# 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 9, 2017

### CORBUS PHARMACEUTICALS HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware000-5532746-4348039(State or other jurisdiction of incorporation)(Commission (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 7.01. Regulation FD Disclosure.

On May 9, 2017, Corbus Pharmaceuticals Holdings, Inc. (the "Company") used the slides attached hereto as Exhibit 99.1 in connection with management presentations to describe its business.

The information in this Current Report on Form 8-K under Item 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	Investor Presentation.

#### **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.

Dated: May 9, 2017

#### CORBUS PHARMACEUTICALS HOLDINGS, INC.

By: /s/ Yuval Cohen

Name: Yuval Cohen

Title: Chief Executive Officer

#### EXHIBIT INDEX

Exhibit No.	Description
99.1	Investor Presentation.



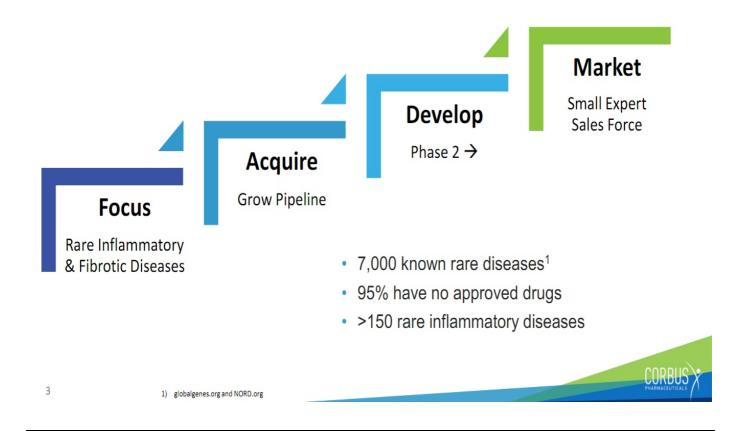
#### FORWARD-LOOKING STATEMENTS

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 forwardlooking 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.



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## THE CORBUS BUSINESS MODEL



#### **MANAGEMENT TEAM**



YUVAL COHEN PH.D. CHIEF EXECUTIVE OFFICER, DIRECTOR

Co-founder and former President of Celsus Therapeutics (CLTX). Expertise in developing anti-inflammatory drugs including for CF



SEAN MORAN C.P.A. M.B.A. CHIEF FINANCIAL OFFICER

Former CFO: InVivo (NVIV), Celsion (CLSN), Transport Pharma, Echo Therapeutics (ECTE) & Anika Therapeutics (ANIK)



MARK TEPPER PH.D. PRESIDENT & CHIEF SCIENTIFIC OFFICER

Former VP U.S. Research & Operations, EMD Serono; Sr. Investigator, Bristol-Myers Squibb



BARBARA WHITE M.D.
CHIEF MEDICAL OFFICER

Board-certified Rheumatologist and clinical immunologist. Previously SVP and Head, R&D Stiefel, a GSK company, VP and Head of Inflammation Clinical Development for UCB & MedImmune, and Director, Medical Affairs, Amgen

#### **BOARD OF DIRECTORS**



#### AMB. ALAN HOLMER (CHAIRMAN OF THE BOARD)

- Former CEO of PhRMA (1996-2005)
- Over two decades of public service in Washington, D.C. including Special Envoy to China (2007-2009)
- Former board member of Inspire Pharma
- Chairman of the Board of the Metropolitan Washington,
   D.C. Chapter of the Cystic Fibrosis Foundation



#### AVERY W. (CHIP) CAITLIN

- CFO Celldex Therapeutics (CLDX) since 2000
- Raised over \$600MM financing
- Over 20 years experience in industry: Repligen (CFO) and Endogen (CFO)



#### DAVID HOCHMAN

- Managing Partner of Orchestra Medical Ventures
- Over 19 years of venture capital and investment banking experience
- Former Managing Director of Spencer Trask Ventures, Inc. securing over \$600MM in equity capital



#### RENU GUPTA, M.D.

- Over 25 years of development, regulatory and senior management experience in the biopharma industry
- Former CMO of Insmed, a specialty CF company and current advisor to the CEO
- Former VP and Head of U.S. Clinical Research and Devp. Novartis (2003-2006)



# ANABASUM (FKA JBT-101/RESUNAB)

- Novel synthetic oral endocannabinoid-mimetic with unique MOA
- First-in-class therapeutic: Positive Ph 2 data in SSc and CF
- Pipeline in a product: opportunities in autoimmune, inflammatory & fibrotic diseases
- IP portfolio → 2033

Anticipated Approval

Systemic Sclerosis (SSc)	Positive Ph 2 Data - Pivotal Ph 3 study to commence Q4 2017 Orphan Designation + Fast Track Status + Open-Label Extension		2020
Cystic Fibrosis (CF)	Positive Phase 2 data – Ph 2b to commence Q4 2017 Orphan Designation + Fast Track Status	\$5MM Award from CFF <sup>1</sup>	2022
Dermatomyositis (DM)	Phase 2 data expected Q3 2017 + Open-Label Extension	NIH Grant Funded <sup>2</sup>	2022
Systemic Lupus Erythematosus (SLE)	Anticipated Phase 2 study launch H2 2017	NIH Grant Funded <sup>2</sup>	2023

1) NIH grants fund Phase 2 trials of anabasum in dermatomyositis and systemic lupus erythematosus; Corbus retains all rights to the product and owns the IND data



### **EXPECTED NEAR-TERM MILESTONES**

Q2 2017

- Complete enrollment of DM study
- Oral presentation at ECFS-17 conference (Seville, 7-10 June)
- Oral presentation at EULAR-17 conference (Madrid, 14-17 June)

Q3 2017

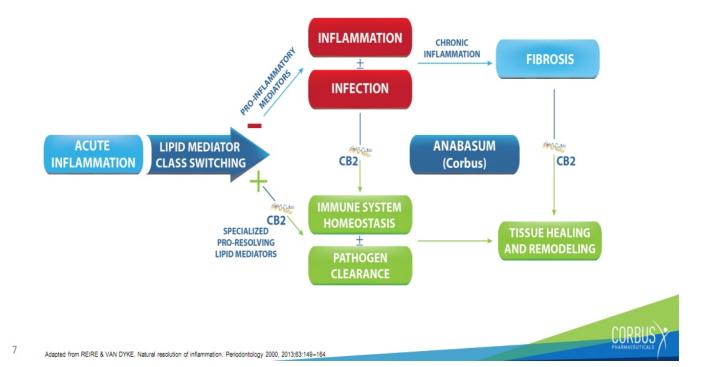
- · Topline data DM study
- Start SLE Ph2 study

Q4 2017

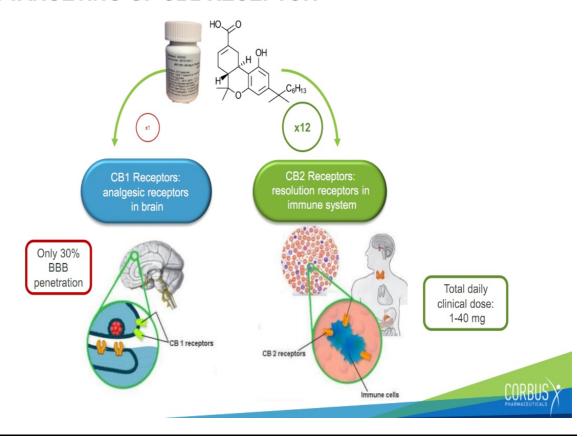
- Launch single Ph 3 SSc study
- · Launch Ph 2b CF study
- NACFC-17 conference
- ACR-17 conference
- · Data from SSc open-label study



# ANABASUM RESTORES HOMEOSTASIS DURING PATHOLOGIC IMMUNE RESPONSES



# **UNIQUE TARGETING OF CB2 RECEPTOR**



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# SYSTEMIC SCLEROSIS

Chronic systemic autoimmune disease causing fibrosis of skin and internal organs

90,000 Patients in U.S. + EU



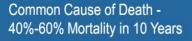
80% Female Patients



40-60 YEARS

Average Age of Patients

# LUNG FIBROSIS



# **KEY TAKE-AWAYS**

- Life-threatening, rare disease
- · No SSc-specific approved drugs
- Current therapy involves steroids and immunosuppressive agents with significant toxicities
- Need for proven safe and effective therapies



#### UPCOMING SINGLE PHASE 3 STUDY OF ANABASUM IN SSc

# **Enrollment Commences Q4 2017**

- · Protocol submitted to FDA on March 31, 2017 based on guidance following successful end-of-Phase 2 meeting
- · Planned Study Design:
  - · Single double-blind, randomized, placebo-controlled study
  - Primary endpoint: change from baseline in skin thickening, using modified Rodnan Skin Score (mRSS)
  - · Secondary endpoints:
    - Change from baseline in patient function, using Health Assessment Questionnaire Disability Index (HAQ-DI)
    - Change from baseline in lung function, using forced vital capacity (FVC)
    - American College of Rheumatology Combined Response Index in diffuse cutaneous Systemic Sclerosis (ACR CRISS) score, a novel composite measure of improvement from baseline that incorporates change from baseline in mRSS, HAQ-DI, FVC, and physician and patient global assessments
  - Patient number: approximately 270 subjects across multiple centers in the US, Europe, and Asia
  - · Treatment duration: 52 weeks
  - Doses: anabasum 20 mg twice per day, anabasum 5 mg twice per day, or placebo twice per day



#### PHASE 2 STUDY OF ANABASUM IN SSc: DESIGN

# **Study Completed Nov 2016**

- Double-blind, randomized, placebo-controlled, Phase 2 study (Part A)
- 9 clinical sites in the U.S.
- 43 adults ages 18 to 70 with diffuse cutaneous systemic sclerosis (SSc)
- 2:1 overall ratio of anabasum:placebo
- 16 week study, 12 weeks of active dosing
- · Immunosuppressive medications allowed
- ClinicalTrials.gov identifier: NCT02465437

#### **Primary Objectives**

- Evaluate safety and tolerability
- Evaluate efficacy, using the American College of Rheumatology Combined Response Index in diffuse cutaneous Systemic Sclerosis (ACR CRISS) score

#### **Secondary Objectives**

- Evaluate efficacy, using each ACR CRISS domain
- Evaluate efficacy, using other patient-reported outcomes

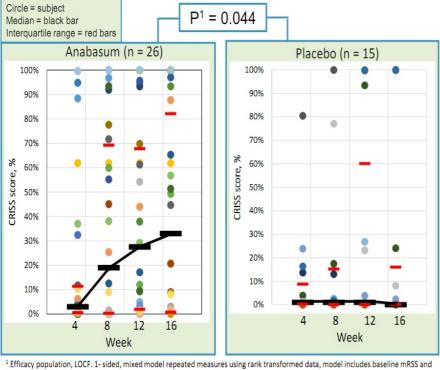


# TREATMENT-EMERGENT ADVERSE EVENTS IN THE PHASE 2 STUDY OF ANABASUM IN SSc

- · 2 serious treatment-emergent adverse events (TEAEs) occurred, both unrelated to study drug
  - · Anabasum cohort: dehydration of moderate severity treated in hospital
  - · Placebo cohort: abdominal pain and nausea of severe severity treated in hospital
- · No unexpected TEAEs related to anabasum
- · Only two severe TEAEs occurred, both in a subject on placebo
- 17 (63.0%) versus 9 (60.0%) of anabasum versus placebo subjects experienced any TEAE
- 66 total TEAEs in the anabasum group versus 34 total TEAEs in the placebo group; same as ratio is the study



# ANABASUM DEMONSTRATED IMPROVEMENTS IN ACR-CRISS SCORES COMPARED TO PLACEBO



- Composite score of change from baseline in mRSS, HAQ-DI, FVC, and physician and patient global assessments
- ACR CRISS scores show improvement from baseline in anabasum-treated subjects > placebo-treated subjects



<sup>-</sup> Efficacy population, LOCF. 1- sided, mixed model repeated measures using rank transformed data, model includes baseline mKSS and disease duration. No effect of immunosuppressive therapy in model.

# ANABASUM DEMONSTRATED INCREASES IN ACR-CRISS SCORES COMPARED TO PLACEBO

#### **Anabasum Trial**

#### Previous Comparator Trial, Post-hoc Analysis

Group	M	Drug			
	Week 4	Week 8	Week 12	Week 16	
Anabasum, N = 26	<b>3.0</b> (0.6, 11.4)	<b>19.0</b> (0.3, 69.2)	<b>27.5</b> (1.9, 67.8)	<b>33.0</b> (0.8, 82.1)	Cyclophospham N = 45
Placebo, N = 15	<b>1.0</b> (0.3, 8.8)	<b>1.0</b> (0.1, 15.2)	<b>1.0</b> (0.1, 60.1)	<b>1.0</b> (0.1, 16.0)	Placebo N = 39

Drug	CRISS Score, % Median (IQR)
	Week 52
Cyclophosphamide <sup>3</sup> N = 45	<b>24.0</b> (0.1, 96.0)
Placebo	0.5
N = 39	(0.0, 32.0)

<sup>&</sup>lt;sup>1</sup> Efficacy population, LOCF. <sup>2</sup> (25<sup>th</sup> percentile, 75<sup>th</sup> percentile). <sup>4</sup> D. Khanna, Scleroderma Clinical Trials Consortium, 2016.

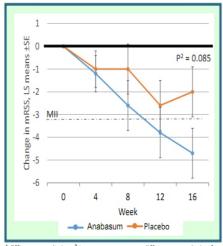


<sup>&</sup>lt;sup>3 D</sup> Khanna, personal communication

# SKIN THICKENING IMPROVED WITH ANABASUM TREATMENT IN PHASE 2 TESTING COMPARED TO PLACEBO

- · Improvement is a reduction in score
- Minimal important improvement (MII) in mRSS is ≥ -3.2 to -5.2 points (Khanna et al, Ann Rheum Dis 2006;65:1325).

#### mRSS Change from Baseline



<sup>&</sup>lt;sup>1</sup> Efficacy population. <sup>2</sup> Least squares mean difference, analysis of covariance model, one-sided p value.

#### **Previous Comparator Trials**

Drug	N	Time	mRSS, mean (SD) change from baseline		
			Active	Placebo	
Six drug trials, all subjects combined <sup>3</sup>	492	~26 weeks	-2.9 (7.2)		
Tocilizumab <sup>4</sup>	77	24 weeks	-3.9	-1.2	
Cyclophosphamide <sup>5</sup>	84	52 weeks	-5.3	-1.7	
Musanhanalatafi	93	Baseline	24.0 (9.8)7		
Mycophenolate <sup>6</sup>	93	12 weeks	22.4 (8.9)		

 $<sup>^3\,\</sup>alpha$  interferon, d-penicillamine, relaxin Ph 2 and 3, minocycline, methotrexate, anti-TGF $\beta$ , Merkel et al, Arthritis Rheum 2012;64:3420.

- Anabasum subjects had greater improvement in mRSS than placebo subjects
- The mean degree of improvement in mRSS in anabasum subjects is clinically important
- The mRSS results with anabasum compare favorably with data from comparator trials



<sup>&</sup>lt;sup>4</sup> Khanna et al, Lancet 2016;387:2630. <sup>5</sup> D. Khanna personal communication 2016. <sup>6</sup> Le et al, Ann Rheum Dis 2011; 70: 1104.

 $<sup>^{\</sup>rm 7}$  Absolute mRSS, mean (SD), not change from baseline.

# SKIN SYMPTOMS IMPROVED WITH ANABASUM TREATMENT IN PHASE 2 TESTING COMPARED TO PLACEBO

· Improvement is a reduction in score

baseline

-5

-10

-15

-20

-25

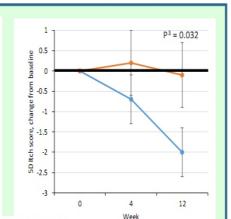
- Ki

0

SSc Skin Symptoms Questionnaire<sup>1</sup>

 $P^3 = 0.044$ 





#### **Previous Comparator Trial**

Davis	Time	5-D Itch, mean change from baseline			
Drug	Time	Active N = 41	Placebo N = 41		
Tocilizumab <sup>4</sup>	24 weeks	-0.94	-1.73		

<sup>&</sup>lt;sup>4</sup> Anti-IL-6 monoclonal antibody. Khanna et al. Lancet 2016:387:2630.

→ JBT-101 → Placebo

P = 0.004

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- · Anabasum-treated subjects had greater improvement in skin symptoms than placebo-treated subjects
- · Improvements were seen as early as 4 weeks with anabasum treatment
- The 5-D Itch results with anabasum also compare favorably with data from a comparator trial

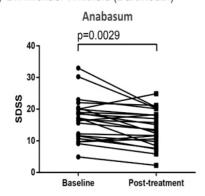


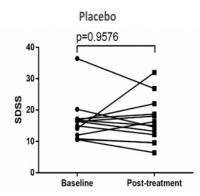
<sup>&</sup>lt;sup>1</sup>Ziemek J et al. Rheumatology 2016;55:911. <sup>2</sup> Elman S et al. Br J Dermatol 2010;162:587. <sup>3</sup> Efficacy population, least squares means ± SE, analysis of covariance model, one-sided p-value.

### "MOLECULAR SKIN SCORE" IN SKIN BIOPSIES FROM PHASE 2 SHOWS IMPROVEMENT COMPARED TO PLACEBO

This "molecular skin score" is a mathematical calculation of skin thickening in SSc based on gene expression in skin biopsies

- · Based on expression levels of specific genes from microarray data
- · Validated in five independent SSc patient cohorts
- Highly correlated with mRSS (r = 0.8)
- · Analyzed by Dr. Michael Whitfield (Dartmouth)

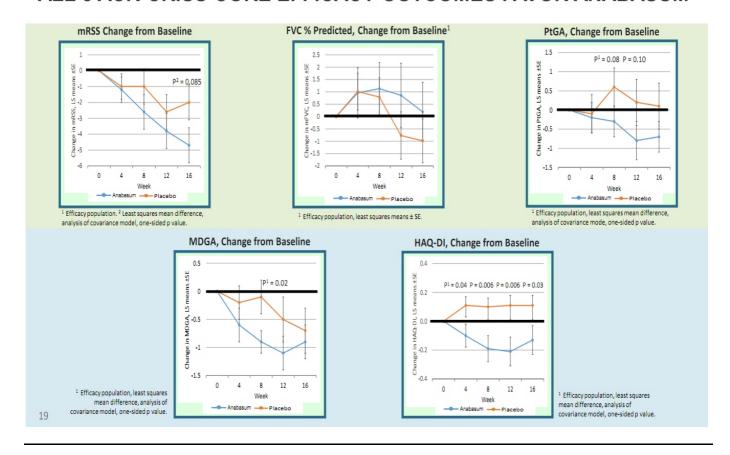




Anabasum-treated subjects had improvement in this molecular skin score whereas placebo-treated subjects did not



## ALL 5 ACR-CRISS CORE EFFICACY OUTCOMES FAVOR ANABASUM



### ONGOING OPEN-LABEL EXTENSION OF PHASE 2 STUDY

## **Data Scheduled for Presentation at ACR 2017**

- Open-label extension of Phase 2 study to collect long-term safety and efficacy data
- 12 months duration, to be extended to 24 months
- All subjects receive anabasum
- Same safety and efficacy measures as in the blinded part of the Phase 2 study
- Plan to report on open-label data at ACR Annual Meeting in November 2017



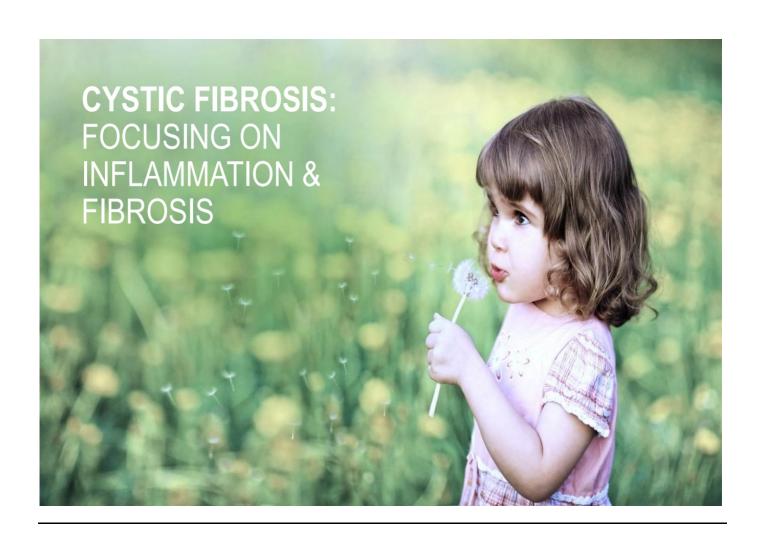
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#### SUMMARY ON ANABASUM CLINICAL DEVELOPMENT IN SSc

- Safety and tolerability profiles of anabasum in SSc are acceptable
- Promising and consistent evidence of clinical benefit in multiple clinical outcomes in SSc
- Evidence of relevant biological activity in involved skin from patients in the Phase 2 study supports clinical benefit in SSc
- Patients achieve expected serum peak concentrations of anabasum
- Long-term open-label data will be available to augment blinded safety data



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# **CYSTIC FIBROSIS**

CF is a life-threatening, genetic disease that primarily affects the lungs and digestive system. CF is characterized by chronic lung inflammation that leads to lung damage and fibrosis.

30,000 Patients in the U.S.



75,000 Patients Worldwide



40 YEARS

Average Life Expectancy of CF Patients

# **KEY TAKE-AWAYS**

- · Life-threatening, rare disease
- Inflammation and fibrosis play key role in CF morbidity and mortality
- Need for safe and effective drugs that target chronic inflammation and fibrosis is unmet and recognized
- Pharmacoeconomics are proven and favorable



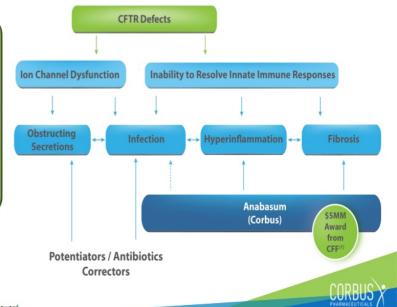
## ANABASUM IS UNIQUELY POSITIONED IN CF

### Potential to be First Therapy for Chronic Inflammation and Fibrosis in CF

- ✓ First-in-class CB2 agonist in CF
- √ Targets inflammation and fibrosis
- ✓ Not immunosuppressive

✓ Add-on to current therapy

- ✓ Could potentially target all CF patients
- ✓ Oral, daily dosing



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#### JBT101-CF-001 PHASE 2 TRIAL DESIGN

## **Study Completed March 2017**

- Double-blind, randomized, placebo-controlled, 16-week trial
- 21 clinical sites in the US, UK, Germany, Italy, and Poland
- Adults ages 18 to 65 with cystic fibrosis (CF)
- · Eligibility criteria
  - · All mutations allowed
  - FEV1 ≥ 40% predicted
  - Stable treatment for CF, background medications including prophylactic antibiotics allowed
  - No intravenous antibiotics for 14 days prior to Day 1

#### **Primary Objective**

- · Evaluate safety and tolerability
  - Pulmonary exacerbations are an event of special interest

#### Secondary / Exploratory Objectives

- Evaluate anabasum plasma concentrations and metabolites
- Evaluate efficacy using FEV1, lung clearance index, and CFQ-R
- Evaluate blood and sputum biomarkers of disease activity and inflammation
- · Evaluate microbiome in sputum
- Evaluate plasma metabolipidomic profile



## PRIMARY ENDPOINT: SAFETY AND TOLERABILITY OUTCOMES

#### **Safety**

• Primary safety outcome: Treatment-emergent adverse events

### Pre-Specified Events of Special Interest Include

· Acute pulmonary exacerbations requiring IV antibiotics

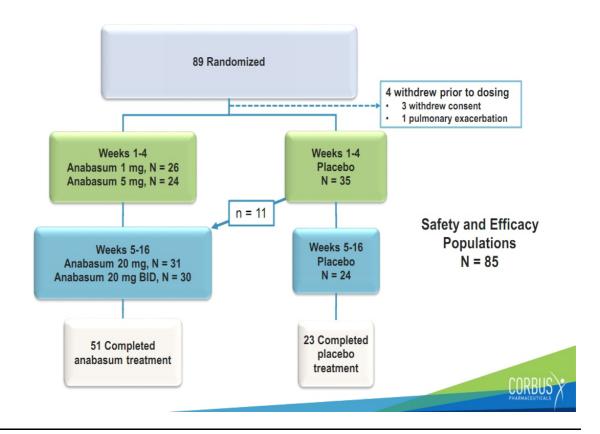
#### **Tolerability**

Discontinuation of study product because of treatment-emergent adverse events



Protocol JBT101-CF-001

# STUDY POPULATIONS



27 t14.1.1.ds

# **BASELINE DEMOGRAPHICS OF SUBJECTS**

		Weeks 1-4		Weeks 5-16			
Characteristic	Anabasum 1 mg QD N = 26	Anabasum 5 mg QD N = 24	Placebo N = 35	Anabasum 20 mg QD N = 31	Anabasum 20 mg BID N = 30	Placebo N = 24	
Male, %	65.4	50.0	48.6	51.6	50.0	62.5	
Age, mean (range)	26.9 (19-52)	28.8 (18-62)	29.2 (18-59)	28.5 (18-62)	26.8 (19-46)	30.2 (18-59)	
Caucasian, %	96.2	100	94.3	96.8	96.7	95.8	
Not Hispanic or Latino, %	100	91.7	100	96.8	96.7	100	



# **BASELINE DISEASE CHARACTERISTICS OF SUBJECTS**

		Weeks 1-4		Weeks 5-8			
Characteristic	JBT-101 1 mg QD N = 26	JBT-101 5 mg QD N = 24	Placebo N = 35	JBT-101 20 mg QD N = 31	JBT-101 20 mg BID N = 30	Placebo N = 24	
F508D: 2 alleles/ 1 alleles/ 0 alleles	13/9/4 50%/35%/15%	14/7/3 58%/29%/13%	21/10/4 60%/29%/11%	14/12/5 45%/39%/16%	20/7/3 67%/23%/19%	14/7/3 58%/29%/13%	
FEV1 % predicted, mean (range)	65.6 (31.5 – 101.8)	63.1 (29.6 – 89.3)	65.3 (39.2 – 113.3)	64.2 (26.8 – 103.2)	64.0 (31.1 – 98.4)	64.9 (25.7 – 106.8)	
Lowest FEV1 % predicted last year, mean (range)		63.9 (32 – 98)	60.2 (10 – 93)	62.9 (10 – 100)	62.8 (10 – 98)	61.7 (33 – 93)	
Number of exacerbations in last year, mean (range)	0.73 (0 – 2)	0.75 (0 – 3)	0.63 (0 – 3)	0.87 (0 – 2)	0.67 (0 – 3)	0.50 (0 – 3)	
CRQ-R Respiratory Symptom Score, mean (range)	65.8 (33.3 – 94.4)	69.9 (16.7 – 100)	71.6 (27.8 – 88.9)	74.4 (27.8 – 100)	66.9 (22.2 – 100)	76.6 (38.9 – 94.4)	
Pancreatic insufficiency, n (%)	21 (83)	20 (83)	26 (74)	24 (77)	26 (87)	17 (71)	
Sinusitis, n (%)	16 (46)	11 (46)	19 (54)	16 (52)	17 (57)	13 (54)	
Nasal polyps, n (%)	8 (31)	4 (17)	12 (34)	7 (23)	9 (30)	8 (33)	
Diabetes mellitus, n (%)	4 (15)	3 (13)	7 (20)	3 (10)	6 (20)	5 (21)	



# **BASELINE MEDICATIONS OF SUBJECTS**

	Subjects, n (%)								
Medication	Anabasum 1 mg QD N = 26	Anabasum 5 mg QD N = 24	Placebo N = 35	Anabasum 20 mg QD N = 31	Anabasum 20 mg BID N = 30	Placebo N = 24			
Azithromycin	8 (30.1)	16 (66.7)	21 (60.0)	14 (45.2)	13 (43.3)	14 (58.3)			
Prophylactic antibiotics excluding azithromycin	13 (50.0)	12 (50.0)	16 (45.5)	18 (58.1)	112 (40.0)	11 (45.8)			
Lumacaftor/ivacaftor	6 (23.1)	7 (29.2)	8 (22.9)	6 (19.4)	9 (30.0)	6 (25.0)			
Ivacaftor	2 (7.7)	0	1 (2.9)	1 (3.2)	2 (6.7)	0			
Dornase alfa	23 (88.5)	19 (79.1)	29 (82.9)	27 (87.1)	25 (83.3)	19 (79.2)			



# SUBJECTS WITH TEAEs BY DOSE

		Subjects, n (%)									
Treatment-Emergent	Weeks 1-4				Weeks 5-12			Post Treatment			
Adverse Event (TEAE)	Anabasum 1 mg N = 26	Anabasum 5 mg N = 24	Placebo N = 35	Anabasum 20 mg N = 31	Anabasum 20 mg BID N = 30	Placebo N = 24	Anabasum 20 mg N = 31	Anabasum 20 mg BID N = 30	Placebo N = 24		
Any TEAE	14 (53.8)	13 (54.2)	15 (42.9)	21 (67.7)	19 (63.3)	14 (58.3)	15 (48.4)	15 (50.0)	11 (45.8)		
Deaths	0	0	0	0	0	0	0	0	0		
Serious Unexpected Severe Adverse Reaction	0	0	0	0	0	0	0	0	0		
Serious TEAEs	1 (3.8)	0	2 (5.7)	3 (9.7)	2 (6.7)	1 (4.2)	2 (6.5)	1 (3.3)	3 (12.5)		
Serious TEAEs Related to Study Drug	0	0	0	0	0	0	0	0	0		
Severe TEAEs	0	0	1 (2.9)	0	2 (6.7)	1 (4.2)	1 (3.2)	0	2 (8.3)		
Related TEAEs	3 (11.5)	4 (16.7)	3 (8.6)	8 (25.8)	4 (13.3)	5 (20.8)	0	1 (3.3)	1 (4.2)		
TEAEs Leading to Study Discontinuation	1 (3.8)	0	1 (2.9)	1 (3.2)	2 (6.7)	0	0	0	0		



# PULMONARY EXACERBATION REQUIRING TREATMENT WITH INTRAVENOUS ANTIBIOTICS

- · Pre-specified event of special interest. Most severe category of pulmonary exacerbation in CF
- · Assignment to treatment arm is by time of onset of symptoms that required intravenous antibiotic treatment

T	Subjects, n (%)			
Treatment Group, N at risk	Weeks 1-4	Weeks 5-12		
Placebo, N = 35	3 (8.6%)			
Anabasum 1 mg, N = 26	1 (3.8%)			
Anabasum 5 mg, N = 24	1 (4.2%)			
Placebo, N = 24		3 (16.7%)		
Anabasum 20 mg, N = 31		3 (6.5%)		
Anabasum 20 mg BID, N = 30		1 (3.3%)		

# Pulmonary Exacerbation Event Rate (Intravenous Antibiotics) 0.86 47% reduction 0.46 75% reduction

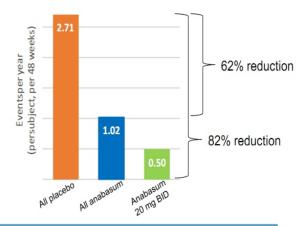
- Anabasum treatment is associated with a dose dependent-reduction in rate of acute pulmonary exacerbations requiring intravenous antibiotics per 48 weeks
- There was a 75% reduction in the 48 week rate of acute pulmonary exacerbations for anabasum at 20 mg BID
- · Placebo rate is similar to that reported in literature and in other studies

# FIRST ACUTE PULMONARY EXACERBATION DEFINED AS TREATMENT WITH <u>NEW</u> ANTIBIOTICS

A broader look at acute pulmonary exacerbations as defined by treatment with new antibiotics for respiratory system symptoms

Treatment Group, N at risk for	Subjects n/N at risk (%)					
1st exacerbation	Weeks 1-4	Weeks 5-12	Post-treatment			
Placebo, N = 34	6 (25.0%)					
Anabasum 1 mg, N = 22	3 (13.6%)					
Anabasum 5 mg, N = 23	3 (13.0%)					
Placebo, N= 18		9 (50.0%)				
Anabasum 20 mg, N = 25		4 (16.0%)				
Anabasum 20 mg BID, N = 24		2 (8.3%)				
Placebo, N = 9			2 (22.2%)			
Anabasum 20 mg, N = 20			6 (30.0%)			
Anabasum 20 mg BID, N = 22			2 (9.1%)			

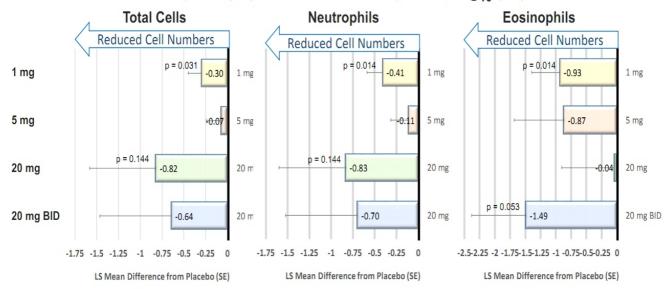
## First Acute Pulmonary Exacerbations (Any New Antibiotic) Per Year



- Anabasum treatment is associated with a dose dependent-reduction in rate of acute pulmonary exacerbations treated with any new antibiotic per 48 weeks
- There was a 82% reduction in the 48 week rate of acute pulmonary exacerbations treated with any new antibiotic for anabasum at 20 mg BID

#### ANABASUM REDUCES INFLAMMATORY CELLS IN CF SPUTUM (1)

Least Squares (LS) mean difference from placebo,  $\log_{10}$  (SE)

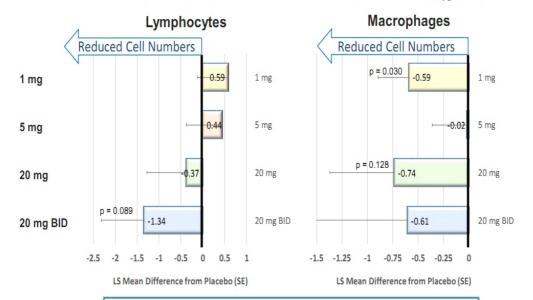


Anabasum reduces sputum total cells, neutrophils and eosinophils, with greater reduction at higher doses of anabasum



#### ANABASUM REDUCES INFLAMMATORY CELLS IN CF SPUTUM (2)

Least Squares (LS) mean difference from placebo,  $\log_{10}$  (SE)

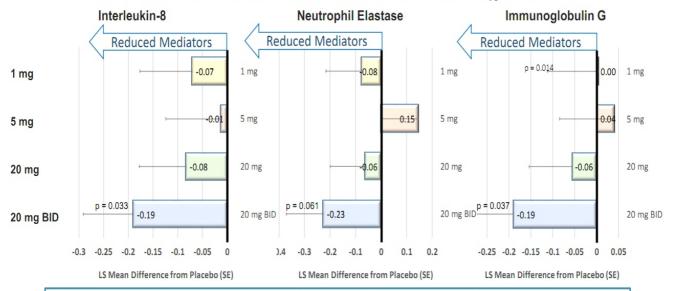


Anabasum reduces sputum lymphocytes and macrophages, with greater reduction at higher doses of anabasum



# ANABASUM REDUCES INFLAMMATORY MEDIATORS IN CF SPUTUM

Least Squares (LS) mean difference from placebo,  $\log_{10}$  (SE)

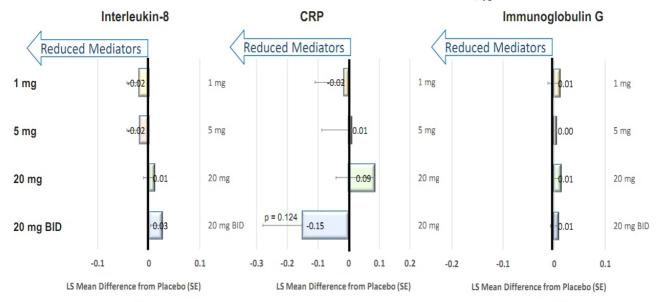


Anabasum 20 mg BID reduces sputum interleukin-8, neutrophil elastase, and immunoglobulin G



# EFFECT OF ANABASUM ON INFLAMMATORY MEDIATORS IN BLOOD

Least Squares (LS) mean difference from placebo,  $\log_{10}$  (SE)



Anabasum 20 mg BID reduces C-reactive protein levels in the blood



#### SUMMARY OF CLINICAL DEVELOPMENT OF ANABASUM IN CF

- Safety and tolerability profiles of anabasum in CF are acceptable
- Promising evidence of clinical benefit in pulmonary exacerbations in CF
- Evidence of relevant biological activity in sputum from patients in the Phase 2 study supports clinical benefit in CF
- Patients achieve expected serum peak concentrations of anabasum (absorption of anabasum similar to NHVs)



#### NEXT STEPS IN CLINICAL DEVELOPMENT OF ANABASUM IN CF

- Submit Pediatric Investigational Plan to EMA
- Obtain expert opinion in the design of Phase 2b study
- Reach agreement on design on Phase 2b study with FDA (Type C meeting) and EMA (Protocol Assistance)
- Phase 2b study planned to start in Q4 2017



#### **CFF STATEMENT ON ANABASUM PHASE 2 RESULTS**

"Corbus Pharmaceuticals reported promising results Thursday from an early stage clinical study of a potential antiinflammatory drug for people with cystic fibrosis. Researchers believe that reducing excessive inflammation in people with CF will reduce lung damage and slow progression of the disease.

The synthetic drug <u>anabasam</u> (formerly known as Resunab) demonstrated in a <u>Phase 2 trial</u> that it was safe and well-tolerated at all doses with no serious or severe adverse events, according to Corbus.

In the 16-week trial involving 85 participants, results demonstrated that anabasum (pronounced ah-NAH-bah-som) reduced multiple markers of inflammation including both inflammatory cells and mediators (chemicals that trigger an exaggerated immune response). Just as important, the drug did not show signs of suppressing the immune response, which has been a problem with other potential CF anti-inflammatories.

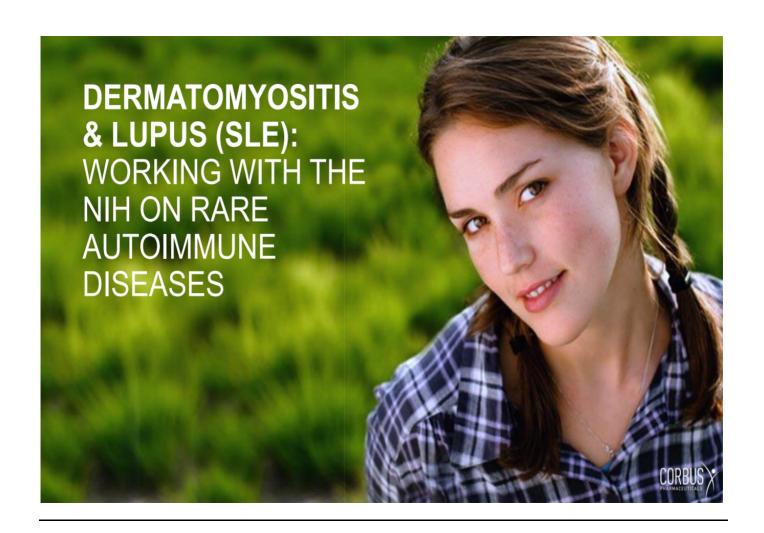
Although this is an early study, the results also suggest a potential clinical benefit. Participants in the trial who took the highest dose had a significant reduction in the annualized rate of pulmonary exacerbations compared to those on the placebo.

These results are considered to be encouraging for an early stage trial and support the continued development of anabasum as a potential anti-inflammatory in cystic fibrosis.

<u>Cystic Fibrosis Foundation Therapeutics Inc.</u> (CFFT), the nonprofit drug discovery and development affiliate of the Cystic Fibrosis Foundation, <u>provided a \$5 million award</u> to support the clinical trial."



March 30th 2017 https://www.cff.org/News/News-Archive/2017/Anti-Inflammatory-Drug-Shows-Promising-Early-Results-for-CF/



## **DERMATOMYOSITIS**

Chronic systemic autoimmune disease characterized by inflammation of skin and muscles

50,000 Patients in the U.S. + EU



## SKIN & MUSCLE

Involvement Can Cause Significant Morbidity and Mortality from Interstitial Lung Disease

### NO FDA

Approved Therapies for Overall Disease Activity

## **KEY TAKE-AWAYS**

- Treated with steroids and immunosuppressive therapies, but with significant toxicities
- Single center study underway at University of Pennsylvania
- · NIH is funding the study
- Data readout expected in Q3 2017



#### ANABASUM: DM PHASE 2 CLINICAL STUDY

#### **Complete Patient Enrollment Expected Q2 2017**

# <u>Primary Endpoint:</u> Change in CDASI Score + Safety/Tolerability

- · Study funded by NIH award to University of Pennsylvania
- Double blind placebo control randomized study in U.S. under IND from FDA
- Primary endpoints: Safety/tolerability + change in skin activity and severity (CDASI)
- Secondary endpoints: Quality of life, biomarkers of inflammation and disease activity in blood and skin, metabolipidomic profile, PK

# Secondary Endpoint: Directional Trends in Efficacy

- Patient number: 22 adults with DM at 1 U.S. site University of Pennsylvania Perlman School
  of Medicine
- Treatment duration: 84 days treatment with 28 days follow-up
- Dose response: 20 mg/day and 20 mg/day twice a day

	Q2 2015	Q3 2015	Q4 2015	Q1 2016	Q2 2016	Q3 2016	Q4 2016	Q1 2017	Q2 2017	Q3 2017
Study launch	✓									
First patient dosed		✓								
Anticipated last patient dosed									×	
Study duration		✓	✓	✓	✓	✓	✓	✓	×	X
Anticipated topline study data										*

#### ANABASUM: DM OPEN-LABEL EXTENSION

- 12-month open-label extension study granted by U.S. FDA in November 2016
- Goal of the open-label extension is to collect long-term safety and efficacy data on anabasum
- · All subjects in the extension study are receiving anabasum
- Same safety and efficacy endpoints used in the concluded double-blind placebo-controlled portion of the Phase 2 study
- Will report open-label data at ACR in November 2017



# SYSTEMIC LUPUS ERYTHEMATOSUS

Chronic systemic autoimmune disease characterized by arthritis, skin rashes, kidney disease, and involvement of the nervous system and other organs

500,000 - 600,000

Patients in the U.S. + EU 10-12:1 Women to Men Higher Incidence and More Severe in Blacks and Asians



NON-IMMUNOSUPRESSIVE TREATMENTS NEEDED

## **KEY TAKE-AWAYS**

- Treated with steroids and immunosuppressive therapies
- Multi-center study planned (n=100)
- NIH is funding the study

#### ANABASUM: SLE PHASE 2 CLINICAL STUDY

#### **Trial Expected to Start in H2 2017**

Primary Endpoint: Safety and Tolerability Secondary Endpoint:
Directional Trends in Efficacy + PK

- Study funded by NIH award to Feinstein Institute for Medical Research
- · Double blind placebo control randomized study in U.S. under IND from FDA
- Primary endpoints: Efficacy in inflammatory pain in subjects with active musculoskeletal disease
- **Secondary endpoints:** Efficacy in overall disease activity, musculoskeletal disease, and quality of life, safety and tolerability, biomarkers of inflammation, metabolipidomic profile, PK
- Patient number: 100 adults with SLE at 10 U.S. sites
- Treatment duration: 84 days treatment with 28 days follow-up
- Dose response: 5 mg/day, 20 mg/day and 20 mg/day twice a day



#### SCIENTIFIC ADVISORS AND PRINCIPAL INVESTIGATORS

#### Scientific Advisors

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#### **Principal Investigators**

James Chmiel, MD US PI for Cystic Fibrosis



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Meggan Mackay, MD
Investigator, The Feinstein Institute

HOFSTRA NORTHWELL SCHOOL OF MEDICINE AT HOFSTRA UNIVERSITY

#### FINANCIAL PROFILE: CRBP (NASDAQ)

## **Current Capital is Sufficient to Fund Operations to End of 2018**

\$311MM Market cap\*

50.2MM

Common shares outstanding

(57.8MM fully diluted)\*\*

\$78MM

Raised to-date

\$20MM

non-dilutive funding from N.I.H. and CF Foundation 1.3MM

50d average daily volume\* \$49MM

Cash balance\*\*



<sup>\*</sup> Based on May 8, 2017 closing price of \$6.20 per share
\*\* Cash balance as of March 31, 2017

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