
**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 9, 2019

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 9, 2019, disclosing financial information and operating metrics for its fiscal quarter ended March 31, 2019 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 9, 2019.</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 9, 2019

By: /s/ Yuval Cohen
Name: Yuval Cohen
Title: Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, issued by Corbus Pharmaceuticals Holdings, Inc. dated May 9, 2019.



Corbus Pharmaceuticals Reports 2019 First Quarter Financial Results and Provides Clinical Updates

- Continued progress made in four ongoing clinical studies as lenabasum advances towards 2020 data readouts in lead indications systemic sclerosis and cystic fibrosis
- Second clinical candidate CRB-4001 expected to commence clinical studies in 2019
- Platform of proprietary drug candidates positions Corbus to become the leader in the treatment of inflammatory and fibrotic diseases targeting the endocannabinoid system (ECS)
- Company to host conference call and webcast today, May 9th at 8:30 a.m. ET

Norwood, MA (May 9, 2019) – Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) (“Corbus” or the “Company”) today announced its financial results for the first quarter ended March 31, 2019. The Company also provided an update on its corporate progress, clinical status and financial position.

Key Achievements in Q1 2019:

- Announced the change of primary endpoint in ongoing RESOLVE-1 Phase 3 study in systemic sclerosis in U.S. to ACR CRISS following meeting with U.S. FDA;
- Completed subject enrollment in RESOLVE-1 Phase 3 study of lenabasum treatment for systemic sclerosis, Company expects to report topline results from this study in the summer of 2020;
- Completed licensing deal for lenabasum in Japan with Kaken Pharmaceuticals. Received \$27M up-front payment, with up to \$173M in potential milestones as well as double-digit royalties;
- Raised \$40M in equity capital from a public offering lead by Jefferies and RBC;
- Cash balance increased by \$48.2M from year-end to \$89.9M at March 31, 2019;
- Appointed Rachelle Jacques to Board of Directors, who brings U.S. and global commercialization and marketing experience, including multiple product launches in rare diseases; and
- Appointed Craig Millian as Chief Commercial Officer to lead global marketing and commercialization strategies.

“We made significant progress during the quarter in our clinical programs and have begun laying the foundation for the commercialization of lenabasum,” commented Yuval Cohen, Ph.D., Chief Executive Officer of Corbus. “We continue to advance lenabasum through the clinic and remain on track with our four ongoing clinical studies. We expect to launch a Phase 1 study of CRB-4001 later this year. We are working to identify additional drug candidates from our unique portfolio of pre-clinical compounds that target the endocannabinoid system. Looking ahead, we are confident that our clinical progress and corporate commercialization strategy, supported by our strong balance sheet, will position Corbus to unlock significant value for all stakeholders.”



Lenabasum – Novel, oral, selective cannabinoid receptor type 2 (CB2) agonist designed to resolve chronic inflammation and fibrotic processes

Systemic Sclerosis (SSc) – Phase 3 “RESOLVE-1” Study Enrolled with Topline Results Expected in summer of 2020

- SSc is a chronic, rare systemic autoimmune disease characterized by inflammation and fibrosis affecting ~200,000 people in the U.S., EU and Japan;
- SSc has the highest mortality rate among the systemic autoimmune diseases;
- Enrollment completed and dosing ongoing in Phase 3 study, Company expects to report topline results from this study in the summer of 2020; and
- No drugs currently approved by the U.S. FDA for treatment of SSc. Treatment options for overall disease control limited to immunosuppressive drugs.

Following a Type C meeting with the U.S. Food and Drug Administration (FDA), Corbus recently announced that it will change the primary efficacy endpoint of the ongoing RESOLVE-1 Phase 3 SSc trial in the U.S. to the American College of Rheumatology Combined Response Index in diffuse cutaneous Systemic Sclerosis (ACR CRISS) score at Week 52 from the current primary endpoint, change in modified Rodnan Skin core (mRSS). The ACR CRISS score was the primary efficacy endpoint of the Phase 2 study evaluating lenabasum for the treatment of diffuse cutaneous SSc. The Company remains on track to complete the RESOLVE-1 study in the summer of 2020 and no changes to the size or length of the study are required. Corbus remains blinded to the treatment assignment of subjects until after database lock occurs in the second quarter of 2020.

Corbus expects to report topline results from the Phase 3 RESOLVE-1 study in the summer of 2020, with commercialization in late 2021 following potential U.S. FDA approval. Lenabasum was granted Orphan Drug Designation for the treatment of SSc from the U.S. FDA and the European Medicines Agency (EMA) and granted Fast Track status from the FDA. For more information on the Phase 3 study, please visit [ClinicalTrials.gov](https://clinicaltrials.gov) and reference Identifier NCT03398837.

Dermatomyositis (DM) – Phase 3 “DETERMINE” Study Underway

- DM is a rare and serious autoimmune condition characterized by skin and muscle inflammation affecting ~80,000 people in the U.S., EU and Japan;
- 5-year mortality as high as 30%;
- Enrollment is ongoing in the Phase 3 study with the American College of Rheumatology/European League Against Rheumatism 2016 Total Improvement Score in myositis as the primary efficacy endpoint.

Lenabasum was granted Orphan Drug Designation for the treatment of DM from the U.S. FDA and EMA. For more information on the Phase 3 study, please visit [ClinicalTrials.gov](https://clinicaltrials.gov) and reference Identifier NCT03813160.



Cystic Fibrosis (CF) – Phase 2b Study Underway, Study Funded in Part by a Development Award for up to \$25 Million from the Cystic Fibrosis Foundation

- CF is a life-threatening genetic disease characterized in part by chronic lung inflammation that leads to lung damage and fibrosis. CF affects ~70,000 people in U.S. and EU;
- Enrollment and dosing are ongoing in the Phase 2b study with event rate of pulmonary exacerbations (PEX) as the primary efficacy endpoint. Pulmonary exacerbations are a clinically relevant event of increase in respiratory symptoms usually accompanied by an acute decrease in lung function and an increase in lung inflammation;
- Pulmonary exacerbations are responsible for about half of long-term decline in lung function experienced by people with CF; and
- There continues to be an unmet need for drugs that reduce rate and severity of PEX in people with CF.

Corbus expects to report topline results for the large Phase 2b CF study in 2020. Lenabasum was granted Orphan Drug Designation for the treatment of CF from the U.S. FDA and the EMA and granted Fast Track status from the FDA. For more information on the Phase 2b study, please visit ClinicalTrials.gov and reference Identifier NCT03451045.

Systemic Lupus Erythematosus (SLE) – Phase 2 Study Underway, Represents the Largest Potential Patient Population Targeted by Lenabasum

- Systemic lupus erythematosus is a severe and sometimes life-threatening systemic autoimmune disease affecting approximately 550,000 people in the U.S., EU and Japan;
- Disease pathology can include inflammation in many different organs, including the kidneys and brain;
- Enrollment and dosing are ongoing in a first-in-patient Phase 2 study being conducted and funded by the National Institutes of Health (NIH); and
- People with SLE continue to have high unmet medical need as standard-of-care often includes immunosuppressive drugs, which can have significant side effects.

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

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

CRB-4001 - 2nd Generation, Peripherally-restricted, Selective Cannabinoid Receptor Type 1 (CB1) Inverse Agonist Targeting Liver Fibrosis

CRB-4001 is rationally designed to be an inverse agonist of cannabinoid receptor type 1. It has been designed to improve certain metabolic abnormalities in people with nonalcoholic steatohepatitis (NASH) or non-alcoholic fatty liver disease (NAFLD), while reducing inflammation and fibrosis in the liver. Preparations are underway to begin a Phase 1 study of CRB-4001 by the end of 2019 followed by a planned Phase 2 study of effects of CRB-4001 in people with metabolic syndrome or NASH, which is expected to be conducted by the NIH.

CRB-4001 is not approved for the treatment of NASH.



Summary of Financial Results for First Quarter 2019 Ended March 31, 2019

For the quarter ended March 31, 2019, the Company reported a net loss of approximately \$26,235,000 or a net loss per diluted share of \$0.43, compared to a net loss of approximately \$11,695,000, or a net loss per diluted share of \$0.21, for the quarter ended March 31, 2018.

For the quarter ended March 31, 2019, revenue from awards increased by approximately \$0.9 million to \$1.9 million due to revenue recognized from the Development Award Agreement with the Cystic Fibrosis Foundation.

Operating expenses for the quarter ended March 31, 2019 increased by approximately \$15.6 million to \$28.4 million. The increase was attributable to increased spending for clinical studies, cost to manufacture and supply Lenabasum for clinical trials, staffing costs, a \$1.2 million increase in non-cash stock compensation expenses and a \$2.7 million sub-royalty payment accrued as of March 31, 2019 due to the CF Foundation as a result of the \$27 million up-front licensing payment received from Kaken Pharmaceuticals.

The Company's cash and cash equivalents balance increased by \$48.2 million from December 31, 2018 to \$89.9 million at March 31, 2019. In January 2019 the Company completed a public offering of common stock which raised \$40 million in gross proceeds and in March 2019 the Company received a \$27 million up-front payment from the licensing deal with Kaken Pharmaceuticals. The Company expects the current cash and cash equivalents together with the remainder of the expected milestone payments from the up to \$25 million Development Award from the Cystic Fibrosis Foundation to fund operations into the fourth quarter of 2020, based on current planned expenditures.

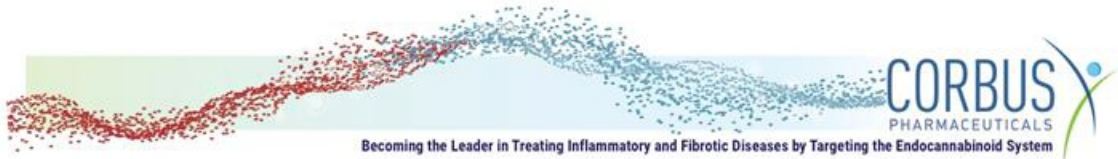
Conference Call and Webcast Information

Corbus management will host a conference call and webcast presentation for investors, analysts and other interested parties today, Thursday, May 9 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). CB2 is preferentially expressed on activated immune cells, fibroblasts, muscle cells, and endothelial cells. In both animal and human studies conducted to-date, lenabasum has induced the production of Specialized Pro-resolving lipid Mediators ("SPMs") that activate endogenous pathways which resolve inflammation and speed bacterial clearance without immunosuppression. Lenabasum is also believed to have a direct effect on fibroblasts to limit production of fibrogenic growth factors and extracellular connective tissue that lead to tissue fibrosis (scarring). 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 an 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 skin-predominant dermatomyositis. ACR CRISS score was the primary efficacy endpoint in the Phase 2 study of lenabasum in diffuse cutaneous SSc and showed a greater treatment effect in subjects who received lenabasum compared to placebo in that study. Lenabasum treatment also was associated with a lower rate of and longer time to pulmonary exacerbations in a Phase 2 cystic fibrosis study. Additional clinical studies are being conducted and/or planned to confirm these results and support applications for regulatory approval.

About CRB-4001

CRB-4001 is a 2nd generation, peripherally-restricted, CB1 inverse agonist. CRB-4001 was developed in collaboration with and financial support from the National Institutes of Health (NIH). CRB-4001 was specifically designed to eliminate blood-brain barrier penetration and brain CB1 receptor occupancy that mediate the neuropsychiatric issues associated with first-generation CB1 inverse agonists such as rimonabant. Corbus expects to initiate a Phase 1 study for CRB-4001 in 2019, intended to be followed by a NIH-funded first-in-patient Phase 2 study.

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 endocannabinoid system-targeting synthetic drug candidates. The Company's lead product candidate, lenabasum, is a novel, synthetic, oral, selective cannabinoid receptor type 2 (CB2) agonist 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 from more than 600 novel compounds targeting the endocannabinoid system. The pipeline includes CRB-4001, a 2nd generation, peripherally-restricted, selective cannabinoid receptor type 1 (CB1) inverse agonist. Potential indications for CRB-4001 include NASH, among others. Corbus plans to start a Phase 1 study of CRB-4001 in 2019, intended to be followed by a National Institutes of Health (NIH)-funded proof-of-concept Phase 2 study.

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 Balance Sheets**

	<u>March 31, 2019</u>	<u>December 31, 2018</u>
	<u>(unaudited)</u>	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 89,919,798	\$ 41,748,468
Prepaid expenses and other current assets	2,904,215	2,491,844
Total current assets	<u>92,824,013</u>	<u>44,240,312</u>
Property and equipment, net	2,694,489	2,705,206
Operating lease right of use assets	5,839,435	—
Other assets	35,589	43,823
Total assets	<u>\$ 101,393,526</u>	<u>\$ 46,989,341</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	\$ 247,384	\$ 394,305
Accounts payable	8,962,750	6,345,335
Accrued expenses	15,563,853	9,851,191
Deferred revenue, current	27,000,000	1,462,503
Operating lease liabilities	266,807	35,996
Total current liabilities	<u>52,040,794</u>	<u>18,089,330</u>
Operating lease liabilities, noncurrent	7,051,781	1,375,891
Total liabilities	<u>59,092,575</u>	<u>19,465,221</u>
Commitments and Contingencies		
Stockholders' equity		
Preferred Stock \$0.0001 par value; 10,000,000 shares authorized, no shares issued and outstanding at March 31, 2019 and December 31, 2018	—	—
Common stock, \$0.0001 par value; 150,000,000 shares authorized, 64,455,221 and 57,247,496 shares issued and outstanding at March 31, 2019 and December 31, 2018	6,446	5,725
Additional paid-in capital	189,899,554	148,888,635
Accumulated deficit	<u>(147,605,049)</u>	<u>(121,370,240)</u>
Total stockholders' equity	<u>42,300,951</u>	<u>27,524,120</u>
Total liabilities and stockholders' equity	<u>\$ 101,393,526</u>	<u>\$ 46,989,341</u>



Corbus Pharmaceuticals Holdings, Inc.
Condensed Consolidated Statements of Operations

	For the Three Months Ended	
	March 31,	
	2019	2018
Revenue from awards	\$ 1,885,682	\$ 950,442
Operating expenses:		
Research and development	21,783,704	9,765,362
General and administrative	6,624,747	3,050,032
Total operating expenses	<u>28,408,451</u>	<u>12,815,394</u>
Operating loss	<u>(26,522,769)</u>	<u>(11,864,952)</u>
Other income (expense):		
Interest income, net	334,595	203,421
Foreign currency exchange loss, net	<u>(46,635)</u>	<u>(33,854)</u>
Other income, net	<u>287,960</u>	<u>169,567</u>
Net loss	<u>\$ (26,234,809)</u>	<u>\$ (11,695,385)</u>
Net loss per share, basic and diluted	<u>\$ (0.43)</u>	<u>\$ (0.21)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>61,675,904</u>	<u>56,367,548</u>

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