
**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): May 10, 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.)*

500 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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 2.02. Results of Operations and Financial Condition.

Corbus Pharmaceuticals Holdings, Inc. (the “Company”) issued a press release on May 10, 2018, disclosing financial information and operating metrics for its fiscal quarter ended March 31, 2018, and discussing its business outlook. A copy of the Company’s press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 7.01. Regulation FD Disclosure.

See “Item 2.02 Results of Operations and Financial Condition” above.

The information in this Current Report on Form 8-K under Items 2.02 and 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 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 or the Securities Exchange Act of 1934, except as shall be expressly set forth by a specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) The following exhibit is furnished with this report:

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release issued by Corbus Pharmaceuticals Holdings, Inc. dated May 10, 2018.</u>

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: May 10, 2018

By: /s/ Yuval Cohen

Name: Yuval Cohen

Title: Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release, issued by Corbus Pharmaceuticals Holdings, Inc. dated May 10, 2018.</u>



EXHIBIT 99.1

Corbus Pharmaceuticals Reports 2018 First Quarter Financial Results and Provides Business Update

– Company continues to make consistent progress in the clinical development programs of lenabasum, in rare, chronic and serious inflammatory and fibrotic diseases –

Norwood, MA (May 10, 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 its financial results for the first quarter ended March 31, 2018.

The Company also provided an update on its corporate progress, clinical status and anticipated milestones for lenabasum, its novel synthetic oral endocannabinoid-mimetic drug designed to resolve chronic inflammation and halt fibrosis in rare autoimmune and inflammatory diseases.

Recent Clinical and Corporate Highlights

- Commenced patient dosing in Phase 3 study in systemic sclerosis;
- Received a Development Award for up to \$25 million from the Cystic Fibrosis Foundation to support the Phase 2b study in cystic fibrosis;
- Commenced patient dosing following agreement with FDA on a Phase 2b cystic fibrosis study design with pulmonary exacerbations as sole primary endpoint;
- Commenced patient dosing in 100-patient Phase 2 clinical study in systemic lupus erythematosus, which is being conducted and funded by the NIH;
- Publication of clinical data demonstrating mechanism of action of lenabasum in human blister model; and
- Ended the first quarter of 2018 with approximately \$71 million in cash and cash equivalents, an increase of \$8.4 million from the start of the year.

“We continued to make progress in the first quarter of 2018 in all four of our clinical programs: systemic sclerosis, cystic fibrosis, dermatomyositis and lupus. We look forward to achieving a number of additional important milestones this year,” stated Yuval Cohen, Ph.D., Chief Executive Officer of the Company.

Systemic Sclerosis Clinical Program Update

Systemic sclerosis is a serious autoimmune disease affecting approximately 90,000 people in the US and Europe and is associated with significant morbidity and up to 60% 10-year mortality. There are currently no drugs specifically approved by the FDA for treatment of systemic sclerosis.



Patient dosing is ongoing in the Phase 3 (“RESOLVE-1”) study of lenabasum for the treatment of diffuse cutaneous systemic sclerosis (“systemic sclerosis”). The international, multicenter Phase 3 RESOLVE-1 study is a double-blind, randomized, placebo-controlled study assessing the efficacy and safety of lenabasum for the treatment of systemic sclerosis. The study will enroll approximately 354 subjects at 70 sites in North America, Europe, Israel, Japan, South Korea and Australia. The planned duration of treatment with study drug is 52 weeks. Subjects are randomized 1:1:1 to receive lenabasum 5 mg twice per day, lenabasum 20 mg twice per day or placebo twice per day.

The primary efficacy outcome of the RESOLVE-1 study will be change from baseline in modified Rodnan Skin Score (“mRSS”), a measure of skin fibrosis and a standard clinical trial outcome in systemic sclerosis. Secondary outcomes of the RESOLVE-1 study include patient- and physician-reported outcomes, forced vital capacity, the American College of Rheumatology Combined Response Index in diffuse cutaneous Systemic Sclerosis (“ACR CRISS”) score, a novel composite measure of clinical improvement from baseline that incorporates change from baseline in mRSS, and lung function. These same outcomes were measured in the Phase 2 study as well as the follow-on open-label extension study for which the 28-week results in all of these efficacy measures were presented in November 2017 at the American College of Rheumatology conference. For more information on the Phase 3 study, please visit [ClinicalTrials.gov](https://clinicaltrials.gov) and reference Identifier NCT03398837.

Corbus expects to report topline results from the Phase 3 RESOLVE-1 study in the first half of 2020 and will provide regular updates from the ongoing open-label extension study.

Lenabasum has been granted Orphan Drug Designation and Fast Track status for the treatment of systemic sclerosis from the FDA and Orphan Designation from the European Medicines Agency (“EMA”).

Cystic Fibrosis (“CF”) Clinical Program Update

Cystic fibrosis is a chronic, life-threatening, genetic rare disease, characterized by chronic lung inflammation that leads to lung damage and fibrosis that affects approximately 30,000 patients in the U.S and 75,000 patients worldwide. The current average life expectancy for CF patients is 40 years. The harmful inflammation and accompanying fibrosis in CF damages multiple organs, impairs organ function, reduces health-related quality of life, and is the most common cause of mortality. There remains a recognized unmet need for safe and effective drugs that target chronic inflammation and fibrosis for the treatment of CF on top of standard of care but without the risk of immunosuppression currently associated with existing anti-inflammatory drugs.

Corbus has commenced its Phase 2b study evaluating lenabasum for the treatment of CF. This Phase 2b CF study was designed with input from the Therapeutic Development Network of the Cystic Fibrosis Foundation and the European Cystic Fibrosis Society Clinical Trials Network and is supported by a Development Award for up to \$25 million from the Cystic Fibrosis Foundation.



The Phase 2b multicenter, double-blinded, randomized, placebo-controlled study will enroll approximately 415 subjects with CF who are at least 12 years of age and at increased risk for pulmonary exacerbations. Secondary efficacy outcomes include other measures of pulmonary exacerbations, change in Cystic Fibrosis Questionnaire-Revised Respiratory domain score and change in forced expiratory volume in 1 second (“FEV1”), % predicted. The study will be conducted in approximately 100 sites across North America, Europe and Australia. Subjects are centrally randomized to one of three cohorts to receive lenabasum 20 mg twice per day, lenabasum 5 mg twice per day, or placebo twice per day for 28 weeks, with 4 weeks follow-up off active treatment. For more information on the Phase 2b study, please visit [ClinicalTrials.gov](https://clinicaltrials.gov) and reference Identifier NCT03451045.

Corbus expects to report topline results for the Phase 2b CF study in the first half of 2020.

Lenabasum was granted Orphan Drug Designation and Fast Track status for the treatment of CF by the FDA in 2015 and Orphan Drug Status from the EMA in 2016.

Dermatomyositis Clinical Program Update

Dermatomyositis is a rare and serious systemic autoimmune condition characterized by skin and muscle inflammation that 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%. Current standard of care includes antimalarial drugs and potent immunosuppressive agents, which often lead to significant adverse effects.

In October 2017, Corbus announced positive topline results from its Phase 2 study evaluating lenabasum for the treatment of skin-predominant dermatomyositis, demonstrating medically and statistically significant improvement in the Cutaneous Dermatomyositis Disease Area and Severity Index (“CDASI”), the primary endpoint in the study. Significant improvements were also seen in multiple secondary patient-reported outcomes. The Company plans to meet with the FDA in this quarter to discuss the next clinical study of lenabasum for the treatment of DM, which is expected to begin by the end of 2018.

Systemic Lupus Erythematosus (“SLE”) Clinical Program Update

SLE is a prototypical autoimmune disease in which the innate immune system is chronically activated by immune complexes containing autoantibodies and self-antigens, which leads to widespread inflammation and tissue damage. According to the CDC, SLE affects between 161,000 - 322,000 people in the US and has many manifestations, including arthritis, rash, photosensitivity, oral ulcers, pleuritis, pericarditis, kidney problems, seizures and psychosis and blood cell abnormalities. Current drugs specifically approved by the FDA for SLE are limited to aspirin, corticosteroids, hydroxychloroquine and belimumab. Physicians commonly treat disease manifestations with immunosuppressive or corticosteroid therapies that have significant toxicities.

Patient dosing has commenced in the Phase 2 randomized, double-blind, placebo-controlled, clinical study evaluating lenabasum for the treatment of systemic lupus erythematosus which is being conducted by the Autoimmunity Centers of Excellence (“ACE”) and is being funded by The National Institutes of Health. The trial will enroll 100 adult SLE patients with active musculoskeletal disease, which is the most common disease manifestation of SLE. Subjects are randomized in a 1:1:1:1 ratio to one of four cohorts to receive placebo or three different doses of lenabasum for 3 months, with 1-month of follow-up. The primary efficacy outcome assesses pain from active musculoskeletal disease, and secondary efficacy outcomes include other assessments of active musculoskeletal disease, overall disease activity using SLE Responder Index, SLE Disease Activity Index (“SLEDAI”) and British Isles Lupus Activity Group (“BILAG”) scoring systems, and patient-reported outcomes.



For more information on the Phase 2 study of lenabasum for the treatment of SLE, please visit ClinicalTrials.gov and reference Identifier NCT03093402.

Summary of Financial Results for First Quarter 2018

For the quarter ended March 31, 2018, the Company reported a net loss of approximately \$11,695,000 or a net loss per diluted share of \$0.21, compared to a net loss of approximately \$7,465,000, or a net loss per diluted share of \$0.16, for the quarter ended March 31, 2017.

Revenue for the quarter decreased by approximately \$0.3 million to \$1.0 million from the quarter ended March 31, 2017. Revenue recognized in 2018 was related to the up to \$25 million Development Award Agreement with the Cystic Fibrosis Foundation that the Company entered into in the first quarter of 2018. Operating expenses for the quarter increased by approximately \$4.1 million to \$12.8 million due to increased spending for clinical studies, manufacturing costs to produce lenabasum for clinical studies and staffing costs.

The Company ended the first quarter with approximately \$71.0 million of cash and cash equivalents, an increase of \$8.4 million from the start of the quarter. The Company received \$6.25 million in milestone payments from the Cystic Fibrosis Foundation during the first quarter and raised approximately \$11.2 million in net proceeds from the sale of common stock. The Company expects the current cash and cash equivalents together with the expected milestone payments from the up to \$25 million Development Award from the Cystic Fibrosis Foundation to fund operations through the fourth quarter of 2019, based on current planned expenditures.

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](#) 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.



Corbus Pharmaceuticals Holdings, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

	For the Three Months Ended	
	March 31,	
	2018	2017
Revenue from awards	\$ 950,442	\$ 1,293,697
Operating expenses:		
Research and development	9,765,362	6,366,112
General and administrative	3,050,032	2,380,125
Total operating expenses	<u>12,815,394</u>	<u>8,746,237</u>
Operating loss	<u>(11,864,952)</u>	<u>(7,452,540)</u>
Other income (expense):		
Interest income, net	203,421	1,366
Foreign currency exchange loss, net	(33,854)	(14,265)
Other income (expense), net	<u>169,567</u>	<u>(12,899)</u>
Net loss	<u>\$ (11,695,385)</u>	<u>\$ (7,465,439)</u>
Net loss per share, basic and diluted	<u>\$ (0.21)</u>	<u>\$ (0.16)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>56,367,548</u>	<u>46,381,482</u>



Corbus Pharmaceuticals Holdings, Inc.
Condensed Consolidated Balance Sheets

	<u>March 31, 2018</u> <u>(Unaudited)</u>	<u>December 31, 2017</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 70,955,652	\$ 62,537,495
Restricted cash	—	158,991
Prepaid expenses and other current assets	3,531,259	2,808,244
Total current assets	74,486,911	65,504,730
Property and equipment, net	2,593,172	1,432,655
Other assets	59,639	40,776
Total assets	<u>\$ 77,139,722</u>	<u>\$ 66,978,161</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	\$ 208,648	\$ 332,861
Accounts payable	4,169,781	3,130,295
Accrued expenses	5,898,274	4,741,519
Total current liabilities	10,276,703	8,204,675
Deferred rent, noncurrent	1,323,415	989,550
Other liabilities	—	375
Total liabilities	11,600,118	9,194,600
Commitments and Contingencies		
Stockholders' equity		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized, no shares issued and outstanding at March 31, 2018 and December 31, 2017	—	—
Common stock, \$0.0001 par value; 150,000,000 shares authorized, 57,139,892 and 55,603,427 shares issued and outstanding at March 31, 2018 and December 31, 2017	5,714	5,560
Additional paid-in capital	142,927,376	123,476,102
Accumulated deficit	(77,393,486)	(65,698,101)
Total stockholders' equity	<u>65,539,604</u>	<u>57,783,561</u>
Total liabilities and stockholders' equity	<u>\$ 77,139,722</u>	<u>\$ 66,978,161</u>



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