor of Experimental Rheumatology at UCL Medical School and Consultant Rheumatologist and Joint Director of the Centre for Rheumatology, Royal Free Hospital, London said, “Whilst the immediate study results are disappointing, RESOLVE-1 provides a rich dataset to understand for the first time how to better target treatments for SSc based upon clinical parameters and concomitant treatment. We are already querying the data to understand the natural history of early diffuse cutaneous SSc and the potential benefits of lenabasum in these subjects. Despite the efficacy of current immunosuppressive treatments in early diffuse cutaneous systemic sclerosis, there is still major unmet need in this patient group. The potential value of a non-immunosuppressive treatment, added-to or used instead of, additional immunosuppressive medications, remains exciting. The safety profile and tolerability of lenabasum is very attractive for use in SSc patients.”

Barbara White, M.D., Chief Medical Officer and Head of Research of Corbus commented, “We will now focus on further analyses of the data to potentially identify groups of patients that may have responded to lenabasum.”

Lenabasum was granted Orphan Drug designation and Fast Track designation for the treatment of SSc from the FDA and Orphan Designation for the treatment of SSc from the European Medicines Agency.

Lenabasum is currently being evaluated in a Phase 3 **D**ETER**MI**NE study in dermatomyositis, a Phase 2 study in systemic lupus erythematosus, and a Phase 2b study in cystic fibrosis.

RESOLVE-1 Phase 3 Study Trial Design

The RESOLVE-1 Phase 3 trial tested the efficacy and safety of lenabasum in people with diffuse cutaneous SSc on background drug therapy, in North America, Europe, Asia, Israel, and Australia. This was a double-blind, randomized, placebo-controlled study, with dosing of lenabasum at 20 mg twice daily, lenabasum at 5 mg twice daily, or placebo twice daily for 52 weeks.

Three hundred and sixty-five patients were dosed in the study. Baseline characteristics of patients across groups were balanced.

The primary efficacy outcome for the Phase 3 RESOLVE-1 is a composite clinical trial endpoint known as the ACR CRISS score, assessed at Week 52. The ACR CRISS score was also the primary efficacy endpoint in the preceding Phase 2 study published in Arthritis & Rheumatology in April 2020. The ACR CRISS score is a composite clinical trial endpoint that assesses probability that the subject has improved from baseline and integrates change from baseline in five endpoints selected by experts to be the most relevant indicators of disease improvement in diffuse cutaneous SSc. Secondary efficacy endpoints include three of the five core items of ACR CRISS assessed as change from baseline at Week 52 in mRSS, Health Assessment Questionnaire-Disability index (HAQ-DI), and forced vital capacity (FVC) percent predicted.

Conference Call details

Management will host a conference call and webcast presentation today, Tuesday, September 8th, 2020 at 8:30 a.m. ET.

To participate in the call, please dial (877) 407-3978 (domestic) or (412) 902-0039 (international). The live webcast will be accessible on the Events page of the investors section of the Corbus website, www.corbuspharma.com, and will be archived for 90 days.

About Lenabasum

Lenabasum is a rationally designed, oral, small molecule that selectively binds as an agonist to the cannabinoid receptor type 2 (CB2), resolves inflammation, and limits fibrosis. CB2 is preferentially expressed on activated immune cells and on fibroblasts, muscle cells, and endothelial cells. In both animal and human studies conducted to date, lenabasum has induced the production of pro-resolving lipid mediators that activate endogenous pathways which resolve inflammation and speed bacterial clearance without immunosuppression. Data from animal models and human clinical studies suggest that lenabasum can reduce expression of genes and proteins involved in inflammation and fibrosis. Lenabasum has demonstrated promising activity in animal models of skin and lung inflammation and fibrosis in systemic sclerosis (SSc). Lenabasum is also active in animal models of lung infection and inflammation in cystic fibrosis and joint inflammation and scarring in rheumatoid arthritis.

Lenabasum has demonstrated acceptable safety and tolerability profiles in clinical studies to date. Lenabasum treatment was associated with improvement in multiple physician-assessed and patient-reported efficacy outcomes in Phase 2 studies in patients with diffuse cutaneous SSc and patients with dermatomyositis with active skin involvement but not currently active muscle involvement. Lenabasum treatment also was associated with a lower rate of and longer time to pulmonary exacerbations in a Phase 2 cystic fibrosis study.

Lenabasum is not approved for the treatment of systemic sclerosis, dermatomyositis, cystic fibrosis or systemic lupus erythematosus.

About Systemic Sclerosis

Systemic sclerosis, a form of scleroderma, is a chronic, rare, debilitating autoimmune disease affecting approximately 200,000 people in the North America, EU and Japan.[1] Systemic sclerosis is considered one of the most life-threatening rheumatic diseases.[2] The disease affects affects the skin and internal organs and is driven by inflammation and fibrosis (scarring of tissue) which can lead to severe damage and failure of multiple organs including the skin, joints, tendons, gastrointestinal tract, lungs, heart, blood vessels and kidneys.[3] There is no cure for systemic sclerosis, and current treatments address the clinical manifestations of the disease, not the underlying mechanisms that drive inflammation and fibrosis.[4]

About Corbus

Corbus Pharmaceuticals Holdings, Inc. is a Phase 3 clinical-stage pharmaceutical company focused on the development and commercialization of novel therapeutics to treat inflammatory and fibrotic diseases by leveraging its pipeline of rationally designed, endocannabinoid system-targeting drug candidates. The Company's lead product candidate, lenabasum, is a novel, oral, selective cannabinoid receptor type 2 (CB2) agonist rationally designed to resolve chronic inflammation and fibrotic processes. Lenabasum is currently being evaluated in systemic sclerosis, cystic fibrosis, dermatomyositis and systemic lupus erythematosus.

Corbus is also developing a pipeline of drug candidates targeting the endocannabinoid system. The pipeline includes CRB-4001, a 2nd generation, selective cannabinoid receptor type 1 (CB1) inverse agonist designed to be peripherally restricted. Potential indications for CRB-4001 include nonalcoholic steatohepatitis (NASH), among others.

Lenabasum is not approved for the treatment of systemic sclerosis, dermatomyositis, cystic fibrosis or systemic lupus erythematosus. CRB-4001 is not approved for the treatment of NASH/NAFLD. For more information on Corbus' clinical programs, please visit here.

Please visit www.CorbusPharma.com and connect with the Company 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.

1. Health Advances, LLC Analysis

2. Elhai M, Meune C, Avouac J, Kahan A, Allanore Y. Trends in mortality in patients with systemic sclerosis over 40 years: a systematic review and meta-analysis of cohort studies. Rheumatology 2012;51(6):1017e26

3. Sierra-Sepulveda A, Esquinca-Gonzalez A, Benavides-Suarez SA, Sordo-Lima DE, Caballero-Islas AE, Cabral-Castaneda AR, et al. Systemic Sclerosis Pathogenesis and Emerging Therapies, beyond the Fibroblast. Biomed Res Int. 2019;2019:4569826

4. Scleroderma." National Institute of Arthritis and Musculoskeletal and Skin Diseases, U.S. Department of Health and Human Services, 7 September 2020, www.niams.nih.gov/health-topics/scleroderma/advanced#tab-risk.

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