
**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): August 8, 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 August 8, 2019, disclosing financial information and operating metrics for its fiscal quarter ended June 30, 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 August 8, 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: August 8, 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 August 8, 2019.



Corbus Pharmaceuticals Reports 2019 Second Quarter Financial Results and Provides Clinical and Corporate Updates

- Clinical development of lenabasum on target for 2020 data readouts in lead indications systemic sclerosis and cystic fibrosis; diseases affect ~270,000 people total in U.S., EU and Japan
- CRB-4001 on course to start Phase 1 study in 2019 as a candidate for NASH
- Proprietary platform generates first group of pre-clinical endocannabinoid mimetic compounds
- Corbus positioned to become the leader in the treatment of inflammatory, fibrotic and metabolic diseases by targeting the endocannabinoid system (ECS)
- Company to host conference call and webcast today, August 8 at 8:30 a.m. ET

Norwood, MA (August 8, 2019) – Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) (“Corbus” or the “Company”), a clinical-stage drug development company pioneering transformative medicines that target the endocannabinoid system, today announced its financial results for the second quarter ended June 30, 2019. The Company also provided an update on its corporate progress, clinical status and financial position.

Q2 2019 Corporate Highlights:

- Lenabasum:
 - Completed subject enrollment in RESOLVE-1 Phase 3 study of lenabasum for the treatment for systemic sclerosis. Company expects to report topline results from this study in the summer of 2020.
 - Presented continued favorable safety and improvement in efficacy outcomes at 21 months for systemic sclerosis (SSc) and 16 months for dermatomyositis (DM) in open-label extensions of lenabasum Phase 2 studies. These data were presented at the annual European Congress of Rheumatology (EULAR 2019) conference.
- Pipeline:
 - Hosted an R&D Day to highlight the Company’s pipeline of drugs that target the endocannabinoid system (ECS). Presentations at R&D Day showcased lenabasum’s late-stage clinical progress, introduced CRB-4001 for NASH and unveiled the first group of active preclinical compounds generated from Corbus’ proprietary platform of endocannabinoid mimetics.
- Leadership:
 - Appointed Rachelle Jacques as a member of the Board of Directors. Ms. Jacques is CEO of Enzyvant Therapeutics, Inc. and the former Global Complement Franchise Head at Alexion Pharmaceuticals, Inc. She brings U.S. and global commercialization and marketing experience, including multiple product launches in rare diseases.
 - Appointed Robert Discordia, Ph.D., as Chief Operating Officer. Dr. Discordia joined the Company in May 2018, bringing >25 years of biopharmaceutical industry experience in CMC development and business operations to Corbus, most recently at Bristol-Myers Squibb. In his new role, Dr. Discordia will be responsible for optimizing the Company’s operational efficiency and effectiveness, corporate planning and performance management.

“Corbus made significant progress during the second quarter as we continued to pioneer transformative medicines that target the endocannabinoid system. We advanced our four ongoing clinical studies for lenabasum and expect to report topline data beginning in the summer of 2020 in systemic sclerosis and cystic fibrosis. Additionally, we continue to execute on our development of CRB-4001 and expect to enter the clinic with a Phase 1 study later this year,” commented Yuval Cohen, Ph.D., Chief Executive Officer of Corbus. “In addition to our lead assets, our team is leveraging our unique platform to generate new endocannabinoid mimetic drugs to fuel the future growth of our pipeline and open the door to potential collaborations. We were pleased to present the first group of these potential compounds at our recent R&D Day in June. With a number of important catalyst achievements ahead, Corbus is well positioned to complete our clinical milestones, lay the foundation for our corporate commercialization strategy and deliver value for our stakeholders.”



Lenabasum – Rationally-Designed, Oral, Selective Cannabinoid Receptor Type 2 (CB2) Agonist

Systemic Sclerosis (SSc) – Phase 3 “RESOLVE-1” Study: Enrollment Complete, Topline Data Expected in Summer of 2020

- SSc is a chronic, rare systemic autoimmune disease characterized by tissue 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.
- Data from the Phase 2 open-label extension was recently presented at the annual EULAR 2019 conference and showed continued favorable safety and durable improvement in efficacy outcomes:
 - ACR CRISS score remains ≥ 0.95 (95%) at 21 months in systemic sclerosis open-label extension (OLE) study
 - 81% systemic sclerosis subjects remain on lenabasum in the OLE ≥ 21 months
 - No serious or severe AEs related to lenabasum reported in the study to date
- There are no drugs currently approved by the U.S. Food and Drug Administration (FDA) for treatment of SSc. Treatment options for overall disease control limited to immunosuppressive drugs.

RESOLVE-1 has enrolled 365 individuals with SSc in an international, multicenter, randomized, double-blind, placebo-controlled study that is being conducted in North America, Europe, Israel, Japan, South Korea and Australia. Corbus expects to report topline results from the study in the summer of 2020, with commercialization in 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, Topline Data Expected in 2021

- DM is a rare and serious autoimmune disease characterized by skin and muscle inflammation affecting ~80,000 people in the U.S., EU and Japan. Five-year mortality is as high as 30%.
- Enrollment is ongoing in 150 patient Phase 3 study with the American College of Rheumatology/European League Against Rheumatism 2016 Total Improvement Score in myositis as the primary efficacy endpoint.
- Data from the Phase 2 open-label extension was recently presented at the annual EULAR 2019 conference and showed continued favorable safety and durable improvement in efficacy outcomes:
 - CDASI activity score reached -21.8 points at 16 months in dermatomyositis OLE study
 - 90% dermatomyositis subjects remain in OLE at ≥ 16 months
 - No serious or severe AEs related to lenabasum reported in the study to date



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 and reference Identifier NCT03813160.

Cystic Fibrosis (CF) – Phase 2b Study Underway, supported by a Development Award for up to \$25 Million from the Cystic Fibrosis Foundation, Topline Data Expected in Summer of 2020

- 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 415 patient Phase 2b study with the event rate of pulmonary exacerbations (PEX) as the primary efficacy endpoint. Pulmonary exacerbations are a clinically relevant event of worsening of 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.
- There continues to be an unmet need for drugs that reduce rate and severity of PEX in people with CF.

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, Topline Data Expected in 2020

- Enrollment and dosing are ongoing in 100 patient Phase 2 study being conducted and funded by the National Institutes of Health (NIH).
- SLE 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.
- 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, Selective Cannabinoid Receptor Type 1 (CB1) Inverse Agonist Targeting Liver Fibrosis, Designed to be Peripherally Restricted

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), 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. We expect this to be followed by an NIH-funded study of blood brain barrier penetration by CRB-4001, then a biomarker study in people with metabolic syndrome or NASH.

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



Fueling the Future Growth of the Clinical Pipeline – Library of >700 Unique Early Stage Drug Compounds Targeting the Endocannabinoid System

Corbus is actively leveraging its proprietary library of >700 unique early stage compounds to develop endocannabinoid mimetics targeting inflammatory, fibrotic, and metabolic diseases. The Company recently introduced its first group of compounds, including both novel CB2 agonists and novel CB1 inverse agonists, generated from its proprietary platform at its R&D day hosted on June 21, 2019 in New York. The compounds are structurally distinct, and each has so far generated a unique profile of effects on inflammation and fibrosis.

Corbus plans to continue exploring the potential of its proprietary platform and advance its library of early stage compounds by transitioning to animal models, selecting initial indications and routes of administration, as well as establishing partnerships with pharmaceutical partners where applicable.

Summary of Financial Results for Second Quarter 2019 Ended June 30, 2019

For the quarter ended June 30, 2019, the Company reported net income of approximately \$2,153,000 or net income per diluted share of \$0.03, compared to a net loss of approximately \$12,100,000, or a net loss per diluted share of \$0.21, for the quarter ended June 30, 2018.

For the quarter ended June 30, 2019, revenue from awards increased by approximately \$1.2 million to \$2.1 million due to revenue recognized from the Development Award Agreement with the Cystic Fibrosis Foundation. Revenue for the quarter ended June 30, 2019 also included \$27 million from the up-front licensing payment received from Kaken Pharmaceuticals in March 2019.

Operating expenses for the quarter ended June 30, 2019 increased by approximately \$14.1 million to \$27.4 million. The increase was attributable to increased spending for clinical studies, the costs to manufacture and supply lenabasum for clinical trials, staffing costs, a \$1.0 million increase in non-cash stock compensation expenses and a \$2.7 million sub-royalty payment paid to the CF Foundation as a result of the \$27 million up-front licensing payment received from Kaken Pharmaceuticals.

The Company ended the quarter with \$73.2 million in cash and cash equivalents. The Company expects the current cash and cash equivalents together with the \$7.5 million 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, August 8 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) and has been designed to resolve inflammation, limit fibrosis and support tissue repair. CB2 is preferentially expressed on activated immune cells and on fibroblasts, muscle cells, and endothelial cells. In both animal and human studies conducted to date, lenabasum has induced the production of pro-resolving lipid mediators that activate endogenous pathways which resolve inflammation and speed bacterial clearance without immunosuppression. 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 patients with DM with active skin involvement but not currently active muscle involvement. 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 to confirm these results and support applications for regulatory approval.

About CRB-4001

CRB-4001 is a 2nd generation, selective cannabinoid receptor type 1 (CB1) inverse agonist designed to be peripherally restricted. Preclinical data show CRB-4001 improves inflammation and has multiple effects on metabolic function relevant to the treatment of nonalcoholic steatohepatitis (NASH). 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. We expect this to be followed by an NIH-funded study of blood brain barrier penetration by CRB-4001, then a biomarker study in people with metabolic syndrome or NASH.

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 700 novel compounds targeting the endocannabinoid system. The pipeline includes CRB-4001, a 2nd generation, selective cannabinoid receptor type 1 (CB1) inverse agonist designed to be peripherally restricted. Potential indications for CRB-4001 include nonalcoholic steatohepatitis (NASH), among others. Corbus expects to initiate a Phase 1 study for CRB-4001 in 2019. We expect this to be followed by an NIH-funded study of blood brain barrier penetration by CRB-4001, then a biomarker study in people with metabolic syndrome or NASH.

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>June 30, 2019</u> <u>(unaudited)</u>	<u>December 31, 2018</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 73,154,916	\$ 41,748,468
Prepaid expenses and other current assets	2,235,947	2,491,844
Total current assets	75,390,863	44,240,312
Property and equipment, net	2,912,335	2,705,206
Operating lease right of use assets	5,695,689	—
Other assets	123,226	43,823
Total assets	<u>\$ 84,122,113</u>	<u>\$ 46,989,341</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	\$ 99,333	\$ 394,305
Accounts payable	7,490,561	6,345,335
Accrued expenses	19,056,618	9,851,191
Deferred revenue	2,482,238	1,462,503
Operating lease liabilities, current	312,289	—
Deferred rent, current	—	35,996
Total current liabilities	29,441,039	18,089,330
Operating lease liabilities, noncurrent	7,307,274	—
Deferred rent, noncurrent	—	1,375,891
Total liabilities	<u>36,748,313</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 June 30, 2019 and December 31, 2018	—	—
Common stock, \$0.0001 par value; 150,000,000 shares authorized, 64,644,093 and 57,247,496 shares issued and outstanding at June 30, 2019 and December 31, 2018	6,465	5,725
Additional paid-in capital	192,819,731	148,888,635
Accumulated deficit	(145,452,396)	(121,370,240)
Total stockholders' equity	<u>47,373,800</u>	<u>27,524,120</u>
Total liabilities and stockholders' equity	<u>\$ 84,122,113</u>	<u>\$ 46,989,341</u>



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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue from awards and licenses	\$ 29,094,583	\$ 853,646	\$ 30,980,265	\$ 1,804,088
Operating expenses:				
Research and development	22,181,409	10,259,868	43,965,113	20,025,229
General and administrative	5,207,962	2,987,549	11,832,709	6,037,581
Total operating expenses	<u>27,389,371</u>	<u>13,247,417</u>	<u>55,797,822</u>	<u>26,062,810</u>
Operating income (loss)	<u>1,705,212</u>	<u>(12,393,771)</u>	<u>(24,817,557)</u>	<u>(24,258,722)</u>
Other income (expense), net:				
Interest income, net	448,717	266,297	783,312	469,717
Foreign currency exchange gain (loss), net	(1,276)	58,123	(47,911)	24,269
Other income, net	447,441	324,420	735,401	493,986
Net income (loss)	<u>\$ 2,152,653</u>	<u>\$ (12,069,351)</u>	<u>\$ (24,082,156)</u>	<u>\$ (23,764,736)</u>
Net income (loss) per share, basic	<u>\$ 0.03</u>	<u>\$ (0.21)</u>	<u>\$ (0.38)</u>	<u>\$ (0.42)</u>
Weighted average number of common shares outstanding, basic	<u>64,546,628</u>	<u>57,157,955</u>	<u>63,119,196</u>	<u>56,764,935</u>
Net income (loss) per share, diluted	<u>\$ 0.03</u>	<u>\$ (0.21)</u>	<u>\$ (0.38)</u>	<u>\$ (0.42)</u>
Weighted average number of common shares outstanding, diluted	<u>68,511,587</u>	<u>57,157,955</u>	<u>63,119,196</u>	<u>56,764,935</u>

Corbus Pharmaceuticals Contacts:

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