

November 10, 2020



## Corbus Pharmaceuticals Reports Third Quarter Financial Results and Provides Corporate Updates

- *Company intends to shorten fully-enrolled Phase 3 dermatomyositis trial to 28 weeks from 52 weeks following recent developments in competitive landscape; data now expected as early as the second quarter of 2021*
- *Expected cash runway extended into second quarter of 2022 as a result of Company restructuring, with potential to extend cash runway even further due to shortening Phase 3 dermatomyositis trial*
- *Company will also focus on progressing pipeline compounds toward clinical testing*
- *Reported topline data from RESOLVE-1 Phase 3 study of lenabasum in systemic sclerosis and data from Phase 2b study of lenabasum in cystic fibrosis; Corbus is exploring potential next steps in both indications*
- *Company to host conference call and webcast today, Tuesday, November 10, 2020 at 8:30 a.m. ET*

**Norwood, MA, Nov. 10, 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 ("ECS"), today reported financial results for the third quarter of 2020. The Company also provided clinical, pipeline and corporate updates.

Yuval Cohen, Ph.D., Chief Executive Officer said, "We are emerging from a very challenging period with a continued focus on our lenabasum dermatomyositis program and preclinical pipeline. Our restructuring significantly improved our cash runway, so we can continue to work toward delivering a much-needed novel therapeutic option for patients while also giving us the resources to look at external assets that will be synergistic to our in-house capabilities. We expect our cash runway to be further extended with the cost savings from our plan to shorten the **DETERMINE** Phase 3 dermatomyositis study to 28 weeks from one year. This decision is driven by recent changes in the dermatomyositis competitive landscape and will accelerate topline data readout to the second quarter of 2021. We see our dermatomyositis program as a potential large value driver for our Company, given that there are about 40,000 dermatomyositis patients in North America and limitations with current treatment options."

Dr. Cohen continued, "While we were disappointed that both the RESOLVE-1 systemic sclerosis study and the Phase 2b cystic fibrosis study did not meet their primary endpoints, we have a solid understanding of what led to those outcomes. The data generated point to

clinical activity associated with lenabasum treatment. The dataset also provided unique insight into disease progression and the impact of current standards of care. With this in mind, we are working with systemic sclerosis and cystic fibrosis experts to further analyze the data and potentially explore paths forward in these programs.”

### **Clinical Program Updates:**

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

*Dermatomyositis* – The Phase 3 “**DETERMINE**” study in dermatomyositis, a rare and life-threatening autoimmune disease characterized by skin and muscle inflammation, is fully enrolled.

#### Key Updates:

- This double-blind, randomized, placebo-controlled, multinational study enrolled 176 patients, which exceeded the original target of 150 patients. Approximately 60% of patients have completed Week 28 of dosing.
- There have been recent changes in the dermatomyositis competitive landscape with studies that are shorter than one year using the same efficacy endpoint as **DETERMINE**. Therefore, Corbus will submit a protocol amendment to the FDA and other regulatory agencies to shorten the treatment duration of **DETERMINE** to 28 weeks from one year. The last subject visit through 28 weeks is expected in March 2021 with topline data to be reported shortly thereafter.
- Baseline patient demographics and disease characteristics were presented at the American College of Rheumatology’s (ACR) Convergence 2020, which took place November 5–9, 2020. ACR poster is available [online](#).
- A separate presentation at ACR Convergence 2020 showed that CB2 expression was increased on immune cells in lesional skin from dermatomyositis subjects in the lenabasum Phase 2 study. Treatment with lenabasum was associated with reduction in immune cell infiltrates, CB2 expression and inflammatory cytokine production in lesional skin from these subjects. ACR poster is available [online](#).
- There is significant unmet need for new medicines to achieve disease control in dermatomyositis because of the limitations of current treatment options. Dermatomyositis affects approximately 80,000 people in North America, EU, and Japan.
- *Systemic Sclerosis* – Topline data from the RESOLVE-1 Phase 3 study of lenabasum for the treatment of systemic sclerosis were [announced](#) on September 8, and additional data were [announced](#) on November 9. RESOLVE-1 was a 52-week, multinational, double-blind, placebo-controlled study that enrolled 365 patients with diffuse cutaneous systemic sclerosis. It was the first large, late-stage clinical study in diffuse cutaneous systemic sclerosis that allowed patients to remain on a wide range of background immunosuppressive therapy.

#### Key Findings:

- Topline data remain as previously reported.
- Exploratory post-hoc analyses showed lenabasum treatment was associated with a benefit in lung function (forced vital capacity) in subjects on established background

immunosuppressant therapies (greater than 2 years).

- Focusing on FVC in patients on established immunosuppressant therapies could address a key unmet need, which Corbus believes represent a potential commercial opportunity.
- Systemic sclerosis is a rare, life-threatening autoimmune disease affecting up to 75K Americans.

#### Next Steps:

- The Company is continuing to analyze the data and will consider the potential for an additional study based on results of these analyses.
- *Cystic Fibrosis* – Topline data from the CF-002 Phase 2b study of lenabasum for treatment of CF were [announced](#) on October 6 and presented at the North American Cystic Fibrosis Conference (NACFC) in October (NACFC Poster #817 available [here](#)). CF-002 was a 28-week multinational, double-blind, randomized, placebo-controlled study that dosed 426 subjects who were at high-risk for recurrent pulmonary exacerbations (PEX). It is the first study to enroll subjects who are prone to exacerbation despite being on standard of care, including CFTR modulators.

#### Key Findings:

- Topline data remain as previously reported.
- Lenabasum did not meet its primary efficacy endpoint in the study.
- Lenabasum was well tolerated with no new safety findings.
- Exploratory post-hoc analyses revealed unexpectedly low PEX rates in subjects from five eastern European countries (21% of total subjects) who received placebo. Pulmonary exacerbations rates in these subjects were 85% lower than in subjects from other countries.
- Exploratory post-hoc analyses in subjects with similar FEV1% predicted at baseline and similar treatment with CFTR-modulators suggested evidence of clinical benefit of lenabasum.
- PEX remains a significant burden in people with CF even with current standard therapies, including antibiotics and CFTR modulators.

#### Next Steps:

- Further analysis of the data is underway to determine potential next steps.
- *Systemic Lupus Erythematosus (SLE)* – The 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 in the first half of 2021.

#### Pipeline Updates:

- Corbus has identified several compounds from its CB1 inverse agonist program which the Company believes has more promising physicochemical and pharmacokinetic properties than CRB-4001. The Company is shifting its focus to prioritize development of these compounds and not continuing with CRB-4001. The Company is also looking for attractive external assets that could have a strong synergy with its organizational

capabilities, pipeline, and expertise in immunology. Corbus will provide an update at its next R&D day.

### **Corporate Updates:**

- On October 8, Corbus announced a reduction in workforce and restructuring of its operations designed to reduce costs and reallocate resources towards its lenabasum clinical development program in dermatomyositis and systemic lupus erythematosus, as well as the Company's pipeline of other novel ECS-targeting drug candidates. The restructuring, which included cost reductions, was intended to extend the Company's cash runway, and, together with the shortening of the DM study to 28 weeks, is designed to extend the Company's cash runway beyond the second quarter of 2022.

### **Financial Results for Third Quarter Ended September 30, 2020:**

For the quarter ended September 30, 2020, the Company reported a net loss of approximately \$34.9 million or a net loss per diluted share of \$0.43, compared to a net loss of approximately \$20.8 million or net loss per diluted share of \$0.32 for the quarter ended September 30, 2019.

For the quarter ended September 30, 2020, revenue decreased by approximately \$1.4 million from the third quarter of 2019 to \$1.2 million, due primarily to revenue recognized under the Cystic Fibrosis Program Related Investment Agreement.

Operating expenses for the quarter ended September 30, 2020 increased by approximately \$7.5 million to \$35.2 million. The increase was primarily attributable to increased clinical trial costs.

Corbus expects its cash and cash equivalents on hand of approximately \$81.9 million at September 30, 2020 together with proceeds from the expected final \$2.5 million milestone payment from the Cystic Fibrosis Foundation and anticipated foreign tax credits to fund operations and its current clinical plan beyond the second quarter of 2022.

### **Conference Call and Webcast Information:**

Corbus management will host a conference call and webcast presentation for investors, analysts, and other interested parties today, Tuesday, November 10, 2020, 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](http://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.

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 statements 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

	September 30, 2020 <u>(unaudited)</u>	December 31, 2019
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 81,870,651	\$ 31,748,686
Restricted cash	350,000	—
Prepaid expenses and other current assets	2,177,383	3,724,932
Contract asset	960,091	2,681,065
Total current assets	<u>85,358,125</u>	<u>38,154,683</u>
Restricted cash	669,900	—

Property and equipment, net	4,402,022	5,083,865
Operating lease right of use asset	5,396,248	5,818,983
Other assets	13,041	84,968
Total assets	<u>\$ 95,839,336</u>	<u>\$ 49,142,499</u>

#### LIABILITIES AND STOCKHOLDERS' EQUITY

##### Current liabilities:

Notes payable	\$ —	\$ 752,659
Accounts payable	11,080,717	11,091,363
Accrued expenses	28,593,049	22,447,939
Derivative liability	757,000	—
Operating lease liabilities, current	972,464	595,745
Total current liabilities	<u>41,403,230</u>	<u>34,887,706</u>
Long-term debt, net of debt discount	17,856,589	—
Operating lease liabilities, noncurrent	7,353,765	8,097,228
Total liabilities	<u>\$ 66,613,584</u>	<u>\$ 42,984,934</u>

##### Stockholders' equity

Preferred Stock \$0.0001 par value: 10,000,000 shares authorized, no shares issued and outstanding at September 30, 2020 and December 31, 2019

— —

Common stock, \$0.0001 par value; 150,000,000 shares authorized, 82,207,405 and 64,672,893 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively

8,220 6,467

Additional paid-in capital

324,698,962 198,975,056

Accumulated deficit

(295,481,430) (192,823,958)

Total stockholders' equity

29,225,752 6,157,565

Total liabilities and stockholders' equity

\$ 95,839,336 \$ 49,142,499

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

	For the Three Months Ended		For the Nine Months Ended	
	September 30,		September 30,	
	2020	2019	2020	2019
Revenue from awards and licenses	<u>\$ 1,230,621</u>	<u>\$ 2,589,783</u>	<u>\$ 3,279,026</u>	<u>\$ 33,570,048</u>
Operating expenses:				
Research and development	27,522,989	22,152,001	82,156,926	66,117,114
General and administrative	7,681,573	5,534,493	23,120,020	17,367,202

Total operating expenses	<u>35,204,562</u>	<u>27,686,494</u>	<u>105,276,946</u>	<u>83,484,316</u>
Operating loss	<u>(33,973,941)</u>	<u>(25,096,711)</u>	<u>(101,997,920)</u>	<u>(49,914,268)</u>
Other income (expense), net:				
Other income (expense), net	(4,972)	4,109,338	4,005	4,109,338
Interest income (expense), net	(454,319)	292,854	(348,654)	1,076,166
Change in fair value of derivative liability	(211,000)	-	(211,000)	-
Foreign currency exchange loss, net	<u>(251,117)</u>	<u>(96,282)</u>	<u>(103,903)</u>	<u>(144,193)</u>
Other income (expense), net	<u>(921,408)</u>	<u>4,305,910</u>	<u>(659,552)</u>	<u>5,041,311</u>
Net loss	<u>\$ (34,895,349)</u>	<u>\$ (20,790,801)</u>	<u>\$ (102,657,472)</u>	<u>\$ (44,872,957)</u>
Net loss per share, basic and diluted	\$ (0.43)	\$ (0.32)	\$ (1.37)	\$ (0.71)
Weighted average number of common shares outstanding, basic and diluted	<u>81,879,119</u>	<u>64,660,017</u>	<u>75,037,418</u>	<u>63,638,447</u>

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Source: Corbus Pharmaceuticals Holdings, Inc.