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**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 9, 2017

**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.)*

**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))

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.

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**Item 7.01. Regulation FD Disclosure.**

On November 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:

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#"><u>Investor Presentation</u></a>

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**CORBUS PHARMACEUTICALS HOLDINGS, INC.**

Dated: November 9, 2017

By: /s/ Yuval Cohen

Name: Yuval Cohen

Title: Chief Executive Officer

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## EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#"><u>Investor Presentation.</u></a>

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**CORBUS**  
PHARMACEUTICALS



**Developing Breakthrough  
Therapies for Rare Inflammatory  
and Fibrotic Diseases**

NASDAQ:CRBP

[www.corbuspharma.com](http://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.

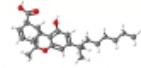
# Overview

Focus on rare, chronic, serious  
inflammatory and fibrotic diseases



Anabasum

First-in-class  
oral synthetic  
endocannabinoid mimetic



Phase 3 SSc Study

Expected Start  
**Q4 2017**



Positive Phase 2 data in 3 indications

Multiple value-driving milestones  
expected in Q4 2017



Intellectual Property



# Anabasum Pipeline: Multiple Opportunities in Rare Autoimmune / Inflammatory / Fibrotic Diseases

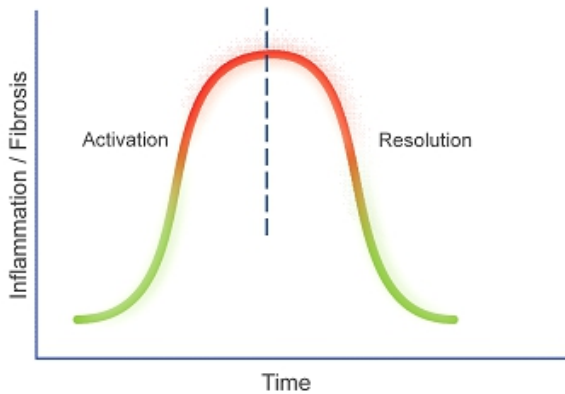
	Indication	Patient Population	Phase of Development	Orphan Designation	Fast Track Status	Open-Label Extension	Nondilutive Funding	Next Catalyst
Autoimmune	Systemic Sclerosis (SSc)	90,000 (US+EU)	Launch Phase 3	✓	✓	✓		Plan to commence Phase 3 study Q4 2017
	Dermatomyositis (DM)	70,000 (US)	Positive Phase 2			✓	NIH Funded <sup>1</sup>	Positive Topline Phase 2 data reported Q4 2017
	Systemic Lupus Erythematosus (SLE)	500,000 (US+EU)	Launch Phase 2				NIH Funded <sup>1</sup>	Plan to commence Phase 2 study Q4 2017
Genetic / Inflammatory	Cystic Fibrosis (CF)	75,000 (worldwide)	Launch Phase 2b	✓	✓		✓ CF Foundation <sup>2</sup>	Plan to commence Phase 2b study by EoY 2017

4 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  
 2) Awarded 2015; project completed



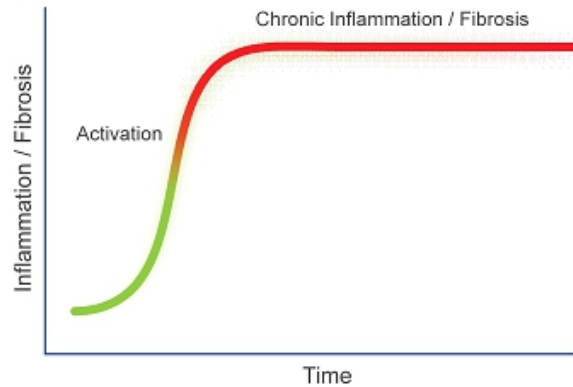
# Normal Inflammatory Process vs. Chronic Inflammation

**Normal Inflammation Process**



Immune System Returns to Homeostasis

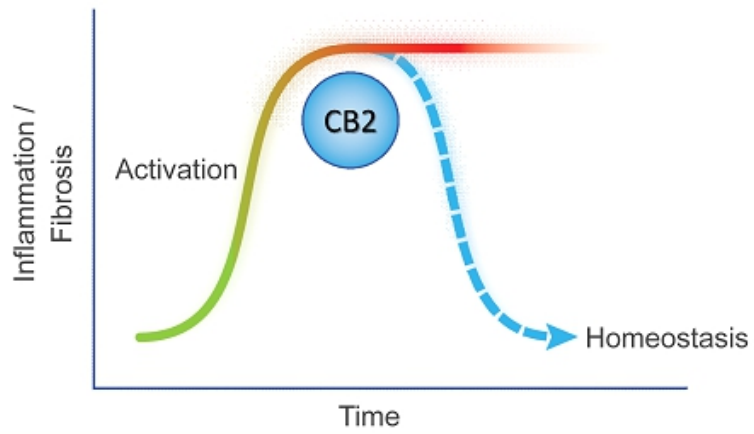
**Inflammatory / Fibrotic Disease**



Immune System is Unable to Return to Homeostasis, Leading to Fibrosis

# Anabasum Promotes Resolution of Inflammation and Fibrotic Responses

## Resolution of Chronic Inflammation and Fibrosis

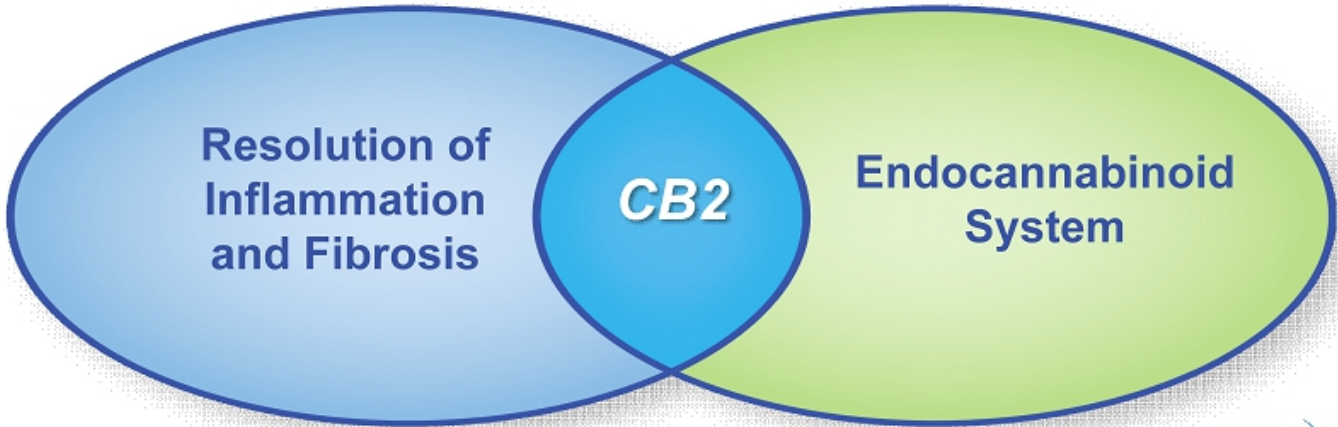


**MOA Applicable to Multiple Inflammatory / Fibrotic Diseases**



# Endocannabinoids Play a Unique Role in Inflammation and Fibrosis

MOA of CB2 agonism: triggers resolution of inflammation<sup>1</sup>



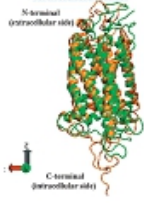





# The Endocannabinoid System Has a Dual Role

**Central Nervous System**


**CB1**



N-terminal (extracellular side)  
C-terminal (intracellular side)




CB1 receptors are mostly found in the brain




- Pain
- Nausea
- Spasms
- Appetite

**Immune System**


**CB2**



N-terminal (extracellular side)  
C-terminal (intracellular side)

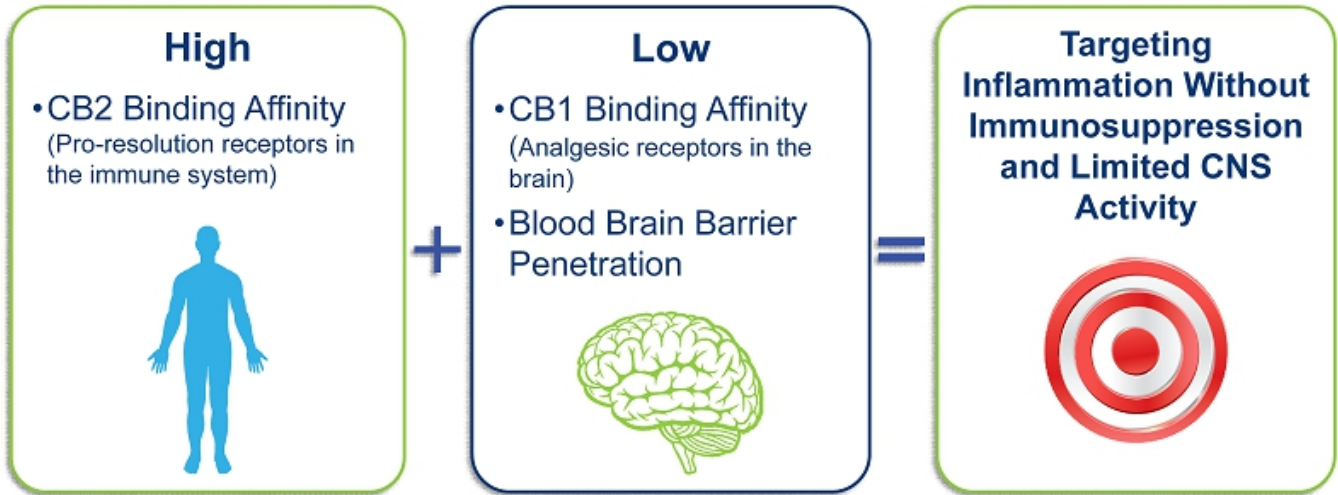


CB2 receptors are mostly within the immune system



- Immune modulation

• **Attractive Candidate for Rare + Chronic Inflammatory / Fibrotic Diseases**



# Diffuse Cutaneous Systemic Sclerosis:

- Positive Phase 2 data
- Ongoing open-label extension
  - Significant and clinically meaningful results demonstrated at 28-weeks
- Phase 3 study planned for Q4 2017
- Potential approval in 2020



# 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

Common cause of death -  
40%-60% mortality in 10 years



# Key Takeaways



Life-threatening, rare disease



No SSc-specific drugs approved



Current therapy:  
Immunosuppressive agents  
(safety risk)



Need for proven safe and  
effective therapies

CORBUS  
PHARMACEUTICALS

## Positive Results of Double-blinded, Placebo-controlled Portion of Trial Reported in November 2016



**43 Adults**  
**2:1** overall ratio of anabasum:placebo

**9** clinical sites across the U.S.



### Double-blind

randomized, placebo-controlled

**16** week study – 12 week active dosing



- Primary Endpoints:**
- Safety and tolerability
  - ACR CRISS

- Secondary Endpoints:**
- ACR-CRISS domains: mRSS; FVC % predicted; PtGA; MDGA; HAQ-DI
  - Patient-reported outcomes



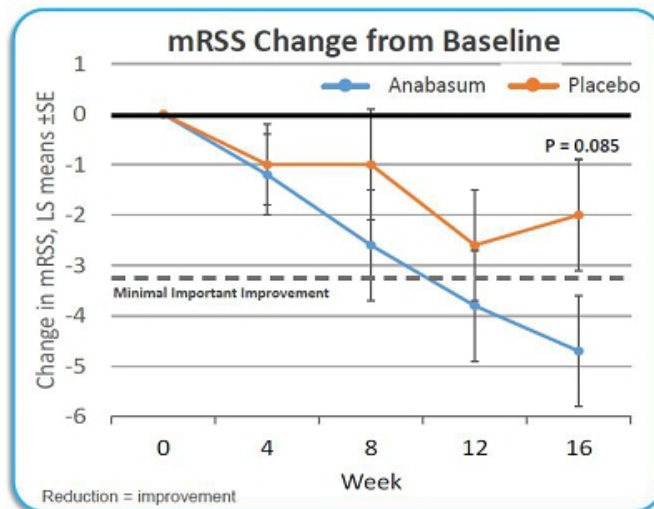


- **Anabasum was well tolerated**
- **No serious or severe anabasum-related TEAEs noted**
- **Most common adverse events were mild/moderate:**
  - Dizziness (22% in anabasum-treated subjects vs. 13% in placebo-treated subjects)
  - Fatigue (19% in anabasum-treated subjects vs. 7% in placebo-treated subjects)



## mRSS: Skin Thickening Improved

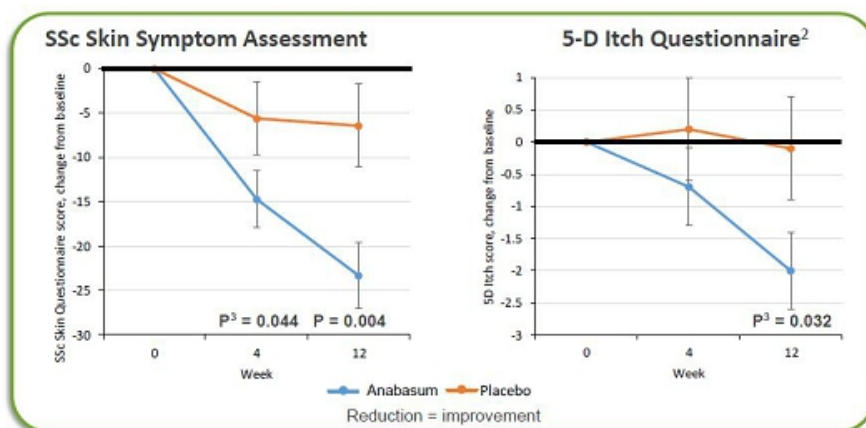
### Primary Endpoint in Planned Phase 3 Study







## Improved Patient Reported Skin Symptoms



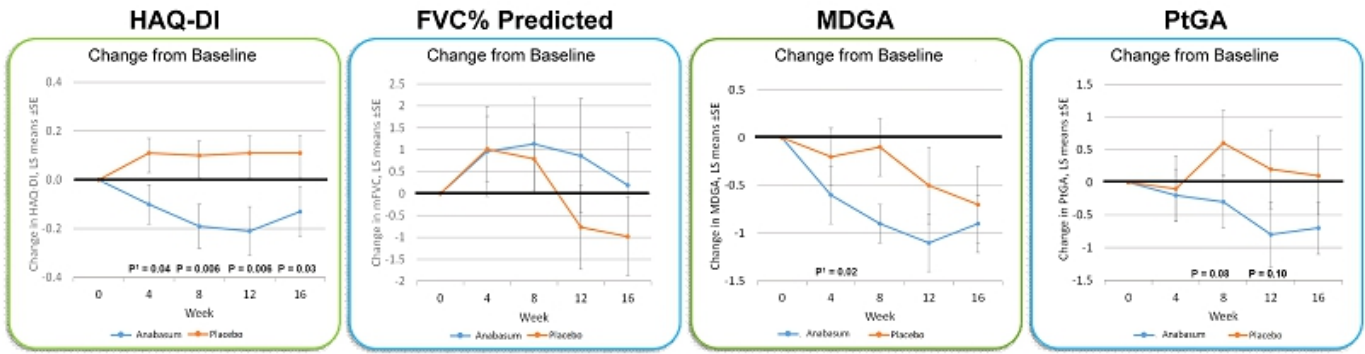
- Greater improvement in skin symptoms than placebo-treated subjects
- Improvements were seen as early as 4 weeks with anabasum treatment

1: Ziemek J et al. Rheumatology 2016;55:911. <sup>2</sup> Elman S et al. Br J Dermatol 2010;162:587.



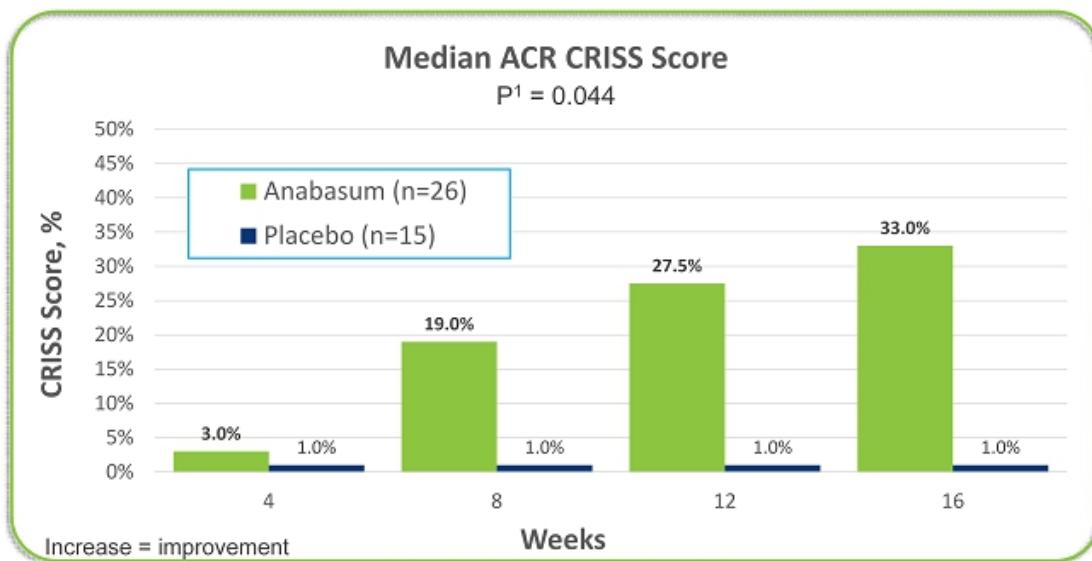


# Additional Efficacy Outcomes Favor Anabasum



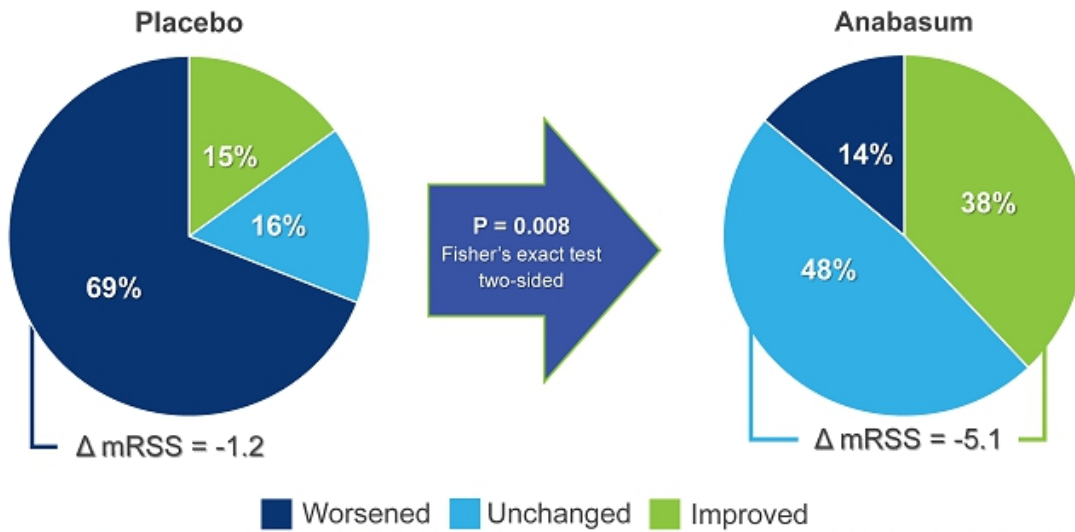


## Improvements in ACR-CRISS Scores



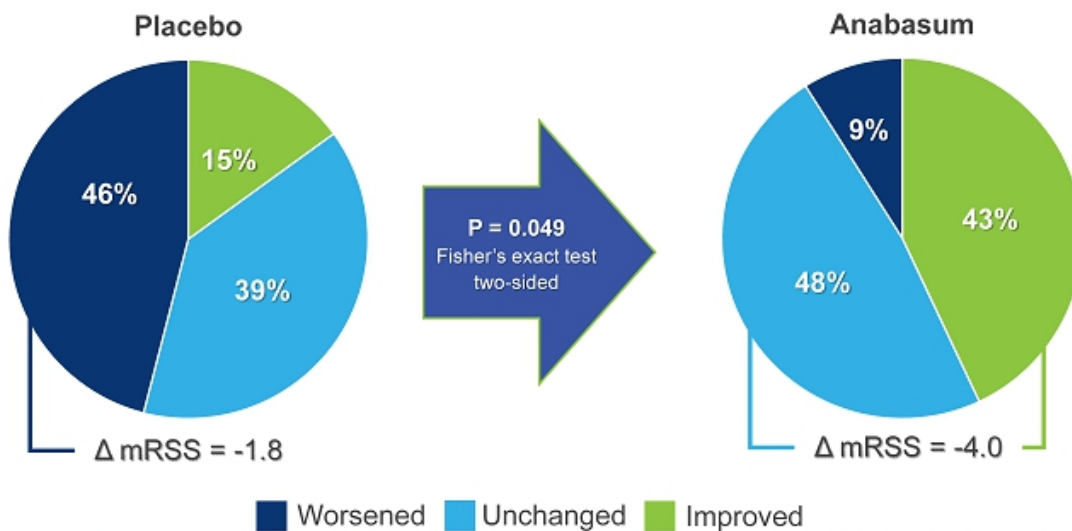
# On Target Effect: Anabasum Reduces *Inflammation* in Skin (Histology Analysis)

Change in *inflammation* after only 12 weeks of treatment



# On Target Effect: Anabasum Reduces *Fibrosis* in Skin (Histology Analysis)

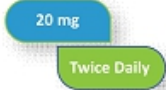
Change in *fibrosis* after only 12 weeks of treatment



# Ongoing Open-Label Extension - Significant Improvement in mRSS and Other Clinical Outcomes at 28-Weeks



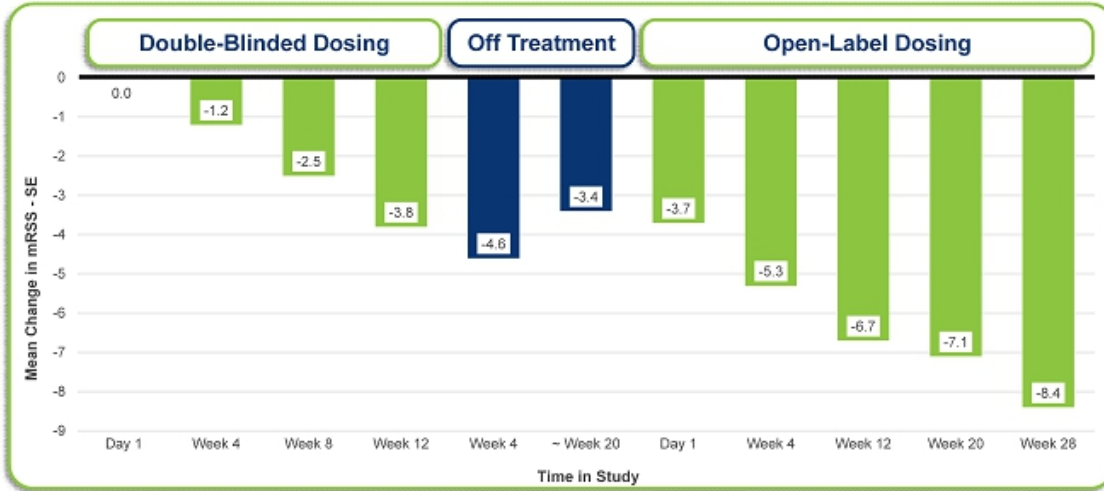
36 Adults



- Achieved reduction in mRSS of 8.4 points from start of study exceeding clinically important improvement
- 75% of subjects achieved degree of improvement in mRSS correlated with improved survival
- Clinical benefit supported by improvement in multiple secondary outcomes and a continued favorable safety profile
- No severe or serious adverse events (AEs) and no clinically significant laboratory abnormalities related to the drug
- Results were presented at the [2017 American College of Rheumatology \("ACR"\) Annual Meeting](#)

# Demonstrated Significant Improvement in mRSS in Open-Label Extension – Primary Outcome for Upcoming Phase 3

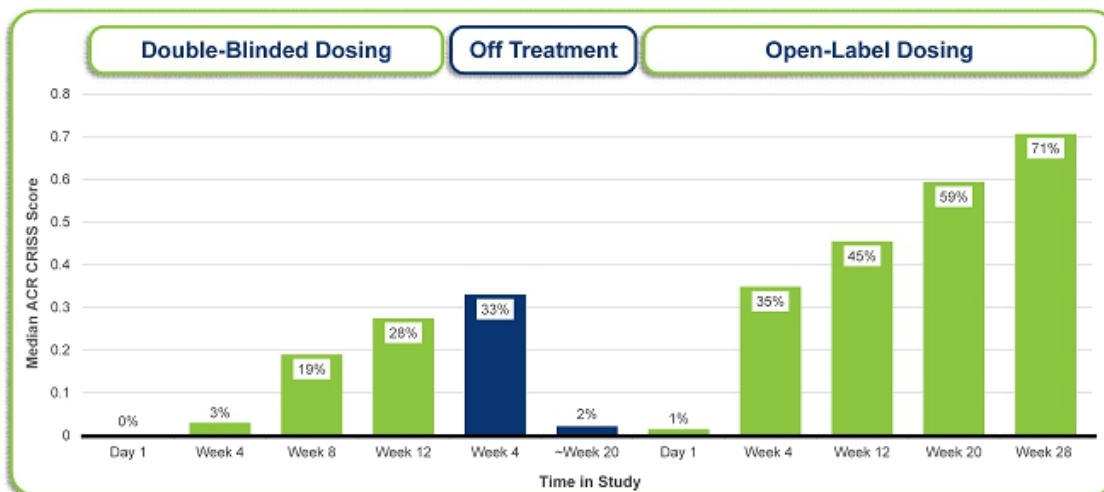
Achieved reduction in mRSS of 8.4 points from start of study  
( $p < 0.0001$ , 2-side paired t-test) exceeding clinically important improvement (-4.7 points)





## Improvement in ACR CRISS in Open-Label Extension

ACR CRISS reached 71% (median) from start of study with 44% of subjects achieving a score > 70%



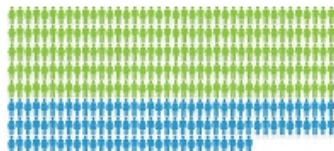


# Planned Design of Upcoming Phase 3 Study

Phase 3 Study Scheduled to Commence Q4 2017

~ 350 Subjects

1:1:1 overall ratio of  
anabasum:placebo



Multinational



Double-blind

randomized, placebo-controlled

52 week study

Dosing  
20 mg BID or  
5 mg BID or placebo

**Primary Endpoint:**

- Change from baseline in mRSS

**Secondary Endpoints:**

- Change from baseline in HAQ-DI
- ACR CRIS
- Change from baseline in FVC % predicted





## Cystic Fibrosis:

- Positive Phase 2 data
- Support from the Cystic Fibrosis Foundation
- Expect to commence Phase 2b study in Q4 2017



# 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 Takeaways



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

# PEx

## PULMONARY EXACERBATIONS

Cost  
\$95,000  
per episode



Annual rate



Multiple  
PEx per year



Frequency, severity  
increase with age  
and FEV1 impairment\*



Dangerous manifestation  
of lung disease



Shortness  
of breath, cough,  
sputum production  
and reduced FEV1



Increased  
inflammation  
precedes PEx



Irreversible lung  
function loss,  
including FEV1



## Design of Completed Phase 2 Study

Positive Data Announced March 2017

85 Adults



5:2 overall ratio  
of anabasum:placebo

21 clinical sites across  
the U.S. and Europe



Double-blind

randomized, placebo-controlled

16 week study – 12 week active dosing



### Primary Objectives:

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

### Secondary Objectives:

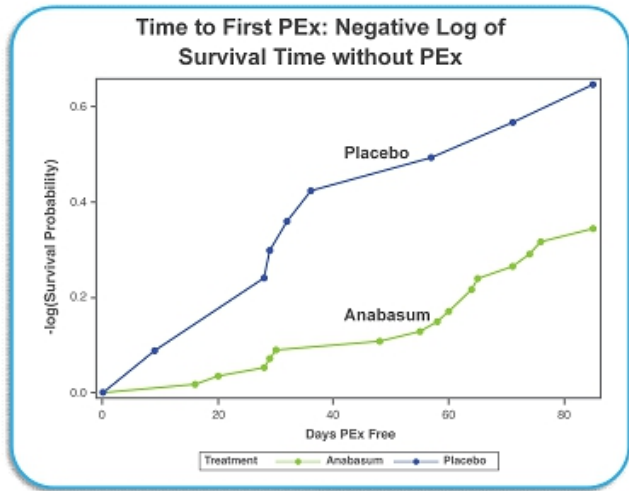
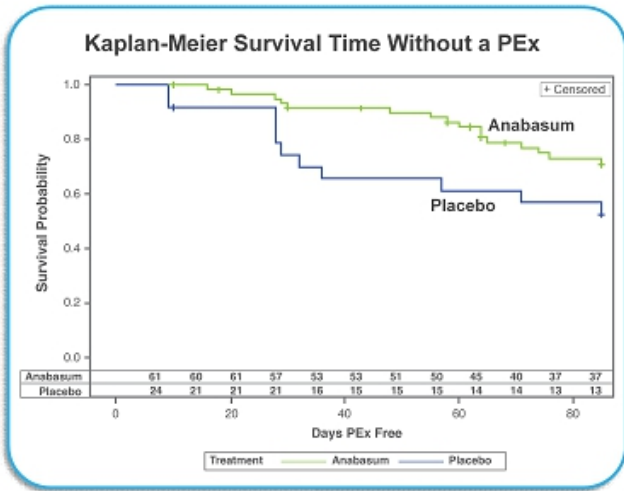
- FEV1 % predicted, lung clearance index and CFQ-R
- Blood and sputum biomarkers
- Microbiome in sputum
- Metabolipidomic profile
- Pharmacokinetics



## Safety and Tolerability Summary

- **Anabasum was well tolerated**
- **No serious or severe anabasum-related TEAEs noted**
- **Most common anabasum-related mild adverse event:**
  - Dry mouth (mild, 13% vs 0% in placebo)
- **FEV-1 remained stable throughout the study across all cohorts**

# Anabasum Increases Time to First New Pulmonary Exacerbations Treated with Oral or IV Antibiotics



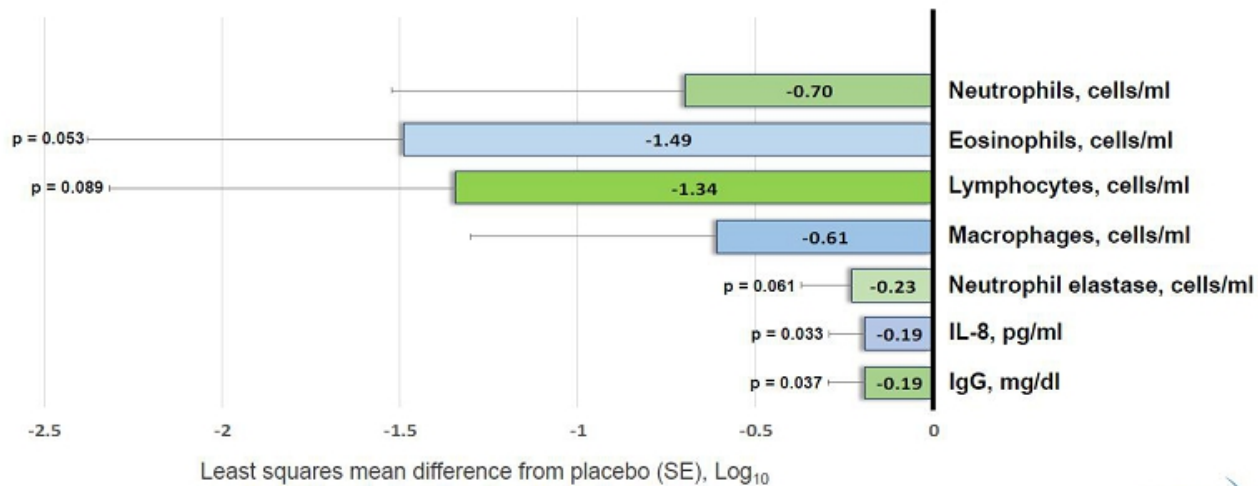
P = 0.047, Cox proportional hazard model, 2-sided, Hazard ratio = 0.452





## Consistent Reduction in Key Inflammatory Biomarkers (Sputum)

Reduction with anabasum 20 mg BID compared to placebo (Log<sub>10</sub>)



## Dermatomyositis:

- Positive Phase 2 data
- Late-breaking data presented at ACR
- Ongoing open-label extension





# Dermatomyositis

Chronic systemic autoimmune disease characterized by inflammation of skin and muscles

70,000

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 Takeaways



Treated with immunosuppressive therapies, but with significant toxicities



Single center study underway at University of Pennsylvania



Collaborating with NIH



# Dermatomyositis Phase 2 Clinical Study

**Positive Data Announced November 2017**

**22 Adults**



**1:1** overall ratio of anabasum:placebo

**1 Site -** University of Pennsylvania  
Perelman School of Medicine



**Double-blind**

randomized, placebo-controlled

**16** week study – 12 week active dosing



**Primary Endpoints:**

- Safety/tolerability
- Change in skin activity using CDASI

**Secondary Endpoints:**

- Quality of life and disease activity outcomes
- Biomarkers of inflammation and disease activity in blood and skin
- Metabolipidomic profile

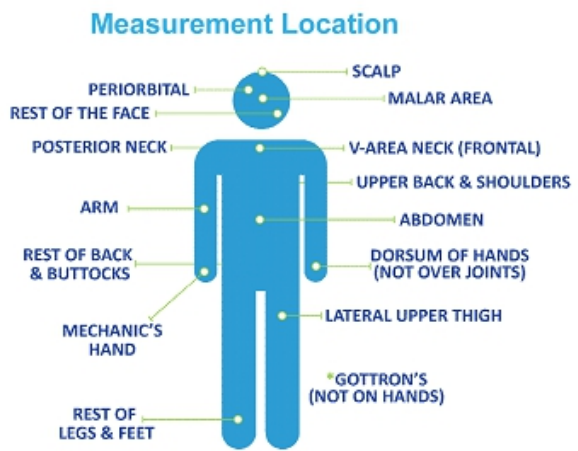
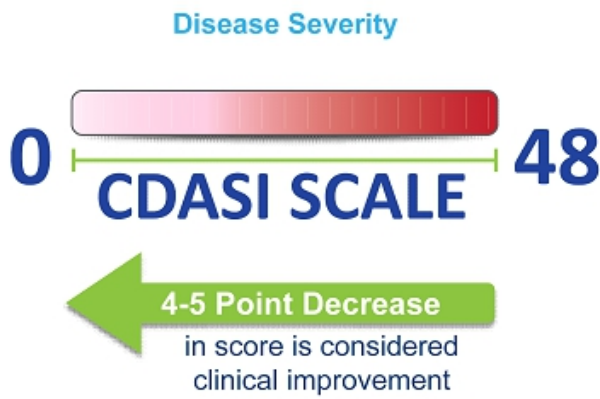


## Safety and Tolerability Summary

- **Anabasum was well tolerated and demonstrated a favorable safety profile**
- **No evidence of immunosuppression**
- **No serious or severe side effects related to anabasum**
- **No subjects dropped out of the study**

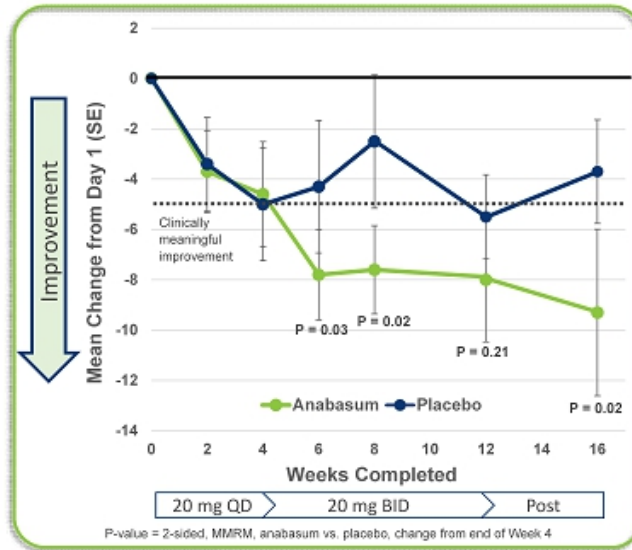
# Cutaneous Dermatomyositis Disease Area and Severity Index (CDASI)

CDASI was developed to measure multiple inflammatory elements in the skin<sup>1</sup>

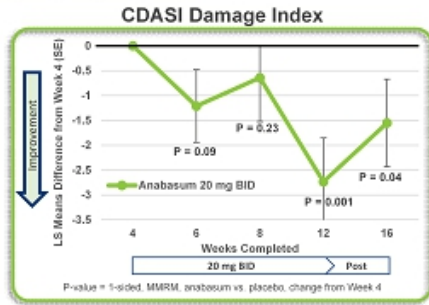
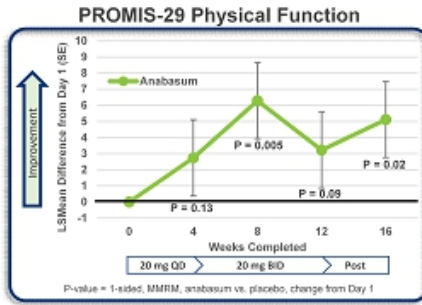
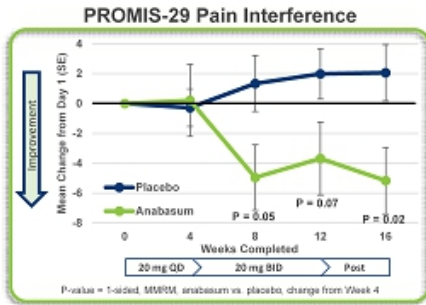
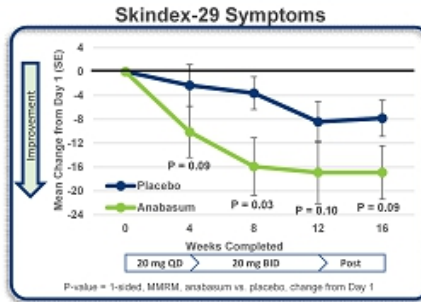
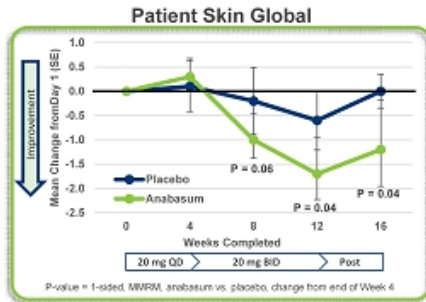


# CDASI Score – Anabasum Demonstrated Clinically Meaningful Improvement

Anabasum improved CDASI by 9.3 vs. 3.7 for placebo;  $p = 0.04$ , 2-sided MMRM



# Additional Efficacy Outcomes Favor Anabasum



## Strong Evidence of Clinical Benefit Merits Further Development in Dermatomyositis

- **First potential treatment for skin-predominant dermatomyositis to show clinical benefit in a double-blind, randomized, placebo-controlled trial**
- **Will meet with regulatory authorities to review data and determine next steps in clinical development plan**

# Management Team



**Yuval Cohen, PhD**  
*Chief Executive Officer, Director*

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



**Mark Tepper, PhD**  
*President & Chief Scientific Officer*

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



**Sean Moran, CPA, MBA**  
*Chief Financial Officer*

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



**Barbara White, MD**  
*Chief Medical Officer*

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

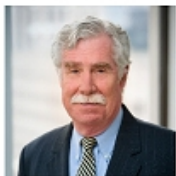


# Board of Directors



**Amb. Alan Holmer Ret.- 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) Catlin**

- CFO Celldex Therapeutics (CLDX) since 2000
- 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.



**Renu Gupta, MD**

- Over 25 years of R&D, regulatory and senior management experience in the biopharma industry
- Former EVP, and CMO of Insmmed, a specialty CF company
- Former VP and Head of U.S. Clinical Research and Development, Novartis
- Senior Advisor to CEOs and Boards of biopharma



**Paris Panayiotopoulos**

- Former President and Chief Executive Officer and a member of the Board of Directors of ARIAD Pharmaceuticals, Inc., which was acquired by Takeda Pharmaceuticals for \$5.2 billion
- Former President of EMD Serono, Inc., President of the Serono Research and Development Institute and President of Merck Serono, Tokyo, Japan
- Has led multiple partnerships, including those with Pfizer Inc., Bristol-Myers Squibb Company, Eli Lilly and Company, Sumitomo Dainippon Pharma Co., Ltd., Mitsubishi Tanabe Pharma Corporation, Otsuka Pharmaceutical Co. Ltd. and Incyte Corporation



## Scientific Advisory and Principal Investigators

### Scientific Advisors

Michael Knowles, MD



THE UNIVERSITY  
of NORTH CAROLINA  
at CHAPEL HILL

Charles Serhan, PhD



HARVARD  
MEDICAL SCHOOL

### Principal Investigators

Robert Spiera, MD  
US PI – SSc



HOSPITAL FOR  
SPECIAL SURGERY

Christopher Denton, PhD, FRCP  
EU PI – SSc



Royal Free London **NHS**  
NHS Foundation Trust

James Chmiel, MD  
US PI – CF



CASE WESTERN RESERVE  
UNIVERSITY — EST. 1866  
think beyond the possible

Stuart Elborn, MD, FRCP  
EU PI – CF



Royal Brompton & Harefield **NHS**  
NHS Foundation Trust

Victoria Werth, MD  
US PI – DM



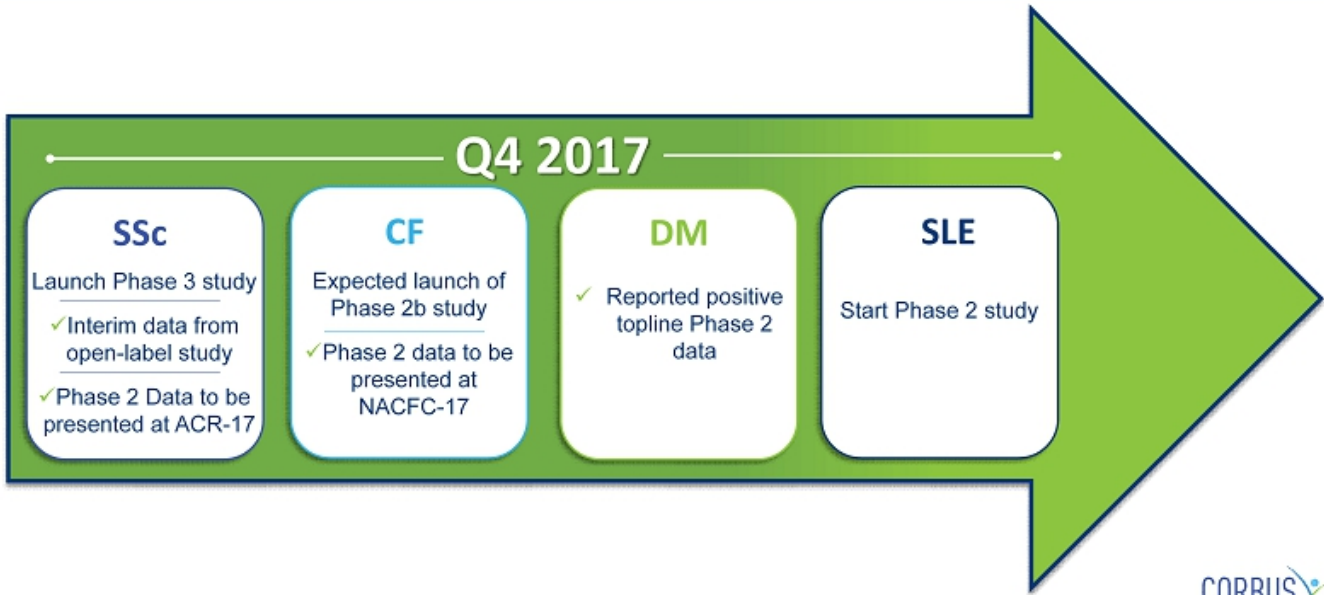
**Penn**  
The State of Pennsylvania

Meggan Mackay, MD  
US PI – SLE



HOFSTRA NORTHWELL  
SCHOOL of MEDICINE  
AT HOFSTRA UNIVERSITY

# Expected Milestones in Q4 2017





## Financial Profile: CRBP (NASDAQ)

**\$376MM**  
Market cap\*





**54.9MM**  
Common shares  
outstanding  
(63.9MM fully diluted)\*\*

**\$115MM**  
Raised to-date  
+  
**\$20MM**  
non-dilutive funding from  
N.I.H. and CF Foundation

**740K**  
50 day average  
daily volume\*

**\$64MM**  
Cash balance\*\*

# Summary

<p>Focused on rare diseases with no current approved therapies</p>	
<p>First-in-class drug targeting inflammation + fibrosis</p>	
<p>Positive Phase 2 data in 3 indications</p>	
<p>Solid execution with multiple milestones expected in Q4 2017</p>	

# CONTACT US

**Corbus Pharmaceuticals  
Holdings, Inc.**

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