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Corbus Pharmaceuticals Reports 2017 Third Quarter Financial Results and Highlights Recent Corporate and Clinical Advancements

NORWOOD, MA -- (Marketwired) -- 11/08/17 --

- *Positive data from three consecutive Phase 2 studies in rare and serious chronic inflammatory and fibrotic diseases provides validation of anabasum's unique activity of resolving inflammation and halting fibrosis without immunosuppression*
- *Company on track to commence Phase 3 study in systemic sclerosis, Phase 2b study in cystic fibrosis and Phase 2 study in systemic lupus erythematosus before year end*
- *Recent public offering completed raising approximately \$32.5 million in gross proceeds extends expected cash runway into Q4 2019*

[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 third quarter ended September 30, 2017.

The Company also provided an update on 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 in rare autoimmune inflammatory diseases.

Recent Clinical and Corporate Achievements

- Reported positive, statistically significant 6-month clinical data from the ongoing open-label extension ("OLE") study in systemic sclerosis ("SSc") which is a continuation of the positive double-blind placebo-controlled Phase 2 study reported in November 2016;
- Reported positive, statistically significant Phase 2 results from the double-blind, randomized, placebo-controlled trial in dermatomyositis ("DM"), a rare autoimmune disease;
- Raised \$32.5 million in gross proceeds from a secondary public offering;
- Appointed Mr. Paris Panayiotopoulos to Board of Directors; and
- Awarded U.S. Patent covering the use of pharmaceutical compositions comprising

anabasum for treatment of rare autoimmune, inflammatory diseases through 2034.

"We are very proud that in less than four years we have successfully executed our clinical development and corporate strategy enabling us to be in position to launch our first Phase 3 late-stage study. Over the past 12 months, we have reported positive Phase 2 clinical data in succession in three distinct rare diseases with significant morbidity and mortality and that, combined, affect over 200,000 individuals in the US and EU," stated [Yuval Cohen, Ph.D., Chief Executive Officer of the Company](#). "This important progress has positioned us for the solid implementation and execution of our four clinical studies in systemic sclerosis, cystic fibrosis, dermatomyositis and lupus. We are looking ahead to an exciting 2018."

Systemic Sclerosis Clinical Program Update

On November 5, 2017 at the American College of Rheumatology ("ACR") Annual Meeting, Corbus [presented 6-month data from the on-going OLE study in systemic sclerosis](#) Thirty-six subjects are participating in the ongoing OLE which followed the conclusion of the 16-week double blind placebo controlled study. Subjects continued to improve in multiple clinical endpoints including a mean improvement in the modified Rodnan Skin Score (mRSS) of -8.4 points ($p < 0.0001$) from baseline at the start of the Phase 2 double blind placebo controlled portion of the study. 75% of subjects achieved a degree of improvement in mRSS (reduction ≥ 5 points and $> 25\%$ baseline) that has been associated with improved survival and exceeds that previously reported in other clinical trials or registries in systemic sclerosis. A third of the subjects reached a low mRSS ≤ 10 points. The ACR Composite Response Index in diffuse cutaneous systemic sclerosis score (ACR CRISS) continued to increase steadily with anabasum treatment and reached 71% (median) from study start. The speed and degree of improvement in multiple efficacy outcomes exceeds that previously reported in other clinical studies or registries in systemic sclerosis. To access the open label data and other five posters presented at ACR please click [here](#).

Corbus is on track to [commence a Phase 3 study of anabasum for the treatment of systemic sclerosis](#) with the mRSS as the primary endpoint before year end and expects to report topline results before the end of 2019.

[Systemic sclerosis](#) is a chronic, systemic autoimmune rheumatic rare disease with an unclear etiology that affects approximately 90,000 people in the United States and Europe, with disease onset typically in mid-life and lung fibrosis resulting in a 10-year mortality rate of 40-60%. Currently, there are no FDA-approved treatments specifically indicated for the treatment of SSc, other than pulmonary artery hypertension secondary to connective tissue diseases such as SSc.

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.

Expected Near-Term Milestones:

- Commence Phase 3 systemic sclerosis study by end of 2017; and
- Report 12-month data from the on-going OLE study in mid-2018.

Cystic Fibrosis ("CF") 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 CF showing that anabasum, compared to placebo, reduced the rate of pulmonary exacerbations, 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 was also recently [presented at the North American Cystic Fibrosis Conference \("NACFC"\)](#). To access the posters presented at NACFC, please click [here](#).

[Cystic fibrosis](#) is a chronic, life-threatening, genetic rare disease, characterized by chronic lung inflammation that leads to lung damage and fibrosis that affects approximately 30,000 patients in the U.S and 75,000 patients worldwide. The current average life expectancy for CF patients is 40 years. The harmful inflammation and accompanying fibrosis in CF damages multiple organs, impairs organ function, reduces health-related quality of life, and is the most common cause of mortality. There remains a recognized unmet need for safe and effective drugs that target chronic inflammation and fibrosis for the treatment of CF without the risk of immunosuppression currently associated with existing anti-inflammatory drugs.

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:

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

Dermatomyositis Clinical Program Update

In October 2017, Corbus [announced positive topline results from its Phase 2 study](#) evaluating anabasum for the treatment of skin-predominant dermatomyositis, demonstrating medically and statistically significant improvement in the Cutaneous Dermatomyositis Disease Area and Severity Index (CDASI), the primary endpoint in the study. Improvements in multiple secondary patient-reported outcomes, including a number that achieved statistical significance, reinforce the signal of activity of anabasum in dermatomyositis.

Detailed Phase 2 results of [safety and primary and secondary efficacy assessments](#) were presented in a late-breaking poster presentation at the ACR Annual Meeting. Demographics and baseline characteristics of subjects were also presented in a second poster presentation. To access the ACR posters please click [here](#).

[Dermatomyositis](#) is a rare and serious systemic autoimmune condition characterized by skin and muscle inflammation that affects as many as 70,000 people in the US. Mortality is high with 5-year survival of 70% and 10-year survival of 57%. Current standard of care includes antimalarial drugs and potent immunosuppressive agents, which often lead to significant adverse effects.

Expected Near-Term Milestones:

- Engage regulatory authorities to review Phase 2 dermatomyositis data and determine next steps in clinical development plan; and
- Report on six-month data from Phase 2 open-label extension study in mid-2018.

Systemic Lupus Erythematosus Clinical Program Update

[Systemic lupus erythematosus](#) ("SLE") is a prototypical autoimmune disease in which the innate immune system is chronically activated by immune complexes containing autoantibodies and self-antigens, which leads to widespread inflammation and tissue damage. According to the CDC, SLE affects between 161,000 - 322,000 people in the United States and has many manifestations, including arthritis, rash, photosensitivity, oral ulcers, pleuritis, pericarditis, kidney problems, seizures and psychosis and blood cell abnormalities. Current drugs specifically approved by the FDA for SLE are limited to aspirin, corticosteroids, hydroxychloroquine and belimumab. Physicians commonly treat disease manifestations with immunosuppressive or corticosteroid therapies that have significant toxicities.

Corbus expects that its Phase 2 clinical study evaluating anabasum for the treatment of systemic lupus erythematosus, which is being funded by the National Institute of Health, will commence before the end of 2017.

Summary of Financial Results for Third Quarter 2017

For the three months ended September 30, 2017, the Company reported a net loss of approximately \$6,966,000, or a net loss per diluted share of \$0.14, compared to a net loss of approximately \$5,347,000, or a net loss per diluted share of \$0.12 for the quarter ended September 30, 2016.

For the nine months ended September 30, 2017, the Company reported a net loss of approximately \$21,728,000, or a net loss per diluted share of \$0.44, compared to a net loss of approximately \$12,428,000, or a net loss per diluted share of \$0.31, for the nine months ended September 30, 2016.

For the three months ended September 30, 2017, operating expenses increased by approximately \$1.7 million to \$7.8 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 third quarter with approximately \$36.6 million of cash and cash equivalents. On October 26, 2017, the Company completed a public offering raising approximately \$32.5 million of gross proceeds. The Company expects the current cash on hand to fund operations into the fourth quarter of 2019, based on current planned expenditures.

About Anabasum

Anabasum is a synthetic oral endocannabinoid-mimetic drug that preferentially binds to cannabinoid receptor type 2 (CB2) expressed on activated immune cells and fibroblasts. CB2 activation triggers physiologic pathways that resolve inflammation, speed bacterial clearance and halt fibrosis. Nonclinical and human clinical studies to date have shown

anabasum has favorable safety, tolerability and pharmacokinetic profiles. It has also demonstrated promising potency in nonclinical 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 a direct effect on fibroblasts to halt tissue scarring. In effect, anabasum is believed to trigger 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 generated positive data in three Phase 2 studies in diffuse cutaneous systemic sclerosis, cystic fibrosis and dermatomyositis. Additionally, the Company is evaluating anabasum in open-label extension studies in systemic sclerosis and skin-predominant dermatomyositis. The Company expects to commence a Phase 2 study in systemic lupus erythematosus, a Phase 3 study in systemic sclerosis and a Phase 2b study in cystic fibrosis in 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 Ended		For the Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
Collaboration revenue	\$ 796,312	\$ 742,558	\$ 2,440,195	\$ 1,535,754
Operating expenses:				
Research and development	5,622,511	4,315,632	17,752,283	10,056,568
General and administrative	2,130,587	1,760,696	6,388,802	3,891,810
Total operating expenses	7,753,098	6,076,328	24,141,085	13,948,378
Operating loss	(6,956,786)	(5,333,770)	(21,700,890)	(12,412,624)
Other income (expense), net:				
Interest income, net	43,402	1,731	50,039	420
Foreign currency exchange loss	(52,212)	(14,729)	(77,071)	(16,196)
Other expense, net	(8,810)	(12,998)	(27,032)	(15,776)
Net loss	\$ (6,965,596)	\$ (5,346,768)	\$ (21,727,922)	\$ (12,428,400)
Net loss per share, basic and diluted	\$ (0.14)	\$ (0.12)	\$ (0.44)	\$ (0.31)
Weighted average number of common shares outstanding, basic and diluted	50,221,597	43,783,504	48,946,335	40,059,364

Corbus Pharmaceuticals Holdings, Inc.
Condensed Consolidated Balance Sheets

	September	December 31,
	30, 2017	2016
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 36,597,469	\$ 14,992,257
Restricted cash	200,000	150,000
Grants receivable	500,000	1,000,000
Stock subscriptions receivable	-	330,413
Prepaid expenses and other current assets	719,868	930,261
Total current assets	38,017,337	17,402,931
Restricted cash	-	50,000
Property and equipment, net	337,297	435,251

Other assets	65,026	-
Total assets	<u>\$ 38,419,660</u>	<u>\$ 17,888,182</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	\$ -	\$ 271,757
Accounts payable	3,776,516	3,419,921
Accrued expenses	2,558,602	3,256,455
Deferred revenue	-	1,940,195
Deferred rent, current	-	10,263
Total current liabilities	<u>6,335,118</u>	<u>8,898,591</u>
Deferred rent, noncurrent	102,561	65,724
Other liabilities	1,482	4,632
Total liabilities	<u>6,439,161</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 September 30, 2017 and December 31, 2016	-	-
Common stock, \$0.0001 par value; 150,000,000 shares authorized, 50,223,010 and 44,681,745 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	5,022	4,468
Additional paid-in capital	86,979,888	42,191,256
Accumulated deficit	(55,004,411)	(33,276,489)
Total stockholders' equity	<u>31,980,499</u>	<u>8,919,235</u>
Total liabilities and stockholders' equity	<u><u>\$ 38,419,660</u></u>	<u><u>\$ 17,888,182</u></u>

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