

**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 14, 2021

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))

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

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, par value \$0.0001 per share	CRBP	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 15, 2021, disclosing financial information and operating metrics for its fiscal year ended December 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 5.03 Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year

Effective March 14, 2021, the Board of Directors of the Company adopted an amendment (the "First Amendment") to the Company's Amended and Restated Bylaws, amending Section 8 of Article VI thereof to designate the federal district courts of the United States as the exclusive forum for any complaint asserting a cause of action under the Securities Act of 1933, as amended.

The foregoing summary and description of the provisions of the First Amendment does not purport to be complete and is qualified in its entirety by reference to the full text of the First Amendment, a copy of which is filed as Exhibit 3.1 with 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.

<u>Exhibit No.</u>	<u>Description</u>
3.1	Amendment No. 1 to Amended and Restated Bylaws
99.1	Press Release issued by Corbus Pharmaceuticals Holdings, Inc. dated March 15, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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 15, 2021

By: /s/ Yuval Cohen
Name: Yuval Cohen
Title: Chief Executive Officer

EXHIBIT INDEX

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**AMENDMENT NO. 1 TO THE
AMENDED AND RESTATED
BYLAWS
OF
CORBUS PHARMACEUTICAL HOLDINGS, INC.
(the "Corporation")**

Article VI of the Amended and Restated Bylaws of Corbus Pharmaceuticals Holdings, Inc., a Delaware corporation, as amended to date (the "Bylaws"), is hereby amended as follows:

A new Article VI, Section 8 is hereby added to the Bylaws, which shall read in its entirety as follows:

"SECTION 8. Federal Forum Selection. Subject to Article X of the Certificate of Incorporation, unless the Corporation consents in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. To the fullest extent permitted by law, any person or entity purchasing or otherwise acquiring or holding any interest in shares of capital stock of the Corporation shall be deemed to have notice of and consented to the provisions of this Section 8."

Adopted by the Board of Directors effective as of March 14, 2021

Corbus Pharmaceuticals Reports Fourth Quarter and Year-End 2020 Financial Results

- Phase 3 study of lenabasum in dermatomyositis on schedule for topline data in Q2 2021
- Company focused on advancing in-house programs in metabolic diseases, fibrotic disorders, and cancer with clinical studies projected for 2022
- Corbus is actively engaging with potential partners to expand its pipeline through acquisition of external assets
- Cash on hand of \$127M, projected runway into 2024
- Company to host conference call and webcast today, Monday, March 15th at 8:30 a.m. ET

Norwood, MA, March 15, 2021 (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 fourth quarter and year-end 2020. The Company also provided clinical and pipeline updates.

Yuval Cohen, Ph.D., Chief Executive Officer said, “We are making progress on our plans to advance development of our internal compounds and expand our pipeline. We look forward to topline results from our **DETERMINE** Phase 3 study of lenabasum in dermatomyositis in the second quarter. Our CB1 inverse agonist program focusing on metabolic diseases and our CB2 agonist program focusing on oncology continue to progress pre-clinically, and we project to initiate clinical studies next year. We are determined to expand our pipeline and are evaluating a number of potential assets.”

Dr. Cohen continued, “We are fortunate to be in a strong financial position with approximately \$127M of cash on hand, which is expected to fund the Company into the first quarter of 2024.”

Clinical Program Updates:

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

- **Dermatomyositis** – The Phase 3 “**DETERMINE**” study is a double-blind, randomized, placebo-controlled, international study of safety and efficacy of lenabasum in adult dermatomyositis patients. This study enrolled 176 subjects, and all subjects are expected to complete Week 28 of the study this month. The primary efficacy endpoint is Total Improvement Score at Week 28, comparing lenabasum 20 mg twice per day and placebo groups. Topline data are on schedule for Q2 2021.

Dermatomyositis is a rare and life-threatening autoimmune disease characterized by skin and muscle inflammation. Dermatomyositis affects approximately 80,000 people in North America, EU, and Japan. There is a significant unmet need for safer and more effective treatments in dermatomyositis because of the limitations of current treatment options.

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- **Systemic Lupus Erythematosus** – This Phase 2b study is a double-blind, randomized, placebo-controlled, U.S.-based study of safety and efficacy of lenabasum in adult systemic lupus erythematosus patients. The ongoing study is expected to dose 100 subjects at 15 sites. Enrollment is expected to be completed in Q2 2021, and topline results are expected in the second half of 2021. The primary efficacy endpoint is change in maximum daily pain numerical rating score at Week 12, comparing lenabasum groups to placebo. The secondary endpoints include change from baseline in Active Lupus Musculoskeletal Disease Activity (BILAG-2004) and Change from baseline in Lupus Disease Activity (SELENA-SLEDAI Score). The National Institutes of Health is funding and managing this trial.
 - **Systemic Sclerosis** – In 2020, lenabasum did not meet the primary endpoint in the RESOLVE-1 Phase 3 study of lenabasum in systemic sclerosis. Currently no systemic sclerosis patients are being treated with lenabasum. The Company is preparing the data from the RESOLVE-1 study for publication and will decide on the next steps in the development process pending the outcome of the DETERMINE study.
 - **Cystic Fibrosis** – In 2020, lenabasum did not meet the primary endpoint in the Phase 2b study of lenabasum in cystic fibrosis. Corbus is preparing the cystic fibrosis study data for publication, but currently it does not have plans for additional clinical studies.

Pipeline Updates:

- The cannabinoid receptor type 1 (CB1) inverse agonist program is in preclinical development for potential treatment of metabolic disorders such as obesity, diabetic nephropathy, diabetic retinopathy, and nonalcoholic steatohepatitis. Several compounds have demonstrated positive data in preclinical models of diet-induced obesity. These data were presented at the New York Academy of Sciences webinar in January 2020. Corbus is moving toward candidate selection and IND-enabling studies, and intends to initiate clinical studies in 2022.
- The cannabinoid receptor type 2 (CB2) agonist program is in preclinical development for potential treatment of cancer, investigating single agent activity and in combination with other cancer therapies such as checkpoint inhibitors. Several compounds have demonstrated positive data in preclinical models of solid tumors. These data were presented at the New York Academy of Sciences webinar in January 2020. The Company is moving toward candidate selection and IND-enabling studies, and intends to initiate clinical studies in 2022.
- Corbus is actively engaging with potential partners to expand its pipeline through acquisition of external assets. The Company is focusing on biology beyond the endocannabinoid system and new indications that will still leverage its expertise and capabilities within immunology.

Financial Results for Fourth Quarter and Year-End December 31, 2020:

Revenue from awards and licenses was \$700,000 for the three months ended December 31, 2020, compared to \$2.6 million in the comparable period in 2019. For the year ended December 31, 2020, revenue from awards and licenses was \$3.9 million, compared to \$36.1 million in the comparable period in 2019. Revenue for the year ended December 31, 2019 included a \$27 million upfront payment received from Kaken Pharmaceutical Co., Ltd. for a license to commercialize and market lenabasum in Japan.

Operating expenses were \$21.5 million for the three months ended December 31, 2020, compared to \$29.8 million in the comparable period in the prior year. For the year ended December 31, 2020, operating expenses were \$126.7 million, compared to \$113.2 million in the comparable period in the prior year. Increased expenses for the year were attributable to increased compensation costs, increased clinical trial costs and restructuring costs. Decreased operating expenses quarter over quarter were attributable to the completion of systemic sclerosis and cystic fibrosis in September and October of 2020, respectively. The Company expects expenses to decline in 2021 as a result of the completion in 2020 of clinical trials in systemic sclerosis and cystic fibrosis.

The Company reported a net loss of approximately \$8.6 million or a net loss per diluted share of \$0.10, for the three months ended December 31, 2020, compared to a net loss of approximately \$26.6 million, or a net loss per diluted share of \$0.41, for the same period in 2019. For the year ended December 31, 2020, the Company reported a net loss of

approximately \$111.3 million, or a net loss per diluted share of \$1.42, compared to a net loss of approximately \$71.5 million, or a net loss per diluted share of \$1.12, for the same period in 2019.

Cash and cash equivalents were \$85.4 million at December 31, 2020. During the fourth quarter of 2020 the Company raised \$20.8 million in net proceeds from the Company's ATM facility, and in 2021 to date, the Company has raised \$58.9 million in net proceeds from the Company's ATM facility. The \$127 million of cash on hand at March 15, 2021 is expected to fund operations into the first quarter of 2024 based on the 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, Monday, March 15, 2021, at 8:30 a.m. ET.

To participate on 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 clinical-stage company focused on the development and commercialization of novel medicines designed to target the endocannabinoid system. The Company's lead product candidate, lenabasum, is a novel, oral, selective cannabinoid receptor type 2 (CB2) agonist designed to provide an alternative to immunosuppressive medications in the treatment of chronic inflammatory and fibrotic diseases. Lenabasum is currently being evaluated in dermatomyositis and systemic lupus erythematosus. Corbus is also developing a pipeline of other preclinical drug candidates from its endocannabinoid system platform.

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Lenabasum is not approved for the treatment of any indication. For more information on Corbus' clinical programs, please visit [here](#).

For more information, visit <http://www.corbuspharma.com/>, and connect with us 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 restructuring, trial results, 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.

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Corbus Pharmaceuticals Holdings, Inc. Condensed Consolidated Balance Sheets

	December 31, 2020	December 31, 2019
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 85,433,441	\$ 31,748,686
Restricted cash	\$ 350,000	—
Stock subscriptions receivable	\$ 960,033	—
Prepaid expenses and other current assets	\$ 3,712,861	3,724,932
Contract asset	\$ 1,618,296	2,681,065
Total current assets	92,074,631	38,154,683
Restricted cash	669,900	—
Property and equipment, net	4,067,837	5,083,865
Operating lease right of use asset	5,248,525	5,818,983
Other assets	234,038	84,968
Total assets	\$ 102,294,931	\$ 49,142,499
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	\$ 710,158	\$ 752,659
Accounts payable	7,381,183	11,091,363
Accrued expenses	22,005,432	22,447,939
Derivative liability	797,000	—
Operating lease liabilities, current	1,004,063	595,745
Total current liabilities	31,897,836	34,887,706
Long-term debt, net of debt discount	18,029,005	—
Operating lease liabilities, noncurrent	7,093,165	8,097,228
Total liabilities	57,020,006	42,984,934
Stockholders' equity		
Preferred Stock \$0.0001 par value:10,000,000 shares authorized, no shares issued and outstanding at December 31, 2020 and December 31, 2019	—	—

Common stock, \$0.0001 par value; 150,000,000 shares authorized, 98,088,253 and 64,672,893 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	9,885	6,467
Additional paid-in capital	349,358,378	198,975,056
Accumulated deficit	(304,093,338)	(192,823,958)
Total stockholders' equity	45,274,925	6,157,565
Total liabilities and stockholders' equity	\$ 102,294,931	\$ 49,142,499

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

	For the Three Months Ended December 31,		For the Twelve Months Ended December 31,	
	2020	2019	2020	2019
Revenue from awards and licenses	\$ 658,204	\$ 2,573,519	3,937,230	\$ 36,143,568
Operating expenses:				
Research and development	16,110,287	23,487,675	98,267,213	89,604,790
General and administrative	5,360,231	6,276,155	28,480,250	23,643,357
Total operating expenses	21,470,518	29,763,830	126,747,463	113,248,147
Operating loss	(20,812,314)	(27,190,310)	(122,810,233)	(77,104,579)
Other income (expense), net:				
Other income (expense), net	13,266,206	472,500	13,270,211	4,581,838
Interest income (expense), net	(679,704)	151,477	(1,028,359)	1,227,643
Change in fair value of derivative liability	(40,000)	-	(251,000)	-
Foreign currency exchange loss, net	(346,058)	(14,428)	(449,999)	(158,620)
Other income (expense), net	12,200,444	609,549	11,540,853	5,650,861
Net loss	\$ (8,611,870)	\$ (26,580,761)	(111,269,380)	\$ (71,453,718)
Net loss per share, basic and diluted	\$ (0.10)	\$ (0.41)	(1.42)	\$ (1.12)
Weighted average number of common shares outstanding, basic and diluted	87,207,293	64,660,017	78,133,289	63,899,184

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