
**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): November 25, 2019

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.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	CRBP	Nasdaq Global Market

Item 8.01. Other Events.

On November 25, 2019, the Company used the slides attached hereto as Exhibit 99.1 in connection with management presentations to describe its business.

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>Investor Presentation</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: November 25, 2019

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



Pioneering transformative medicines that target the
endocannabinoid system

  @corbuspharma

NASDAQ: CRBP
www.corbuspharma.com

Forward-Looking Statements

This presentation contains certain forward-looking statements, including those relating to the Company's product development, clinical trials, 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. Additional written and oral forward-looking statements may be made by the Company from time to time in filings with the Securities and Exchange Commission (SEC) or otherwise. The Private Securities Litigation Reform Act of 1995 provides a safe-harbor for forward-looking statements. 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 SEC. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this presentation. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Corbus at a Glance

- Targeting the endocannabinoid system
- Focus on inflammatory and fibrotic diseases
- Key catalysts expected in 2020 (4 clinical program readouts)
- Large markets with significant unmet need

VITAL STATS

CRBP

Ticker

2014

Founded in

100+

Employees

Norwood, MA

\$168M

Capital raised to-date

~\$45M

Additional awards and grants from NIH and CFF

\$27M

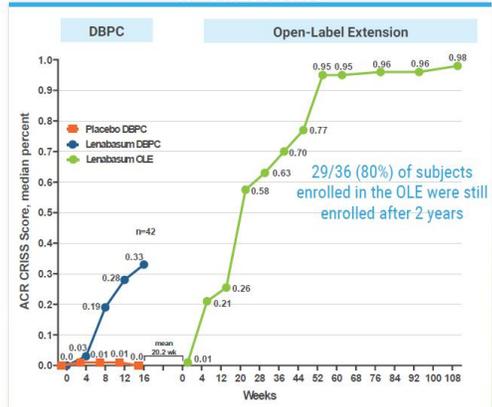
Upfront payment from Kaken collaboration



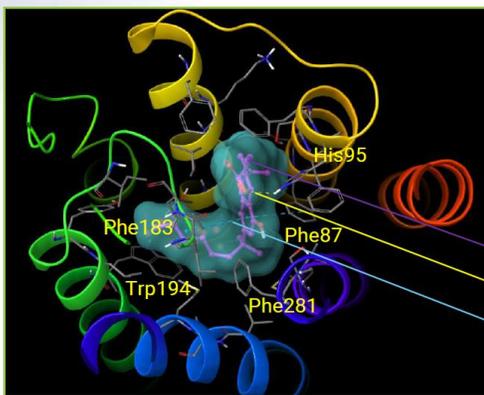
Lenabasum: Phase 3 Data in Systemic Sclerosis Expected in Summer 2020



Phase 2 Study: Improvement in Primary Endpoint
ACR CRISS Score



Lenabasum MOA: CB2 Agonist Targeting Innate Immune Response



- Oral new chemical entity (NCE)
- G protein-coupled receptors (GPCRs) activation (CB2)
- Resolves inflammation
- Limits fibrosis
- IP until 2034

- Lenabasum molecule (purple)
- Highlighted H-bond interaction (yellow dashed line)
- pi stacking interaction (blue dashed line)

What is the Endocannabinoid System (ECS)?

- 2 related GPCRs (CB1 and CB2)
- Endogenous agonists (Anandamide and 2-AG)
- Metabolic enzymes (FAAH and MAGL)

CB1

- Mostly in CNS
- Analgesic, anti-emetic, euphoric, appetite...
- Also found in liver, kidney and lung where it's pro-inflammatory

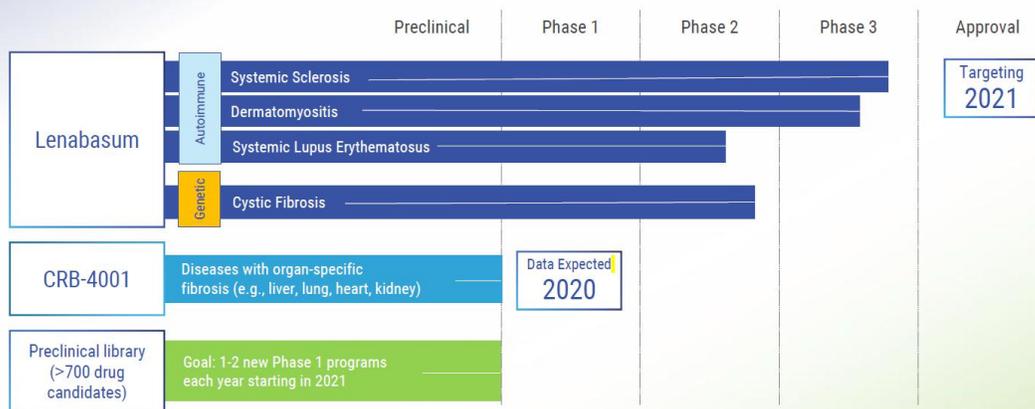
CB2

- Mostly in immune system
- Anti-inflammatory and anti-fibrotic
- Non-psychoactive

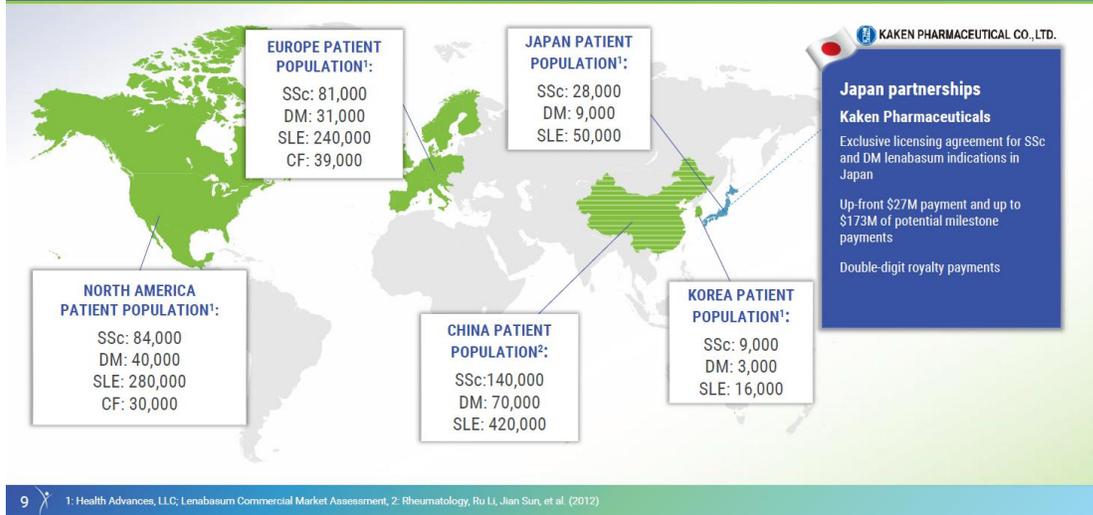
Growing Recognition of Therapeutic Potential of Targeting the ECS

Company	Drug Candidate	Phase	Target	Type of Compound
	Lenabasum (CB2 agonist)	Phase 3 in SSc & DM Phase 2 in CF & SLE	SSc, DM, CF & SLE	Small molecule (NCE)
	CRB-4001 (CB1 inverse agonist)	Phase 1 safety data expected in 2020	NASH	Small molecule (NCE)
	RO6871304 (CB2 agonist)	Preclinical	Uveitis	Small molecule (NCE)
 	GFB-024 (CB1 antagonist)	Preclinical (Phase 1 planned 2H 2020)	Diabetic kidney disease	Monoclonal antibody (mAb)
	Nimacimab (CB1 antagonist)	Phase 1 completed	NAFLD & diabetes or pre-diabetes	Monoclonal antibody (mAb)
	JNJ-42165279 (FAAH inhib)	Phase 2	Autism Spectrum Disorder & Social Anxiety Disorders	Small molecule (NCE)
 	ABX-1431 (MGLL inhib)	Phase 2, Acquired by H. Lundbeck A/S	Tourette Syndrome	Small molecule (NCE)
	Cesamet (nabilone) (THC)	Commercial	Nausea & Vomiting Associated with Cancer Chemotherapy	Phytocannabinoid
	Marinol® (THC)	Commercial	Anorexia Associated with Weight Loss in Patients with AIDS, Nausea & Vomiting Associated with Cancer Chemotherapy	Phytocannabinoid
	Epidiolex® (CBD)	Commercial	Seizures Associated with Lennox-Gastaut Syndrome or Dravet Syndrome	Phytocannabinoid
	Sativex® (CBD & THC)	Commercial in EU	Symptomatic Relief of Spasticity in MS	Phytocannabinoid

Corbus Pipeline: Early and Late Stage Programs



Robust Domestic and Foreign Intellectual Property Rights for Lenabasum Provide Strategic Optionality





Lenabasum

Systemic Sclerosis (SSc) at a Glance

Rare and life-threatening autoimmune disease characterized by tissue inflammation and fibrosis

Most lethal of the systemic autoimmune diseases¹

Pathogenesis Autoimmune disease with chronic activation of immune system, fibrosis and vascular damage

Common Symptoms Thick, tight, painful, itchy skin; fatigue, anorexia, weight loss; shortness of breath; swallowing problems, reflux; painful joints and tendons; Raynaud's; digital ulcers

Current Standard of Care Immunosuppressive drugs with potential for significant toxicity



~200,000

people with SSC in U.S., EU and Japan²

40-60%

mortality in 10 years with severe internal organ involvement³

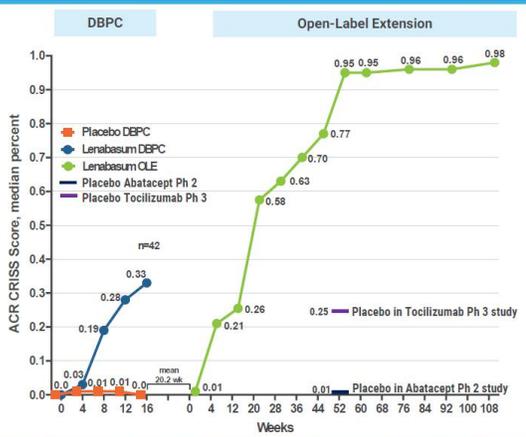
Zero

SSc-specific drugs approved

Orphan Drug Designation from FDA & EMA, Fast Track status from FDA

Phase 2 Study: Improvement in Primary Endpoint

Stable standard-of-care drugs, including immunosuppressive drugs



29/36 (80%) of subjects enrolled in the OLE were still enrolled after 2 years

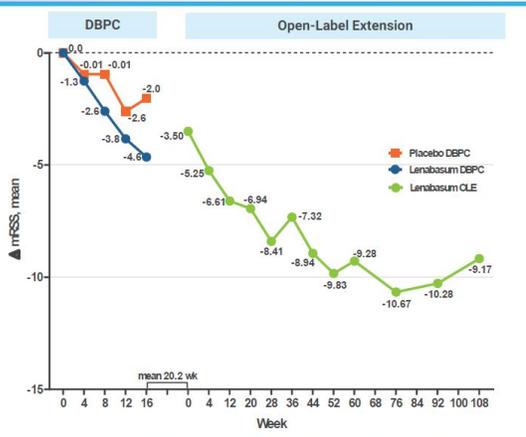
Comparator trials

Drug	N	Time (wks)	ACR CRIS score	
			Active	PBO
Cyclophosphamide ¹	84	52	0.24	0.01
Tocilizumab ² , Ph 2	69 ³	24	0.23	0.01
Tocilizumab ² , Ph 2	62 ³	48	0.31	0.0
Tocilizumab ³ + rescue immunosuppressive drugs after 16 weeks if needed, Ph 3	210	48	0.89	0.25
Abatacept ⁴ + rescue immunosuppressive drugs after 26 weeks if needed, Ph 2	69 ⁵	52	0.68	0.01

¹ Khanna et al. ACR abstract 726, 2017; Khanna et al. Arthritis Rheumatol. 2016; 68:299-311 ² Khanna et al. EULAR abstract SAT0373, 2017 ³ Completers only, Initial N = 87.3 ⁴ Khanna et al. ACR abstract 898, 2018 ⁵ Khanna et al. ACR abstract 900, 2018 69 completers

Phase 2 Study: Improvement in Secondary Endpoints

Stable standard-of-care drugs, including immunosuppressive drugs



-4 to -5 points is generally considered minimal clinically important difference (MCID)¹

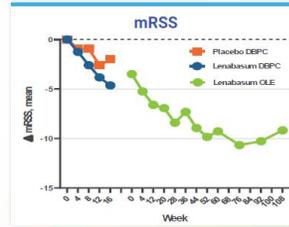
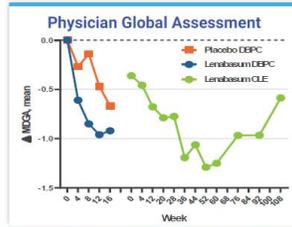
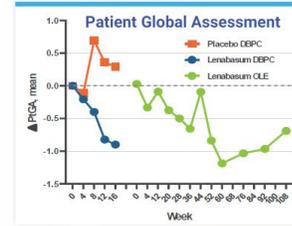
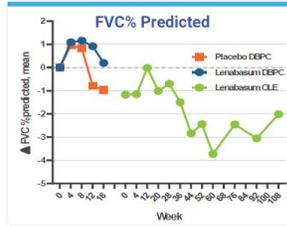
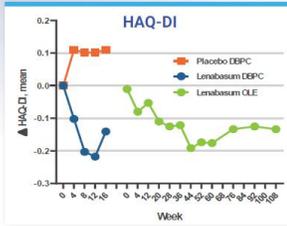
Comparator trials

Drug	N	Time (wks)	mRSS, mean (SD) change from baseline	
			Active	PBO
Six drug trials ¹	492	~26	-2.9	-
Cyclophosphamide ²	84	52	-5.3	-1.7
Tocilizumab ³ , Ph 2	67	24	-4.2	-2.1
		58	48	-5.9
Tocilizumab ⁴ + rescue immunosuppressive drugs after 16 weeks if needed, Ph 3	212	48	-6.1	-4.4
			-	-
Abatacept ⁵ + rescue immunosuppressive drugs after 26 weeks if needed, Ph 2	88 ⁶	52	-6.2	-4.5

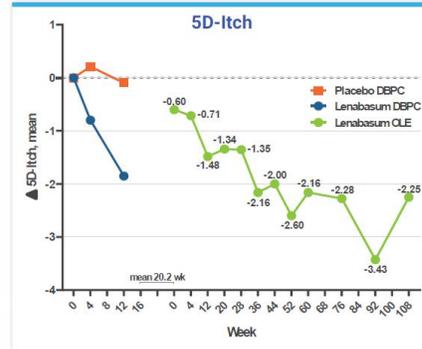
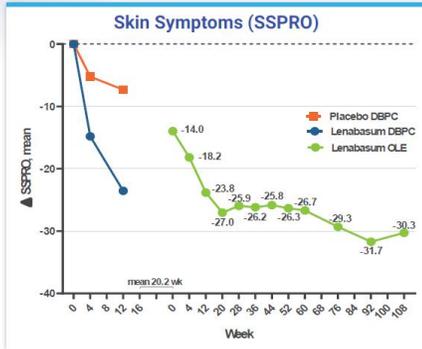
¹ a interferon, d penicillamine, rituximab Ph 2 and 3, minocycline, methotrexate, anti-TGFβ, Merkel et al, Arthritis Rheum 2012;54:3420.
² Khanna et al, ACR abstract 2016. ³ Le et al, Ann Rheum Dis 2011; 70: 1104. ⁴ Khanna et al, EULAR abstract SAT0373, 2017. ⁵ Khanna et al, ACR abstract 898, 2018 ⁶ Khanna et al, ACR abstract 900, 2018 * 69 completers

13 Baseline mRSS mean mRSS (SD) = 23.6 (10.4) for lenabasum arm and 26.2 (11.1) for placebo arm in Part A and 20.4 (11.0) for all subjects at start of open label dosing. 1: Khanna et al, Ann Rheum Dis 2006;55:1325

Measurements Across All 5 Domains of CRISS



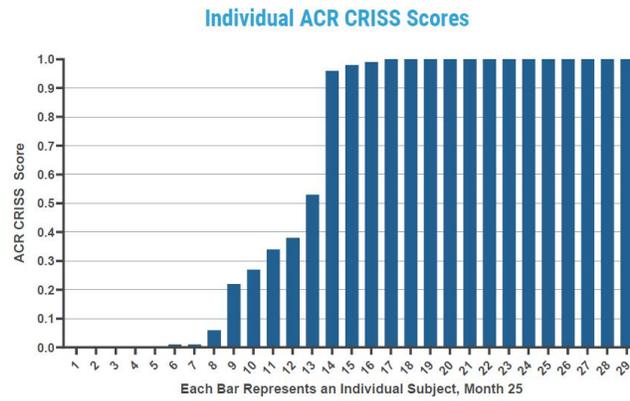
Change from Baseline in SSPRO and 5D-Itch



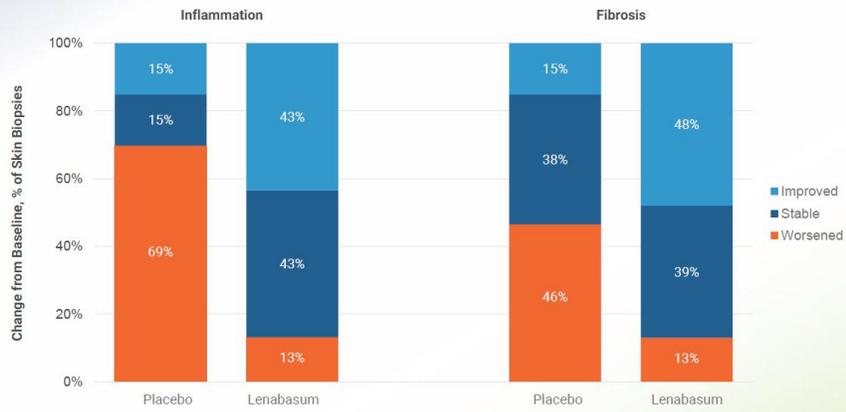
Patient Distribution of ACR CRISS Scores at Month 25 in Open-Label Extension Study

Lenabasum - SSC

45% of subjects achieved CRISS score of 1.0



Lenabasum Treatment Improves/Stabilizes Histological Findings of Inflammation and Fibrosis in Skin Biopsies Compared to Placebo



**HAS ACCEPTABLE
SAFETY PROFILE
AND IS WELL-
TOLERATED BASED
ON DATA TO-DATE**

- The majority of adverse reactions observed in clinical studies conducted to date are mild or moderate
- Most common adverse reactions are transient dizziness and dry mouth, which are consistent with expected class effects
- 2 withdrawals in treated subjects for AEs related to lenabasum
- Minimal changes from baseline in vital signs and laboratory safety tests and similar to those seen with placebo
- Data in blinded clinical studies are consistent with that observed in unblinded studies (n > 800)

Enrollment Complete | Topline Data Expected Summer of 2020 | Patent Protection Through 2034

Double-blind, randomized, placebo-controlled study



Week study



Multinational



365 subjects

20 mg BID

5 mg BID

Placebo

1:1:1 dosing

Primary Endpoint in U.S. & EU: ACR CRISS

Secondary Endpoints: Change from baseline in mRSS, Change from baseline in HAQ-DI,
Change from baseline in FVC % predicted

Key Insights Provide Foundation for Commercial Strategy in SSc*

Significant unmet need and no approved treatments for totality of disease



- Often lengthy and challenging journey to diagnosis
- Current therapies address symptoms or specific organ involvement only
- No other drug candidates in late-stage development

"Treatment for scleroderma is the number one unmet need in rheumatology today." Treatment Center Rheum

Care for patients extends beyond centers



- Rheums oversee SSc patient care with support from other specialists
- Scleroderma centers have deep, multi-disciplinary expertise to manage complex disease manifestations
- Sizable amount of community Rheums diagnose and are comfortable treating

"Most of the time I'm managing treatment for scleroderma patients. We will send them to a treatment center for clinical trials." Community Rheum

Rheums and patients had favorable reaction to potential lenabasum profile



- Favorable and enthusiastic reaction to potential safety, tolerability and efficacy profile
- Rheums appreciate that lenabasum is oral, not immunosuppressive and can be used with other medications
- Experts embrace the ACR CRISS endpoint, but clear opportunity to educate community rheums

"It looked like it may make a major difference in the CRISS score." Community Rheum

Commercial Launch Team



Craig Millian, MBA
 Chief Commercial Officer
 25 years of experience leading commercial organizations for a range of pharmaceutical companies as well as a successful track record building pharmaceutical brands



Kaizar Lehri, MBA
 Head of Global Supply Chain
 Accomplished executive with more than 25 years of supply chain management and technology implementation experience



Brian Walsh, MBA
 Head, Global Marketing
 More than 10 years of commercial leadership roles in healthcare management, consulting and sales



Keith White
 Head of Market Access
 Proven commercial leader with more than 20 years of professional experience at leading commercial stage biotech companies



Quinn Dinh, MD
 Vice President, Medical Affairs
 Experienced senior leader with more than 10 years of medical affairs and R&D experience, with a focus on rare and complex diseases



Jeanne Penn, MS
 Market Research Consultant
 More than 20 years of experience in the biopharma industry leading market insights, planning and operations with deep expertise in rare diseases



Combined Drug Experience



Dermatomyositis (DM) at a Glance

Rare and life-threatening autoimmune disease characterized by skin and muscle inflammation

Pathogenesis

Autoimmune disease with organ inflammation, fibrosis, atrophy and vascular changes

Common Symptoms

Proximal muscle weakness, rash, pain, itch, shortness of breath

Current Standard of Care

Immunosuppressive drugs with potential for significant toxicity



~80,000

people with DM in U.S., EU and Japan¹

30%

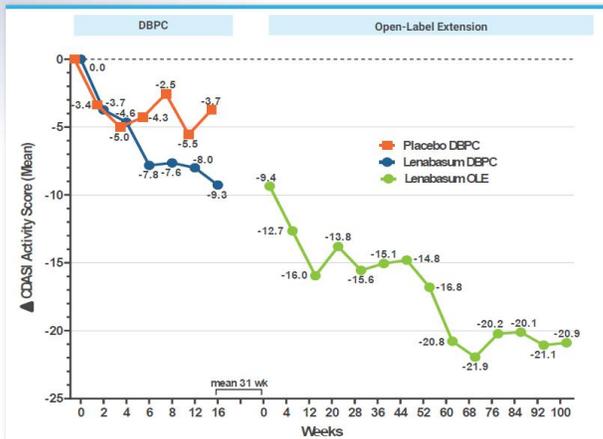
mortality in 5 years²

Zero

DM-specific drugs approved

Orphan Drug Designation from FDA & EMA

Phase 2 Clinically Meaningful Improvement in Skin & Other Outcomes



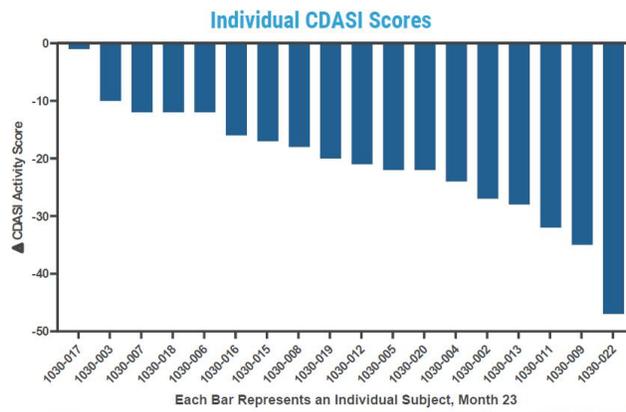
18/20 (90%) of subjects enrolled in the OLE were still enrolled after 23 months

- Continued improvement in open-label extension study
- 72% achieved low skin disease activity (CDASI ≤ 14) by Week 100
- Improvement -4 to -5 points is considered clinically meaningful¹
- Improvement of -4 points or more is associated with improvement in skin-related quality of life outcomes, itch, and pain²

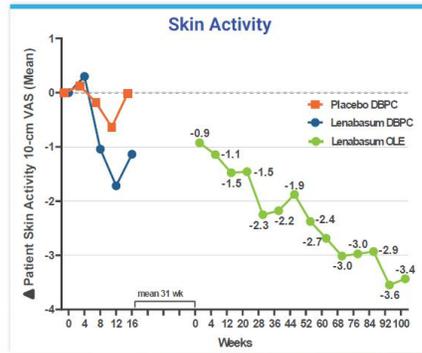
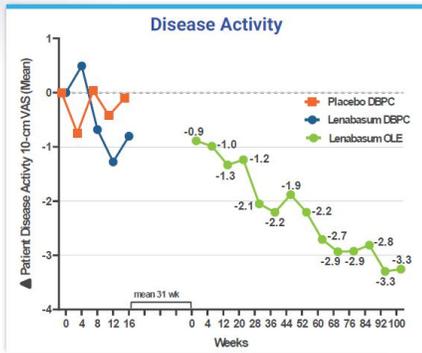
Distribution of CDASI Scores at Month 23 in Open-Label Extension Study

Lenabasum - DM

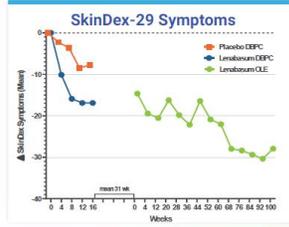
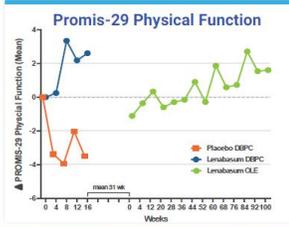
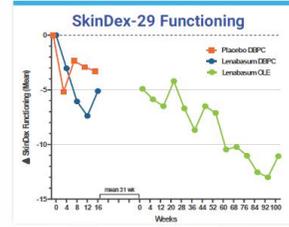
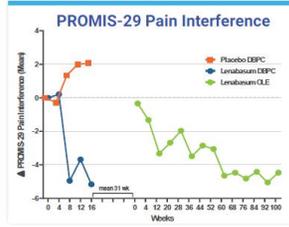
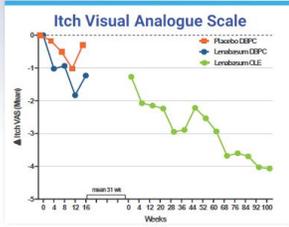
72% achieved low skin disease activity (CDASI ≤ 14) by Week 100



Patient Activity Visual Analogue Scale Scores



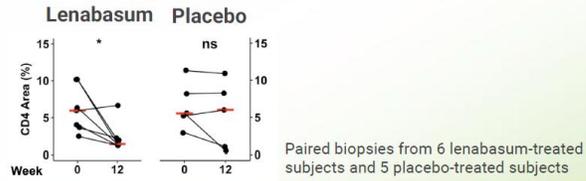
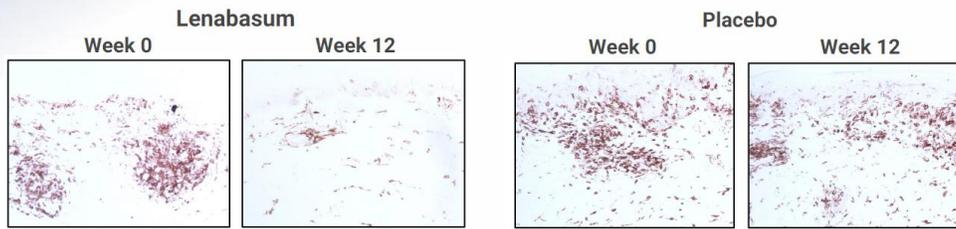
Patient-Reported Outcomes



Lenabasum Treatment was Associated with Reduction in T Cell Infiltration in Skin Biopsies in DM

Lenabasum - DM

Associated with Improvement in CD4+ T Cells in Skin Biopsies



Ongoing Phase 3 DETERMINE Study

Topline Data Expected 2021 | Patent Protection Through 2034

Double-blind, randomized, placebo-controlled study



Week study



Multinational



~150 subjects

20 mg BID

5 mg BID

Placebo

2:1:2 dosing

Primary Endpoint: American College of Rheumatology (ACR) / European League Against Rheumatism (EULAR) 2016 Total Improvement Score (TIS) in Adult Dermatomyositis & Polymyositis

Secondary Endpoints: Mean MMT-8 Score, CDASI activity score, Investigator Global Assessment scale of skin activity, Short Form-36 physical functioning domain score, Corticosteroid dose, FVC % predicted

CF: Targeting Pulmonary Exacerbations (PEX)



18 days

spent in the hospital each year by average person with cystic fibrosis (CF)¹

Up to

\$120K 

cost of pulmonary exacerbations in patients with severe lung disease²



2.9 pulmonary exacerbations per year²
per person



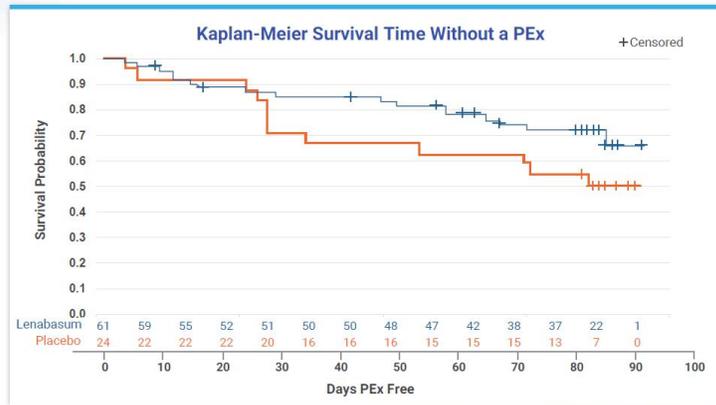
Need

for drugs to reduce pulmonary exacerbations

Pulmonary exacerbations are common in people with CF



Lenabasum Treatment was Associated with Longer Time to PEx in Phase 2 Study (n = 85)



Ongoing CF Phase 2b Study

Enrollment Complete | Topline Data Expected Summer of 2020 | Patent Protection Through 2034

Double-blind, randomized, placebo-controlled study



Week study



Multinational



426 subjects

20 mg BID

5 mg BID

Placebo

2:1:2 dosing

Primary Endpoint: Event rate of PEx

Open to people with CF 12 years and older, regardless of mutation or current background medications, including Orkambi[®], Kalydeco[®] and Symdeko[®]

Secondary Endpoints: Other measures of PEx, Cystic Fibrosis Questionnaire-Revised Respiratory Domain Score, FEV₁ % predicted

Topline Data Expected 2020 | Patent Protection Through 2034

Double-blind, randomized, placebo-controlled study



Week study



15 sites in U.S.



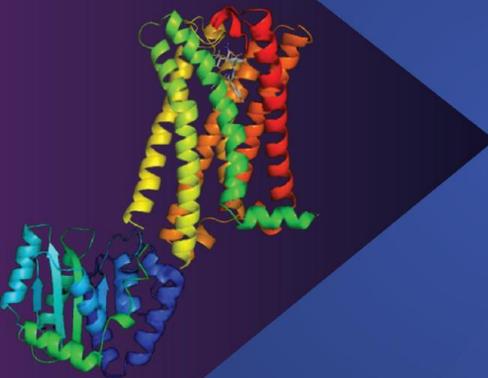
~100 subjects



1:1:1:1 dosing

Primary Endpoint: Change from baseline in the 7-Day Average of the Maximum Daily NRS-Pain Score

Secondary Endpoints: BILAG-2004, SELENA-SLEDAI Score, SELENA-SLEDAI Flare Index, Patient Global Assessment, PROMIS-29, SLE Responder Index, Swollen or Tender Joint Count



CRB-4001

Targeting NASH Using the
Endocannabinoid System

2006: Targeting CB1 for Metabolism was Highly Desirable

Drug Name	Company	Stage
Rimonabant	 SANOFI	Launched in EU
Taranabant	 MERCK	Phase 3
Otenabant	 Pfizer	Phase 3
Surinabant	 SANOFI	Phase 2
Ibipinabant	 Bristol-Myers Squibb	Phase 2

Projected Annual Sales of Rimonabant were \$3bn*

...But It Ended Poorly in 2008



CB1 binding in the brain
led to **depression** and
suicidality



Rimonabant (Acompla)
withdrawn



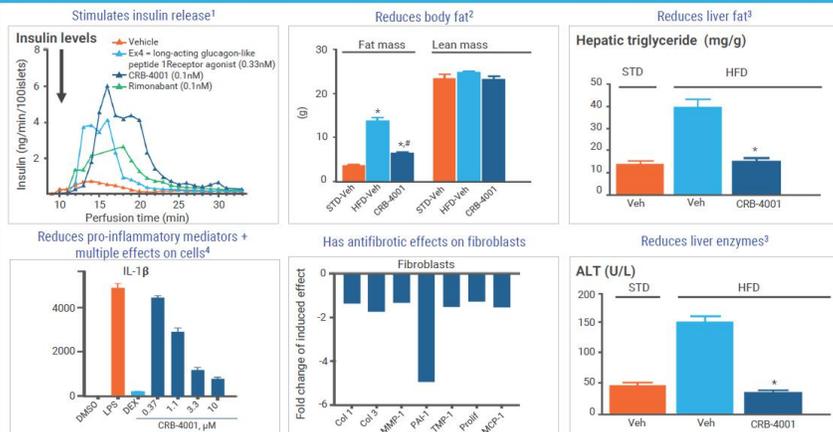
Entire drug class
terminated

2019: Focusing on CB1 Without Affecting the Brain

Company	Compound	Phase	MOA	Type of compound
	CRB-4001	Phase 1 safety data expected in 2020	CB1 inverse agonist	Oral small molecule
 	GFB-024	Preclinical (Phase 1 planned 2H 2020)	CB1 antagonist	Injectable mAb
	Nimacimab (JNJ-2463)	Phase 1 completed	CB1 antagonist	Injectable mAb

- Strong preclinical data around CRB-4001
- Preferentially binds CB1b, predominant isoform in liver in obesity
- Limited CB1 occupancy in mouse brain

CRB-4001 Blocks Metabolic Abnormalities and Reduces Biomarkers of Liver Damage Common in NASH



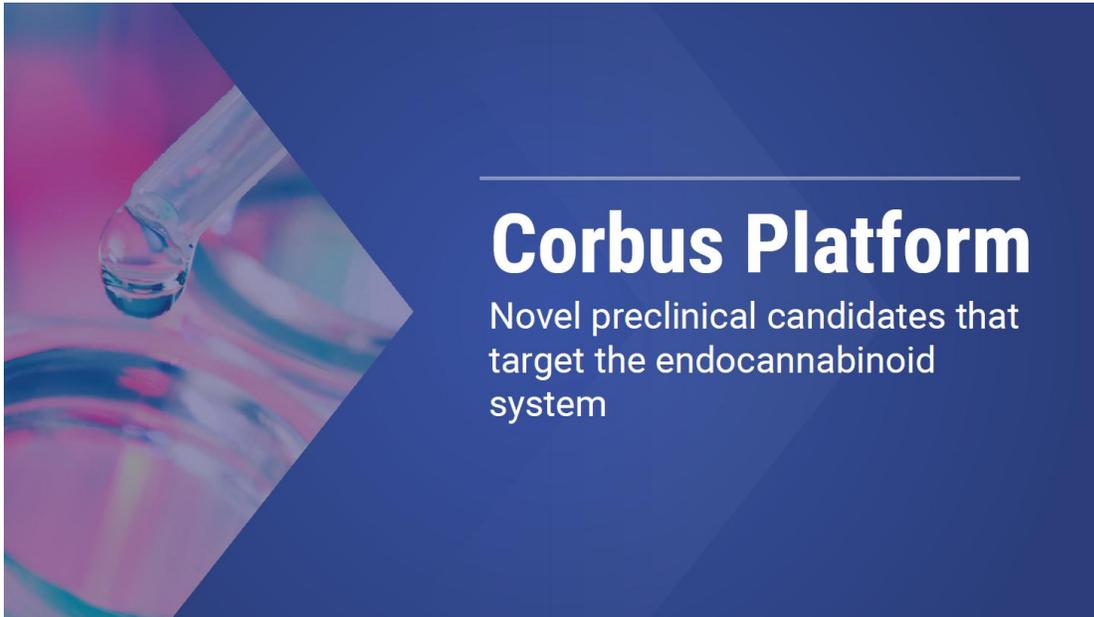
¹ Gonzalez-Martinez et al. Sci. Rep. 2016; 6: 35302; insulin release from isolated islet cells perfused with 7.5 nM glucose alone (blue line) and in combination with 0.33 nM Ex4 (red line, half-max stimulation) or with 0.1 nM CRB-4001 (green line) or 0.1 nM rimonabant (purple line). Treatment time point is indicated by arrow. Islet cells isolated from obese individual. ² Tam et al. Cell Metabolism 2012; 16: 167-179; N = 6/group. *p < 0.005 relative to STD, # p < 0.01 relative to high-fat diet (HFD) vehicle group. ³ Cell Metabolism 2012; 16: 167-179; STD = standard diet, HFD = high fat diet. 6-7 DIO mice per group; Veh = vehicle. CRB-4001 at 3 mg/kg/day X 28 days. * = p < 0.01 vs HFD vehicle; # = p < 0.01 vs HFD vehicle. ⁴ Data as concentration of cytokine, pg/ml.

Phase 1 safety data expected in 2020



Key question: demonstrate differentiated brain CB1 binding to Rimonabant

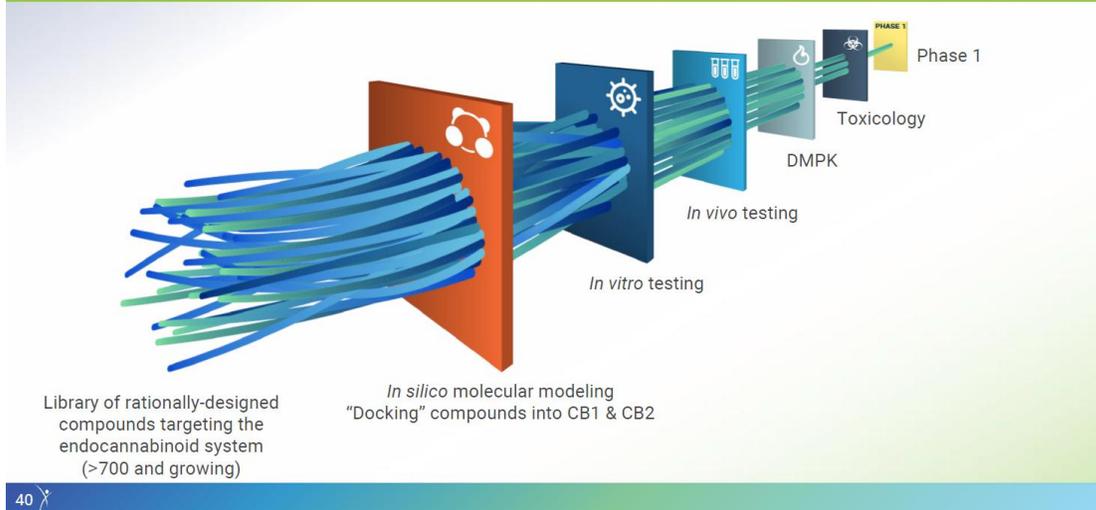




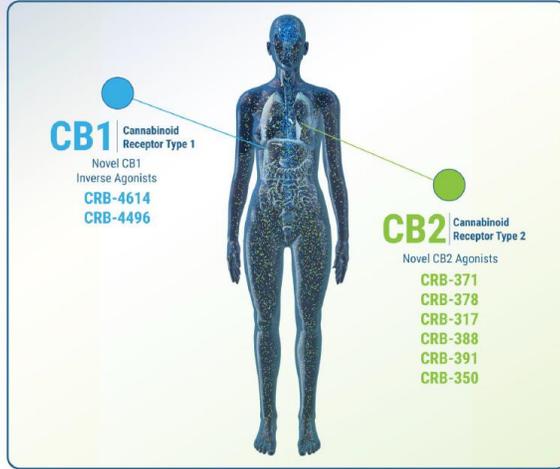
Corbus Platform

Novel preclinical candidates that target the endocannabinoid system

Corbus Platform of Preclinical Drug Development



First Group of Compounds Generated from Our Proprietary Platform in Preclinical Development



IP protection until
2039

Management Team with Proven Record of Execution

**Yuval Cohen, PhD**

Chief Executive Officer, Director
More than 13 years of executive leadership experience in inflammatory disease drug development

**Barbara White, MD**

Chief Medical Officer and Head of Research
Previous academician with more than 15 years of industry clinical development and medical affairs experience in inflammatory and autoimmune diseases

**Sean Moran, CPA, MBA**

Chief Financial Officer
More than 20 years of senior financial experience with emerging biotechnology, drug delivery and medical device companies

**Robert Discordia, PhD**

Chief Operating Officer
More than 25 years of biopharmaceutical industry experience in CMC development and business operations

**Craig Millian, MBA**

Chief Commercial Officer
25 years of experience leading commercial organizations for a range of pharmaceutical companies as well as a successful track record building pharmaceutical brands

**Ross Lobell**

VP, Regulatory Affairs
More than 35 years of regulatory affairs experience with an extensive biopharmaceutical background in leading preclinical, clinical and nonclinical regulatory strategies

Experienced and Engaged Board of Directors



Amb. Alan Holmer Ret.

Chairman of the Board
More than two decades of public service in Washington, D.C. including Special Envoy to China; Former CEO of PhRMA



Avery W. (Chip) Catlin

Director
More than 25 years of senior financial leadership experience in life science companies; Former CFO and Secretary of Celldex Therapeutics



Yuval Cohen, PhD

Chief Executive Officer, Director
More than 13 years of executive leadership experience in inflammatory disease drug development



Rachelle Jacques

Director
More than 25-year professional career, experience in U.S. and global biopharmaceutical commercial leadership, including multiple high-profile product launches in rare diseases; CEO of Enzyvant Therapeutics



David Hochman

Director
More than 20 years of healthcare, entrepreneurial and venture capital experience; Chairman & CEO, Orchestra BioMed; Chairman, Motus GI Holdings, Inc. (NASDAQ: MOTS)



John K. Jenkins, MD

Director
Distinguished 25-year career serving at the U.S. FDA, including 15 years of senior leadership in CDER and OND



Paris Panayiotopoulos

Director
More than 20 years of pharmaceutical experience; Former President and CEO of ARIAD Pharmaceuticals, Inc., which was acquired by Takeda Pharmaceuticals for \$5.2 billion

- \$168M equity raised to-date
- \$45M non-dilutive funding from NIH and CF Foundation¹

64.6M

Common shares outstanding
(78.4M fully diluted)

\$54.8M

Cash balance as of 9/30/2019

\$296M

Market Cap²



Pioneering transformative medicines that
target the endocannabinoid system

Corbus Pharmaceutical Holdings, Inc.

617.963.0100

info@corbuspharma.com

Consistent Reduction in Key Inflammatory Biomarkers (Sputum)

Reduction with Lenabasum 20 mg BID Compared to Placebo (Log₁₀)

