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Corbus Pharmaceuticals Reports 2017 Second Quarter Financial Results and Provides Business Update

NORWOOD, MA -- (Marketwired) -- 08/09/17 --

- *Data from Phase 2 open-label extension study of anabasum for the treatment of systemic sclerosis expected in Q4 2017*
- *Phase 3 study of anabasum for the treatment of systemic sclerosis expected to commence in Q4 2017*
- *Topline data from Phase 2 study of anabasum in skin-predominant dermatomyositis expected to be reported in Q4 2017*

[Corbus Pharmaceuticals Holdings, Inc.](#) (NASDAQ: CRBP) ("Corbus" or the "Company"), a clinical stage drug development company targeting rare, chronic, serious inflammatory and fibrotic diseases, announced today its financial results for the second quarter ended June 30, 2017.

The Company also provided an update to its corporate progress, clinical status and anticipated milestones for [anabasum](#), its novel synthetic oral endocannabinoid-mimetic drug that is designed to resolve chronic inflammation and halt fibrosis.

"We have made significant progress on the corporate, operational and clinical fronts, enabling the Company to move forward with a strong balance sheet and plans to execute on multiple potentially impactful milestones coming up in the second half of this year," stated [Yuval Cohen, Ph.D., Chief Executive Officer of the Company](#)

Systemic Sclerosis Clinical Program Update

Following an end-of-Phase 2 meeting with the U.S. Food and Drug Administration ("FDA") and a protocol assistance meeting with the European Medicines Agency ("EMA"), Corbus plans to [commence a Phase 3 study of anabasum for the treatment of systemic sclerosis](#) in the fourth quarter of 2017.

The international Phase 3 study is a double-blind, randomized, placebo-controlled, parallel dose, multi-center study that will be conducted in approximately 350 adults with diffuse cutaneous systemic sclerosis. Subjects will be randomized to receive anabasum 20 mg twice per day, anabasum 5 mg twice per day, or placebo twice per day for 52 weeks. The primary efficacy outcome of the Phase 3 study will be change from baseline at week 52 in modified Rodnan Skin Score ("mRSS"), a measure of skin fibrosis and thickening in systemic

sclerosis. The Company expects to conclude this pivotal Phase 3 study by the end of 2019.

In November 2016, the Company reported positive topline data from its Phase 2 study in systemic sclerosis. The Company reported that anabasum outperformed placebo in the mRSS, the American College of Rheumatology Combined Response Index in diffuse cutaneous Systemic Sclerosis ("ACR CRISS") and multiple individual core measures in the ACR CRISS. In June 2017, at the European League Against Rheumatism ("EULAR") Annual Meeting, the Company presented additional supportive clinical and translational data including patient-reported outcomes and gene transcript analysis from skin biopsies. On August 7, 2017, Corbus presented histology data from the Phase 2 study at the 15th International Workshop on Scleroderma Research demonstrating significant reductions in inflammation and fibrosis in skin biopsies of patients who received anabasum versus placebo. These data provide further evidence for a direct, on-target effect of anabasum in resolution of innate immune responses and correspond with mRSS benefit seen in the Phase 2 study.

Anabasum has been granted [Orphan Drug Designation](#) and [Fast Track](#) status for the treatment of systemic sclerosis from the FDA and [Orphan Designation](#) from the EMA.

Currently, the Company is conducting an open-label extension study in systemic sclerosis as a continuation of the Phase 2 study. The open-label study began enrolling subjects in September 2016 and a majority of the Phase 2 study patient participants are enrolled in this open-label extension study. The open-label extension has been extended from one year to two years' duration.

Expected Near-Term Milestones:

- Present data from the Phase 2 open-label extension study in Q4 2017; and
- Commence Phase 3 systemic sclerosis study in Q4 2017.

Cystic Fibrosis Clinical Program Update

In March 2017, Corbus reported [positive topline data from the double-blind, randomized, placebo-controlled Phase 2 study](#) of anabasum for the treatment of [cystic fibrosis](#) ("CF") showing that anabasum, compared to placebo, reduced the rate of pulmonary exacerbations treated with antibiotics, reduced multiple inflammatory biomarkers and had an acceptable safety and tolerability profile. The 16-week study was an international, multi-center study supported by a [\\$5 million Development Award from Cystic Fibrosis Foundation Therapeutics, Inc.](#) Data from this study was presented at the European Cystic Fibrosis Society ("ECFS") conference in June 2017 and also will be presented at the North American Cystic Fibrosis Conference ("NACFC") in November 2017.

Anabasum has been granted [Orphan Drug Designation and Fast Track](#) status for the treatment of CF by the FDA and [Orphan Designation](#) from the EMA.

Expected Near-Term Milestones:

- Present Phase 2 CF clinical results at NACFC in November 2017;
- Conclude Phase 2b CF study protocol design in collaboration with the Cystic Fibrosis Foundation Therapeutic Development Network;

- Obtain guidance from the FDA and EMA on protocol design for the Phase 2b CF study;
- Submit Pediatric Investigational Plan to EMA; and
- Planning to initiate the Phase 2b clinical study by the end of 2017.

Dermatomyositis Clinical Program Update

Corbus is currently evaluating anabasum in an on-going Phase 2 study for the treatment of skin-predominant [dermatomyositis](#). Enrollment was completed in May 2017. In November 2016, the Company [commenced a one-year, open-label extension](#) to provide subjects in the Phase 2 study with the option of continuing anabasum treatment beyond their completion of the four-month, double-blind placebo controlled portion of the study. Corbus expects to report topline data from the Phase 2 study in Q4 2017.

The primary objectives of the Phase 2 study are to evaluate anabasum's safety, tolerability, and clinical efficacy in up to 22 adult subjects with moderate to severe skin-predominant dermatomyositis that is refractory to standard-of-care. Efficacy will be assessed using the Cutaneous Dermatomyositis Disease Area and Severity Index activity score ("CDASI"), a validated measure of skin disease activity in dermatomyositis. Secondary objectives include evaluating anabasum's effects on quality of life with the Skindex-29+3 questionnaire and the PROMIS-29 Short Form, as well as on skin and blood biomarkers of inflammation. Study subjects are treated with anabasum for 84 days, with a follow-up period of 28 days.

The single-center, Phase 2 study in skin-predominant dermatomyositis is being conducted at the University of Pennsylvania School of Medicine and is funded by a grant from the National Institute of Arthritis and Musculoskeletal and Skin Diseases of the National Institutes of Health ("NIH"). For more information on the Phase 2 study with anabasum for the treatment of skin-predominant dermatomyositis, please visit [ClinicalTrials.gov](#) and reference Identifier NCT02466243.

Expected Near-Term Milestones:

- Report topline data from Phase 2 DM study early in Q4 2017; and
- Continue ongoing Phase 2 open-label extension study.

Systemic Lupus Erythematosus Clinical Program Update

Corbus expects that the Phase 2 clinical study evaluating anabasum for the treatment of systemic lupus erythematosus ("SLE"), which will be funded by the NIH and will be operationally-executed by the NIH, will begin in the fourth quarter of 2017. The Phase 2 SLE study will evaluate anabasum in 100 patients at doses of 5 mg, 20 mg, and 20 mg twice daily, administered orally for 12 weeks, with 28 days follow-up, at approximately 14 U.S. sites.

Summary of Financial Results for Second Quarter 2017

For the quarter ended June 30, 2017, the Company reported a net loss of approximately \$7,297,000, or a net loss per diluted share of \$0.15, compared to a net loss of approximately \$4,189,000, or a net loss per diluted share of \$0.11 for the quarter ended June 30, 2016.

Operating expenses increased by approximately \$3.1 million to \$7.6 million due to increased spending for clinical studies, manufacturing costs to produce anabasum for clinical studies

stock compensation expense and staffing costs.

The Company ended the second quarter with approximately \$43.0 million of cash and cash equivalents, and expects the cash on hand to fund operations into the fourth quarter of 2018, based on current planned expenditures.

About Anabasum

Anabasum is a novel synthetic oral endocannabinoid-mimetic drug that preferentially binds to the CB2 receptor expressed on activated immune cells and fibroblasts. CB2 activation triggers endogenous pathways that resolve inflammation and halt fibrosis. Preclinical and human clinical studies have shown anabasum to have a favorable safety, tolerability and pharmacokinetic profile. It has also demonstrated promising potency in preclinical models of inflammation and fibrosis. Anabasum is designed to trigger the production of "Specialized Pro-resolving Lipid Mediators" that activate an endogenous cascade responsible for the resolution of inflammation and fibrosis, while reducing production of multiple inflammatory mediators. Anabasum also is designed to have direct effects on fibroblasts to halt tissue scarring. In effect, anabasum triggers endogenous pathways to turn "off" chronic inflammation and fibrotic processes, without causing immunosuppression

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 rare, chronic, and serious inflammatory and fibrotic diseases. The Company's lead product candidate, anabasum, is a novel synthetic oral endocannabinoid-mimetic drug designed to resolve chronic inflammation and fibrotic processes. Anabasum has demonstrated positive results in two Phase 2 studies, one in diffuse cutaneous systemic sclerosis and one in cystic fibrosis. Additionally, anabasum is being evaluated in open-label extension studies in systemic sclerosis and skin-predominant dermatomyositis, and soon in another Phase 2 study in systemic lupus erythematosus.

Corbus plans to commence a Phase 3 study of anabasum for the treatment of systemic sclerosis in the fourth quarter of 2017. The Company is also planning to initiate a larger and longer Phase 2b study of anabasum for the treatment of cystic fibrosis by the end of the fourth quarter of 2017.

For more information, please visit www.CorbusPharma.com and connect with the Company on [Twitter](#), [LinkedIn](#), [Google+](#) 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 Statements of Operations
(Unaudited)

	For the Three Months		For the Six Months Ended	
	Ended		June 30,	
	2017	2016	2017	2016
Collaboration revenue	\$ 350,186	\$ 396,598	\$ 1,643,883	\$ 793,196
Operating expenses:				
Research and development	5,763,660	3,567,003	12,129,772	5,740,936
General and administrative	1,878,090	1,021,225	4,258,215	2,131,114
Total operating expenses	<u>7,641,750</u>	<u>4,588,228</u>	<u>16,387,987</u>	<u>7,872,050</u>
Operating loss	<u>(7,291,564)</u>	<u>(4,191,630)</u>	<u>(14,744,104)</u>	<u>(7,078,854)</u>
Other income (expense), net:				
Interest income (expense), net	5,271	4,049	6,637	(1,311)
Foreign currency exchange loss	(10,594)	(1,810)	(24,859)	(1,467)
Other income (expense), net	<u>(5,323)</u>	<u>2,239</u>	<u>(18,222)</u>	<u>(2,778)</u>
Net loss	<u>\$ (7,296,887)</u>	<u>\$ (4,189,391)</u>	<u>\$ (14,762,326)</u>	<u>\$ (7,081,632)</u>
Net loss per share, basic and diluted	<u>\$ (0.15)</u>	<u>\$ (0.11)</u>	<u>\$ (0.31)</u>	<u>\$ (0.19)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>50,193,726</u>	<u>38,748,452</u>	<u>48,298,135</u>	<u>38,176,831</u>

Corbus Pharmaceuticals Holdings, Inc.

Condensed Consolidated Balance Sheets

	<i>June 30, 2017</i>	<i>December 31, 2016</i>
	<u>(Unaudited)</u>	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 43,032,762	\$ 14,992,257
Restricted cash	150,000	150,000
Grants receivable	-	1,000,000
Stock subscriptions receivable	-	330,413
Prepaid expenses and other current assets	844,855	930,261
Total current assets	<u>44,027,617</u>	<u>17,402,931</u>
Restricted cash	50,000	50,000
Property and equipment, net	418,508	435,251
Other assets	65,026	-
Total assets	<u>\$ 44,561,151</u>	<u>\$ 17,888,182</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	\$ 39,041	\$ 271,757
Accounts payable	3,859,863	3,419,921
Accrued expenses	2,705,744	3,256,455
Deferred revenue	296,311	1,940,195
Deferred rent, current	12,866	10,263
Total current liabilities	<u>6,913,825</u>	<u>8,898,591</u>
Deferred rent, noncurrent	58,206	65,724
Other liabilities	2,559	4,632
Total liabilities	<u>6,974,590</u>	<u>8,968,947</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, 2017 and December 31, 2016	-	-
Common stock, \$0.0001 par value; 150,000,000 shares authorized, 50,220,510 and 44,681,745 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	5,022	4,468
Additional paid-in capital	85,620,354	42,191,256
Accumulated deficit	<u>(48,038,815)</u>	<u>(33,276,489)</u>
Total stockholders' equity	<u>37,586,561</u>	<u>8,919,235</u>
Total liabilities and stockholders' equity	<u>\$ 44,561,151</u>	<u>\$ 17,888,182</u>

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Source: Corbus Pharmaceuticals Holdings, Inc.