
**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, 2020

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))

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	CRBP	The Nasdaq Global Market

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, 2020, disclosing financial information and operating metrics for its fiscal year ended December 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 March 12, 2020.</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.

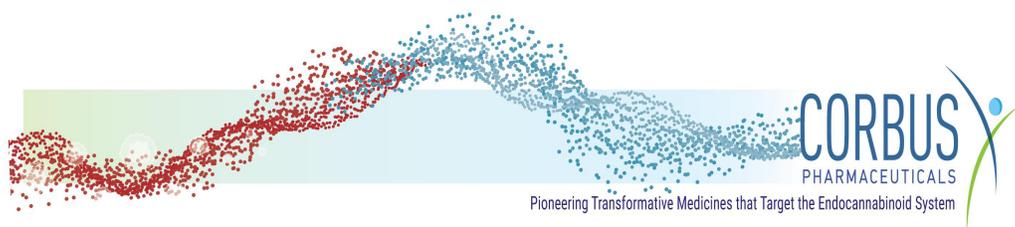
CORBUS PHARMACEUTICALS HOLDINGS, INC.

Dated: March 12, 2020

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 March 12, 2020.



Corbus Pharmaceuticals Reports Fourth Quarter and Year-End 2019 Financial Results

Topline results for Phase 3 study in systemic sclerosis on schedule for summer of 2020 followed by Phase 2b study results in cystic fibrosis

Completed \$46 million public offering in February 2020

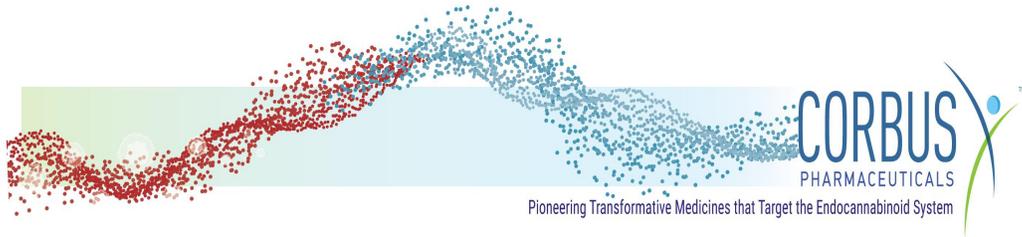
Company to host conference call and webcast today, March 12 at 8:30 am ET

Norwood, MA, March 12, 2020 – 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 reported financial results for the fourth quarter and year ended December 31, 2019. The Company also provided clinical and corporate updates.

“We are poised for a transformational year in 2020 with four expected data readouts, including topline data in our Phase 3 study for systemic sclerosis this summer,” commented Yuval Cohen, Ph.D., Chief Executive Officer. “We are preparing for commercialization and the recently completed public offering has strengthened our balance sheet. We remain committed to advancing our additional programs to treat inflammatory, fibrotic and metabolic diseases.”

2019 and Recent Clinical and Corporate Highlights and Achievements:

- Presented new Phase 2b open label extension (OLE) data evaluating lenabasum for systemic sclerosis (SSc) and dermatomyositis (DM) at the American College of Rheumatology (ACR) 2019 Annual Meeting in November. Data showed continued favorable safety and durable outcomes for patients still enrolled at 25 and 23 months, respectively. OLE data further supports rationale for Corbus’ ongoing Phase 3 RESOLVE-1 study in SSc, with topline results expected in summer 2020.
- Completed enrollment in RESOLVE-1 Phase 3 SSc study of lenabasum in May.
- Completed enrollment in Phase 2b study of lenabasum for cystic fibrosis (CF) in November.
- Commercial launch activities underway. Disease education campaign for SSc recently launched.
- Completed strategic collaboration with Kaken Pharmaceutical in January 2019 to develop and commercialize lenabasum in Japan for SSc and DM in January. The licensing agreement includes \$200 million of potential payments to Corbus, including a \$27 million upfront payment.
- Closed public offerings for gross proceeds of approximately \$46 million and \$40 million in February 2020 and January 2019, respectively.



Clinical Program Updates:

Lenabasum

Systemic Sclerosis: RESOLVE-1 Phase 3 Study

- In an oral presentation at the 2019 ACR Annual meeting in November, new Phase 2b OLE data evaluating lenabasum in SSc showed high retention, with 29/36 (81%) of subjects still enrolled at 25 months. In addition, the data demonstrated improved and durable efficacy from month 12 to month 25, with ACR CRISS (Combined Response Index in diffuse cutaneous Systemic Sclerosis) score above ≥ 0.95 (vs. score of ≥ 0.60 at 12 months reported to be medically important) and mRSS (modified Rodnan Skin Score) improvement >9.2 points (vs. -4 to -5 point at 12-months). Data continued to show favorable safety profiles.
- In May, the Company completed enrollment of 365 patients in the Phase 3 RESOLVE-1 study of lenabasum for SSc. The multicenter study is randomized 1:1:1 for twice a day dosing of lenabasum at 5mg, 20mg, or placebo for 52 weeks, with a 4-week follow up. Primary endpoint is ACR CRISS score, consistent with the Phase 2 study. All other study design and baseline characteristics of subjects in Phase 3 are similar to those in the Phase 2 study. Phase 3 topline results remain on track for the summer of 2020.

Dermatomyositis: DETERMINE Phase 3 Study

- At the 2019 ACR Annual meeting, new Phase 2b OLE data evaluating lenabasum in DM showed high retention of study participants, with 18/20 (90%) subjects still enrolled at 23 months. Data also showed sustained safety and durability, with improvement in mean change of -20.9 in CDASI (Cutaneous Dermatomyositis Activity and Severity Index) activity score from baseline at 23 months (vs. -4 to -5 point at 12-months reported to be medically important).
- The Phase 3 DETERMINE study in DM is ongoing, with enrollment expected to be completed in 2020. Topline data are expected in 2021.

Cystic Fibrosis: Phase 2b Study

- In November, the Company announced completion of enrollment in the Phase 2b study evaluating lenabasum in 426 individuals with CF. The multicenter study is randomized 1:2:2 for twice a day dosing of lenabasum at 5mg, 20mg, or placebo for 28 weeks, with a 4-week follow up. Primary endpoint is event rate of pulmonary exacerbation. Topline data expected in the summer of 2020 following RESOLVE-1 topline results.

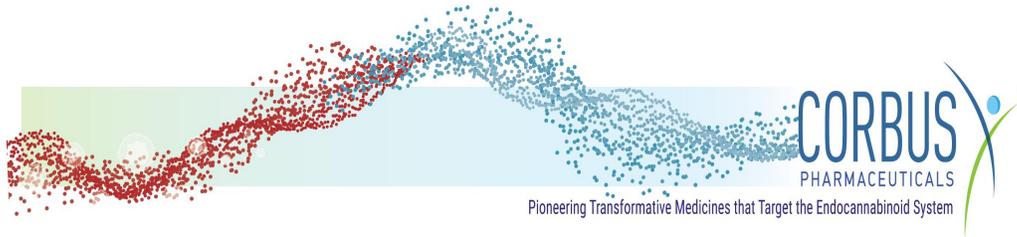
Systemic Lupus Erythematosus (SLE): Phase 2b Study

- The study, funded and managed by the National Institutes of Health (NIH), is currently enrolling 100 patients at 15 sites in the U.S. Topline data are expected in late 2020.

CRB-4001

Nonalcoholic fatty liver disease (NAFLD/NASH): Phase 1 Study

- Corbus' second drug, CRB-4001, is a peripherally restricted CB1 inverse agonist, designed to avoid the central nervous system side effects seen with rimonabant. The first indication for study under the CRB-4001 clinical program is NAFLD/NASH. Phase 1 safety data are expected in 2020.



Financial Results for Fourth Quarter and Year-End December 31, 2019

Revenue from awards and licenses was \$2.6 million for the three months ended December 31, 2019, compared to \$1.9 million in the comparable period in 2018. For the year ended December 31, 2019, revenue from awards and licenses was \$36.1 million, compared to \$4.8 million in the comparable year ago period, due mainly to \$27 million in up-front licensing payment received from Kaken Pharmaceuticals in March 2019.

Operating expenses increased by \$10.3 million to \$29.8 million for the three months ended December 31, 2019, compared to \$19.5 million for the year ago period. For the year ended December 31, 2019, operating expenses increased by \$51.6 million to \$113.2 million, compared with \$61.6 million in the prior year. Increased spending was attributable to clinical studies, the costs to manufacture and supply lenabasum for clinical trials, staffing costs, commercialization costs and non-cash stock compensation expense.

The Company reported a net loss of approximately \$26.6 million or a net loss per diluted share of \$0.41, for the three months ended December 31, 2019, compared to a net loss of approximately \$17.3 million, or a net loss per diluted share of \$0.30, for the same period in 2018. For the year ended December 31, 2019, the Company reported a net loss of approximately \$71.5 million, or a net loss per diluted share of \$1.12, compared to a net loss of approximately \$55.7 million, or a net loss per diluted share of \$0.98, for the same period in 2018.

Cash and cash equivalents were \$31.7 million at December 31, 2019. In February 2020, the company completed a public offering with gross proceeds of \$46 million and net proceeds of \$43 million. Cash and cash equivalents of \$31.7 million at December 31, 2019 together with the \$43 million net proceeds from the February 2020 offering and the \$7.5 million remainder of the expected milestone payments from the \$25 million Development Award from the Cystic Fibrosis Foundation are expected to fund operations into the fourth quarter of 2020.

Conference Call and Webcast Information

Corbus management will host a conference call and webcast presentation for investors, analysts and other interested parties today, Thursday, 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.

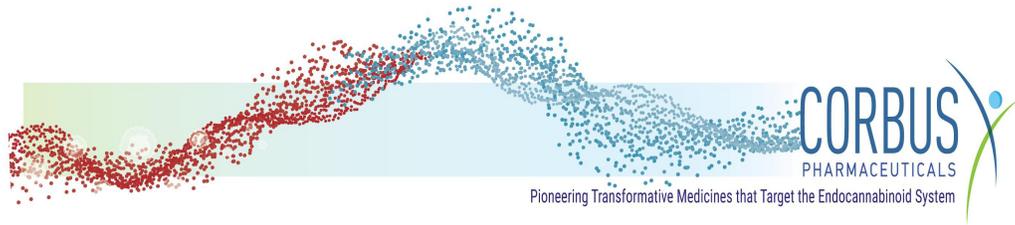
About Corbus

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.

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. For more information on Corbus' clinical programs, please visit [here](#).

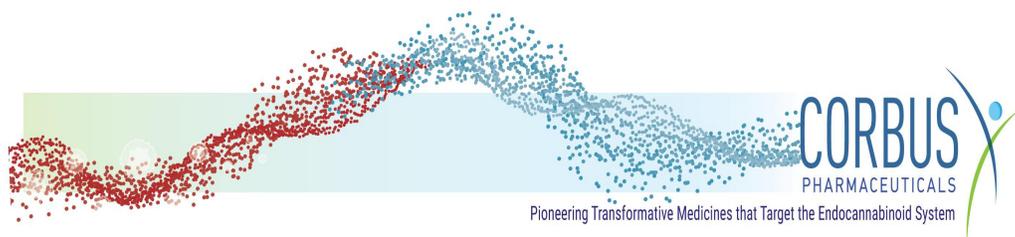
Please visit www.CorbusPharma.com and connect with the Company on [Twitter](#), [LinkedIn](#), and [Facebook](#).



Forward-Looking Statements

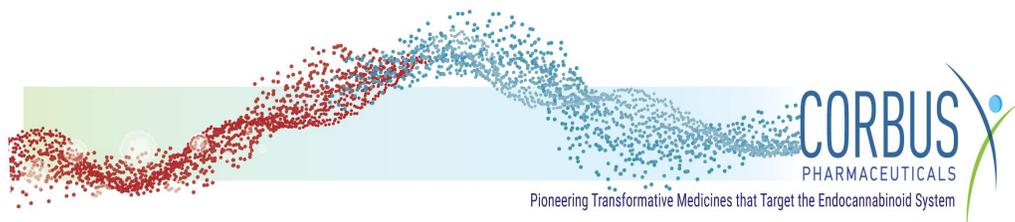
This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company’s product development, 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,	
	2019	2018
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 31,748,686	\$ 41,748,468
Prepaid expenses and other current assets	6,405,997	2,491,844
Total current assets	38,154,683	44,240,312
Property and equipment, net	5,083,865	2,705,206
Operating lease right of use asset	5,818,983	—
Other assets	84,968	43,823
Total assets	<u>\$ 49,142,499</u>	<u>\$ 46,989,341</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	\$ 752,659	\$ 394,305
Accounts payable	11,091,363	6,345,335
Accrued expenses	22,447,939	9,851,191
Deferred revenue, current	—	1,462,503
Operating lease liabilities, current	595,745	—
Deferred rent, current	—	35,996
Total current liabilities	34,887,706	18,089,330
Operating lease liabilities, noncurrent	8,097,228	1,375,891
Deferred rent, noncurrent	—	—
Total liabilities	42,984,934	19,465,221
Commitments and Contingencies		
Stockholders' equity		
Preferred Stock \$0.0001 par value; 10,000,000 shares authorized, no shares issued and outstanding at December 31, 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 December 31, 2019 and December 31, 2018, respectively	6,467	5,725
Additional paid-in capital	198,975,056	148,888,635
Accumulated deficit	(192,823,958)	(121,370,240)
Total stockholders' equity	6,157,565	27,524,120
Total liabilities and stockholders' equity	<u>\$ 49,142,499</u>	<u>\$ 46,989,341</u>



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

	For the Three Months Ended December 31,		For the Year Ended December 31,	
	2019 (unaudited)	2018	2019 (unaudited)	2018
Revenue from awards and licenses	\$ 2,573,520	\$ 1,927,306	\$ 36,143,568	\$ 4,822,272
Operating expenses:				
Research and development	23,487,676	15,780,928	89,604,790	48,613,957
General and administrative	6,276,155	3,737,370	23,643,357	12,956,022
Total operating expenses	29,763,831	19,518,298	113,248,147	61,569,979
Operating loss	(27,190,311)	(17,590,992)	(77,104,579)	(56,747,707)
Other income (expense), net:				
Other income	472,500	—	4,581,838	—
Interest income, net	151,477	244,725	1,227,643	982,777
Foreign currency exchange gain (loss)	(14,427)	40,075	(158,620)	92,791
Other income, net	609,550	284,800	5,650,861	1,075,568
Net loss	\$ (26,580,761)	\$ (17,306,192)	\$ (71,453,718)	\$ (55,672,139)
Net loss per share, basic and diluted	\$ (0.41)	\$ (0.30)	\$ (1.12)	\$ (0.98)
Weighted average number of common shares outstanding, basic and diluted	64,672,893	57,242,604	63,899,184	56,999,741

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