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

Q1 2017 marked by positive data from Phase 2 study of anabasum for the treatment of cystic fibrosis

Company ended the quarter with \$49 million of cash which is sufficient to fund operations through the end of 2018

NORWOOD, MA -- (Marketwired) -- 05/09/17 -- [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 first quarter ended March 31, 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 in both the corporate and clinical areas in the first quarter of 2017 and are in a strong financial position, which is expected to take us through key milestones for the Company over the next 20 months," stated [Yuval Cohen, Ph.D., Chief Executive Officer of the Company](#).

Systemic Sclerosis Clinical Program Update

Corbus reported positive topline data results from a Phase 2 study in diffuse cutaneous [systemic sclerosis](#) ("systemic sclerosis") in November 2016, showing a clear signal of clinical benefit with anabasum. The 12-month open-label extension of this Phase 2 study is ongoing and is designed to capture long-term safety and efficacy data in subjects dosed with anabasum 20 mg twice per day. To date, subjects have been safely dosed with anabasum for up to 10 months and Corbus intends to present data at the 2017 American College of Rheumatology ("ACR") Annual Meeting.

Following an end-of-Phase 2 meeting with the U.S. Food and Drug Administration ("FDA"), Corbus submitted a protocol to the FDA for its Phase 3 study in systemic sclerosis on March 31, 2017, and is moving forward as planned. The Company expects to commence this study in the fourth quarter of 2017. Protocol assistance from the European Medicines Agency ("EMA") on the Phase 3 study design is expected in the second quarter of 2017.

The planned Phase 3 study is a double-blind, randomized, placebo-controlled, parallel dose, multi-center study to be conducted in approximately 270 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 planned Phase 3 study will be change from baseline at Week 52 in modified Rodnan Skin Score ("mRSS"), a measure of skin thickening and a validated clinical outcome measure in systemic sclerosis. Toplevel results of the [Phase 2 study](#) showed that the mean improvement from baseline in mRSS for anabasum-treated subjects was greater than for the placebo-treated subjects, and considered medically meaningful. The improvement in mRSS was accompanied by statistically significant improvement in the anabasum arm in patient-reported skin symptoms and reduced expression of genes associated with inflammation and fibrosis in skin biopsies. Corbus expects to complete enrollment of the 52-week study in 2018. The Company also expects results by the end of 2019 and a New Drug Application ("NDA") application to be filed in 2020.

Anabasum was granted [Orphan Drug Designation](#) and [Fast Track](#) status for the treatment of systemic sclerosis from the FDA in 2015 and [Orphan Designation](#) from the European Medicines Agency ("EMA") in January 2017. The Company was not granted Breakthrough Designation for systemic sclerosis, however Corbus' existing Fast Track status already grants it similar eligibility for more frequent meetings with the FDA to discuss the development plan for anabasum, as well as Priority Review and Rolling Reviews of completed sections of the NDA.

Expected Near-Term Milestones:

- Presentation of anabasum Phase 2 systemic sclerosis data at EULAR in June 2017;
- Continue Phase 2 anabasum open-label extension study and present a data update at the 2017 ACR Annual Meeting in November 2017; and
- Commence anabasum Phase 3 study of systemic sclerosis in the fourth quarter of 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 had an acceptable safety and tolerability profile, reduced pulmonary exacerbations treated with antibiotics, and reduced multiple inflammatory biomarkers in sputum collected from subjects in the study. The 16-week study was an international, multi-center study supported by a [\\$5 million Development Award from Cystic Fibrosis Foundation Therapeutics, Inc.](#)

Anabasum successfully achieved the primary objective of the study by demonstrating an acceptable safety and tolerability profile with no serious or severe adverse events related to the study drug. Anabasum cohorts showed a reduction in a number (event rate per subject) of pulmonary exacerbations treated with intravenous antibiotics compared to placebo, which was a prespecified event of special interest in the protocol, as well as the number (event rate per subject) of pulmonary exacerbations treated with any new antibiotic. Patients in the highest dose cohort of anabasum (20 mg orally, twice per day) had a 75% reduction in the annualized rate of pulmonary exacerbations requiring IV antibiotics compared to placebo cohort. Forced expiratory volume in 1 second (FEV1) remained stable throughout the study

in all treatment cohorts.

Additionally, patients receiving anabasum showed a reduction in multiple inflammatory cell types in sputum, including total leukocytes, neutrophils, eosinophils, and macrophages. Also, a dose-dependent reduction in sputum inflammatory mediators, including interleukin-8, neutrophil elastase, and immunoglobulin G was observed. These data provide evidence of pharmacologic activity of anabasum at resolving ongoing innate immune responses in lungs of CF patients and support the potential of anabasum to reduce in pulmonary exacerbations in CF.

Anabasum was granted [Orphan Drug Designation and Fast Track](#) status for the treatment of CF by the FDA in 2015 and [Orphan Designation](#) from the EMA in 2016.

Expected Near-Term Milestones:

- Presentation of the CF Phase 2 clinical results at the European Cystic Fibrosis ("ECFS") conference in June 2017 and the North American Cystic Fibrosis Conference ("NACFC") in November 2017;
- Obtain expert opinion regarding the design of Phase 2b CF study from the Cystic Fibrosis Foundation Therapeutics ("CFFT"), Inc., CFFT Therapeutic Development Network and European Cystic Fibrosis Society Clinical Trials Network;
- Reach agreement on design of Phase 2b CF study with the FDA and EMA by third quarter 2017; and
- Submit Pediatric Investigational Plan to EMA.

Dermatomyositis Clinical Program Update

Corbus is currently evaluating anabasum in an on-going Phase 2 study for the treatment of skin-predominant [dermatomyositis](#). In November 2016, the Company [commenced a one-year, open-label extension](#) to provide all enrolled subjects in the Phase 2 study with the option of receiving anabasum for one year after they complete the four-month, double-blind placebo controlled portion of the study.

The Phase 2 study in skin-predominant dermatomyositis is being funded by a grant from the National Institute of Arthritis and Musculoskeletal and Skin Diseases of the National Institutes of Health to the University of Pennsylvania School of Medicine. 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:

- Complete enrollment of Phase 2 clinical study in dermatomyositis in Q2 2017;
- Report topline data from Phase 2 DM study in the fourth quarter of 2017; and
- Continue dosing in the 12-month open-label extension of the Phase 2 DM study.

Systemic Lupus Erythematosus Clinical Program Update

Corbus expects the National Institutes of Health ("NIH")-funded and operationally-executed Phase 2 clinical study evaluating anabasum for the treatment of systemic lupus erythematosus ("SLE") to begin in the second half of 2017. The Phase 2 SLE study will evaluate anabasum at doses of 5 mg, 20 mg, and 20 mg twice daily, administered orally for

12 weeks, with 1 month follow-up, at approximately 12 U.S. sites.

"We are very pleased with our progress in the clinical development of anabasum over the past two years, advancing this experimental drug into multiple first-in-patient studies in serious chronic indications with high unmet medical needs, two of which have delivered positive clinical data and are moving ahead to their next stages of clinical development by year end," concluded Dr. Cohen.

Summary of Financial Results for First Quarter 2017

For the quarter ended March 31, 2017, the Company reported a net loss of approximately \$7,465,000, or a net loss per diluted share of \$0.16, compared to a net loss of approximately \$2,892,000, or a net loss per diluted share of \$0.08 for the quarter ended March 31, 2016.

Collaboration revenue for the quarter increased by approximately \$0.9 million to \$1.3 million due to revenue recognized from the \$5 million development award received from the Cystic Fibrosis Foundation Therapeutics, Inc. Operating expenses increased by approximately \$5.4 million to \$8.7 million due to increased spending for clinical studies, manufacturing costs to produce anabasum for clinical studies and staffing costs.

The Company ended the first quarter with \$48.9 million of cash and cash equivalents, an increase of \$33.9 million from the start of the quarter. The Company raised \$41 million of capital during the first quarter including the following:

- In February 2017, the Company completed a registered direct offering and received \$27.2 million of net proceeds from the issuance of approximately 3,888,000 shares of common stock at a selling price of \$7 per share.
- During the first quarter of 2017, the Company received net proceeds totaling \$13.3 million from sales under an At the Market Offering of approximately 1,414,000 shares of common stock at an average selling price of \$9.71 per share.

The Company expects the cash on hand to fund operations through 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 clinical stage pharmaceutical company focused

on the development and commercialization of novel therapeutics to treat rare, chronic, and serious inflammatory and fibrotic diseases. Our lead product candidate, anabasum, is a novel synthetic oral endocannabinoid-mimetic drug designed to resolve chronic inflammation, and fibrotic processes. Anabasum is currently in development for the treatment of cystic fibrosis, diffuse cutaneous systemic sclerosis, skin-predominant dermatomyositis, and systemic lupus erythematosus.

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

	For the Three Months Ended March 31,	
	2017	2016
Collaboration revenue	\$ 1,293,697	\$ 396,598
Operating expenses:		
Research and development	6,366,112	2,173,933
General and administrative	2,380,125	1,109,889
Total operating expenses	8,746,237	3,283,822
Operating loss	(7,452,540)	(2,887,224)
Other income (expense):		

Interest income (expense), net	1,366	(5,360)
Foreign currency exchange (loss) gain, net	(14,265)	343
Other expense, net	(12,899)	(5,017)
Net loss	<u>\$ (7,465,439)</u>	<u>\$ (2,892,241)</u>
Net loss per share, basic and diluted	<u>\$ (0.16)</u>	<u>\$ (0.08)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>46,381,482</u>	<u>37,605,210</u>

**Corbus Pharmaceuticals Holdings, Inc.
Condensed Consolidated Balance Sheets**

	March 31, 2017	December 31, 2016
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 48,927,125	\$ 14,992,257
Restricted cash	150,000	150,000
Grants receivable	-	1,000,000
Stock subscriptions receivable	-	330,413
Prepaid expenses	1,070,441	930,261
Total current assets	<u>50,147,566</u>	<u>17,402,931</u>
Restricted cash	50,000	50,000
Property and equipment, net	409,786	435,251
Total assets	<u>\$ 50,607,352</u>	<u>\$ 17,888,182</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	\$ 155,726	\$ 271,757
Accounts payable	3,266,729	3,419,921
Accrued expenses	2,874,118	3,256,455
Deferred revenue, current	646,498	1,940,195
Deferred rent, current	12,433	10,263
Total current liabilities	<u>6,955,504</u>	<u>8,898,591</u>
Deferred rent, noncurrent	62,182	65,724
Other liabilities	3,609	4,632
Total liabilities	<u>7,021,295</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 March 31, 2017 and December 31, 2016	-	-
Common stock, \$0.0001 par value; 150,000,000 shares authorized, 50,143,742 and 44,681,745 shares issued and outstanding at March 31, 2017 and December 31, 2016	5,014	4,468
Additional paid-in capital	84,322,971	42,191,256
Accumulated deficit	<u>(40,741,928)</u>	<u>(33,276,489)</u>

Total stockholders' equity	43,586,057	8,919,235
Total liabilities and stockholders' equity	<u>\$ 50,607,352</u>	<u>\$ 17,888,182</u>

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