
**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): November 8, 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 November 8, 2018, disclosing financial information and operating metrics for its fiscal quarter ended September 30, 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 November 8, 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: November 8, 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 November 8, 2018.</u>



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

- *Licensed Jenrin Discovery's extensive library of small molecules targeting the endocannabinoid system (ECS) positioning Corbus with the leading pipeline focused on treating inflammatory and fibrotic diseases through ECS pathways*
- *Reported long-term open-label extension data from both Phase 2 systemic sclerosis and dermatomyositis studies showing maintenance of favorable safety profile and further improvement in multiple efficacy endpoints*
- *Company to host conference call and webcast today, November 8, 2018, at 8:30 a.m. ET*

Norwood, MA (November 8, 2018) – Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) (“Corbus” or the “Company”), a clinical stage drug development company with the industry leading pipeline focused on treating inflammatory and fibrotic diseases through the endocannabinoid system (“ECS”) pathways, announced today its financial results for the third quarter ended September 30, 2018 along with updates on recent milestones.

“The third quarter was marked by the completion of the Jenrin transaction, which we view as a transformative development for the Company,” commented Yuval Cohen, Ph.D., Chief Executive Officer of Corbus. “Our expanded pipeline of ECS-targeting drug candidates is now diversified with lenabasum, our lead late-stage clinical asset in four rare inflammatory indications with expected clinical read-out in 2020, together with CRB-4001, which is expected to enter the clinic in 2019 as a novel candidate for nonalcoholic steatohepatitis, or NASH. We have progressed in securing a platform for potential future growth for our Company from our library of over 600 compounds targeting ECS pathways.”

Recent Clinical and Corporate Achievements:

- Reported 18-month systemic sclerosis (“SSc”) and one-year dermatomyositis (“DM”) Phase 2 open-label extension (“OLE”) data at the American College of Rheumatology (“ACR”) 2018 Annual Meeting, demonstrating continued favorable safety profile and further improvement in multiple efficacy endpoints;
- Presented new data demonstrating lenabasum’s effect on airway macrophages from human cystic fibrosis lungs at the 2018 North American Cystic Fibrosis Conference. Data showed lenabasum decreased inflammatory biomarkers and increased pro-resolving mediators in airway macrophages of cystic fibrosis patients;
- Completed licensing transaction and gained exclusive worldwide rights to develop, manufacture and market drug candidates from more than 600 compounds targeting the endocannabinoid system from Jenrin Discovery, LLC (“Jenrin”). The pipeline includes CRB-4001, Jenrin’s 2nd generation, peripherally-restricted, CB1 inverse agonist targeting liver, lung, heart and kidney fibrotic diseases;
- Appointed George Kunos, M.D., Ph.D., Scientific Director of the National Institute on Alcohol Abuse and Alcoholism (NIAAA), a part of the NIH, to the Company’s Scientific Advisory Board to provide scientific support for the development of compounds that target the endocannabinoid system as therapeutics for a broad range of diseases;



- Received Orphan Designation for lenabasum for the treatment of DM in the European Union;
- Granted Notice of Allowance for key patent covering the use of pharmaceutical compositions comprising Lenabasum for the treatment of all fibrotic diseases; and
- Received guidance from FDA for design of a single Phase 3 study to evaluate efficacy and safety of lenabasum for treatment of DM.

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

- Rare and life-threatening autoimmune disease characterized by tissue inflammation and fibrosis;
- Affects approximately 120,000 people in the U.S., Europe and Japan;
- Approximately 40% to 60% 10-year mortality;
- Treatment options for overall disease control limited to immunosuppressive drugs with no drugs currently approved by the FDA for treatment of SSc;
- Lenabasum was granted Orphan Drug Designation and Fast Track status for the treatment of systemic sclerosis from the FDA and Orphan Designation from the EMA; and
- Enrollment and dosing are ongoing in the Phase 3 study.

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.

The Company recently presented safety and efficacy data from the 18-month OLE of the Phase 2 study of lenabasum for the treatment of systemic sclerosis at the ACR 2018 Annual Meeting demonstrating favorable safety profile and further improvement in efficacy outcomes. Click [here](#) to access the poster of the Phase 2 SSc OLE data presented at ACR.

Dermatomyositis Clinical Program Overview – Phase 3 Study to Commence Before Year End

- Rare and serious autoimmune condition related to SSc and characterized by skin and muscle inflammation;
- Affects ~80,000 people in the U.S., EU and Japan;
- 5-year mortality as high as 30%;
- High unmet medical need. Current standard-of-care treatment includes antimalarial drugs and potent immunosuppressive agents, which can lead to significant side effects;
- Lenabasum was granted FDA Orphan Drug Designation in July 2018 and Orphan Designation in the European Union for the treatment of DM in September 2018; and
- Received guidance from FDA for design of a single Phase 3 study scheduled to commence by the end of 2018.



The Company recently presented safety and efficacy data from the 12-month OLE of the Phase 2 study of lenabasum for the treatment of dermatomyositis at ACR demonstrating a favorable safety profile and further improvement in efficacy endpoints. Click [here](#) to access the poster of the Phase 2 DM OLE data presented at ACR. The double-blinded, placebo-controlled portion of 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.

Cystic Fibrosis Clinical Program Overview – Ongoing Phase 2b Study Funded in Part by a Development Award for up to \$25 Million from the Cystic Fibrosis Foundation

- Life-threatening rare genetic disease that affects ~30,000 patients in the U.S. and ~75,000 patients worldwide;
- Current average life expectancy for CF patients is approximately 40 years;
- Pathologic inflammation damages multiple organs including the lungs, impairs organ function, and reduces health-related quality of life;
- Continued 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;
- 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 European Medicines Agency (“EMA”) in 2016; and
- Enrollment and dosing are ongoing in a Phase 2b study. This Phase 2b CF study was designed with input from the Cystic Fibrosis Therapeutics Development Network and the European Cystic Fibrosis Society Clinical Trials Network. FDA provided guidance on the overall study design.

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 and reference Identifier NCT03451045.

The Company recently presented new data demonstrating lenabasum’s effect on airway macrophages harvested from human cystic fibrosis lungs at the 2018 North American Cystic Fibrosis Conference. Click [here](#) to access the poster of the CF data presented at NACFC.

Systemic Lupus Erythematosus Clinical Program Overview – Represents the Largest Indication Targeted by Lenabasum

- Prototypical multisystem autoimmune disease in which the innate immune system is chronically activated by immune complexes containing autoantibodies and self-antigens, leading to tissue inflammation and damage;
- Affects ~300,000 people in U.S. with a 2.4-fold increase in mortality;
- Patients with SLE continue to have high unmet medical need with current treatments focused on immunosuppressive agents, that can lead to significant side effects; and
- Enrollment and dosing are ongoing in a first-in-patient Phase 2 randomized, double-blind, placebo-controlled, clinical study evaluating efficacy and safety of lenabasum for the treatment of SLE. This study is being conducted and funded by the Autoimmunity Centers of Excellence, National Institutes of Health.

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



CRB-4001 Clinical Program Overview - Peripheral CB1 Inverse Agonist Targeting Peripheral Organ Fibrosis with Strong Pre-Clinical Data

CRB-4001, the lead candidate in development from Jenrin's pipeline, is specifically designed to avoid blood-brain barrier penetration and/or occupy CB1 brain receptors, thus mediating the neuropsychiatric issues associated with first-generation CB1 inverse agonists. CRB-4001 was developed in collaboration with and with financial support from the NIH. To provide scientific support for the expanded development of Corbus' pipeline compounds, George Kunos, M.D., Ph.D., Scientific Director of the National Institute on Alcohol Abuse and Alcoholism ("NIAAA"), a part of the NIH, joined the Company's Scientific Advisory Board. Dr. Kunos is an expert in the biology of the endocannabinoid system with a particular focus on its role in the regulation of metabolic, neuroendocrine, and cardiovascular functions as well as addictive behaviors, and the related therapeutic implications.

The National Center for the Advancement of Translational Science ("NCATS"), a part of the NIH, conducted and sponsored IND-enabling studies of CRB-4001. Dr. Kunos led the work at the NIH to advance CRB-4001 to clinical testing, including studies in animal models of non-alcoholic fatty liver disease ("NAFLD"), type 2 diabetes, diet-induced insulin resistance, and type 2 diabetic nephropathy. Dr. Kunos plans to coordinate a Phase 2 proof-of-concept clinical study at the NIH, following the completion of a Phase 1 study by Corbus. Preparations are underway to commence the Phase 1 study of CRB-4001 for the treatment of NASH in 2019. 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.

Intellectual Property Estate Strengthened

Corbus has continued to build an expanding and comprehensive portfolio of patents directed to lenabasum. The Company recently received a Notice of Allowance from the U.S. Patent and Trademark Office ("USPTO") for U.S. Patent Application No. 15/698,544 covering pharmaceutical compositions of lenabasum. A number of other important patents have also been issued covering uses of lenabasum in inflammatory and fibrotic diseases. The issued patents provide exclusivity in the U.S. for the use of lenabasum through 2034 and provides Corbus with commercial rights to increase the Company's strategic optionality.

Summary of Financial Results for Third Quarter 2018

For the quarter ended September 30, 2018, the Company reported a net loss of approximately \$14,601,000 or a net loss per diluted share of \$0.26, compared to a net loss of approximately \$6,966,000, or a net loss per diluted share of \$0.14, for the quarter ended September 30, 2017.

For the nine months ended September 30, 2018, the Company reported a net loss of approximately \$38,366,000, or a net loss per diluted share of \$0.67, compared to a net loss of approximately \$21,728,000, or a net loss per diluted share of \$0.44, for the nine months ended September 30, 2017.



Revenue for the quarter increased by approximately \$0.3 million to \$1.1 million from the quarter ended September 30, 2017. Revenue recognized in 2018 was related to the up to \$25 million Development Award Agreement with the Cystic Fibrosis Foundation. Operating expenses for the quarter increased by approximately \$8.2 million to \$16.0 million due to increased spending for clinical studies, manufacturing costs to produce lenabasum for clinical studies and staffing costs.

The Company ended the third quarter with approximately \$55.7 million of cash and cash equivalents. 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 2019, 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, November 8, 2018 at 8:30 a.m. EDT.

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 60 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 favorable 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 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 licensed the exclusive worldwide rights to develop, manufacture and market drug candidates from more than 600 novel compounds targeting the endocannabinoid system from Jenrin Discovery LLC. The pipeline includes CRB-4001, a 2nd generation, peripherally-restricted, selective cannabinoid receptor type 1 (CB1) inverse agonist designed to eliminate blood-brain barrier penetration and subsequent brain CB1 receptor occupancy that mediates the neuropsychiatric adverse events 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. Corbus plans to enter 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

	September 30,	December 31,
	2018	2017
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 55,659,346	\$ 62,537,495
Restricted cash	—	158,991
Prepaid expenses and other current assets	2,800,023	2,808,244
Total current assets	58,459,369	65,504,730
Property and equipment, net	2,702,266	1,432,655
Other assets	19,939	40,776
Total assets	\$ 61,181,574	\$ 66,978,161
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	\$ —	\$ 332,861
Accounts payable	6,153,041	3,130,295
Accrued expenses	7,385,596	4,741,519
Deferred revenue	3,389,809	—
Total current liabilities	16,928,446	8,204,675
Deferred rent, noncurrent	1,382,396	989,550
Other liabilities	—	375
Total liabilities	18,310,842	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 September 30, 2018 and December 31, 2017	-	-
Common stock, \$0.0001 par value; 150,000,000 shares authorized, 57,237,496 and 55,603,427 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	5,724	5,560
Additional paid-in capital	146,929,056	123,476,102
Accumulated deficit	(104,064,048)	(65,698,101)
Total stockholders' equity	42,870,732	57,783,561
Total liabilities and stockholders' equity	\$ 61,181,574	\$ 66,978,161



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

	For the Three Months Ended		For the Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Revenue from awards	\$ 1,090,878	\$ 796,312	\$ 2,894,966	\$ 2,440,195
Operating expenses:				
Research and development	12,807,800	5,622,511	32,833,029	17,752,283
General and administrative	3,181,071	2,130,587	9,218,652	6,388,802
Total operating expenses	15,988,871	7,753,098	42,051,681	24,141,085
Operating loss	(14,897,993)	(6,956,786)	(39,156,715)	(21,700,890)
Other income (expense), net:				
Interest income, net	268,335	43,402	738,052	50,039
Foreign currency exchange gain (loss)	28,447	(52,212)	52,716	(77,071)
Other income (expense), net	296,782	(8,810)	790,768	(27,032)
Net loss	\$ (14,601,211)	\$ (6,965,596)	\$ (38,365,947)	\$ (21,727,922)
Net loss per share, basic and diluted	\$ (0.26)	\$ (0.14)	\$ (0.67)	\$ (0.44)
Weighted average number of common shares outstanding, basic and diluted	57,218,832	50,221,597	56,917,897	48,946,335

Investor Contacts:

Institutional Investor Inquiries

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