
**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 6, 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.)

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of Each Class</u>	<u>Trading Symbol</u>	<u>Name of Each Exchange on Which Registered</u>
Common Stock, par value \$0.0001 per share	CRBP	Nasdaq Global Market

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 6, 2020, disclosing financial information and operating metrics for its fiscal quarter ended June 30, 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 August 6, 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: August 6, 2020

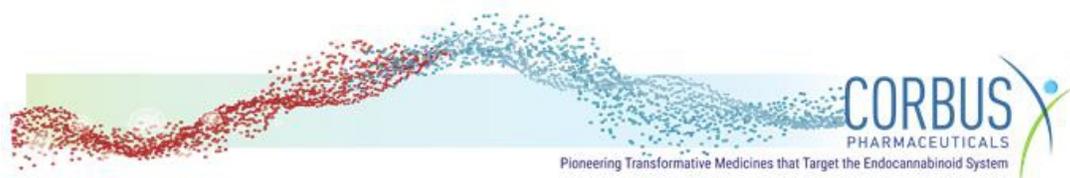
By: /s/ Yuval Cohen

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 August 6, 2020.



Corbus Pharmaceuticals Reports Second Quarter Financial Results and Corporate Updates

- *RESOLVE-1 Phase 3 study of lenabasum for treatment of systemic sclerosis on schedule for topline data this summer*
- *Phase 2b study of lenabasum for cystic fibrosis topline results on schedule in Q3 2020*
- *Balance sheet strengthened with up to \$121M in new capital*
- *Company to host conference call and webcast today, August 6, 2020 at 8:30 a.m. ET*

Norwood, MA, August 6, 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 second quarter of 2020. The Company also provided clinical and corporate updates.

“We had a busy second quarter as we prepare for a potentially transformative second half of the year with two expected data readouts, including topline data in our Phase 3 study for systemic sclerosis this summer, followed by our Phase 2b study in cystic fibrosis. We recently announced that we completed sales of \$71 million through our ATM program and entered a debt financing agreement for up to \$50 million with the first \$20 million already received, strengthening our balance sheet and putting us in a solid financial position before topline data,” said Yuval Cohen, Ph.D., Chief Executive Officer. “We have also appointed a new board member, Dr. George Golumbeski who brings considerable expertise in corporate and business development. With these recent updates, a strong balance sheet and the critical data readouts now closer than ever, we continue to prepare the groundwork for NDA submission and commercialization following potential FDA approval.”

Recent Corporate Highlights and Achievements:

- Strengthened the Company’s balance sheet with up to \$121 million in new capital, bolstering its strategic flexibility. The Company received an aggregate of \$71 million in gross proceeds from its at-the-market offering coupled with the execution of a \$50 million debt financing facility with K2 HealthVentures, a healthcare-focused specialty finance company.
 - In July, Corbus announced the appointment of George Golumbeski, Ph.D., to its Board of Directors. Dr. Golumbeski brings years of industry experience with a track record of growing companies and advancing innovation. During his corporate career, Dr. Golumbeski held senior leadership positions in business development at Celgene, Novartis, Elan Pharmaceuticals and Schwarz Pharma.
 - The Company presented at several conferences during the second quarter. In May, Corbus announced the publication of two abstracts at the European League Against Rheumatism (“EULAR”) 2020 E-Congress. The first abstract highlighted pre-clinical data suggesting that biologic effects of lenabasum include inhibition of inflammasome activation. The second abstract outlined baseline characteristics of RESOLVE-1 patients in the European Union. Additionally, new data from the lenabasum Phase 2 open-label extension study were presented at the 6th Systemic Sclerosis World E-Congress. Analyses show the American College of Rheumatology Combined Response Index in diffuse cutaneous Systemic Sclerosis (“ACR CRIS”) score correlates with improvements from baseline in how patients feel and function. The presentations are available in the Scientific Conferences section of Corbus’ website.
 - In June, the Company announced the publication of baseline patient demographics and disease characteristics in its Phase 2b study of lenabasum in cystic fibrosis. The information was published in an electronic supplement of the Journal of Cystic Fibrosis in connection with the 43rd European Cystic Fibrosis Conference.
 - Lenabasum recently received Orphan Drug Designation for systemic sclerosis from Japan’s PMDA.
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Clinical Program Updates:

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

- *Systemic Sclerosis (SSc)* – Last subject visit in RESOLVE-1 Phase 3 study of lenabasum for treatment of systemic sclerosis was announced on May 27. Topline results in SSc, a rare disease and the most lethal of the systemic autoimmune diseases, remain on track for this summer. 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 the ACR CRISS score. The open-label extension of this study is active. There are no FDA-approved therapies for the overall treatment of SSc.
 - *Cystic Fibrosis (CF)* – Last subject visit in Phase 2b study of lenabasum for CF was announced on June 22. Phase 2b topline results of lenabasum in patients with CF who are at high-risk for recurrent pulmonary exacerbation will follow the RESOLVE-1 data results in the third quarter of 2020. The multicenter study of 425 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 (“PEX”). Treatment of inflammation to reduce PEX remains a key unmet need in CF.
 - *Dermatomyositis (DM)* – Phase 3 “DETERMINE” study in DM, a rare and life-threatening autoimmune disease characterized by skin and muscle inflammation, is ongoing. Last subject’s first visit in the double-blind, randomized, placebo controlled, multinational DETERMINE study of lenabasum DM was announced on August 5 with 176 subjects enrolled, with topline data expected in the fourth quarter of 2021. The primary endpoint is ACR / EULAR 2016 Total Improvement Score (“TIS”) in Adult Dermatomyositis & Polymyositis. The open-label extension of this study is active. There is significant unmet need for new treatments to achieve disease control in DM because of limited efficacy or toxicity of immunosuppressive agents or refractory disease.
 - *Systemic Lupus Erythematosus (SLE)* – Phase 2b study is ongoing. The study, funded and managed by the National Institutes of Health (NIH), is enrolling at 15 sites in the U.S., with enrollment expected to be completed by end of this year or early 2021.
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CRB-4001: a peripherally restricted CB1 inverse agonist and additional candidate compounds

- *Nonalcoholic fatty liver disease (NAFLD/NASH)* – CRB-4001 is a CB1 inverse agonist which improves metabolic abnormalities and reduces inflammation and fibrosis in non-clinical models of disease. CRB-4001 is undergoing chronic pharmacokinetic studies in primates to measure brain exposure to CRB-4001. Results of these studies are expected this year and will be considered in the design of Phase 1 studies.
- Corbus has selected CRB-317 as an additional candidate to add to its pipeline. CRB-317 is a CB2 agonist that has significant potency and selectivity for CB2 and biological activity in animal models of inflammation and fibrosis. IND enabling pre-clinical studies and formulation work are underway. Phase 1 safety testing is expected in 2021.

Financial Results for Second Quarter Ended June 30, 2020:

For the quarter ended June 30, 2020, the Company reported a net loss of approximately \$38.1 million or a net loss per diluted share of \$0.52, compared to net income of approximately \$2.2 million or net income per diluted share of \$0.03, for the quarter ended June 30, 2019.

For the quarter ended June 30, 2020 revenue decreased by approximately \$28.8 million to \$0.3 million, due primarily to revenue for the quarter ended June 30, 2019 including \$27 million from the up-front licensing payment received from Kaken Pharmaceuticals in March 2019.

Operating expenses for the quarter ended June 30, 2020 increased by approximately \$11.0 million to \$38.4 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.

On July 29, 2020, Corbus announced that it received an aggregate of \$71 million in gross proceeds from its at-the-market (“ATM”) offering coupled with the execution of a \$50 million debt financing facility with K2 HealthVentures. Pursuant to the previously disclosed \$75 million ATM facility, Corbus sold 9,167,080 shares at a weighted average price of \$7.70 per share. Corbus has received the first \$20 million tranche from the debt financing facility and has the option to draw \$20 million from the second tranche and \$10 million from the third tranche, in each case upon achievement of certain regulatory and developmental milestones.

Corbus expects its cash and cash equivalents on hand of approximately \$101 million at July 28, 2020 to fund operations into the third quarter of 2021.



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 6, 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.

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](http://www.corbuspharma.com).

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 and the potential impact of 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

	June 30, 2020	December 31, 2019
	<u>(unaudited)</u>	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 63,468,769	\$ 31,748,686
Customer receivable	\$ 5,000,000	\$ —
Stock subscriptions receivable	\$ 16,675,971	\$ —
Prepaid expenses and other current assets	2,872,275	3,724,932
Contract asset	—	2,681,065
Total current assets	<u>88,017,015</u>	<u>38,154,683</u>
Property and equipment, net	4,547,303	5,083,865
Operating lease right of use assets	5,539,677	5,818,983
Other assets	14,085	84,968
Total assets	<u>\$ 98,118,080</u>	<u>\$ 49,142,499</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	\$ 108,936	\$ 752,659
Accounts payable	12,697,845	11,091,363
Accrued expenses	28,144,144	22,447,939
Deferred revenue	270,530	—
Operating lease liabilities, current	873,525	595,745
Total current liabilities	<u>42,094,980</u>	<u>34,887,706</u>
Operating lease liabilities, noncurrent	7,609,221	8,097,228
Total liabilities	<u>49,704,201</u>	<u>42,984,934</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, 2020 and December 31, 2019	—	—
Common stock, \$0.0001 par value; 150,000,000 shares authorized, 80,655,848 and 64,672,893 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	8,065	6,467
Additional paid-in capital	308,991,895	198,975,056
Accumulated deficit	(260,586,081)	(192,823,958)
Total stockholders' equity	<u>48,413,879</u>	<u>6,157,565</u>
Total liabilities and stockholders' equity	<u>\$ 98,118,080</u>	<u>\$ 49,142,499</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,	
	2020	2019	2020	2019
Revenue from awards and licenses	\$ 286,346	\$ 29,094,583	\$ 2,048,405	\$ 30,980,265
Operating expenses:				
Research and development	30,686,071	22,181,409	54,633,937	43,965,113
General and administrative	7,738,968	5,207,962	15,438,447	11,832,709
Total operating expenses	38,425,039	27,389,371	70,072,384	55,797,822
Operating income (loss)	(38,138,693)	1,705,212	(68,023,979)	(24,817,557)
Other income (expense), net:				
Interest income, net	12,649	448,717	114,642	783,312
Foreign currency exchange gain (loss), net	20,721	(1,276)	147,214	(47,911)
Other income, net	33,370	447,441	261,856	735,401
Net income (loss)	\$ (38,105,323)	\$ 2,152,653	\$ (67,762,123)	\$ (24,082,156)
Net income (loss) per share, basic	\$ (0.52)	\$ 0.03	\$ (0.95)	\$ (0.38)
Weighted average number of common shares outstanding, basic	73,885,548	64,546,628	71,578,975	63,119,196
Net income (loss) per share, diluted	\$ (0.52)	\$ 0.03	\$ (0.95)	\$ (0.38)
Weighted average number of common shares outstanding, diluted	73,885,548	68,511,587	71,578,975	63,119,196

Corbus Pharmaceuticals Contacts:

Ted Jenkins, Senior Director, Investor Relations and Corporate Communications
Phone: +1 (617) 415-7745
Email: ir@corbuspharma.com

Lindsey Smith, Director, Investor Relations and Corporate Communications
Phone: +1 (617) 415-7749
Email: mediainfo@corbuspharma.com

Christina Tartaglia Stern IR, Inc.
Phone: +1 (212) 362-1200
Email: christina.tartaglia@sternir.com