# 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 8, 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 File Number)(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.

Corbus Pharmaceuticals Holdings, Inc. (the "Company") is using 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: March 8, 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.

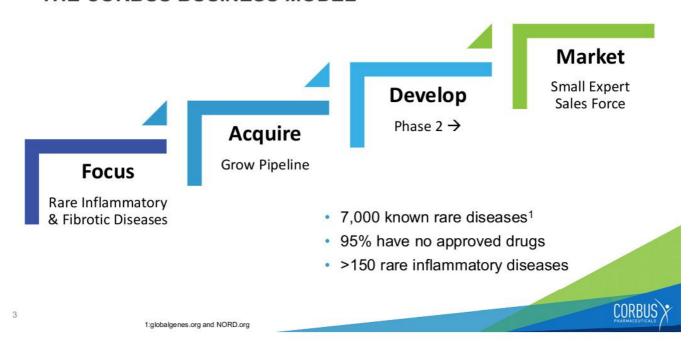


### FORWARD-LOOKING STATEMENTS

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 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.



# 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



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.

Board-certified Rheumatologist and clinical immunologist. Previously SVP and Head, R&D Stiefel, VP and Head of Inflammation Clinical Development for UCB & Med Immune, 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
- 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)

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### **JBT-101**

- · Novel synthetic oral endocannabinoid-mimetic with unique MOA
- · First-in-class therapeutic currently targeting four indications
- IP portfolio → 2033

Approval Systemic Sclerosis Phase 2 completed and positive data released Q4 2016 2019 (SSc) Orphan Designation + Fast Track Status + Open-Label Extension **Cystic Fibrosis** Phase 2 completed and data expected Q1 2017 2021 Award from CFF<sup>1</sup> (CF) Orphan Designation + Fast Track Status Dermatomyositis 2022 Phase 2 data expected Q3 2017 + Open-Label Extension Grant Funded<sup>2</sup> (DM) **Systemic Lupus** Anticipated Phase 2 study launch H1 2017 Grant 2023 **Erythematosus (SLE)** Funded<sup>2</sup>

1) As of September 30, 2016 Corbus has received \$3.5MM of the \$5.MM CFF award
2) NIH grants fund Phase 2 trials of JBT-101 in dermatomyositis and systemic lupus erythematosus; Corbus retains all rights to the product and owns the IND data



Anticipated

# **EXPECTED NEAR-TERM MILESTONES**

Q1 2017

- Q2 2017
- Q4 2017

• Topline data from CF Phase 2 ✓ ODD for SSc in EU

✓ SSc meeting with FDA

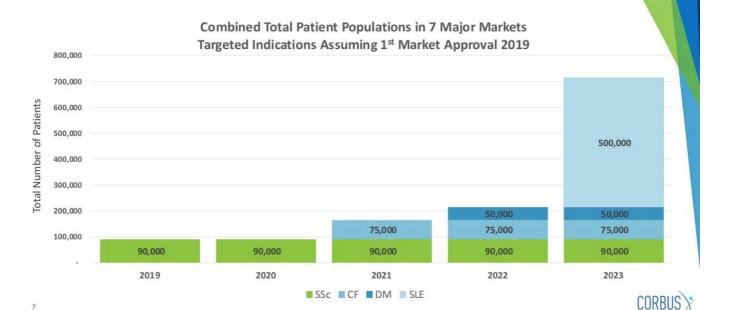
- · Complete enrollment of DM study
- · Launch Phase 2 SLE study
- EULAR conference
- · ECFS conference
- Launch next SSc study

Q3 2017

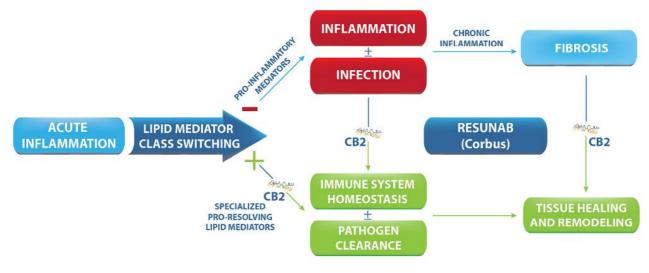
- · Topline data DM study
- Launch next CF study
- NACFC conference
- ACR conference

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# MARKET SIZE INCREASE WITH ADDITIONAL INDICATIONS



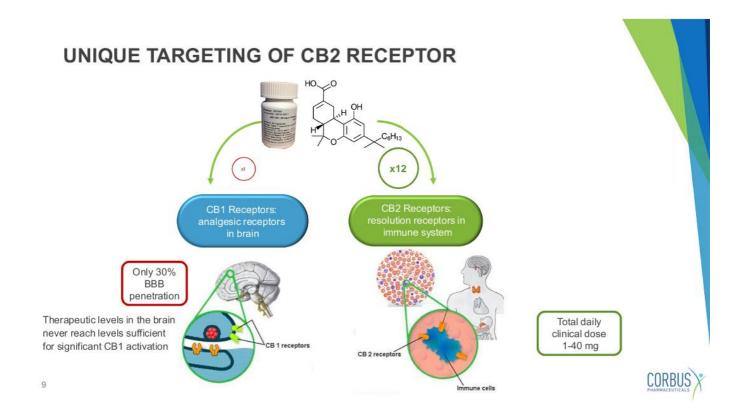
# JBT-101 RESTORES HOMEOSTASIS DURING PATHOLOGIC IMMUNE RESPONSES



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Adapted from REIRE & VAN DYKE. Natural resolution of inflammation. Period ontology 2000, 2013;63:149–164





# 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

40%-60% Mortality in 10 Years

# **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



# JBT101-SSc-001 PHASE 2 TRIAL DESIGN

- Double-blind, randomized, placebo-controlled, Phase 2 trial (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 JBT-101: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 (CRISS) score

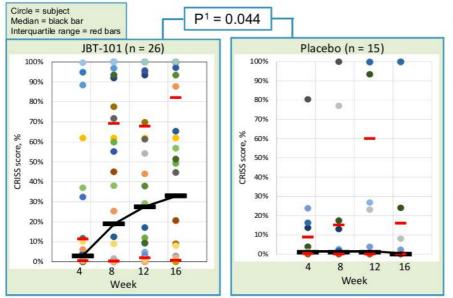
### **Secondary Objectives**

- Evaluate efficacy using categories of CRISS response and each CRISS domain
- Evaluate efficacy with other patient-reported outcomes



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# DISTRIBUTION OF ACR-CRISS SCORES BY WEEK



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

#### Statistical analysis

- Statistical hypothesis is JBT-101 will provide clinical benefit compared to placebo
- CRISS scores are not normally distributed

(Khanna et al, Arthritis Rheumatol 2016; 68:299)

 Use of non-parametric descriptive statistics and statistical analyses is indicated

(Schlenker. Methods Mol Bio 2016;1366:271)

 The mechanism of action of JBT-101 - activation of resolution of innate immune responses – may allow persistence of clinical benefit for a time after treatment is stopped, hence, planned analysis across 16 weeks



# **CRISS SCORES BY WEEK**

### JBT-101 Trial

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

Group	CRISS Score <sup>1</sup> , % Median (Interquartile Range or IQR) <sup>2</sup>							
,	Week 4	Week 8	Week 12	Week 16				
JBT-101, 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)				
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)				

Drug	CRISS Score, % Median (IQR)
	Week 52
Cyclophosphamide <sup>3</sup>	24.0
N = 45	(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.

Given CRISS score ≥ 20% is medically significant<sup>4</sup>, the majority of JBT-101 subjects achieve a medically significant response

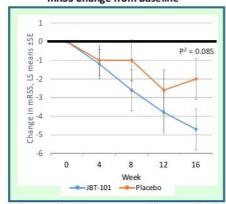


<sup>5</sup> Khanna et al, ACR abstract 2016.

# **CHANGE IN MODIFIED RODNAN SKIN SCORE**

- Lower score = less skin involvement. Improvement is a reduction in score.
- Estimates of the minimal important improvement in mRSS are between 3.2-5.2 points (Khanna et al, Ann Rheum Dis 2006;65:1325).

#### mRSS Change from Baseline



#### <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	chang	nean (SD) ge from eline	
			Active	Placebo	
Six drug trials, all subjects combined <sup>3</sup>	492	~26 weeks	-2.9 (7.2)		
Tocilizumab <sup>4</sup>	77	77	24 weeks	-3.9	-1.2
Cyclophosphamide <sup>5</sup>	84	52 weeks	-5.3	-1.7	
N	02	Baseline	24.0 (9.8) <sup>7</sup>		
Mycophenolate <sup>6</sup>	93	12 weeks	22.4	(8.9)	

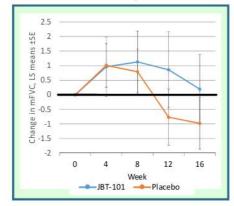
- <sup>3</sup> α interferon, d-penicillamine, relaxin Ph 2 and 3, minocycline, methotrexate, anti-TGFB, Merkel et al, Arthritis Rheum 2012;64:3420. <sup>4</sup> Khanna et al, Lancet 2016;387:2630. <sup>5</sup> Khanna et al, ACR abstract 2016. <sup>6</sup> Le et al, Ann Rheum Dis 2011; 70: 1104. <sup>7</sup> Absolute mRSS, mean (SD),
- not change from baseline.
- JBT-101 subjects had greater improvement in mRSS than placebo subjects
- The mean degree of improvement in mRSS in JBT-101 subjects was ~ minimal important improvement
- The mRSS results with JBT-101 compare favorably with data from comparator trials



# CHANGE IN FORCED VITAL CAPACITY (FVC), % PREDICTED

• Higher value = greater FVC % predicted. Improvement is an increase in FVC % predicted.

#### FVC % Predicted, Change from Baseline<sup>1</sup>



Drug	N	Time	FVC, % predicted, mea (SD) change from baseline		
			Active	Placebo	
Six different drug trials combined <sup>2</sup>	379	~26 weeks	-1.7 (9.0)		
Tocilizumab <sup>3</sup>	77	24 weeks	-0.7 -4.5		
Cyclophosphamide <sup>4</sup>	87	52 weeks	-1.2 -2.8		

**Previous Comparator Trials** 

At Weeks 12 and 16, JBT-101 subjects had a mild increase or stability in FVC, % predicted, compared to placebo subjects



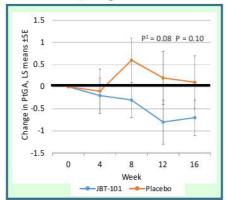
 $<sup>^2</sup>$   $\alpha$  interferon, d-penicillamine, relaxin Ph 2 and 3, minocycline, methotrexate, anti-TGFB. Merkel et al, Arthritis Rheum 2012;64:3420.  $^3$  Khanna et al. Lancet 2016;387:2630.  $^4$  Khanna et al, ACR abstract 2016. Subjects selected for lung involvement.

 $<sup>^{\</sup>rm 1}$  Efficacy population, least squares means  $\pm$  SE.

# **CHANGE IN PATIENT GLOBAL ASSESSMENT (PtGA)**

- Lower score = better global health assessment. Improvement is a reduction in score.
- The minimal important improvement in PtGA is -0.67 points, adjusted for as scale of 1-10 (Sekhon et al, J Rheumatol 2010;37:591).

### PtGA, Change from Baseline



#### **Previous Comparator Trials**

Drug	N	Time	PtGA, mean (SD) change from baseline		
			Active	Placebo	
Six different drug trials combined <sup>2</sup>	439	~26 weeks	018	(2.27)3	
To cil izumab <sup>4</sup>	84	24 weeks	-0.233³	0.1523	
Cyclophosphamide <sup>5</sup>	84	52 weeks	-0.42 -0.23		

<sup>2</sup> α interferon, d-penicillamine, relaxin Ph 2 and 3, minocycline, methotrexate, anti-TGFβ. Merkel et al, Arthritis Rheum 2012;64:3420. <sup>3</sup> PtGA scale adjusted from 0-100 to 0-10 to match scale in current trial. <sup>4</sup> Khanna et al, Lancet 2016;387:2630. <sup>3</sup> Khanna et al, ACR abstract 2016.

- · JBT-101 subjects had greater improvement in PtGA
- The mean degree of improvement in PtGA in JBT-101 subjects was ~ minimal important difference at Wk 12
- · The PtGA results with JBT-101 compare favorably with data from multiple comparator trials

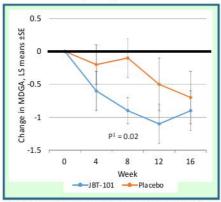


<sup>&</sup>lt;sup>1</sup> Efficacy population, least squares mean difference, analysis of covariance mode, one-sided p value

# CHANGE IN PHYSICIAN GLOBAL ASSESSMENT (MDGA)

Lower score = better global health assessment. Improvement is a reduction in score.

#### MDGA, Change from Baseline



<sup>1</sup> Efficacy population, least squares mean difference, analysis of covariance model, one-sided p value

#### **Previous Comparator Trials**

Drug	N	Time	MDGA, mean (SD) change from baseline			
			Active	Placebo		
Tocilizumab <sup>2</sup>	80 24 weeks		-0.83 <sup>3</sup>	-0.73		
Relaxin <sup>4</sup>	189	24 weeks	-0.723	-0.80		
Methotrexate <sup>5</sup>	Base		5.1 (0.4)6	5.8 (0.4)		
Methotrexate <sup>2</sup>	62	12 weeks	5.2 (0.4)	5.7 (0.3)		
Cyclophosphamide <sup>7</sup>	80	52 weeks	0.047	1.0		
	-		1			

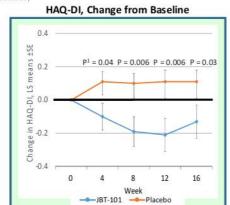
<sup>2</sup> Khanna et al, Lancet 2016;387:2630. <sup>3</sup> PtGA scale adjusted from 0-100 to 0-10 to match scale in current trial. <sup>4</sup> Khanna et al, Arthritis Rheum 2009;60:.1102 <sup>3</sup> Pope et al, Arthritis Rheum 2001;44:1351. <sup>6</sup> Data at baseline and 12 weeks are MDGA values, mean (SD), not MDGA change from baseline. <sup>7</sup> Khanna et al, ACR abstract 2016. <sup>8</sup> MDGA extrapolated.

- JBT-101 subjects had greater improvement in MDGA
- · JBT-101 subjects had less worsening of MDGA
- · The MDGA results with JBT-101 compare favorably with data from multiple comparator trials



# **CHANGE IN HAQ-DI**

- Lower score = less functional impairment. Improvement is reduction in score.
- Minimum important difference (MID) for improvement is a reduction in HAQ-DI = 0.10 0.14 and more than MID improvement is > 0.21 (Khanna et al, Ann Rheum Dis 2006:65:1325)



#### <sup>1</sup> Efficacy population, least squares mean difference, analysis of covariance model, one-sided p value.

### **Previous Comparator Trials**

Drug	N	Time	HAQ-DI, mean (SI change from baseline		
			Active	Placebo	
Six different drug trials combined <sup>2</sup>	600	~26 weeks	0.05 (0.45)		
Tocilizumab <sup>3</sup>	84	24 weeks	0.14	0.12	
Cyclophosphamide <sup>4</sup>	80	52 weeks	-0.13 0.1		

 <sup>&</sup>lt;sup>2</sup> α interferon, d-penicillamine, relaxin Ph 2 and 3, minocycline, methotrexate, anti-TGFβ. Merkel et al, Arthritis Rheum 2012;64:3420.
 <sup>3</sup> Khanna et al Lancet 2016;387:2630.
 <sup>4</sup> Khanna et al, ACR abstract 2016.

- · JBT-101 subjects had a mean improvement in HAQ-DI, whereas placebo subjects had a mean worsening
- The mean degree of improvement in HAQ-DI in JBT-101 subjects was more than the minimal important difference



# SAFETY: TREATMENT-EMERGENT ADVERSE EVENTS (TEAEs)

- No unexpected TEAEs related to JBT-101
- · 2 serious TEAEs, both unrelated to study drug
  - JBT-101: dehydration of moderate severity treated in hospital
  - · Placebo: abdominal pain and nausea of severe severity treated in hospital
- · Only 2 severe TEAEs occurred, both in a subject on placebo
- 17 (63.0%) versus 9 (60.0%) of JBT-101 versus placebo subjects experienced any TEAE
- 66 total TEAEs in the JBT-101 group versus 34 total TEAEs in the placebo group

JBT-101 shows no signs of immunosuppression



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### CONCLUSIONS

- In a 16 week study in diffuse cutaneous SSc, JBT-101 provided significant and medially meaningful efficacy, as assessed with the ACR CRISS score
- Results of multiple secondary efficacy outcome measures consistently support efficacy of JBT-101 in diffuse cutaneous SSc
- The safety profile of JBT-101 was acceptable, with no serious, severe, or unexpected treatment-related adverse events associated with JBT-101 treatment
- · JBT-101 was well tolerated
- The risk:benefit profile of JBT-101 in diffuse cutaneous SSc is favorable to date and supports discussions with regulatory authorities about next steps
- These data support cannabinoid receptor type 2 as a target for chronic inflammatory and fibrotic diseases

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# JBT-101-SSc-001 OPEN-LABEL EXTENSION

- 12-month open-label extension study granted by FDA 04/16 & launched 09/16
- · Goal of the open-label extension is to collect long term safety and efficacy data
- All subjects in the extension study are receiving JBT-101
- Same safety and efficacy endpoints used in the concluded double-blind placebocontrolled portion of the Phase 2 study

### **NEXT CLINICAL STEPS FOR JBT-101 IN SSc**

- Conducted end of Phase 2 Meeting with FDA on February 28, 2017
- Our proposal (subject to FDA approval) is a single pivotal Phase 3 study
- N = approximately 250-300, multinational study
- Expect to commence trial by the end of Q3 2017
- · Will seek Breakthrough designation





# **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



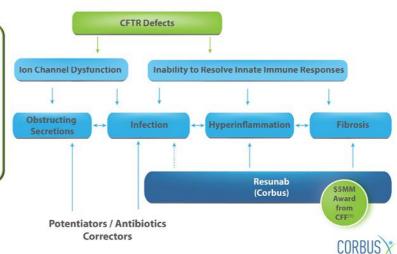
# JBT-101 IS UNIQUELY POSITIONED IN CF

# Change The CF Treatment Paradigm: Daily Foundational Treatment For All CF Patients

- √ 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

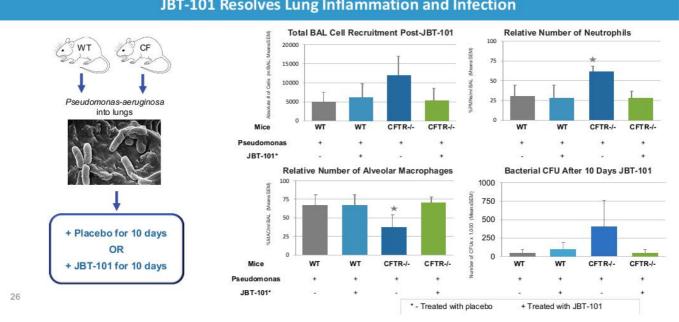


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1) As of September 30, 2016 Corbus has received \$3.5MM of the \$5.MM CFF award

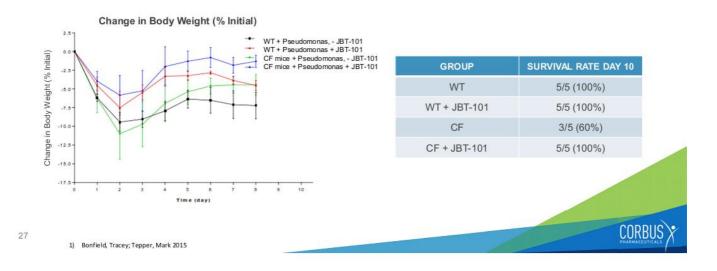
# PSEUDOMONAS-AERUGINOSA INFECTED CF MOUSE MODEL

# JBT-101 Resolves Lung Inflammation and Infection



# PSEUDOMONAS-AERUGINOSA INFECTED CF MOUSE MODEL

# JBT-101 Reduces Weight Loss and Improves Survival in CF Mice Infected with Pseudomonas



# JBT-101: CF PHASE 2 CLINICAL STUDY

# **Topline Data Expected March 2017**

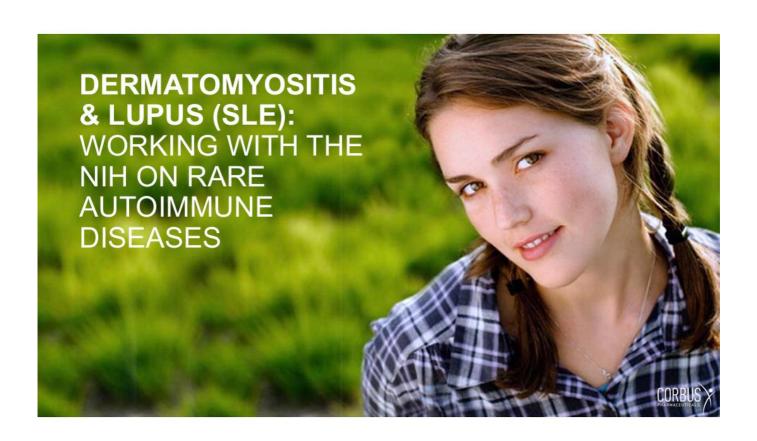
Primary Endpoint: Safety and Tolerability

Secondary Endpoint: Directional Trends in Efficacy + PK

Study Completed: Last patient last visit January 2017

- · Double blind randomized placebo control study in the U.S. and EU
- · Primary endpoints: Safety/tolerability
- Secondary endpoints: Trends in efficacy (FEV1, Lung Clearance Index, CFQ-R Respiratory Symptom Score) + PK
- Exploratory endpoints: Metabolipidomic profile for MOA, biomarkers of disease activity and inflammation in blood and sputum, and microbiota in the lungs
- Patient number: 83 adults with CF in ~25 sites U.S. & EU
- Treatment duration: 84 days treatment with 28 days follow-up
- Dose response: 1 mg/day, 5 mg/day, 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
IND open with FDA	✓							
Study launch		✓						
First patient dosed			1					
Expected to complete enrollment						1		
Anticipated last patient final dose							1	
Study duration			1	1	1	✓	<b>/</b>	×
Anticipated topline study data								×



# **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 read out expected in Q3 2017

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# JBT-101: DM PHASE 2 CLINICAL STUDY

# **Complete Patient Enrollment Expected Q2 2017**

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

Secondary Endpoint: Directional Trends in Efficacy

- · 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
- 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	<b>*</b>									
First patient dosed		✓								
Anticipated last patient dosed									×	
Study duration		4	4	4	4	4	4	X	×	X
Anticipated topline study data										_×_

# JBT-101-DM-001 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 JBT-101
- All subjects in the extension study are receiving JBT-101
- Same safety and efficacy endpoints used in the concluded double-blind placebocontrolled portion of the Phase 2 study



# 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
- Data read out expected in Q4 2018

## JBT-101: SLE PHASE 2 CLINICAL STUDY

# **Trial Expected to Start in H1 2017**

Primary Endpoint: Safety and Tolerability <u>Secondary Endpoint:</u>
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

de re de



Michael Knowles, MD, PhD

Charles N. Serhan, PhD



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

Daniel Furst, MD



### **Principal Investigators**

James Chmiel, MD
US PI for Cystic Fibrosis



Robert Spiera, MD US PI for Scleroderma



Victoria Werth, MD US PI for Dermatomyositis



Stuart Elborn, MD, FRCP EU PI for Cystic Fibrosis



Meggan Mackay, MD
Investigator, The Feinstein Institute



# FINANCIAL PROFILE: CRBP (NASDAQ)

\$448MM Market cap\* 48.7MM

Common shares outstanding

(56.4MM fully diluted)\*

\$64MM

Raised to-date

\$20MM

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

753K

50d average daily volume\*

\$39MM

Cash balance\*\*

\* Based on March 2, 2017 closing price of \$9.38 per share

\*\* Cash balance as of March 2, 2017



### CORBUS TO HOST RESEARCH AND DEVELOPMENT DAY

# March 13, 2017 - 11:00am - 1:00pm

- New data on JBT-101's mechanism of action in cystic fibrosis and inflammatory resolution models, biomarker data from our clinical Phase 2 trial in systemic sclerosis, and updates on our clinical development programs for JBT-101
- · Presenting Key Opinion Leaders:

#### James Chmiel, M.D., M.P.H.

Professor of Pediatrics, Case Western Reserve University, Associate Director of the LeRoy W. Matthews Cystic Fibrosis Center at University Hospitals Rainbow Babies and Children's Hospital in Cleveland, and Principle Investigator of the Company's Phase 2 cystic fibrosis clinical study

#### Derek Gilroy, Ph.D.

Head, Centre for Clinical Pharmacology and Professor of Immunology at Queen Mary College, University College London, and expert in resolution of inflammation

#### Michael Knowles, M.D.

Professor of Pulmonary and Critical Care Medicine at University of North Carolina Chapel Hill and member of the Company's Scientific Advisory Board, and expert in inflammation in CF

#### Michael L. Whitfield, Ph.D.

Department of Genetics, Dartmouth Medical School, and expert in gene expression patterns associated with systemic sclerosis

 Live video webcast and accompanying slide presentation available on the <u>Events</u> page of the <u>Investors</u> section of the Company's website at <u>www.CorbusPharma.com</u>

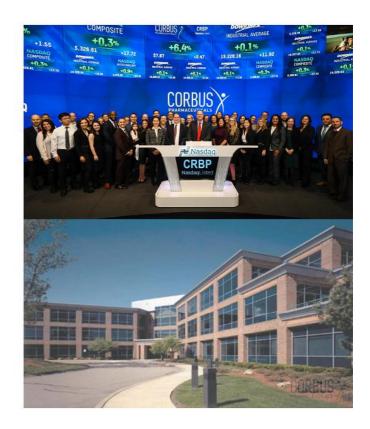


# **CONTACT US**

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# **APPENDIX**



# AN ATTRACTIVE SAFETY PROFILE

- · Dose-dependent, mild to moderate AEs, no SAEs, no significant lab abnormalities
- · Patients treated with JBT-101 with up to 240mg/d for up to 7 days
- · Consistent with class effects at all doses, no unexpected AE's

Treatment Emergent Adverse Event	All subjects all doses, number of subjects (% of 123 subjects who received any dose)			Subjects receiving doses ≥ 1 mg to ≤ 60 mg total daily dose, number of subjects (% of 52 subjects who received these doses)			Subjects receiving ≥ 80 mg to ≤ 240 mg total daily dose, number of subjects (% of 71 subjects who received these doses)		
	All TEAEs	Mild TEAEs	Moderate TEAEs	All TEAEs	Mild TEAEs	Moderate TEAEs	All TEAEs	Mild TEAEs	Moderate TEAEs
Dizziness	31 (18.8%)	18 (10.9%)	13 (7.9%)	3 (5.8%)	3 (5.8%)	0	28 (39.4%)	15 (21.1%)	13 (18.3%)
Nausea	19 (11.5%)	14 (8.5%)	5 (3.0%)	2 (3.8%)	2 (3.8%)	0	17 (23.9%)	12 (16.9%)	5 (3.0%)
Dry Mouth	14 (8.5%)	13 (7.9%)	1 (0.6%)	1 (1.9%)	1 (1.9%)	0	13 (7.9%)	12 (7.3%)	1 (0.6%)
Somnolence	10 (6.1%)	9 (5.5%)	1 (0.6%)	1 (1.9%)	1 (1.9%)	0	9 (5.5%)	8 (4.8%)	1 (0.6%)
Vomiting	10 (6.1%)	5 (3.0%)	5 (3.0%)	1 (1.9%)	1 (1.9%)	0	9 (5.5%)	4 (2.4%)	5 (3.0%)
Fatigue	9 (5.5%)	7 (4.2%)	2 (1.2%)	0	0	0	9 (5.5%)	7 (4.2%)	2 (1.2%)



# **CRISS SCORE**

Description	Advantages		
Single number between 0-1 or 0-100% that indicates overall improvement from baseline. Has floor and ceiling for responses	Measures overall improvement, not just improvement in skin or lungs		
Developed to reflect physician assessment of overall improvement	Endorsed by the American College of Rheumatology (Khanna et al, Arthritis Rheumatol. 2016; 68:299)		
Score includes change from baseline in five domains  •Two physician assessments – skin thickness (mRSS) and physician global assessment (MDGA)  •Two patient assessments – Health Assessment Questionnaire Disability-Index (HAQ-DI) and patient global assessment (PtGA)  •Forced vital capacity (FVC)	Rewards for improvement in more than one domain and penalizes for worsening in any domain. Subject must improve more than worsen to achieve CRISS score > 0.		
A no. 1 rank of importance in assessing improvement was assigned to mRSS (44.1%) > FVC, % predicted (14.9%) > PtGA (11.0%) > MDGA (9.1%) > HAQ-DI (8%) > other items	The domains of mRSS, FVC, % predicted, MDGA, and HAQ-DI all are associated with survival (Tyndall et al, Ann Rheum Dis 2010;69:1809; Harel et al, J Rheumatol 2016; 43:1510; Sultan et al, Rheumatology 2004;43:472)		
CRISS score ≥ 20% is considered medically significant (D. Khanna, Sderoderma Clinical Trials Consortium, 2016)			



# **BASELINE CHARACERISTICS OF SUBJECTS**

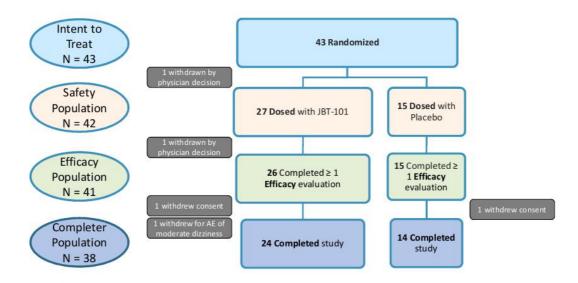
Characteristic	Safety Population			Efficacy Population			Meta-analysis of Six Previous Clinical	
Characteristic	JBT-101 n = 27	Placebo n = 15	P-value		Placebo n = 15	P-value	Trials <sup>2</sup> N = 629	
Female, %	85.2%	60.0%	NS <sup>3</sup>	84.6%	60.0%	NS	82%	
Age, mean (SD)	48.7 (10.4)	46.5 (11.1)	NS	48.8 ± 10.6	46.7 (11.2)	NS	46.5 (11.8)	
Caucasian, %	81.5%	80.0%	NS	80.8%	80.0%	NS		
Not Hispanic of Latino, %	81.5%	93.3%	NS	80.8%	93.3%	NS		
Disease duration <sup>1</sup> , months, mean (SD)	37.1 (19.0)	40.6 (19.5)	NS	38.7 (19.2)	40.6 (19.5)	NS	19.4 (15.9)	
Concomitant immunosuppressive or immuno-modulating drugs, n (%)	92.9%	80.0%	NS	100.0%	80.0%	P = 0.043	Usually prohibited except low dose corticosteroids	

Since first non-Raynaud's symptom. <sup>2</sup> Alpha interferon, d-penicillamine, relaxin Ph 2 and 3, methotrexate, minocycline, anti-TGFbeta, Merkel et al, Arthritis Rheum 2012;64:3420. <sup>2</sup> NS = Not statistically significant, P > 0.05, two-tailed t test for continuous data or two-tailed Fisher's exact test for categorical data

- Subjects have a broader range of disease duration and greater use of concomitant immunosuppressive / modulating drugs than subjects enrolled in previous trials in SSc
- Slightly higher use of immunosuppressive / modulating drugs in JBT-101 group may indicate a more refractory population



# SUBJECT DISPOSITION



1/27 (3.7%) subjects dosed with JBT-101 withdrew for an adverse event

