
**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): June 13, 2018

CORBUS PHARMACEUTICALS HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37348
(Commission
File Number)

46-4348039
(IRS Employer
Identification No.)

100 River Ridge Drive, Norwood, MA
(Address of principal executive offices)

02062
(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))

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 June 13, 2018, Corbus Pharmaceuticals Holdings, Inc. (the “Company”) issued a press release announcing the presentation of data from the open-label extensions of its systemic sclerosis (“SSc”) and dermatomyositis (“DM”) Phase 2 clinical studies at the Annual European Congress of Rheumatology. 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 Events

On June 13, 2018 the Company announced that data from open-label extensions (“OLEs”) of its systemic sclerosis and dermatomyositis Phase 2 studies were presented at the Annual European Congress of Rheumatology.

Systemic Sclerosis

Study Design

Thirty-six subjects with diffuse cutaneous SSc received open-label dosing with lenabasum at 20 mg twice per day following 16-weeks participation in the preceding double-blinded placebo-controlled phase of the lenabasum Phase 2 study. There was an average 20-week wash-out from investigational product prior to the start of the OLE. Twenty-seven subjects completed 1-year follow-up in the OLE at the time of this data-cut. Lenabasum treatment was in addition to standard-of-care treatments for SSc, including stable doses of concomitant immunosuppressive drugs in 94% of subjects.

Efficacy Outcomes

The modified Rodnan Skin Score (mRSS), a physician assessment of skin involvement and the primary outcome for the upcoming Phase 3 study of lenabasum in SSc, improved by a mean of -9.4 points from baseline at the start of the Phase 2 study. The baseline mRSS at study start was 24 points. At 1 year, 77% of subjects achieved a degree of improvement in mRSS that is considered medically meaningful (reduction \geq 5 points), and 50% achieved \geq 10 points improvement in mRSS.

The ACR Composite Response Index in diffuse cutaneous Systemic Sclerosis score (ACR CRISS) increased steadily with lenabasum treatment and reached 92% (median), with 50% of subjects achieving a score \geq 95% at 1 year. Patient-reported disability, function, skin symptoms and global health all improved from study start and OLE start.

The mRSS and ACR CRISS, responses exceeded those seen in the 16-week double-blind placebo-controlled phase and the 6-month time point in the OLE.

Safety

There were no severe or serious AEs and no clinically significant laboratory abnormalities related to the drug. Thirty-three (92%) subjects experienced AEs, and 7 (19%) subjects experienced AEs related to lenabasum during open-label dosing. AEs that occurred in \geq 10% of subjects (n, %) were upper respiratory tract infection (8, 22%), arthralgia, skin ulcer, and urinary tract infection (5, 13.9% each), and diarrhea (4, 11.1%).

Lenabasum has been granted Orphan Drug Designation and Fast Track status for the treatment of SSc from the FDA and Orphan Designation from the EMA. Lenabasum is currently being evaluated in the international multicenter Phase 3 RESOLVE-1 study, a double-blind, randomized, placebo-controlled study assessing the efficacy and safety for the treatment of diffuse cutaneous SSc.

Dermatomyositis

Study Design

Twenty subjects with refractory, skin-predominant DM received open-label dosing with lenabasum at 20 mg twice per day following 16-weeks participation in the preceding double-blinded placebo-controlled part of the lenabasum Phase 2 study. There was a mean 31-week wash-out off investigational product prior to the start of the OLE. Seventeen subjects completed 6-months (28-weeks) follow-up in the OLE at the time of data-cut. Lenabasum treatment was in addition to standard-of-care treatments for DM, including stable doses of concomitant immunosuppressive drugs in 91% of subjects.

Efficacy Outcomes

At 6 months (28 weeks), the CDASI activity score improved by a mean of -15.4 points from baseline at the start of the Phase 2 double-blind, placebo-controlled phase of the study. The baseline CDASI activity score at study start was 35 points. At 6 months, 88% of subjects achieved reduction ≥ 5 points, which is considered medically meaningful, 82% achieved reduction ≥ 10 points, and 47% had achieved a low CDASI activity score (≤ 14 points). Patient-reported global disease activity, global skin disease, function, pain, and skin symptoms all improved from study start and OLE start, as did physician global disease and skin activity assessments.

Safety

There were no severe or serious AEs and no clinically significant laboratory abnormalities related to the drug. Thirteen (65%) subjects experienced AEs, and 5 (25%) subjects experienced AEs related to lenabasum during open-label dosing. A DM flare, which is an episode of worsening of the disease, was the only AE that occurred in ≥ 2 subjects, occurring in 2 subjects (one of which experienced a reduction of 14 points in CDASI activity from study start and another of which experienced an increase of 5 points from study start).

Forward- Looking Statements

This Current Report on Form 8-K 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 product development, clinical trials, 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 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit

No. Description

99.1 [Press Release, dated June 12, 2018 by Corbus Pharmaceuticals Holdings, Inc.](#)

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: June 13, 2018

By: /s/ Yuval Cohen

Name: Yuval Cohen

Title: Chief Executive Officer

Exhibit Index

Exhibit No.	Description
99.1	<u>Press Release, dated June 12, 2018 by Corbus Pharmaceuticals Holdings, Inc.</u>



Corbus Pharmaceuticals Presents 1-Year Systemic Sclerosis and 6-Month Dermatomyositis Data from Open-Label Extension of Phase 2 Lenabasum Studies at EULAR 2018

- *Multiple key efficacy outcomes further improved in open-label extensions of systemic sclerosis (SSc) and dermatomyositis (DM) Phase 2 studies*
- *Lenabasum continues to demonstrate a favorable safety profile with chronic dosing*
- *SSc and DM are related, rare and serious systemic autoimmune diseases with limited treatment options*
- *120,000 individuals with diffuse cutaneous SSc and DM in US, EU and Japan*

Norwood, MA (June 13, 2018) – Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) (“Corbus” or the “Company”), a Phase 3 clinical-stage pharmaceutical company focused on the development and commercialization of novel therapeutics to treat rare, chronic and serious inflammatory and fibrotic diseases, announced today that data from open-label extensions (OLEs) of its systemic sclerosis (SSc) and dermatomyositis (DM) Phase 2 studies are being presented at the Annual European Congress of Rheumatology (EULAR 2018).

Key highlights from the data being presented include:

SSc OLE 1-Year Results

- mRSS improved by a mean of -9.4 from baseline at the start of the Phase 2 double-blind, placebo-controlled phase of the study;
- ACR CRISS increased steadily with lenabasum treatment and reached 92% (median), with 50% of subjects achieving a score $\geq 95\%$ at 1 year; and
- 77% of subjects achieved a degree of improvement in mRSS that is considered medically meaningful (reduction ≥ 5 points), and 50% achieved ≥ 10 points improvement in mRSS.

DM OLE 6-Month Results

- CDASI activity score improved by a mean of -15.4 points from baseline at the start of the Phase 2 double-blind, placebo-controlled phase of the study; and
- 88% of subjects achieved reduction ≥ 5 points, which is considered medically meaningful, 82% achieved reduction ≥ 10 points, and 47% had reached a low CDASI activity score (≤ 14 points).

“We now have long-term safety and efficacy data in two related, rare and serious autoimmune diseases, SSc and DM,” Barbara White, M.D., Chief Medical Officer of the Company stated. “I believe that the favorable safety profile and the consistency and magnitude of changes in efficacy outcomes affirm a durability of treatment effect for lenabasum and show a cross-substantiation of data between the two studies. The degree of improvement in mRSS and CRISS scores in the SSc study, and in CDASI activity scores in the DM study are considerable, increased over time, and strengthen our confidence that lenabasum could offer benefit to patients with these diseases.”



Systemic Sclerosis Oral Presentation Overview

The abstract entitled, “*Safety and Efficacy of Lenabasum (JBT-101) In Diffuse Cutaneous Systemic Sclerosis Subjects Treated for One Year in An Open-Label Extension of Trial JBT101-SSc-001,*” (Abstract #3512) was presented in an oral presentation by Robert Spiera, M.D., Director of the Vasculitis and Scleroderma Program at the Hospital for Special Surgery, Weill Cornell Medical College in New York City and Principal Investigator of the Phase 2 and Phase 3 trials in SSc. To access the presentation, click [here](#).

Study Design

Thirty-six subjects with diffuse cutaneous SSc received open-label dosing with lenabasum at 20 mg twice per day following 16-weeks participation in the preceding double-blinded placebo-controlled phase of the lenabasum Phase 2 study. There was an average 20-week wash-out from investigational product prior to the start of the OLE. Twenty-seven subjects completed 1-year follow-up in the OLE at the time of this data-cut. Lenabasum treatment was in addition to standard-of-care treatments for SSc, including stable doses of concomitant immunosuppressive drugs in 94% of subjects.

Efficacy Outcomes

The modified Rodnan Skin Score (mRSS), a physician assessment of skin involvement and the primary outcome for the upcoming Phase 3 study of lenabasum in SSc, improved by a mean of -9.4 points from baseline at the start of the Phase 2 study. The baseline mRSS at study start was 24 points. At 1 year, 77% of subjects achieved a degree of improvement in mRSS that is considered medically meaningful (reduction ≥ 5 points), and 50% achieved ≥ 10 points improvement in mRSS.

The ACR Composite Response Index in diffuse cutaneous Systemic Sclerosis score (ACR CRISS) increased steadily with lenabasum treatment and reached 92% (median), with 50% of subjects achieving a score $\geq 95\%$ at 1 year. ACR CRISS is a measure of improvement in systemic sclerosis which is based on an exponentially weighted algorithm of change from baseline that includes the mRSS as well as physician and patient assessments and forced vital capacity (FVC). Patient-reported disability, function, skin symptoms and global health all improved from study start and OLE start.

The mRSS and ACR CRISS, responses exceeded those seen in the 16-week double-blind placebo-controlled phase and the 6-month time point in the OLE.

Safety

There were no severe or serious AEs and no clinically significant laboratory abnormalities related to the drug. Thirty-three (92%) subjects experienced AEs, and 7 (19%) subjects experienced AEs related to lenabasum during open-label dosing. AEs that occurred in $\geq 10\%$ of subjects (n, %) were upper respiratory tract infection (8, 22%), arthralgia, skin ulcer, and urinary tract infection (5, 13.9% each), and diarrhea (4, 11.1%).

Lenabasum has been granted [Orphan Drug Designation](#) and [Fast Track](#) status for the treatment of SSc from the FDA and [Orphan Designation](#) from the EMA. Lenabasum is currently being evaluated in the international multicenter Phase 3 RESOLVE-1 study, a double-blind, randomized, placebo-controlled study assessing the efficacy and safety for the treatment of diffuse cutaneous SSc.



Dermatomyositis Poster Presentation Overview

The abstracts entitled, “*A Phase 2 Study of Safety and Efficacy of Lenabasum (JBT-101), A Cannabinoid Receptor Type 2 Agonist, In Refractory Skin-Predominant Dermatomyositis,*” (Abstract #3531) and “*Safety and Efficacy of Lenabasum In Refractory Skin-Predominant Dermatomyositis Subjects Treated in An Open Label Extension of Trial JBT101-DM-001,*” (Abstract #5629) will be presented in poster presentations by Victoria Werth, M.D., Professor of Dermatology and Medicine at the University of Pennsylvania School of Medicine and Principal Investigator in the Phase 2 study. To access the poster, click [here](#).

The DM Phase 2 study was funded by a grant from the National Institute of Arthritis and Musculoskeletal and Skin Diseases of the National Institutes of Health to the University of Pennsylvania Perelman School of Medicine. For more information about the Phase 2 study in dermatomyositis, please visit [ClinicalTrials.gov](https://clinicaltrials.gov) and reference identifier NCT02466243.

Study Design

Twenty subjects with refractory, skin-predominant DM received open-label dosing with lenabasum at 20 mg twice per day following 16-weeks participation in the preceding double-blinded placebo-controlled part of the lenabasum Phase 2 study. There was a mean 31-week wash-out off investigational product prior to the start of the OLE. Seventeen subjects completed 6-months (28-weeks) follow-up in the OLE at the time of data-cut. Lenabasum treatment was in addition to standard-of-care treatments for DM, including stable doses of concomitant immunosuppressive drugs in 91% of subjects.

Efficacy Outcomes

At 6 months (28 weeks), the CDASI activity score improved by a mean of -15.4 points from baseline at the start of the Phase 2 double-blind, placebo-controlled phase of the study. The baseline CDASI activity score at study start was 35 points. At 6 months, 88% of subjects achieved reduction ≥ 5 points, which is considered medically meaningful, 82% achieved reduction ≥ 10 points, and 47% had achieved a low CDASI activity score (≤ 14 points). Patient-reported global disease activity, global skin disease, function, pain, and skin symptoms all improved from study start and OLE start, as did physician global disease and skin activity assessments.

Safety

There were no severe or serious AEs and no clinically significant laboratory abnormalities related to the drug. Thirteen (65%) subjects experienced AEs, and 5 (25%) subjects experienced AEs related to lenabasum during open-label dosing. A DM flare, which is an episode of worsening of the disease, was the only AE that occurred in ≥ 2 subjects, occurring in 2 subjects (one of which experienced a reduction of 14 points in CDASI activity from study start and another of which experienced an increase of 5 points from study start).



About Systemic Sclerosis

Systemic sclerosis is a rare and serious systemic autoimmune rheumatic disease with an unclear etiology. Systemic sclerosis affects approximately 90,000 people in the United States and Europe, with disease onset typically in mid-life. About 80 percent of SSc patients are women. The disease process in systemic sclerosis includes activation of the immune system, with damage to small blood vessels and fibrosis of the skin on internal organs, including lungs, heart, kidneys, gastrointestinal tract and musculoskeletal system. Chronic disease burden, morbidity and mortality are significant. Ten-year mortality rates are high at about 40-60%. Cardiopulmonary disease is the major cause of death in SSc. Immunosuppressive medications such as oral corticosteroids, mycophenolate, methotrexate and cyclophosphamide are used to treat patients with more severe signs and symptoms of disease. Currently, there are no FDA-approved treatments specifically indicated for the treatment of systemic sclerosis, other than pulmonary artery hypertension secondary to connective tissue diseases such as systemic sclerosis.

About Dermatomyositis

Dermatomyositis is a rare and serious systemic autoimmune condition characterized by skin and muscle involvement. Like other autoimmune diseases, it affects more women than men and morbidity is more severe in black, Asian and Native American populations. The disease is characterized by distinct skin lesions that can be accompanied by erosions, photosensitivity, itch, ulcers, calcinosis and hair loss as well as other abnormalities. Muscle inflammation and atrophy is a characteristic of the disease and can manifest as weakness. Dermatomyositis affects as many as 70,000 people in the US. Mortality is high with 5-year survival of 70% and 10-year survival of 57%. Standard of care includes antimalarial drugs and potent immunosuppressive agents, which often lead to significant adverse effects.

About Lenabasum

Lenabasum (formerly known as anabasum) is a synthetic, oral, small-molecule, selective cannabinoid receptor type 2 (CB2) agonist that preferentially binds to CB2 expressed on activated immune cells and fibroblasts. CB2 activation triggers physiologic pathways that resolve inflammation, speed bacterial clearance and halt fibrosis. CB2 activation also induces the production of specialized pro-resolving lipid mediators that activate an endogenous cascade responsible for the resolution of inflammation and fibrosis, while reducing production of multiple inflammatory mediators. Through activation of CB2, lenabasum also is designed to have a direct effect on fibroblasts to halt tissue scarring. Lenabasum is believed to induce resolution rather than immunosuppression by triggering biological pathways to turn "off" chronic inflammation and fibrotic processes. Lenabasum has demonstrated promising potency in preclinical models of inflammation and fibrosis. Preclinical and human clinical studies have shown lenabasum to have a favorable safety, tolerability and pharmacokinetic profile. Further, the drug has demonstrated clinical benefit and positive impact on inflammatory and immunological markers in Phase 2 studies in diffuse cutaneous systemic sclerosis, dermatomyositis and cystic fibrosis.



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 rare, chronic, and serious inflammatory and fibrotic diseases. The Company's lead product candidate, lenabasum, is a novel, synthetic oral endocannabinoid-mimetic drug designed to resolve chronic inflammation and fibrotic processes. Lenabasum is currently being evaluated in systemic sclerosis, cystic fibrosis, dermatomyositis, and systemic lupus erythematosus.

For more information, please visit www.CorbusPharma.com and connect with the Company on [Twitter](#), [LinkedIn](#), [Google+](#) 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 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 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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