
**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): August 8, 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 August 8, 2018, disclosing financial information and operating metrics for its fiscal quarter ended June 30, 2018 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>
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99.1	<u>Press Release issued by Corbus Pharmaceuticals Holdings, Inc. dated August 8, 2018.</u>
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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: August 8, 2018

By: /s/ Yuval Cohen
Name: Yuval Cohen
Title: Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release, issued by Corbus Pharmaceuticals Holdings, Inc. dated August 8, 2018.</u>



EXHIBIT 99.1

Corbus Pharmaceuticals Reports 2018 Second Quarter Financial Results and Provides Business Update

- *Lenabasum has reached Phase 3 clinical stage in two orphan autoimmune indications: systemic sclerosis and dermatomyositis, affecting up to 200,000 patients in the USA, EU and Japan*
- *Recent long-term open-label extension Phase 2 clinical data presented at EULAR indicates continued favorable safety profile and improvement in efficacy outcomes in systemic sclerosis and dermatomyositis*
- *Unencumbered global rights together with agreement on Phase 3 design reached with FDA, EMA and Japanese PMDA provide strong strategic optionality*
- *Board is strengthened with addition of Dr. John Jenkins, former head of Office of New Drugs at CDER at FDA*

Norwood, MA (August 8, 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 second quarter ended June 30, 2018.

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 control inflammation and fibrosis.

“The first half of this year was marked by important progress in key corporate, clinical and regulatory milestones across all of our indications,” commented Yuval Cohen, Ph.D., Chief Executive Officer Corbus. “With two Phase 3 international clinical programs and Corbus owning the unencumbered global rights to lenabasum, we believe our strategic optionality is very strong. Having demonstrated to-date, favorable safety and improvement in clinical efficacy outcomes, we believe lenabasum is positioned to potentially become the leading therapy in these first two orphan autoimmune indications affecting up to 200,000 patients in the USA, EU and Japan.”

Recent Clinical and Corporate Achievements:

- 1-year diffuse cutaneous systemic sclerosis (“SSc”) and 6-month dermatomyositis (“DM”) open-label extension (“OLE”) data presented at EULAR continued to show a favorable safety profile and improvement in efficacy outcomes with continued dosing;
 - Orphan Drug Designation for lenabasum for the treatment of DM granted by the U.S. Food and Drug Administration (“FDA”);
 - Guidance received from FDA for design of a single Phase 3 study to evaluate efficacy and safety of lenabasum for treatment of DM;
 - Reached agreement with PMDA in Japan that participation of Japanese SSc patients in ongoing Phase 3 study in SSc could be used to support registration in Japan;
 - Participated in the BIO Asia International pharmaceutical partnering conference in Tokyo;
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- Received a \$6.25 million milestone payment in the second quarter of 2018 from the Development Award of up to \$25 million granted by the Cystic Fibrosis Foundation (a total of \$12.5 million received to date);
- Presented lenabasum data at the New York Academy of Sciences' Resolution of Inflammation, Infection and Tissue Regeneration Conference;
- Named two key executives, Robert Discordia, Ph.D., and Ross Lobell, to lead CMC and Regulatory Operations; and
- Appointed John K. Jenkins, MD, former Director of FDA Office of New Drugs, to Board of Directors.

Systemic Sclerosis Clinical Program Overview – Late-Stage Clinical Program with Potential Commercialization in 2021

- Rare and life-threatening autoimmune disease characterized by tissue inflammation and fibrosis;
- Affects approximately 120,000 people in the U.S., Europe and Japan;
- Approximately 40% to 60% 10-year mortality;
- Treatment options for overall disease control limited to immunosuppressive drugs with no drugs currently approved by the FDA for treatment of SSc;
- Lenabasum was granted Orphan Drug Designation and Fast Track status for the treatment of systemic sclerosis from the FDA and Orphan Designation from the EMA;
- Enrollment and dosing are ongoing in the Phase 3 study; and
- Agreement reached with FDA, EMA and Japanese PMDA on design of ongoing study.

The international, multicenter Phase 3 RESOLVE-1 study is a double-blind, randomized, placebo-controlled study assessing the efficacy and safety of lenabasum for the treatment of SSc. The study will enroll approximately 354 subjects at approximately 70 sites in North America, Europe, Israel, Japan, South Korea and Australia. The planned duration of treatment with study drug is 52 weeks. Subjects are 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 is change from baseline in modified Rodnan Skin Score ("mRSS"), a measure of skin fibrosis. Secondary efficacy outcomes include change from baseline in patient-reported function and forced vital capacity, as well as the American College of Rheumatology Combined Response Index in diffuse cutaneous Systemic Sclerosis ("ACR CRISS") score, a composite measure of improvement that incorporates change from baseline in mRSS, patient- and physician-reported outcomes and forced vital capacity. These same outcomes were measured in the Phase 2 study and its follow-on OLE study.

Corbus expects to report topline results from the Phase 3 RESOLVE-1 study in the first half of 2020. For more information on the Phase 3 study, please visit [ClinicalTrials.gov](https://www.clinicaltrials.gov) and reference Identifier NCT03398837.



The Company recently presented safety and efficacy data from the 1-year OLE of the Phase 2 study of lenabasum for the treatment of systemic sclerosis at the Annual European Congress of Rheumatology (EULAR 2018). Highlights at the time of most recent OLE data-cut include:

- Safety profile continues to be acceptable with no serious or severe adverse events related to lenabasum and no significant changes from baseline in laboratory safety tests related to lenabasum.
- At 1-year dosing in the OLE, mRSS improved by a mean of -9.4 points from the start of the Phase 2 double-blind, placebo-controlled phase of the study;
- At 1-year in the OLE, 77% of subjects achieved improvement in mRSS (reduction \leq -5 points) that is considered medically meaningful and 50% achieved improvement in mRSS \leq -10 points;
- ACR CRISS increased steadily with lenabasum treatment and reached 92% (median), with 50% of subjects achieving a score $>$ 95% at 1-year; and
- Multiple secondary endpoints continue to improve.

Click [here](#) to view the Phase 2 SSc OLE data presented at EULAR.

Dermatomyositis Clinical Program Overview – Phase 3 Study to Commence Before Year End

- Rare and serious autoimmune condition related to SSc and characterized by skin and muscle inflammation;
- Affects ~80,000 people in the U.S., EU and Japan;
- 5-year mortality as high as 30%;
- High unmet medical need. Current standard-of-care treatment includes antimalarial drugs and potent immunosuppressive agents, which can lead to significant side effects;
- Lenabasum was granted FDA Orphan Drug Designation for the treatment of DM in July 2018; and
- The Company plans to commence its Phase 3 trial testing the efficacy and safety of lenabasum for the treatment of DM by the end of 2018. FDA recently provided guidance on the overall study design of this single Phase 3 study at an end-of-Phase 2 meeting.

The international Phase 3 trial will be a 1-year, double-blind, randomized, placebo-controlled study testing efficacy and safety of lenabasum in approximately 150 adults with DM. Subjects will be randomized to receive lenabasum 20 mg twice per day, lenabasum 5 mg twice per day, or placebo twice per day in a 2:1:2 ratio. The primary efficacy outcome will be ACR/ European League Against Rheumatism 2016 Total Improvement Score (“TIS”) in myositis, a composite measure of improvement from baseline in six endpoints: Physician Global Activity, Patient Global Activity, Health Assessment Questionnaire, Manual Muscle Testing, muscle enzymes, and extra-muscular activity, which would include skin activity. Change in the Cutaneous Dermatomyositis Activity and Severity Index (“CDASI”) activity score will be a secondary efficacy outcome.



The Company recently presented data from the analyses of 6-month OLE data of the Phase 2 study of lenabasum for the treatment of DM at EULAR 2018. Highlights at the time of most recent OLE data-cut include:

- Safety profile continues to be acceptable;
- CDASI activity score improved by a mean of -15.4 points from baseline at the start of the Phase 2 double-blind, placebo-controlled phase of the study;
- 88% of subjects achieved CDASI improvement by at least -5 points, which is considered medically meaningful, 82% achieved improvement of at least -10 points, and 47% achieved a low CDASI activity score (≤ 14 points total score); and
- Improvement was seen in multiple secondary efficacy endpoints.

Click [here](#) to view the Phase 2 DM OLE data presented at EULAR.

Cystic Fibrosis (“CF”) Clinical Program Overview – Ongoing Phase 2b study supported by a Development Award for up to \$25 million from the Cystic Fibrosis Foundation

- Life-threatening rare genetic disease that affects ~30,000 patients in the U.S. and ~75,000 patients worldwide;
- Current average life expectancy for CF patients is approximately 40 years;
- Pathologic inflammation damages multiple organs including the lungs, impairs organ function, and reduces health-related quality of life;
- Continued need for drugs to treat pulmonary exacerbations, which are acute episodes of lung inflammation which cause significant decline in respiratory function, high medical costs, and frequently irreversible lung damage;
- Lenabasum was granted Orphan Drug Designation and Fast Track status for the treatment of CF by the FDA in 2015 and Orphan Drug Status from the European Medicines Agency (“EMA”) in 2016; and
- Enrollment and dosing are ongoing in a Phase 2b study. This Phase 2b study was designed with input from the Therapeutic Development Network of the Cystic Fibrosis Foundation and the European Cystic Fibrosis Society Clinical Trials Network. FDA provided guidance on the overall study design.

The Phase 2b multicenter, double-blinded, randomized, placebo-controlled study will enroll approximately 415 subjects with CF who are at least 12 years of age and at increased risk for pulmonary exacerbations. The primary efficacy outcome is the event rate of pulmonary exacerbations, which is the average number of pulmonary exacerbations per subject per time period. 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 and Australia. Subjects are 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 in a 2:1:2 ratio.

Corbus expects to report topline results for the Phase 2b CF study in the first half of 2020. For more information on the Phase 2 study, please visit [ClinicalTrials.gov](https://clinicaltrials.gov) and reference Identifier NCT03451045.



Systemic Lupus Erythematosus (“SLE”) Clinical Program Overview – Represents the Largest Indication Targeted by Lenabasum

- Prototypical multisystem autoimmune disease in which the innate immune system is chronically activated by immune complexes containing autoantibodies and self-antigens, leading to tissue inflammation and damage;
- Affects ~300,000 people in U.S. with a 2.4-fold increase in mortality;
- As with both SSc and DM, patients with SLE continue to have high unmet medical need with current treatments focused on immunosuppressive agents, that can lead to significant side effects; and
- Enrollment and dosing are ongoing in a first-in-patient Phase 2 randomized, double-blind, placebo-controlled, clinical study evaluating efficacy and safety of lenabasum for the treatment of SLE. This study is being conducted and funded by the Autoimmunity Centers of Excellence, National Institutes of Health.

The trial will enroll approximately 100 adult SLE patients with active musculoskeletal disease, which is the most common disease manifestation of SLE. Subjects are randomized in a 1:1:1:1 ratio to one of four cohorts to receive placebo or three different doses of lenabasum (5 mg twice per day, 20 mg once per day, or 20 mg twice per day) for 3 months, with 1-month of 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 and reference Identifier NCT03093402.

Summary of Financial Results for Second Quarter 2018

For the quarter ended June 30, 2018, the Company reported a net loss of approximately \$12,100,000 or a net loss per diluted share of \$0.21, compared to a net loss of approximately \$7,297,000, or a net loss per diluted share of \$0.15, for the quarter ended June 30, 2017.

Revenue for the quarter increased by approximately \$0.5 million to \$0.9 million from the quarter ended June 30, 2017. Revenue recognized in 2018 was related to the up to \$25 million Development Award Agreement with the Cystic Fibrosis Foundation that the Company entered into in the first quarter of 2018. Operating expenses for the quarter increased by approximately \$5.6 million to \$13.2 million due to increased spending for clinical studies, manufacturing costs to produce lenabasum for clinical studies and staffing costs.

The Company received a \$6.25 million milestone payment from the Cystic Fibrosis Foundation during the second quarter and ended the quarter with approximately \$64.7 million of cash and cash equivalents. The Company expects the current cash and cash equivalents together with the expected milestone payments from the up to \$25 million Development Award from the Cystic Fibrosis Foundation to fund operations into 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 has been shown to preferentially binds to CB2 expressed on activated immune cells and fibroblasts in animal studies. 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 believed to have a direct effect on fibroblasts to halt tissue scarring. In preclinical and clinical studies conducted so far, lenabasum has been shown 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 data and clinical studies to date have shown lenabasum to have a favorable safety, tolerability and pharmacokinetic profile. Data to date suggest that the drug may have clinical benefit as well as a beneficial impact on inflammatory and immunological markers in Phase 2 studies in diffuse cutaneous systemic sclerosis, dermatomyositis and cystic fibrosis. Additional clinical studies are being conducted and/or planned to confirm these preliminary results and support applications for regulatory approval.

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](#), 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 Balance Sheets

	<u>June 30,</u> <u>2018</u> <u>(unaudited)</u>	<u>December 31,</u> <u>2017</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 64,676,538	\$ 62,537,495
Restricted cash	—	158,991
Prepaid expenses and other current assets	2,876,261	2,808,244
Total current assets	67,552,799	65,504,730
Property and equipment, net	2,671,258	1,432,655
Other assets	64,427	40,776
Total assets	<u>\$ 70,288,484</u>	<u>\$ 66,978,161</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	\$ 83,704	\$ 332,861
Accounts payable	3,081,212	3,130,295
Accrued expenses	5,804,815	4,741,519
Deferred revenue	4,480,687	—
Total current liabilities	13,450,418	8,204,675
Deferred rent, noncurrent	1,352,906	989,550
Other liabilities	—	375
Total liabilities	<u>14,803,324</u>	<u>9,194,600</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, 2018 and December 31, 2017	-	-
Common stock, \$0.0001 par value; 150,000,000 shares authorized, 57,192,496 and 55,603,427 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	5,719	5,560
Additional paid-in capital	144,942,278	123,476,102
Accumulated deficit	(89,462,837)	(65,698,101)
Total stockholders' equity	<u>55,485,160</u>	<u>57,783,561</u>
Total liabilities and stockholders' equity	<u>\$ 70,288,484</u>	<u>\$ 66,978,161</u>



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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2018	2017	2018	2017
Revenue from awards	\$ 853,646	\$ 350,186	\$ 1,804,088	\$ 1,643,883
Operating expenses:				
Research and development	10,259,868	5,763,660	20,025,229	12,129,772
General and administrative	2,987,549	1,878,090	6,037,581	4,258,215
Total operating expenses	13,247,417	7,641,750	26,062,810	16,387,987
Operating loss	(12,393,771)	(7,291,564)	(24,258,722)	(14,744,104)
Other income (expense), net:				
Interest income, net	266,297	5,271	469,717	6,637
Foreign currency exchange gain (loss)	58,123	(10,594)	24,269	(24,859)
Other income (expense), net	324,420	(5,323)	493,986	(18,222)
Net loss	\$ (12,069,351)	\$ (7,296,887)	\$ (23,764,736)	\$ (14,762,326)
Net loss per share, basic and diluted	\$ (0.21)	\$ (0.15)	\$ (0.42)	\$ (0.31)
Weighted average number of common shares outstanding, basic and diluted	57,157,955	50,193,726	56,764,935	48,298,135



Investor Contacts:

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