
**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): March 12, 2018

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.)*

500 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 2.02. Results of Operations and Financial Condition.

Corbus Pharmaceuticals Holdings, Inc. (the “Company”) issued a press release on March 12, 2018, disclosing financial information and operating metrics for its fiscal year ended December 31, 2017, 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:

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release issued by Corbus Pharmaceuticals Holdings, Inc. dated March 12, 2018.</u>

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: March 12, 2018

By: /s/ Yuval Cohen

Name: Yuval Cohen

Title: Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, issued by Corbus Pharmaceuticals Holdings, Inc. dated March 12, 2018.



EXHIBIT 99.1

Corbus Pharmaceuticals Reports 2017 Financial Results and Provides Clinical Update

- *Advancing clinical studies in four rare and serious inflammatory diseases with significant morbidity and mortality and clear unmet medical needs*
- *Reported positive data in Phase 2 dermatomyositis clinical study*
- *Reported clinical data from ongoing Phase 2 open-label extension in systemic sclerosis demonstrating continued benefit*
- *Received development award for up to \$25MM by the Cystic Fibrosis Foundation for upcoming Phase 2b study*
- *Multiple clinical and regulatory milestones expected in 2018*

Norwood, MA (March 12, 2018) – Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) (“Corbus” or the “Company”), 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, announced today its financial results for the year ended December 31, 2017.

The Company also provided an update on its corporate progress, clinical status and anticipated milestones for lenabasum, its novel synthetic oral endocannabinoid-mimetic drug designed to resolve chronic inflammation and halt fibrosis in rare autoimmune and inflammatory diseases.

Recent Clinical and Corporate Highlights

- Commenced patient dosing in Phase 3 study in systemic sclerosis (SSc) expected to enroll 354 patients;
 - Initiated Phase 2b study in cystic fibrosis (CF) expected to enroll 415 patients with pulmonary exacerbations as sole primary endpoint;
 - Received Development Award from the Cystic Fibrosis Foundation for up to \$25 million to support Phase 2b CF study;
 - Reported six-month clinical data from the ongoing Phase 2 open-label extension study in SSc showing continued benefit;
 - Reported positive Phase 2 results in dermatomyositis (DM);
 - Commenced patient dosing in NIH-funded, 100-patient Phase 2 clinical study in systemic lupus erythematosus (SLE);
 - Announced peer-reviewed publication of human clinical inflammatory model demonstrating lenabasum as the first experimental therapy to activate the resolution of inflammation;
 - Granted two key U.S. patents covering lenabasum for the treatment of inflammatory and fibrotic diseases through 2034; and
 - Raised gross proceeds of \$78.4 million from public offerings in 2017, including \$37.4 million in the fourth quarter of 2017. Ended 2017 with \$62.5 million in cash and cash equivalents.
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“We made significant progress during 2017 executing our clinical and corporate strategy on multiple fronts. We believe we are well positioned to advance clinical development of lenabasum in rare inflammatory diseases with no or limited treatment options. Importantly we are poised for solid execution on our four clinical programs, and we are preparing to evolve into a commercial-stage pharmaceutical company,” stated Yuval Cohen, Ph.D., Chief Executive Officer of the Company.

Systemic Sclerosis Clinical Program Update

SSc is a serious autoimmune disease affecting approximately 90,000 people in the U.S. and Europe and is associated with significant morbidity and up to 60% 10-year mortality. There are currently no drugs specifically approved by the FDA for treatment of SSc.

In January 2017, Corbus initiated patient dosing in its Phase 3 RESOLVE-1 study, a double-blind, randomized, placebo-controlled trial assessing the efficacy and safety of lenabasum for the treatment of SSc. The study is expected to enroll approximately 354 subjects at 70 sites worldwide. The planned duration of treatment with lenabasum is 52 weeks. Subjects will be randomized 1:1:1 to receive lenabasum 5 mg twice per day, lenabasum 20 mg twice per day, or placebo twice per day.

The primary efficacy outcome of the RESOLVE-1 study will be the modified Rodnan Skin Score (mRSS). Secondary outcomes include patient- and physician-reported outcomes, forced vital capacity and the American College of Rheumatology Combined Response Index in diffuse cutaneous Systemic Sclerosis (ACR CRISS) score. For more information on the Phase 3 study, please visit [ClinicalTrials.gov](https://clinicaltrials.gov) and reference Identifier NCT03398837.

In November 2017, the Company presented six-month safety and efficacy data at the American College of Rheumatology Annual Meeting from 36 patients in the ongoing open-label extension (OLE) study. Lenabasum demonstrated a significant and clinically meaningful reduction in mRSS reaching minus 8.4 ($p < 0.0001$ 2-paired t-test) and an unprecedented ACR CRISS of 71% at 28 weeks.

Lenabasum has been granted Orphan Drug Designation (ODD) and Fast Track status for the treatment of systemic sclerosis from the FDA and Orphan Designation from the European Medicines Agency (EMA).

Expected Milestones:

- Report 12-month data from the ongoing OLE study in mid-2018; and
- Complete the RESOLVE-1 study and report topline data in H1 2020.



Cystic Fibrosis Clinical Program Update

CF 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 function of multiple organs, reduces health-related quality of life, drives progression of the disease 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.

In January 2018, the Company initiated a Phase 2b study in CF supported by a development award for up to \$25 million from the Cystic Fibrosis Foundation. The Phase 2b multicenter, double-blinded, randomized, placebo-controlled study is expected to enroll approximately 415 subjects with CF who are at least 12 years of age with an increased risk for pulmonary exacerbations. The study's primary outcome is the event rate of pulmonary exacerbations. Secondary efficacy outcomes include other measures of pulmonary exacerbations, change in Cystic Fibrosis Questionnaire-Revised Respiratory domain score and change in forced expiratory volume in 1 second (FEV1), % predicted. The study will be conducted in approximately 100 sites across North America, Europe, Israel and Australia. Subjects will be centrally randomized to one of three cohorts to receive lenabasum 20 mg twice per day, lenabasum 5 mg twice per day, or placebo twice per day for 28 weeks, with 4 weeks follow-up off active treatment. This Phase 2b CF study was designed with input from the Therapeutic Development Network of the Cystic Fibrosis Foundation and the European Cystic Fibrosis Society Clinical Trials Network. For more information on the Phase 2b study, please visit [ClinicalTrials.gov](https://clinicaltrials.gov) and reference Identifier NCT03451045.

Lenabasum was granted ODD and Fast Track status for the treatment of CF by the FDA in 2015 and Orphan Drug Status from the EMA in 2016.

Expected Milestones:

- Commence patient dosing in Phase 2b CF study in Q1 2018;
- Submit Pediatric Investigational Plan to EMA; and
- Complete Phase 2b study and report top line data by H1 2020.

Dermatomyositis Clinical Program Update

DM 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 have significant side effects that lead to adverse effects.

In October 2017, the Company completed a 22-patient, double-blind placebo-controlled Phase 2 study in diffuse cutaneous skin-predominant DM and reported positive results. The mean improvement (reduction) in the primary efficacy outcome, the Cutaneous Dermatomyositis Disease Area and Severity Index (CDASI) activity score, an outcome measure of skin disease severity, was 9.3 points for lenabasum treatment versus a reduction of 3.7 points for placebo treatment ($p = 0.04$) at sixteen weeks. Lenabasum also outperformed placebo in multiple secondary efficacy outcomes studied. Lenabasum was well tolerated with no severe or serious side effects associated with the drug. No subjects dropped out. The data was presented at the ACR Annual Meeting. The Phase 2 DM trial was funded by a grant from the National Institutes of Health.



Expected Milestones:

- Report on six-month data from Phase 2 open-label extension study in mid-2018; and
- Consult with FDA and initiate next clinical study before the end of 2018.

Systemic Lupus Erythematosus Clinical Program Update

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. About 500,000 individuals in the U.S. and in the E.U. suffer from SLE and the disease 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.

In February 2018 patient dosing commenced in a Phase 2 clinical study of lenabasum for SLE. The Phase 2 SLE clinical trial is being conducted by the Autoimmunity Centers of Excellence (ACE) program, which is funded by the National Institute of Allergy and Infectious Diseases (NIAID), within the National Institutes of Health (NIH).

The randomized, double-blind, placebo-controlled, Phase 2 trial is being conducted at 15 sites across the U.S. and is expected to enroll 100 adult SLE patients with active musculoskeletal disease, which is the most common manifestation of SLE. Subjects will be randomized in a 1:1:1:1 ratio to one of four cohorts to receive placebo or three different doses of lenabasum for 3 months, with 1-month follow-up. The primary efficacy outcome assesses pain from active musculoskeletal disease, and secondary efficacy outcomes include other assessments of active musculoskeletal disease, overall disease activity using SLE Responder Index, SLE Disease Activity Index (SLEDAI) and British Isles Lupus Activity Group (BILAG) scoring systems, and patient-reported outcomes.

For more information on the Phase 2 study of lenabasum for the treatment of SLE, please visit [ClinicalTrials.gov](https://clinicaltrials.gov) and reference Identifier NCT03093402.

Summary of Financial Results for 2017

For the year ended December 31, 2017, Corbus reported a net loss of approximately \$32,422,000, or a net loss per diluted share of \$0.65, compared to a net loss of approximately \$19,999,000, or a net loss per diluted share of \$0.49 for the year ended December 31, 2016.



Revenue from awards increased by approximately \$529,000 to \$2.4 million due to revenue recognized from the \$5 million development award received from the Cystic Fibrosis Foundation Therapeutics, Inc. Operating expenses increased by approximately \$13.1 million to \$35.0 million due to increased spending for clinical studies, manufacturing costs to produce lenabasum for clinical studies and staffing costs.

The Company's cash and cash equivalents balance at December 31, 2017 was approximately \$62.5 million and increased by \$47.5 million during 2017. In the fourth quarter of 2017, the Company completed a secondary public offering resulting in approximately \$37.4 million of gross proceeds. The Company expects the current cash on hand together with the expected milestone payments from the up to \$25 million Development Award from the Cystic Fibrosis Foundation to fund operations through the fourth quarter of 2019, based on current planned expenditures.

About Lenabasum

Lenabasum (formerly known as anabasum) is a synthetic, oral, small-molecule, selective cannabinoid receptor type 2 (CB2) agonist that preferentially binds to CB2 expressed on activated immune cells and fibroblasts. CB2 activation triggers physiologic pathways that resolve inflammation, speed bacterial clearance and halt fibrosis. CB2 activation also induces 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. Through activation of CB2, lenabasum also is designed to have a direct effect on fibroblasts to halt tissue scarring. Lenabasum is believed to induce resolution rather than immunosuppression by triggering biological pathways to turn "off" chronic inflammation and fibrotic processes. Lenabasum has demonstrated promising potency in preclinical models of inflammation and fibrosis. Preclinical and human clinical studies have shown lenabasum to have a favorable safety, tolerability and pharmacokinetic profile. Further, the drug has demonstrated clinical benefit and positive impact on inflammatory and immunological markers in Phase 2 studies in diffuse cutaneous systemic sclerosis, dermatomyositis and cystic fibrosis.

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, lenabasum, is a novel, synthetic oral endocannabinoid-mimetic drug designed to resolve chronic inflammation and fibrotic processes. Lenabasum is currently being evaluated in systemic sclerosis, cystic fibrosis, 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.
Consolidated Statements of Operations

	For the Years Ended December 31,		
	2017	2016	2015
Revenue from awards	\$ 2,440,195	\$ 1,911,424	\$ 648,382
Operating expenses:			
Research and development	26,038,965	15,436,735	5,888,659
General and administrative	8,964,046	6,459,747	3,613,416
Total operating expenses	35,003,011	21,896,482	9,502,075
Operating loss	(32,562,816)	(19,985,058)	(8,853,693)
Other income (expense):			
Interest income, net	183,112	477	977
Foreign currency exchange gain (loss)	(41,908)	(14,094)	1,977
Other income (expense), net	141,204	(13,617)	2,954
Net loss	\$ (32,421,612)	\$ (19,998,675)	\$ (8,850,739)
Net loss per share, basic and diluted	\$ (0.65)	\$ (0.49)	\$ (0.28)
Weighted average number of common shares outstanding, basic and diluted	50,176,953	41,137,518	31,350,145



Corbus Pharmaceuticals Holdings, Inc.
Condensed Consolidated Balance Sheets

	December 31,	
	2017	2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 62,537,495	\$ 14,992,257
Restricted cash	158,991	150,000
Grants receivable	—	1,000,000
Stock subscriptions receivable	—	330,413
Prepaid expenses and other current assets	2,808,244	930,261
Total current assets	65,504,730	17,402,931
Restricted cash	—	50,000
Property and equipment, net	1,432,655	435,251
Other assets	40,776	—
Total assets	\$ 66,978,161	\$ 17,888,182
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	\$ 332,861	\$ 271,757
Accounts payable	3,130,295	3,419,921
Accrued expenses	4,741,519	3,256,455
Deferred revenue, current	—	1,940,195
Deferred rent, current	—	10,263
Total current liabilities	8,204,675	8,898,591
Deferred rent, noncurrent	989,550	65,724
Other liabilities	375	4,632
Total liabilities	9,194,600	8,968,947
Commitments and Contingencies		
Stockholders' equity		
Preferred Stock \$0.0001 par value; 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2017 and December 31, 2016	—	—
Common stock, \$0.0001 par value; 150,000,000 shares authorized, 55,603,427 and 44,681,745 shares issued and outstanding at December 31, 2017 and December 31, 2016, respectively	5,560	4,468
Additional paid-in capital	123,476,102	42,191,256
Accumulated deficit	(65,698,101)	(33,276,489)
Total stockholders' equity	57,783,561	8,919,235
Total liabilities and stockholders' equity	\$ 66,978,161	\$ 17,888,182



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