
**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): June 7, 2017

CORBUS PHARMACEUTICALS HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware
*(State or other jurisdiction
of incorporation)*

000-55327
*(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 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 7.01. Regulation FD Disclosure.

On June 7, 2017, Corbus Pharmaceuticals Holdings, Inc. (the “Company”) will be 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:

<u>Exhibit No.</u>	<u>Description</u>
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.

Corbus Pharmaceuticals Holdings, Inc.

Dated: June 7, 2017

By: /s/ Yuval Cohen

Name: Yuval Cohen

Title: Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Investor Presentation.



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

NASDAQ:CRBP

www.corbuspharma.com





Forward-Looking Statements

This presentation contains certain forward-looking statements, including those relating to the Company's product development, clinical trials, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statements that are predictive in nature. Additional written and oral forward-looking statements may be made by the Company from time to time in filings with the Securities and Exchange Commission (SEC) or otherwise. The Private Securities Litigation Reform Act of 1995 provides a safe-harbor for forward-looking statements. These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the SEC. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this presentation. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Management



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



Sean Moran, CPA, MBA
Chief Financial Officer

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



Mark Tepper, PhD
President & Chief Scientific Officer

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



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 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 in 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, MD

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



Targeting Rare + Chronic + Serious Inflammatory / Fibrotic Diseases

Anabasum:

- Novel synthetic oral endocannabinoid-mimetic with unique MOA
- 4 clinical programs
- Positive Phase 2 data: systemic sclerosis and cystic fibrosis
- Multiple opportunities to expand into additional indications
- IP portfolio → 2033

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	✓	✓	✓		Commence Phase 3 study H2 2017
	Dermatomyositis (DM)	50,000 (US+EU)	Phase 2			✓	✓ NIH Funded ¹	Phase 2 data expected H2 2017
	Systemic Lupus Erythematosus (SLE)	500,000 (US+EU)	Phase 2				✓ NIH Funded ¹	Commence Phase 2 study H2 2017
Genetic / Inflammatory	Cystic Fibrosis (CF)	75,000 (worldwide)	Launch Phase 2b	✓	✓		✓ CF Foundation ²	Commence Phase 2b study H2 2017

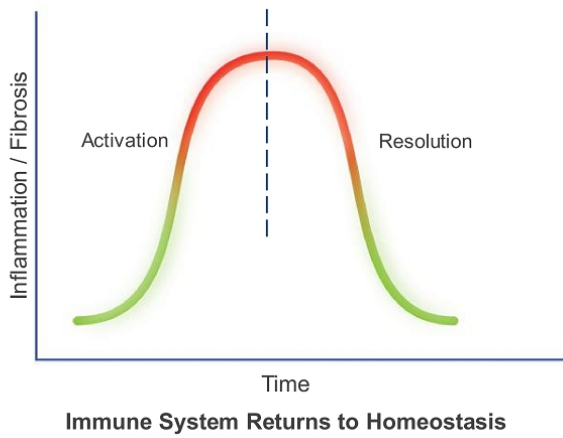
- 1) NIH grants fund Phase 2 trials of anabasum in dermatomyositis and systemic lupus erythematosus; Corbus retains all rights to the product and owns the IND data;
 2) Awarded 2015; project completed



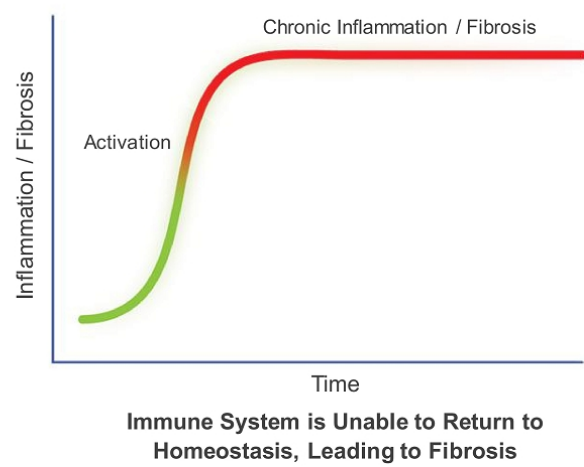


Normal Inflammatory Process vs. Chronic Inflammation

Normal Inflammation Process

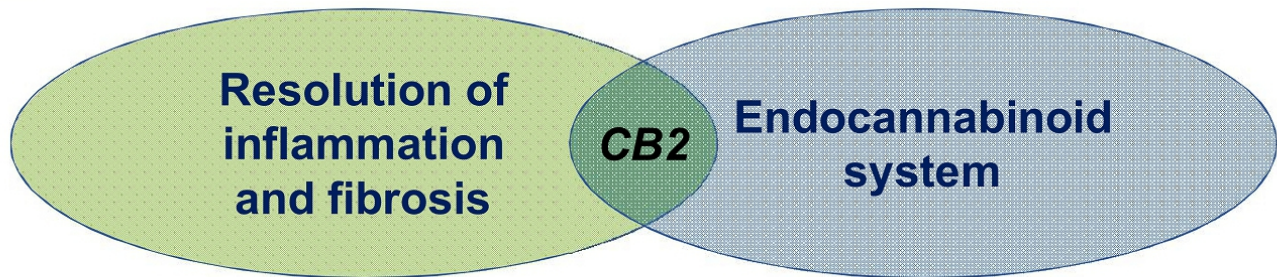


Inflammatory / Fibrotic Disease



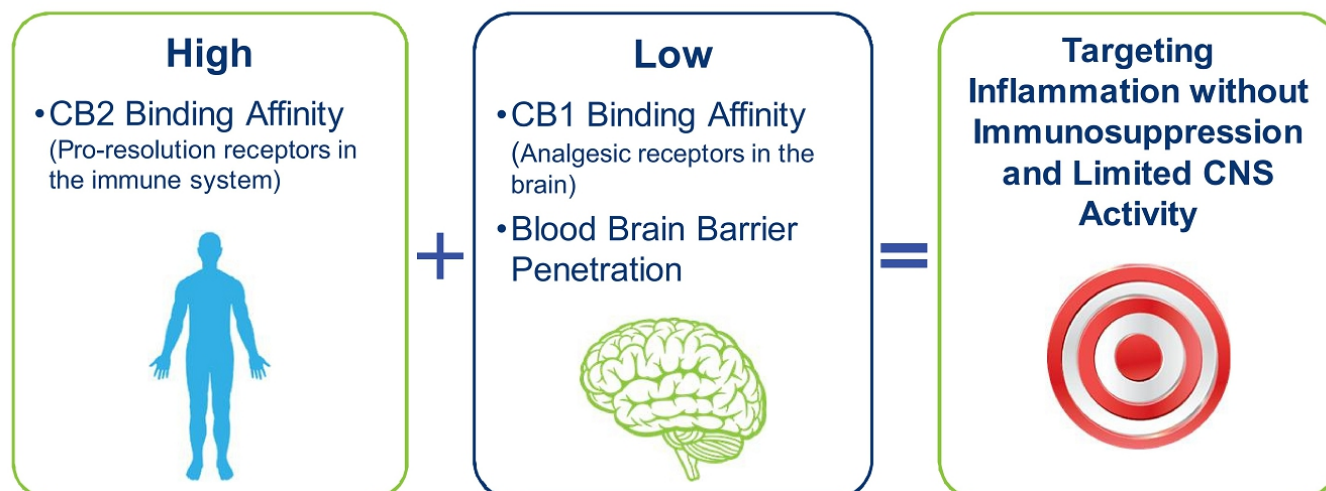


Endocannabinoids Play a Unique Role in Inflammation and Fibrosis



- Short-lived on-demand lipid mediators produced by multiple cell types
- Modulate innate immune responses¹ via cannabinoid receptor type 2 (CB2) on immune cells²
- CB2 mouse knockouts have exaggerated innate immune responses and fibrosis³
- CB2 human polymorphisms ↑ inflammation⁴ and ↑ risk of autoimmunity⁵
- MOA of CB2 agonism: triggering of resolution of innate immune responses⁶

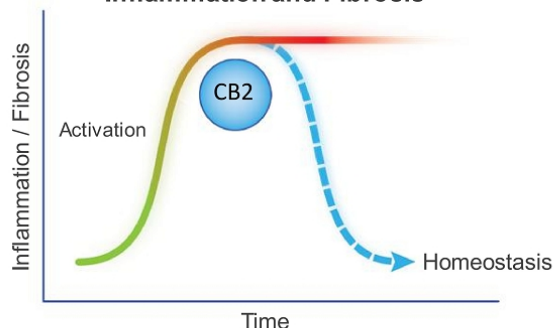
Unique Characteristics of Anabasum Make It an Attractive Candidate for Rare + Chronic Inflammatory / Fibrotic Diseases





Anabasum Promotes Resolution of Inflammation and Fibrotic Responses

Resolution of Chronic Inflammation and Fibrosis



Anabasum : Triggers Resolution of Innate Immune Responses

Decreases

- ✓ Pro-inflammatory lipids
- ✓ Vasodilation / edema
- ✓ Chemokines
- ✓ Tissue infiltration with neutrophils and other inflammatory cells
- ✓ Pro-inflammatory cytokines
- ✓ Pro-fibrotic growth factors
- ✓ Myofibroblast accumulation
- ✓ Extracellular matrix production

Increases

- ✓ Pro-resolving lipid mediators
- ✓ Pro-resolving macrophages
- ✓ Clearance of bacteria
- ✓ Clearance of cellular debris
- ✓ Resolution of tissue infiltration with inflammatory cells

MOA Broadly Applicable to Multiple Inflammatory / Fibrotic Diseases

Diffuse Cutaneous Systemic Sclerosis:

- Positive Phase 2 data
- Ongoing open-label extension
- Commencing Phase 3 study in H2 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



Clinical Development of Anabasum in Systemic Sclerosis

- Positive data in Phase 2 study
- Well tolerated and not immunosuppressive
- Consistent clinical benefit in multiple efficacy outcomes
- Improvement of biomarkers in skin biopsies
- Ongoing open-label extension of Phase 2 study
- Phase 3 study to commence H2 2017



Design of Completed Phase 2 Study

Positive Results Reported in November 2016

- Double-blind, randomized, placebo-controlled
- 9 clinical sites in the U.S.
- 43 adults ages 18 to 70 with SSc
- 2:1 overall ratio of anabasum:placebo
- 16 week study, 12 weeks of active dosing
- Immunosuppressive medications allowed

Primary Endpoints:

- Safety and tolerability
- ACR CRISS

Secondary Endpoints:

- ACR-CRIS domains: mRSS; FVC % predicted; PtGA; MDGA; HAQ-DI
- Patient-reported outcomes

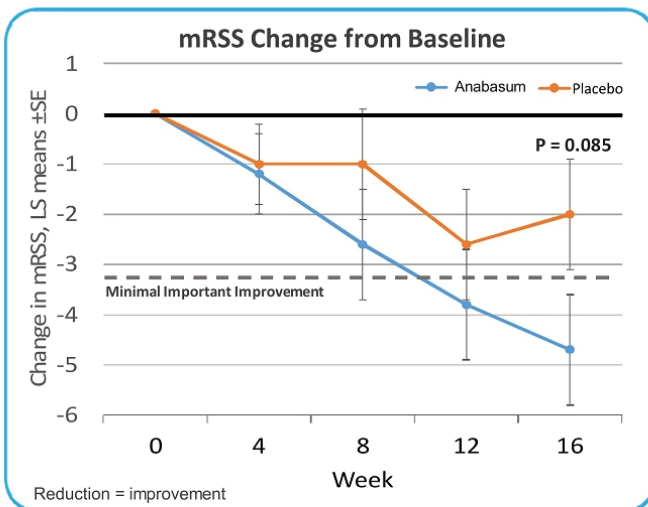


Safety and Tolerability Summary

- 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

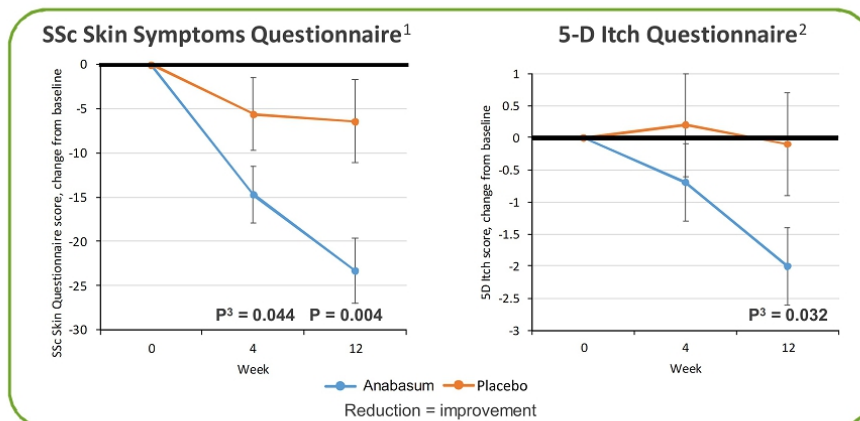


Primary Endpoint in Upcoming Phase 3 Study

- mRSS improved at week 16 from baseline -4.7 ± 1.1 (SE) for anabasum subjects vs. -2.0 ± 1.5 for placebo subjects
- Improvement from baseline of -4.7 points in anabasum subjects is clinically important



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

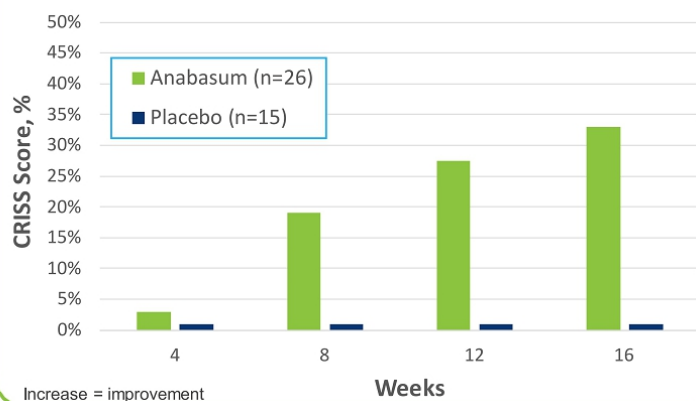
¹ Ziemek J et al. Rheumatology 2016;55:911. ² Elman S et al. Br J Dermatol 2010;162:587.

³ Efficacy population, least squares means \pm SE, analysis of covariance model, one-sided p-value.



Improvements in ACR-CRISS Scores

Median CRISS Score



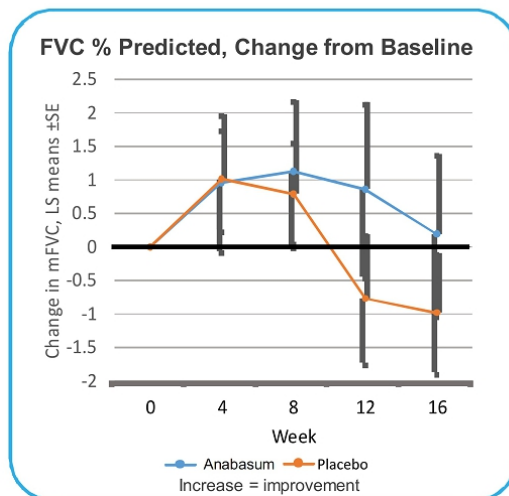
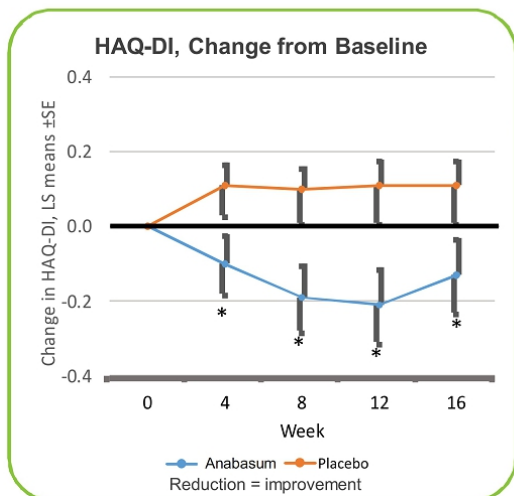
- Composite score of change from baseline in mRSS, HAQ-DI, FVC % predicted, and physician and patient global assessments
- mRSS represents largest weighted factor in ACR-CRISS composite
- ACR-CRISS scores show improvement in anabasum-treated subjects > placebo-treated subjects

Group	CRISS Score, %			
	Median (Interquartile Range or IQR) ¹			
	Week 4	Week 8	Week 12	Week 16
Anabasum, N = 26	3.0 (0.6, 11.4)	19.0 (0.3, 69.2)	27.5 (1.9, 67.8)	33.0 (0.8, 82.1)
Placebo, N = 15	1.0 (0.3, 8.8)	1.0 (0.1, 15.2)	1.0 (0.1, 60.1)	1.0 (0.1, 16.0)



Additional Efficacy Outcomes Favor Anabasum (Part 1)

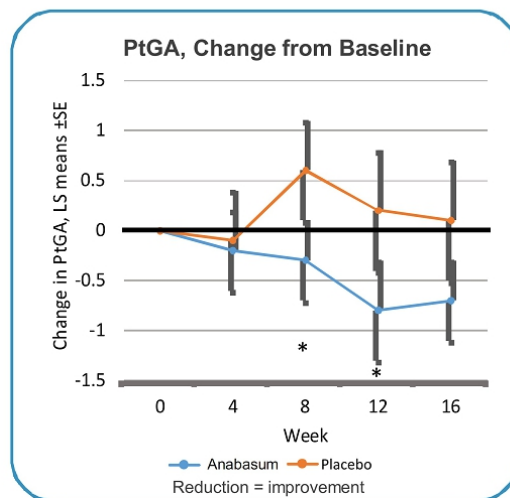
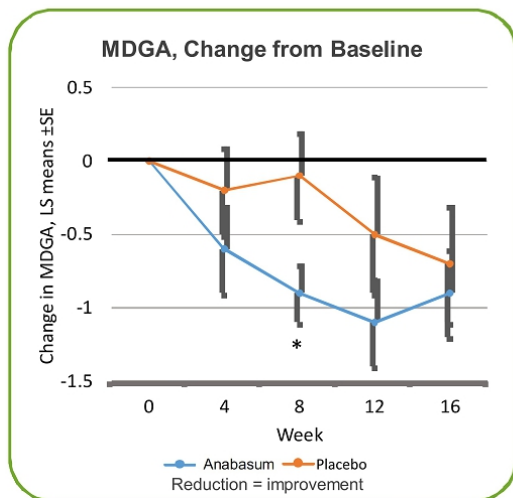
* P < 0.05





Additional Efficacy Outcomes Favor Anabasum (Part 2)

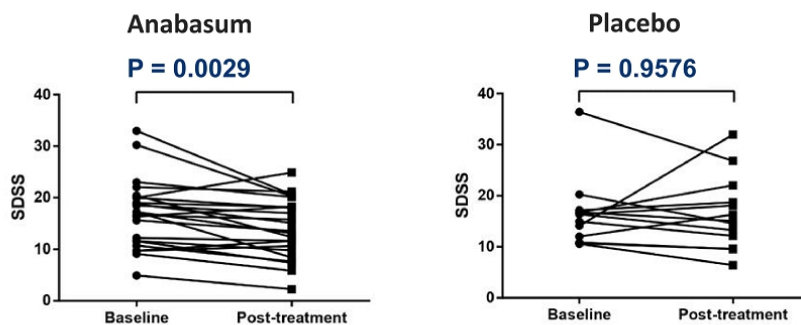
* $P \leq 0.05$





“Molecular Skin Score” in Skin Biopsies from Phase 2 Show Improvement Compared to Placebo

- Mathematical calculation of skin thickening based on gene expression
 - 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)





Ongoing Open-Label Extension of Phase 2 Study

Interim Data Expected H2 2017

- Open-label extension to collect long-term safety and efficacy data
- 12-month duration, planning to extend to 24 months
- All subjects receive anabasum



Planned Design of Upcoming Phase 3 Study

Phase 3 Study Scheduled to Commence H2 2017

- Double-blind, randomized, placebo-controlled
- Patient number: n = 270 multinational
- 52 week study
- Dose: anabasum 20 mg BID; 5 mg BID, or placebo BID

Primary Endpoint:

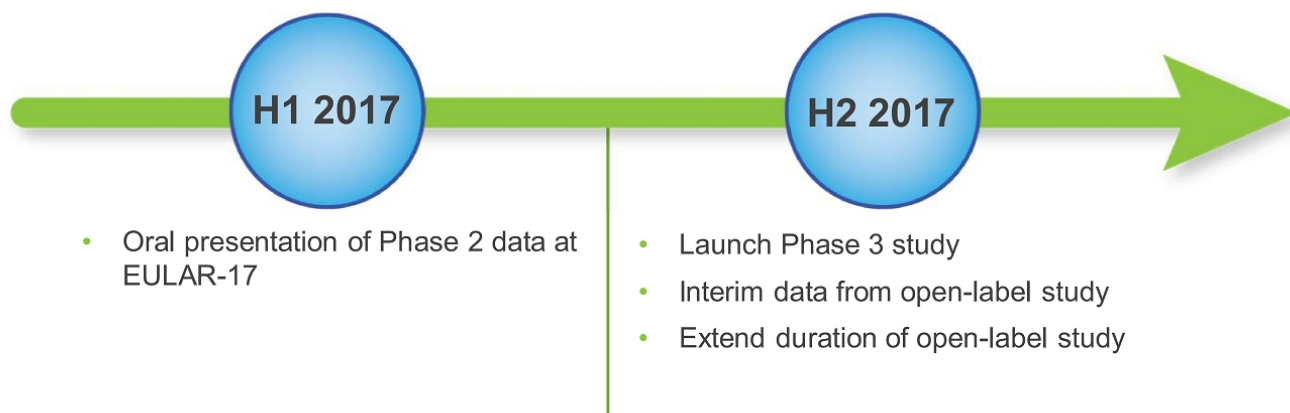
- Change from baseline in mRSS

Secondary Endpoints:

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



Systemic Sclerosis Clinical Development Milestones



Cystic Fibrosis:

- Positive Phase 2 data
- Support from the Cystic Fibrosis Foundation
- Expected to commence Phase 2b study in H2 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



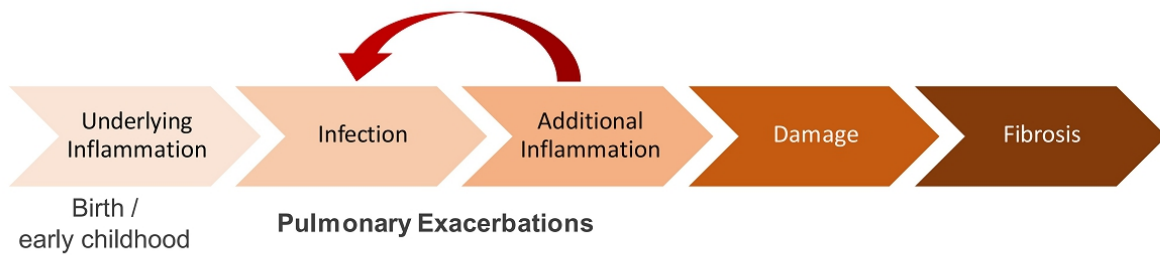
Pharmacoeconomics are proven and favorable





Inflammation: a Key Driver of CF Morbidity and Life-Span

- CFTR interacts with multiple actors in the inflammatory cascade³
- CF cell lines and animal models exhibit increased inflammation even in absence of any infection¹
- CFTR-blockers increase inflammation *in vitro*²
- Evidence of *in utero* inflammatory abnormalities in animals and humans⁴
- Unresolved inflammation drives fibrosis

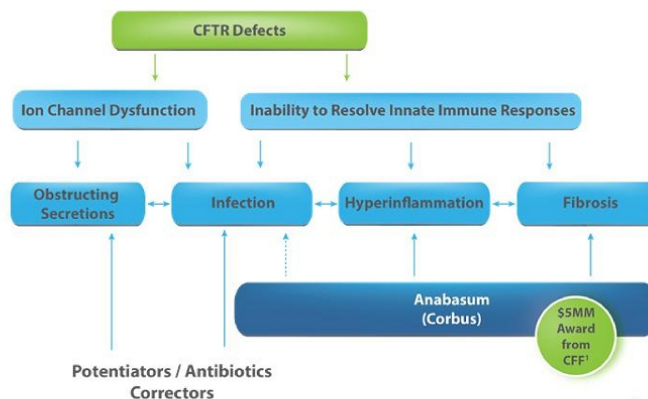
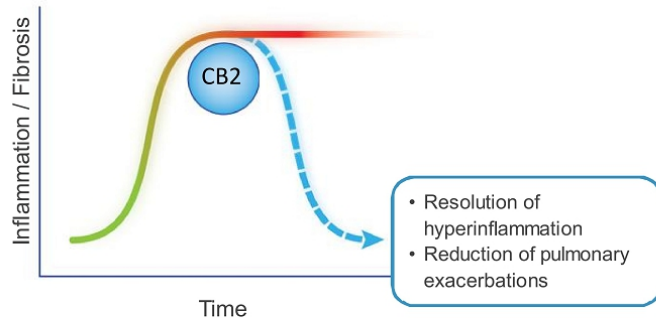




Anabasum is Uniquely Positioned in Cystic Fibrosis

Potential to be First Approved Therapy Targeting Inflammation and Fibrosis in CF

Resolution of Chronic Inflammation / Fibrosis in CF





Clinical Development of Anabasum in Cystic Fibrosis

- **Targeting all patients: mutation/pathogen/medication agnostic**
- Positive data in Phase 2 study
- Well tolerated and not immunosuppressive
- Reduction in pulmonary exacerbations
- Reduction in inflammatory cells and mediators in sputum
- Expected to launch Phase 2b study H2 2017



Design of Completed Phase 2 Study

Data Announced March 2017

- Double-blind, randomized, placebo-controlled
- 21 clinical sites in the U.S. and Europe
- 85 adults ages 18 to 65 with CF
- 16 week study, 12 weeks of active dosing
- Eligibility criteria
 - All mutations allowed
 - FEV1 \geq 40% predicted
 - Background medications including prophylactic antibiotics allowed
 - No intravenous antibiotics for 14 days prior to Day 1

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



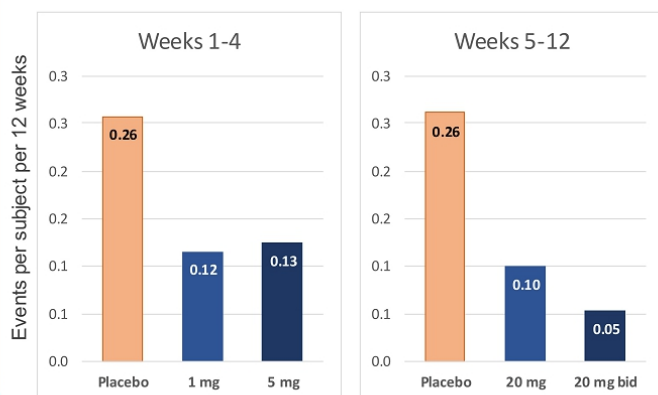
Safety and Tolerability Summary

- 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)



Pulmonary Exacerbation Requiring Treatment with IV Antibiotics

Rate of Pulmonary Exacerbations Requiring IV Antibiotics



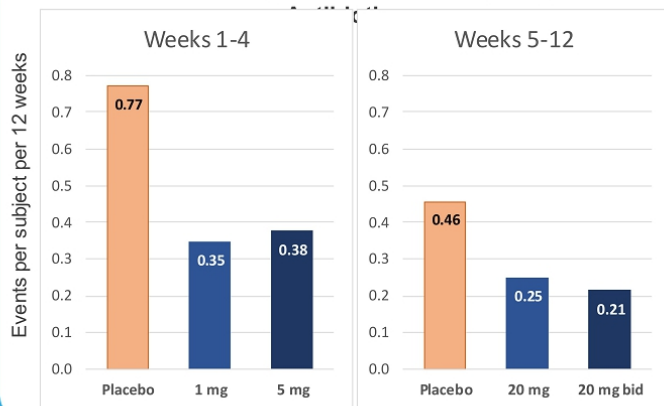
- Pulmonary exacerbations (PEX) captured as an event of special interest
- PEX are respiratory or systemic symptoms requiring new antibiotics
- Reduction in PEX seen in all treatment arms compared to placebo

Clear reduction in the rate of pulmonary exacerbations treated with IV antibiotics for anabasum



Pulmonary Exacerbations Treated with Any New Antibiotic

Rate of Pulmonary Exacerbations Requiring New Antibiotic

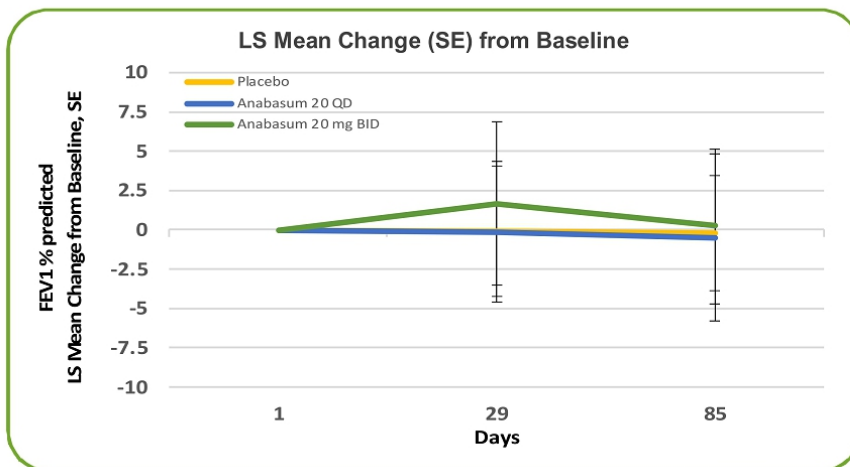


- A broader look at acute pulmonary exacerbations as defined by treatment with any new antibiotics for respiratory system symptoms
- Reduction from placebo rate seen in all anabasum cohorts

Clear reduction in the rate of pulmonary exacerbations treated with any new antibiotic for anabasum



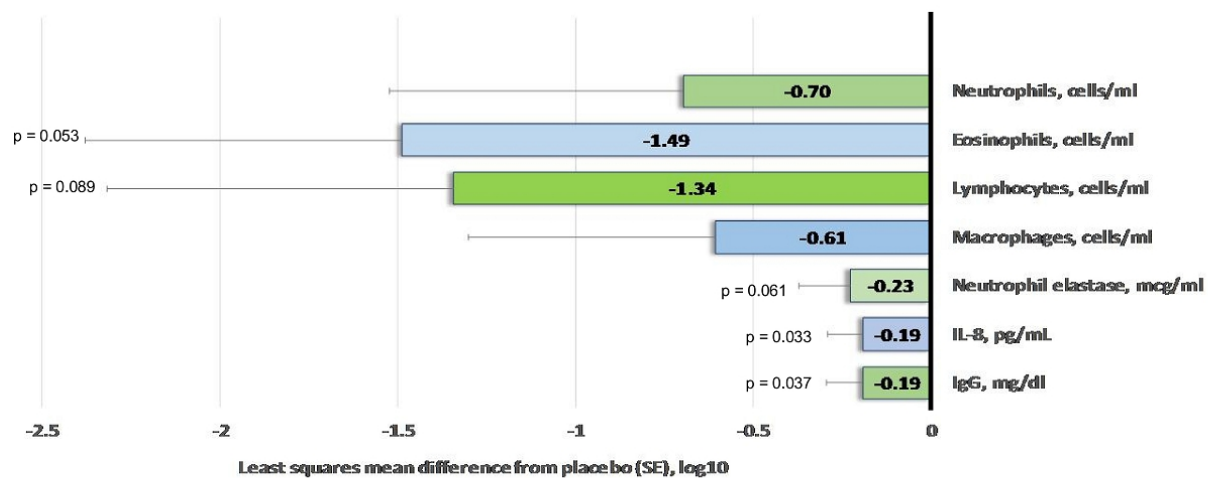
FEV1 % Predicted Values Remained Stable Throughout Study





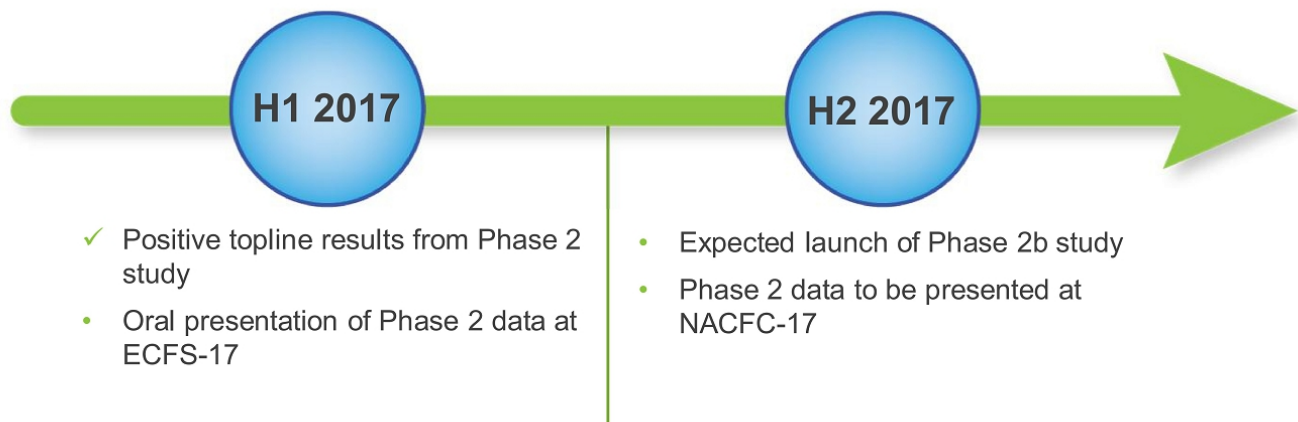
Consistent Reduction in Key Inflammatory Biomarkers (Sputum)

Reduction in anabasum 20 mg BID compared to placebo (Log¹⁰)





Cystic Fibrosis Clinical Development Milestones



Dermatomyositis & Systemic Lupus Erythematosus:

- Dermatomyositis
 - Ongoing Phase 2 study - topline results expected H2 2017
 - Ongoing open-label extension
 - NIH funded
- Systemic Lupus Erythematosus
 - Launching Phase 2 study H2 2017
 - NIH funded



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 Takeaways



Treated with immunosuppressive therapies, but with significant toxicities



Single center study underway at University of Pennsylvania



NIH is funding the study



Data readout expected H2 2017





Dermatomyositis Phase 2 Clinical Study

Topline Results Expected H2 2017

- Double-blind placebo control randomized study
- 1 site - University of Pennsylvania Perlman School of Medicine
- 22 adults with refractory skin-predominant DM
- 16 week study, 12 weeks of active dosing
- Dose response: 20 mg QD, 20 mg BID or placebo

Primary Endpoints:

- Safety/tolerability
- Change in skin activity using CDASI

Secondary Endpoints:

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



Dermatomyositis Open-Label Extension Underway

- Open-label extension to collect long-term safety and efficacy data
- 12-month open-label extension
- All subjects receive anabasum

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-IMMUNOSUPPRESSIVE TREATMENTS NEEDED

Key Takeaways



Treated with immunosuppressive therapies



Multi-center study planned (n=100)



NIH is funding the study





Systemic Lupus Erythematosus Phase 2 Clinical Study

Commence Patient Enrollment Expected H2 2017

- Double-blind, placebo controlled randomized study
- 10 sites in the U.S.
- 100 adults with SLE
- 16 week study, 12 weeks of active dosing
- Dose response: 20 mg BID, 20 QID 5 mg QID, or placebo

Primary Endpoints:

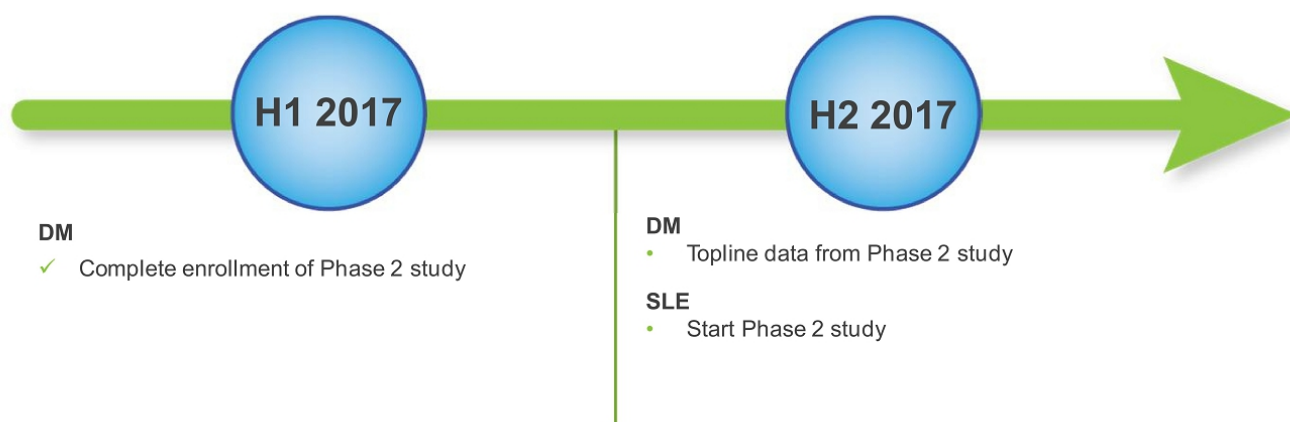
- Safety/tolerability
- Efficacy in inflammatory joint pain in subjects with active musculoskeletal disease

Secondary Endpoints:

- Efficacy in overall disease activity, musculoskeletal disease, and quality of life
- Biomarkers of inflammation
- Pharmacokinetics



DM and SLE Clinical Development Milestones





Scientific Advisory and Principal Investigators

Scientific Advisors

Michael Knowles, MD, PhD



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. 1836
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
UNIVERSITY OF PENNSYLVANIA

Meggan Mackay, MD
US PI – SLE



HOFSTRA NORTHWELL
SCHOOL of MEDICINE
AT HOFSTRA UNIVERSITY



Financial Profile: CRBP (NASDAQ)

Current Capital Funds Operations Through End of 2018

\$353MM

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

1.11MM

50d average
daily volume*

\$49MM

Cash balance**

CONTACT US

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Holdings, Inc.**

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