
**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): March 12, 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 March 12, 2019, disclosing financial information and operating metrics for its fiscal year ended December 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 March 12, 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: March 12, 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. March 12, 2019.



**Corbus Pharmaceuticals Reports Fourth Quarter and Full Year 2018
Financial Results and Provides Clinical Updates**

- *Pipeline of rationally-designed synthetic cannabinoids position Corbus to become the leader in treating inflammatory and fibrotic diseases by targeting the endocannabinoid system (ECS)*
- *Continued progress in four ongoing clinical studies as lenabasum moves towards expected 2020 topline data readouts in systemic sclerosis and cystic fibrosis studies*
- *Strategic agreement with Kaken Pharmaceuticals Co., Ltd. for Japanese market establishes roadmap for commercialization of lenabasum with unencumbered rights in all other geographies*
- *Second clinical candidate CRB-4001 expected to commence clinical studies in 2019*
- *Company to host conference call and webcast today, March 12 at 8:30 a.m. ET*

Norwood, MA (March 12, 2019) – Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) (“Corbus” or the “Company”), a clinical stage drug development company with the industry’s leading pipeline focused on treating inflammatory and fibrotic diseases through the endocannabinoid system pathways, announced today its financial results for the fourth quarter and year ended December 31, 2018. The Company also provided an update on its corporate progress, clinical status and financial position.

Recent Clinical and Corporate Achievements:

- Entered into strategic collaboration with Kaken Pharmaceutical Co., Ltd. for the development and commercialization of lenabasum in Japan. Deal included a \$27 million upfront payment, up to \$173 million of additional potential milestone payments and double-digit royalties;
- Appointed Craig Millian as Chief Commercial Officer to lead global marketing and commercialization strategies;
- Announced the successful closing of \$40 million public offering of common stock;
- Strengthened lenabasum intellectual property protection through 2034 with issuance of four U.S. patents (#’s10,154,986, 10,085,964, 9,801,849 and 9,820,964) covering composition of matter and broad use in inflammatory and fibrotic diseases;
- Initiated Phase 3 lenabasum study in dermatomyositis (DM), titled “**DETERMINE**”; and
- Presented ongoing Phase 2 lenabasum open label extension (OLE) data for both Systemic Sclerosis and Dermatomyositis at the 2018 American College of Rheumatology (ACR) Annual Meeting and the 2018 Annual European Congress of Rheumatology Meeting (EULAR).

“2018 was a year of significant progress for Corbus. We made meaningful advancements in the clinical development of lenabasum, and we also completed two transformational commercial transactions, which expanded our clinical pipeline and broadened our global commercial opportunity. We believe the acquisition of more than 600 ECS-targeting drug candidates will fuel sustained growth of our platform and cement our leadership position in the field. The most advanced candidate, CRB-4001, is expected to enter Phase 1 clinical study later this year and to be followed by a Phase 2 study in patients with NASH. Our strategic collaboration with Kaken Pharmaceutical in Japan is our first step towards commercializing lenabasum in key markets outside of the United States,” commented Yuval Cohen, Ph.D., Chief Executive Officer of Corbus.



Dr. Cohen continued, “Looking ahead, we are focused on positioning the Company for a successful commercial launch of lenabasum, following potential U.S. FDA approval in 2021. We are excited for the opportunities ahead and look forward to continuing to develop meaningful solutions for patients, while driving value for our shareholders.”

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

Systemic Sclerosis – Late-Stage Clinical Program with Potential Commercialization in 2021

- Systemic Sclerosis is a rare and life-threatening autoimmune disease characterized by inflammation and fibrosis affecting ~200,000 people in the U.S., Europe and Japan;
- Approximately 40% to 60% 10-year mortality;
- 18-month OLE data presented at ACR demonstrated an acceptable safety profile and further improvement in efficacy outcomes. The modified Rodnan Skin Score (mRSS) improved by a mean of -10.7 points in the OLE. The ACR CRISS score steadily improved and reached a median score of 99% with 50% of the subjects achieving an ACR CRISS of 100%;
- Enrollment and dosing are ongoing in the Phase 3 international RESOLVE-1 study; and
- No drugs currently approved by the FDA for treatment of SSc. Treatment options for overall disease control limited to immunosuppressive drugs.

Corbus expects to report topline results from the Phase 3 RESOLVE-1 study in 2020. For more information on the Phase 3 study, please visit [ClinicalTrials.gov](https://clinicaltrials.gov) and reference Identifier NCT03398837.

Dermatomyositis – 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%;
- 12-month OLE data presented at ACR demonstrated an acceptable safety profile and further improvement in efficacy outcomes. The CDASI activity score improved by a -17.6 points in the OLE, with an improvement of -4 to -5 points being considered medically important;
- Commenced Phase 3 study titled “DETERMINE” in December 2018; and
- Lenabasum granted Orphan Drug Designation in the U.S and in Europe.

For more information on the Phase 3 study, please visit [ClinicalTrials.gov](https://clinicaltrials.gov) and reference Identifier NCT03813160.



Cystic Fibrosis—Phase 2b Study Funded by a Development Award for up to \$25 Million from the Cystic Fibrosis Foundation

- Cystic Fibrosis is a life-threatening genetic disease characterized by chronic lung inflammation that leads to lung damage and fibrosis;
- Affects ~70,000 people in 7 major markets;
- Current average life expectancy for CF patients is approximately 40 years;
- Enrollment and dosing are ongoing in the Phase 2b study with Pulmonary Exacerbations as the primary efficacy endpoint; and
- Continued unmet need for drugs to treat pulmonary exacerbations, which are acute episodes of lung inflammation which cause significant decline in respiratory function, high medical costs, and frequently irreversible lung damage.

Corbus expects to report topline results for the Phase 2b CF study in 2020. For more information on the Phase 2b study, please visit [ClinicalTrials.gov](https://clinicaltrials.gov) and reference Identifier NCT03451045.

Systemic Lupus Erythematosus (SLE) – Represents the Largest Patient Population Targeted by Lenabasum

- Enrollment and dosing are ongoing in a first-in-patient Phase 2 study being conducted and funded by the National Institute of Health;
- Prototypical multisystem autoimmune disease in which the innate immune system is chronically activated leading to tissue inflammation and damage;
- Affects ~300,000 people in U.S. with a 2.4-fold increase in mortality; and
- Patients with SLE continue to have high unmet medical need as current treatments are generally immunosuppressive agents, which can lead to significant side effects.

For more information on the Phase 2 study of lenabasum for the treatment of SLE, please visit [ClinicalTrials.gov](https://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 - Peripheral CB1 Inverse Agonist Targeting Liver Fibrosis

CRB-4001 is rationally designed to have a potent effect on deactivating CB1 to reduce inflammation and fibrosis in target organs such as the liver or kidneys while avoiding blood-brain barrier penetration to limit impact on CB1 brain receptors, thus mediating the neuropsychiatric issues associated with first-generation CB1 inverse agonists or antagonists. Preparations are underway to commence a Phase 1 study of CRB-4001 followed by a planned Phase 2 NASH study expected to be conducted by the NIH. Potential indications for CRB-4001 include NASH, primary biliary cholangitis, idiopathic pulmonary fibrosis, radiation-induced pulmonary fibrosis, myocardial fibrosis after myocardial infarction, and acute interstitial nephritis, among others.



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

Summary of Financial Results for Fourth Quarter and Year Ended December 31, 2018

For the quarter ended December 31, 2018, the Company reported a net loss of approximately \$17,306,000 or a net loss per diluted share of \$0.30, compared to a net loss of approximately \$10,694,000, or a net loss per diluted share of \$0.20, for the quarter ended December 31, 2017.

For the year ended December 31, 2018, the Company reported a net loss of approximately \$55,672,000 or a net loss per diluted share of \$0.98, compared to a net loss of approximately \$32,422,000, or a net loss per diluted share of \$0.65, for the year ended December 31, 2017.

For the year ended December 31, 2018, revenue from awards increased by approximately \$2.4 million to \$4.8 million due to revenue recognized from the up to \$25 million Development Award Agreement with the Cystic Fibrosis Foundation. Operating expenses increased by approximately \$26.6 million to \$61.6 million due to increased spending for clinical studies, manufacturing costs to produce lenabasum for clinical studies and staffing costs. For the quarter ended December 31, 2018, revenue from awards increased by approximately \$1.9 million and operating expenses increased by approximately \$8.7 million.

The Company's cash and cash equivalents balance at December 31, 2018 was approximately \$41.7 million. In January 2019, the Company completed a \$40 million public offering before deducting underwriting discounts and offering expenses and the Company will receive a \$27 million up-from payment from the Kaken licensing deal. The Company expects the current cash and cash equivalents 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, Tuesday, March 12 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 improved multiple physician-assessed and patient-reported efficacy outcomes in Phase 2 studies in patients with diffuse cutaneous SSc and skin-predominant dermatomyositis. Lenabasum also reduced 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, followed by an NIH-funded first-in-patient Phase 2 study.

About Corbus

Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) 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 industry leading pipeline of endocannabinoid system-targeting 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 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. Potential indications for CRB-4001 include NASH, primary biliary cholangitis, idiopathic pulmonary fibrosis, radiation-induced pulmonary fibrosis, myocardial fibrosis after myocardial infarction and acute interstitial nephritis, among others. CRB-4001 is scheduled to enter a Phase 1 study in 2019 followed by a National Institutes of Health (NIH)-funded first-in-patient 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

	December 31,	
	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 41,748,468	\$ 62,537,495
Restricted cash	—	158,991
Prepaid expenses and other current assets	2,491,844	2,808,244
Total current assets	44,240,312	65,504,730
Property and equipment, net	2,705,206	1,432,655
Other assets	43,823	40,776
Total assets	\$ 46,989,341	\$ 66,978,161
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	\$ 394,305	\$ 332,861
Accounts payable	6,345,335	3,130,295
Accrued expenses	9,851,191	4,741,519
Deferred revenue, current	1,462,503	—
Deferred rent, current	35,996	—
Total current liabilities	18,089,330	8,204,675
Deferred rent, noncurrent	1,375,891	989,550
Other liabilities	—	375
Total liabilities	19,465,221	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 December 31, 2018 and December 31, 2017	—	—
Common stock, \$0.0001 par value; 150,000,000 shares authorized, 57,247,496 and 55,603,427 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	5,725	5,560
Additional paid-in capital	148,888,635	123,476,102
Accumulated deficit	(121,370,240)	(65,698,101)
Total stockholders' equity	27,524,120	57,783,561
Total liabilities and stockholders' equity	\$ 46,989,341	\$ 66,978,161



**Corbus Pharmaceuticals Holdings, Inc.
Consolidated Statements of Operations**

	For the Three Months Ended December 31,		For the Year Ended December 31,	
	2018	2017	2018	2017
Revenue from awards	\$ 1,927,306	\$ —	\$ 4,822,272	\$ 2,440,195
Operating expenses:				
Research and development	15,780,928	8,286,682	48,613,957	26,038,965
General and administrative	3,737,370	2,575,244	12,956,022	8,964,046
Total operating expenses	19,518,298	10,861,926	61,569,979	35,003,011
Operating loss	(17,590,992)	(10,861,926)	(56,747,707)	(32,562,816)
Other income (expense), net:				
Interest income, net	244,725	133,073	982,777	183,112
Foreign currency exchange gain (loss)	40,075	35,163	92,791	(41,908)
Other income, net	284,800	168,236	1,075,568	141,204
Net loss	\$ (17,306,192)	\$ (10,693,690)	\$ (55,672,139)	\$ (32,421,612)
Net loss per share, basic and diluted	\$ (0.30)	\$ (0.20)	\$ (0.98)	\$ (0.65)
Weighted average number of common shares outstanding, basic and diluted	57,242,604	53,828,680	56,999,741	50,176,953

Investor Contacts:

Institutional Investor Inquiries

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