
**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 7, 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 November 7, 2019, disclosing financial information and operating metrics for its fiscal quarter ended September 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 November 7, 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: November 7, 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 November 7, 2019.



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

- Phase 3 “RESOLVE-1” study of lenabasum for treatment of systemic sclerosis on track for topline results in summer of 2020
- Systemic sclerosis is a rare autoimmune disease affecting ~200,000 people in the U.S., EU and Japan and has the highest mortality rate among the systemic autoimmune diseases
- Phase 2b study of lenabasum for treatment of cystic fibrosis on track for topline results in summer of 2020
- Phase 1 for CRB-4001 is on track for 2020
- Corbus owns global commercial rights to lenabasum with exception of Kaken Pharmaceuticals Japanese Partnership
- Company to host conference call and webcast today, November 7 at 8:30 a.m. ET

Norwood, MA (November 7, 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 third quarter ended September 30, 2019. The Company also provided an update on its corporate progress, clinical status and financial position.

“We remain on schedule for topline data from our RESOLVE-1 study for the treatment of systemic sclerosis and Phase 2b study in cystic fibrosis next summer. In addition, we anticipate that our CBI inverse agonist, CRB-4001, targeting liver inflammation and fibrosis will read out Phase 1 safety data in 2020. We are developing strategic partnerships to expand potential lenabasum commercialization beyond the U.S. and Japan, with other countries in Asia as the primary focus. Lastly, we are making steady progress on preclinical programs to expand our pipeline and plan to eventually partner some of them,” commented Yuval Cohen, Ph.D., Chief Executive Officer of Corbus.

Corporate Highlights:

- **Systemic Sclerosis (SSc) – Phase 3 “RESOLVE-1” study topline results on track for readout in summer of 2020, with potential approval in 2021.** Oral and poster presentations of latest open-label extension data from ongoing Phase 2 study (21 months) will be presented at the [American College of Rheumatology \(ACR\) 2019 Annual Meeting](#) being held November 8-13 in Atlanta, GA. Baseline subject demographics and disease characteristics for “RESOLVE-1” Phase 3 study will also be presented.
 - **Cystic Fibrosis (CF) – Phase 2b study topline results, utilizing pulmonary exacerbations as a primary endpoint, on track for readout in summer of 2020.** Patient screening complete; enrollment of Phase 2b study expected to complete within next few weeks. Study has been funded in part by a Development Award for up to \$25 million from the Cystic Fibrosis Foundation. Despite important advances in the treatment of CF including CFTR-targeting medications, people with CF continue to face significant risk and treatment burden from pulmonary exacerbations.
 - **Dermatomyositis (DM) – Phase 3 “DETERMINE” study enrollment ongoing, with topline data of lenabasum expected in 2021.** Oral presentation of 68-week safety and efficacy data from Phase 2 open-label extension study will be given at the ACR 2019 Annual Meeting.
 - **Systemic Lupus Erythematosus (SLE) – Phase 2 study ongoing with topline data of lenabasum expected in 2020.** Phase 2 study is funded and managed by the National Institutes of Health (NIH). SLE represents the largest indication currently explored in the clinic with lenabasum with approximately 550,000 patients in the U.S., EU, and Japan.
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- **CRB-4001 – First-in-human clinical study is scheduled for 2020.** Novel inverse agonist of cannabinoid receptor type 1 (CB1) designed to avoid the psychiatric side effects of rimonabant that were due to that drug's interaction with CB1 in the brain. Clinical development will target NAFLD/NASH.
- **Early-stage, novel drug compounds targeting the endocannabinoid system will fuel expansion of the Company's clinical pipeline.** Corbus recently introduced a group of early-stage CB2 agonists and CB1 inverse agonists with positive activity in assays of inflammation and fibrosis. Company will explore partnerships for development of certain early-stage compounds.
- **Groundwork for commercialization has commenced.** Craig Millian, our Chief Commercial Officer, and his team have been conducting market research and preparing for a potential approval of lenabasum in 2021. We will be sharing first details of this on the call today.

For more information on Corbus' clinical programs, please visit the Company's website at www.corbuspharma.com.

Lenabasum is not approved for the treatment of systemic sclerosis, dermatomyositis, cystic fibrosis or systemic lupus erythematosus. CRB-4001 is not approved for the treatment of NASH/NAFLD.

Summary of Financial Results for Third Quarter 2019 Ended September 30, 2019

For the quarter ended September 30, 2019, the Company reported a net loss of approximately \$20,791,000 or a net loss per diluted share of \$0.32, compared to a net loss of approximately \$14,601,000, or a net loss per diluted share of \$0.26, for the quarter ended September 30, 2018.

For the nine months ended September 30, 2019, the Company reported a net loss of approximately \$44,873,000, or a net loss per diluted share of \$0.71, compared to a net loss of approximately \$38,366,000, or a net loss per diluted share of \$0.67, for the nine months ended September 30, 2018.

For the quarter ended September 30, 2019, revenue from awards increased by approximately \$1.5 million to \$2.6 million due to revenue recognized from the Development Award Agreement with the Cystic Fibrosis Foundation.

Operating expenses for the quarter ended September 30, 2019 increased by approximately \$11.7 million to \$27.7 million. The increase was attributable to increased spending for clinical studies, the costs to manufacture and supply lenabasum for clinical trials, staffing costs, and non-cash stock compensation expense.

The Company ended the quarter with \$54.8 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 third quarter of 2020, through topline data readouts in systemic sclerosis and cystic fibrosis, 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 7 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 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 rationally designed, endocannabinoid system-targeting drug candidates. The Company's lead product candidate, lenabasum, is a novel, oral, selective cannabinoid receptor type 2 (CB2) agonist rationally 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 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 data from its Phase 1 safety study in 2020.

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, 2019	December 31, 2018
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 54,849,365	\$ 41,748,468
Prepaid expenses and other current assets	2,685,923	2,491,844
Total current assets	57,535,288	44,240,312
Property and equipment, net	4,891,063	2,705,206
Operating lease right of use assets	5,569,999	—
Other assets	134,034	43,823
Total assets	<u>\$ 68,130,384</u>	<u>\$ 46,989,341</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	\$ —	\$ 394,305
Accounts payable	6,193,507	6,345,335
Accrued expenses	23,969,303	9,851,191
Deferred revenue	—	1,462,503
Operating lease liabilities, current	386,618	—
Deferred rent, current	—	35,996
Total current liabilities	30,549,428	18,089,330
Operating lease liabilities, noncurrent	7,940,283	—
Deferred rent, noncurrent	—	1,375,891
Total liabilities	<u>38,489,711</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 September 30, 2019 and December 31, 2018	—	—
Common stock, \$0.0001 par value; 150,000,000 shares authorized, 64,672,893 and 57,247,496 shares issued and outstanding at September 30, 2019 and December 31, 2018	6,467	5,725
Additional paid-in capital	195,877,403	148,888,635
Accumulated deficit	(166,243,197)	(121,370,240)
Total stockholders' equity	<u>29,640,673</u>	<u>27,524,120</u>
Total liabilities and stockholders' equity	<u>\$ 68,130,384</u>	<u>\$ 46,989,341</u>



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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue from awards and licenses	\$ 2,589,783	\$ 1,090,878	\$ 33,570,048	\$ 2,894,966
Operating expenses:				
Research and development	22,152,001	12,807,800	66,117,114	32,833,029
General and administrative	5,534,493	3,181,071	17,367,202	9,218,652
Total operating expenses	27,686,494	15,988,871	83,484,316	42,051,681
Operating loss	(25,096,711)	(14,897,993)	(49,914,268)	(39,156,715)
Other income (expense), net:				
Other income	4,109,338	—	4,109,338	—
Interest income, net	292,854	268,335	1,076,166	738,052
Foreign currency exchange gain (loss), net	(96,282)	28,447	(144,193)	52,716
Other income, net	4,305,910	296,782	5,041,311	790,768
Net loss	\$ (20,790,801)	\$ (14,601,211)	\$ (44,872,957)	\$ (38,365,947)
Net loss per share, basic and diluted	\$ (0.32)	\$ (0.26)	\$ (0.71)	\$ (0.67)
Weighted average number of common shares outstanding, basic and diluted	64,660,017	57,218,832	63,638,447	56,917,897

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