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): May 16, 2016

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.)

100 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))

Item 2.02. Results of Operations and Financial Condition.

Corbus Pharmaceuticals Holdings, Inc. (the "Company") issued a press release on May 16, 2016, disclosing financial information and operating metrics for the three months ended March 31, 2016, 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 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.

(d) The following exhibit is furnished with this report:

Exhibit No. Description

99.1 Press Release issued by Corbus Pharmaceuticals Holdings, Inc. dated May 16, 2016.

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: May 16, 2016

By: <u>/s/ Yuval Cohen</u> Name: Yuval Cohen Title: Chief Executive Officer

EXHIBIT INDEX

 Exhibit No.
 Description

 99.1
 Press Release, issued by Corbus Pharmaceuticals Holdings, Inc. dated May 16, 2016.



Corbus Pharmaceuticals Reports 2016 First Quarter Financial Results and Provides Business Update

- Company has Three Phase 2 Studies Ongoing with Top-Line Data Expected Starting 4Q 2016 -

- Phase 2 Clinical Study for Treatment of Systemic Lupus Erythematosus Expected to Commence 1Q 2017 -

Norwood, MA (May 16, 2016) – <u>Corbus Pharmaceuticals Holdings, Inc.</u> (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, 2016.

The Company also provided an update on its corporate progress and the clinical status and anticipated milestones for <u>Resunab</u>, its novel synthetic oral endocannabinoid-mimetic drug that is designed to resolve chronic inflammation and halt fibrosis. Resunab is currently being evaluated in three separate Phase 2 clinical studies in <u>cystic fibrosis</u> ('CF"), diffuse cutaneous <u>systemic sclerosis</u> ("systemic sclerosis"), and skin-predominant <u>dermatomyositis</u> and plans to initiate a clinical study in <u>systemic lupus erythematosus</u> ("SLE") in the first quarter of 2017.

Recent Corporate Highlights

- Received U.S. Food and Drug Administration ("FDA") approval for open-label extension to Corbus' Phase 2 Clinical Study of <u>Resunab for systemic sclerosis</u>; the extension enables all the participants in the study to be dosed with Resunab for an additional 12 months;
- Announced the <u>expansion of Resunab's clinical development with a planned Phase 2, 100-patient ten center clinical study for the treatment of SLE</u>, a clinical program selected for funding by the National Institute of Health's Autoimmunity Centers of Excellence program; and
- Successfully <u>added a protocol amendment to existing FDA Investigational New Drug application (IND) for Phase 2 clinical study of Resunab for the treatment of SLE.</u>

"We continue to advance our clinical and regulatory strategies forward, paving the way for key clinical data readouts starting in the fourth quarter of this year," stated Yuval Cohen, Ph.D., Chief Executive Officer of the Company.

Expected Near-Term Milestones

- Complete patient enrollment in the U.S. Phase 2 Clinical study for systemic sclerosis;
- Complete patient enrollment in the Phase 2 clinical study for CF;



- Obtain Orphan Drug Designation in Europe for the treatment of both CF and systemic sclerosis;
- Report top-line safety and efficacy data of Phase 2 clinical studies for systemic sclerosis and CF in Q4 2016;
- Commence the open-label extension study in systemic sclerosis;
- Continue to advance the Phase 2 clinical study in dermatomyositis, which is expected to be completed in the first quarter of 2017;
- Complete preparation for the launch of the Phase 2 clinical study in adults with SLE, which is expected to launch in the first quarter of 2017;
- Conduct additional mechanism of action studies with Resunab in relevant pre-clinical models; and
- Participate in scientific conferences throughout 2016, including the European Cystic Fibrosis Society Conference, the North American Cystic Fibrosis Conference and the American College of Rheumatology Annual Meeting.

"Corbus' mission is to develop novel drugs that engage the immune system to treat rare and uncommon life-threatening diseases that have clear unmet medical needs. This is underscored by our ongoing Phase 2 clinical studies of Resunab in three rare inflammatory diseases with significant unmet needs and the expansion into our fourth indication in the first quarter of next year. Our longer-term business strategy is to expand our pipeline with additional assets while maintaining our focus on these rare inflammatory indications," concluded Dr. Cohen.

Summary of Financial Results for First Quarter 2016

For the quarter ended March 31, 2016, the Company reported a net loss of approximately \$2,892,000 or a net loss per diluted share of \$0.08, compared to a net loss of approximately \$1,536,000, or a net loss per diluted share of \$0.06 for the quarter ended March 31, 2015. The increase in the net loss for the quarter ended March 31, 2016 is attributable to expenses related to our clinical studies for systemic sclerosis and CF, and increased staffing costs. The Company ended the quarter with approximately \$9,688,000 of cash and cash equivalents and the Company has the potential to receive \$2.5 million in additional milestone payments under its development award with the Cystic Fibrosis Foundation Therapeutics, Inc.

About Resunab

Resunab 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 Phase 1 studies have shown Resunab to have a favorable safety, tolerability and pharmacokinetic profile. It has also demonstrated promising potency in preclinical models of inflammation and fibrosis. Resunab is designed to trigger the production of "Specialized Proresolving Lipid Mediators" that activate an endogenous cascade responsible for the resolution of inflammation and fibrosis, while reducing production of pro-inflammatory eicosanoids and cytokines. Resunab has direct effects on fibroblasts to halt tissue scarring. In effect, Resunab triggers endogenous pathways to turn "off" chronic inflammation and fibrotic processes, without causing immunosuppression.

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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, Resunab, is a novel synthetic oral endocannabinoid-mimetic drug designed to resolve chronic inflammation, and fibrotic processes. Resunab is currently in Phase 2 clinical studies 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 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 which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements. 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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Source: Corbus Pharmaceuticals Holdings, Inc.

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

	For the Three Months Ended March 31,			
	2016		2015	
Collaboration revenue	\$ 396,598	\$		
Operating expenses:				
Research and development	2,173,933		723,430	
General and administrative	1,109,889		811,869	
Total operating expenses	3,283,822		1,535,299	
Operating loss	(2,887,224)		(1,535,299)	
Other income (expense):		_		
Interest expense	(6,430)		(979)	
Interest income	1,070		560	
Foreign currency exchange gain	343			
Other expense, net	(5,017)		(419)	
Net loss	\$ (2,892,241)	\$	(1,535,718)	
Net loss per share, basic and diluted	\$ (0.08)	\$	(0.06)	
Weighted average number of common shares outstanding, basic and diluted	 37,605,210		25,871,796	

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Corbus Pharmaceuticals Holdings, Inc. Condensed Consolidated Balance Sheets

		March 31, 2016 (Unaudited)	December 31, 2015		
ASSETS					
Current assets:					
Cash and cash equivalents	\$	9,687,805	\$	12,338,275	
Prepaid expenses		474,560		376,515	
Total current assets		10,162,365		12,714,790	
Restricted cash		36,375		36,375	
Property and equipment, net		296,534	_	124,138	
Total assets	\$	10,495,274	\$	12,875,303	
LIABILITIES AND STOCKHOLDERS' EQUITY	_				
Current liabilities:					
Notes payable	\$	92,958	\$	162,019	
Accounts payable		1,230,449		1,314,377	
Accrued expenses		1,297,988		562,279	
Deferred revenue, current		1,455,020		1,591,358	
Total current liabilities		4,076,415		3,630,033	
Deferred revenue, noncurrent		—		260,260	
Other long-term liabilities		14,852		_	
Total liabilities		4,091,267		3,890,293	
Commitments and Contingencies					
Stockholders' equity					
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized, no shares issued					
and outstanding at March 31, 2016 and December 31, 2015		—		—	
Common stock, \$0.0001 par value; 150,000,000 shares authorized, 37,605,827					
and 37,605,134 shares issued and outstanding at March 31, 2016 and December					
31, 2015		3,761		3,761	
Additional paid-in capital		22,570,301		22,259,063	
Accumulated deficit		(16,170,055)		(13,277,814)	
Total stockholders' equity	_	6,404,007		8,985,010	
Total liabilities and stockholders' equity	\$	10,495,274	\$	12,875,303	
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