
**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): May 11, 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))

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 May 11, 2020, disclosing financial information and operating metrics for its fiscal quarter ended March 31, 2020 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 May 11, 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.

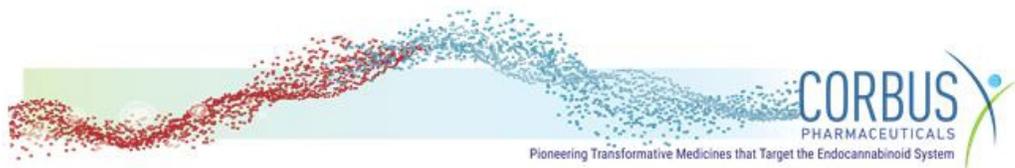
CORBUS PHARMACEUTICALS HOLDINGS, INC.

Dated: May 11, 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 May 11, 2020.



Corbus Pharmaceuticals Reports First Quarter Financial Results and Corporate Updates

- *Topline results for lenabasum Phase 3 RESOLVE-1 study in systemic sclerosis remain on schedule for summer of 2020, followed by Phase 2b study data in cystic fibrosis*
- *Phase 1 trial of CRB-4001 remains on track to initiate in third quarter of 2020*
- *Recent appointment of Dr. Pete Salzmann to Board of Directors*
- *Implemented COVID-19 mitigation and monitoring plan to ensure patient safety, data integrity and completion of key clinical studies*
- *Company to host conference call and webcast today, May 11, 2020 at 8:30 a.m. ET*

Norwood, MA, May 11, 2020 (GLOBE NEWSWIRE) — 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 first quarter of 2020. The Company also provided clinical and corporate updates.

“We had a busy first quarter as we implemented a comprehensive mitigation and monitoring COVID-19 plan to help ensure the integrity of our clinical programs. As a result of this plan, we are reiterating that we continue to expect topline data for RESOLVE-1 this summer, followed by our Phase 2b study results in cystic fibrosis,” said Yuval Cohen, Ph.D, Chief Executive Officer. “We are grateful to the patients, physicians, site staff and our own employees who remain committed to these studies and for the significant additional effort that they provided to overcome this unique challenge. Our other programs remain on track, with focused emphasis on preparations for potential lenabasum NDA submission, FDA approval and commercial launch. Lastly, our organization is functioning well with remote working practices.”

Recent Corporate Highlights and Achievements:

- Implemented COVID-19 mitigation plan to ensure safety of employees and adequate oversight of safety of subjects in ongoing studies while maintaining data integrity in our studies.
- In February, raised \$46 million in gross proceeds from a public offering of 7,666,667 shares of common stock, priced at \$6.00 per share, including 1,000,000 shares sold pursuant to the full exercise of the underwriters’ option to purchase additional shares.
- In March, announced the appointment of Pete Salzmann, M.D., MBA, to the Board of Directors. Dr. Salzmann brings 20 years of industry experience with a track record of successfully launching and commercializing a number of drugs, including autoimmune products.
- Commercial launch preparation activities for lenabasum in systemic sclerosis and cystic fibrosis are advancing. Corbus introduced a disease education campaign called “Total SSc” to educate healthcare providers on total disease burden of systemic sclerosis, current treatment limitations, and potential new treatment approach of targeting the endocannabinoid system.

- Published previously reported Phase 2 safety and efficacy results of lenabasum in randomized, placebo-controlled trial of adults with systemic sclerosis in *Arthritis and Rheumatology*, the official journal of the American College of Rheumatology.

Clinical Program Updates:

Lenabasum: a novel, oral, selective cannabinoid receptor type 2 (CB2) agonist

- Topline results for lenabasum systemic sclerosis study remain on schedule for summer 2020, followed by cystic fibrosis study results.
- *Systemic Sclerosis (SSc)* – Phase 3 “RESOLVE-1” topline results in SSc, a rare disease and the most lethal of the systemic autoimmune diseases, remain on track for the summer of 2020. The multicenter study of 365 patients is randomized 1:1:1 for twice a day dosing of lenabasum at 5 mg, 20 mg, or placebo for 52 weeks, with a 4-week follow up. The primary endpoint is ACR CRISS score. The open-label extension of this study is active.
- *Cystic fibrosis (CF)* – Phase 2b topline results of lenabasum in people with CF who are at high-risk for recurrent pulmonary exacerbation expected following RESOLVE-1 data results. The multicenter study of 426 patients is randomized 1:2:2 for twice a day dosing of lenabasum at 5 mg, 20 mg, or placebo for 28 weeks, with a 4-week follow up. The primary endpoint is event rate of pulmonary exacerbation.
- *Dermatomyositis (DM)* – Phase 3 “DETERMINE” study in DM, a rare and life-threatening autoimmune disease characterized by skin and muscle inflammation, is ongoing with enrollment expected to be completed in 2020, and topline data expected in 2021. The double-blind, randomized, placebo controlled, multinational study expects to enroll 150 subjects. The primary endpoint is ACR / EULAR 2016 Total Improvement Score (TIS) in Adult Dermatomyositis & Polymyositis. The open-label extension of this study is already active.
- *Systemic Lupus Erythematosus* – The randomized, double-blind, placebo-controlled, U.S. study, funded and managed by the National Institutes of Health (NIH), has enrolled 86/100 patients to date.

CRB-4001: a peripherally restricted CB1 inverse agonist potentially for NASH

- Phase 1 study of CRB-4001 continues to be expected to commence in the third quarter of 2020. The study will evaluate the safety, tolerability and pharmacokinetics of CRB-4001. CRB-4001 has demonstrated potent effects on glucose tolerance, insulin sensitivity, lipid metabolism, body fat, and hepatic fat in animal models of disease, with robust literature supporting these beneficial metabolic effects.
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Additional Candidate Compounds

- Corbus anticipates the selection of an additional candidate compound this year for IND enabling pre-clinical studies.

Financial Results for First Quarter Ended March 31, 2020:

For the quarter ended March 31, 2020, the Company reported a net loss of approximately \$29,657,000 or a net loss per diluted share of \$0.43, compared to a net loss of approximately \$26,235,000, or a net loss per diluted share of \$0.43, for the quarter ended March 31, 2019.

For the quarter ended March 31, 2020 revenue decreased by approximately \$0.1 million to \$1.8 million, due to a decrease in the revenue from the \$25 million Development Award from the Cystic Fibrosis Foundation.

Operating expenses for the quarter ended March 31, 2020 increased by approximately \$3.2 million to \$31.6 million. The increase was attributable to clinical studies costs, the costs to manufacture and supply lenabasum for clinical trials, staffing costs, commercialization costs and non-cash stock compensation expense.

The Company completed a public offering in February 2020 that raised approximately \$43 million in net proceeds. The Company ended the quarter with approximately \$46.6 million in cash and cash equivalents and expects its cash and cash equivalents on hand at March 31, 2020 together with the \$7.5 million remainder of the expected milestone payments from the \$25 million Development Award from the Cystic Fibrosis Foundation 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, Monday, May 11, 2020 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, including the potential impact of the recent COVID-19 pandemic, including sustained social distancing efforts, on our operations, clinical development plans and timelines, 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

	March 31, 2020 (unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 46,617,921	\$ 31,748,686
Prepaid expenses and other current assets	3,596,908	3,724,932
Contract asset	4,443,124	2,681,065
Total current assets	54,657,953	38,154,683
Property and equipment, net	4,851,317	5,083,865
Operating lease right of use asset	5,680,467	5,818,983
Other assets	14,085	84,968
Total assets	<u>\$ 65,203,822</u>	<u>\$ 49,142,499</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	\$ 432,905	\$ 752,659
Accounts payable	9,960,544	11,091,363
Accrued expenses	23,516,354	22,447,939
Operating lease liabilities, current	742,893	595,745
Total current liabilities	34,652,696	34,887,706
Operating lease liabilities, noncurrent	7,859,636	8,097,228
Total liabilities	42,512,332	42,984,934
Commitments and Contingencies		
Stockholders' equity		
Preferred Stock \$0.0001 par value; 10,000,000 shares authorized, no shares issued and outstanding at March 31, 2020 and December 31, 2019	—	—
Common stock, \$0.0001 par value; 150,000,000 shares authorized, 72,490,449 and 64,672,893 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	7,249	6,467
Additional paid-in capital	245,164,999	198,975,056
Accumulated deficit	(222,480,758)	(192,823,958)
Total stockholders' equity	22,691,490	6,157,565
Total liabilities and stockholders' equity	<u>\$ 65,203,822</u>	<u>\$ 49,142,499</u>

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

	For the Three Months Ended	
	March 31,	
	2020	2019
Revenue from awards	\$ 1,762,059	\$ 1,885,682
Operating expenses:		
Research and development	23,947,866	21,783,704
General and administrative	7,699,479	6,624,747
Total operating expenses	31,647,345	28,408,451
Operating loss	(29,885,286)	(26,522,769)
Other income (expense):		
Interest income, net	101,993	334,595
Foreign currency exchange gain (loss), net	126,493	(46,635)
Other income, net	228,486	287,960
Net loss	\$ (29,656,800)	\$ (26,234,809)
Net loss per share, basic and diluted	\$ (0.43)	\$ (0.43)
Weighted average number of common shares outstanding, basic and diluted	69,272,402	61,675,904

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