

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 10, 2014

Corbus Pharmaceuticals Holdings, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

333-198563
(Commission File Number)

46-4348039
(IRS Employer
Identification No.)

100 River Ridge Drive Norwood, MA 02062

(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (617) 963-0100

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 (17CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13-e-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, 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) Exhibits

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, CORP.

Date: November 10, 2014

By: /s/ Yuval Cohen

Yuval Cohen
Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Investor Presentation.



Exhibit 99.1

OTCQB: CRBP

www.CorbusPharma.com

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



Forward-Looking Statement

This presentation contains certain forward-looking statements, including those relating to the Company's product development, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement 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," "will" and similar expressions and the negatives of those terms. These statements 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. 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

- Corbus Pharma is focusing on rare, life-threatening, chronic inflammatory diseases
- Lead drug *Resunab*[™]: a first-in-class oral anti-inflammatory/fibrosis small molecule
- Acts to trigger inflammatory resolution: the *switch* for chronic inflammation
- Proven safe in Phase 1 + promising pre-clinical potency in multiple animal models
- Phase 2 clinical trials to commence 2015:
 - Cystic Fibrosis (CF)
 - Diffuse Systemic Sclerosis (SSC) also known as “Scleroderma”
- Successful \$10.3m private financing round (May 2014)
- Obtained \$1.3m in NIH grants
- IP protection until 2033 and potentially longer
- Commenced trading on OTC.QB in October 2014

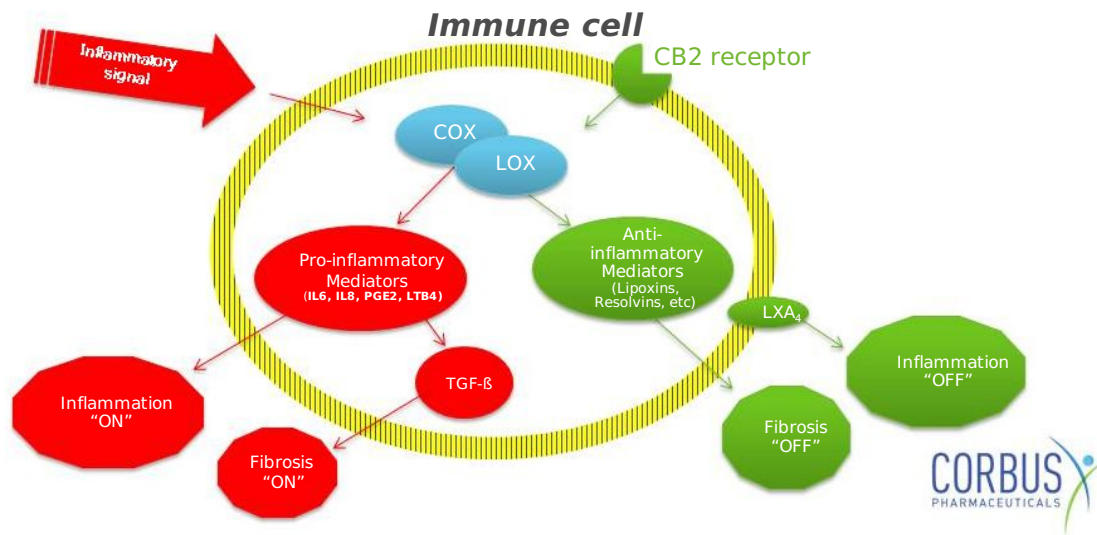


Our Target Indications: Current & Future

Indication	Patient numbers (USA)	Estimated Market size	Current therapies for inflammation	Drawbacks to current therapies
Current lead indications:				
Cystic Fibrosis	30,000	>\$3B	Steroids, ibuprofen	Considerable side effects
Diffuse Systemic Sclerosis (Scleroderma)	50,000	>\$2B	Steroids, methotrexate	Side effects, poor efficacy
Potential future indications:				
Dermatomyositis	13,000	>\$1B	Steroids, mAbs	Side effects, poor efficacy
Marfan Syndrome	5,000	>\$1B	N/A	
Lupus (SLE)	500,000-1.5MM	>\$3B	Steroids, mAbs	Side effects, poor efficacy
Idiopathic Pulmonary Fibrosis (IPF)	70,000	>\$1B	Pirfenidone	Limited efficacy InterMune bought by Roche for \$8.5B (2014)

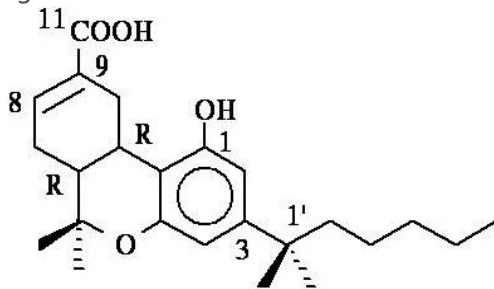
CB2 Receptor: Turns inflammation “off”

- CB2 receptor is present on immune cells and activated by endogenous lipid mediators
- Activation of CB2 turns inflammation off (“inflammatory resolution”)
- Resunab expected to be first CB2-binding anti-inflammatory drug to reach market
- Upstream of other approaches: potential for better safety and potency



Resunab

- Resunab: synthetic oral CB2 agonist small-molecule
- Designed to trigger the resolution of chronic inflammation
- Full manufacturing, drug supply, non-clinical safety & pharmacology package for Phase 2 programs
- Excellent clinical safety profile to date: two prior Phase 1 clinical trials (n=121)
 - Lacks CNS side effects of other CB2-binding class members
 - Lacks GI side effects of NSAID's (e.g. Aspirin™, ibuprofen, Celebrex™)
 - Lacks metabolic side effects of corticosteroids
- Preparing to launch two Phase 2 clinical studies in 2015



Resunab: Only CB2-Agonist Targeting Inflammation

Company	Indication	Brain penetration	Status	Affects CNS
Corbus Pharma	Inflammation	Minimal	Entering Phase 2	No
AbbVie	Pain	Full	Phase 1	Yes
Glenmark	Pain	Full	Phase 1	Yes
Eli Lilly	Knee pain	Full	Phase 2	Yes
AstraZeneca	Post operative pain	Full	Phase 2	Yes

Resunab is the only CB2 drug that can be used to treat inflammation because it does not target the brain



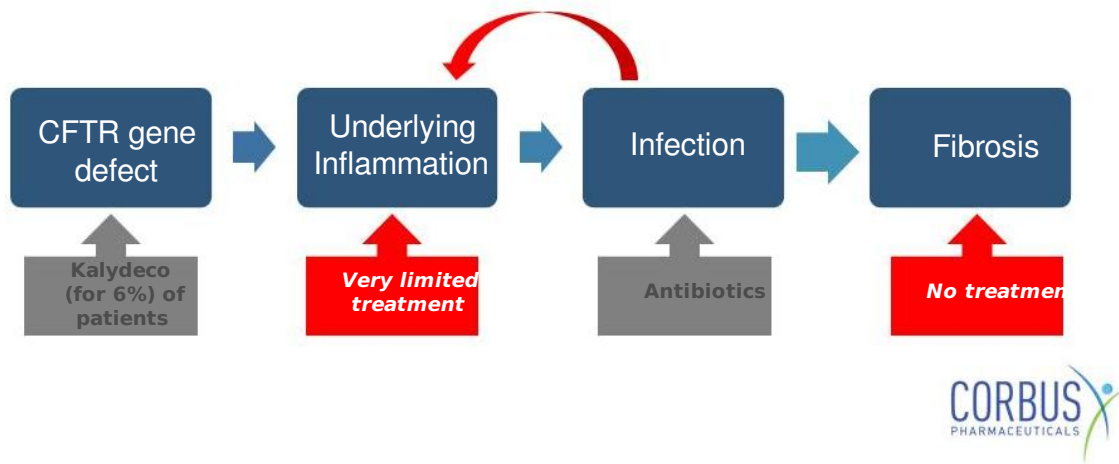
Cystic Fibrosis

Targeting inflammation at the core of the disease



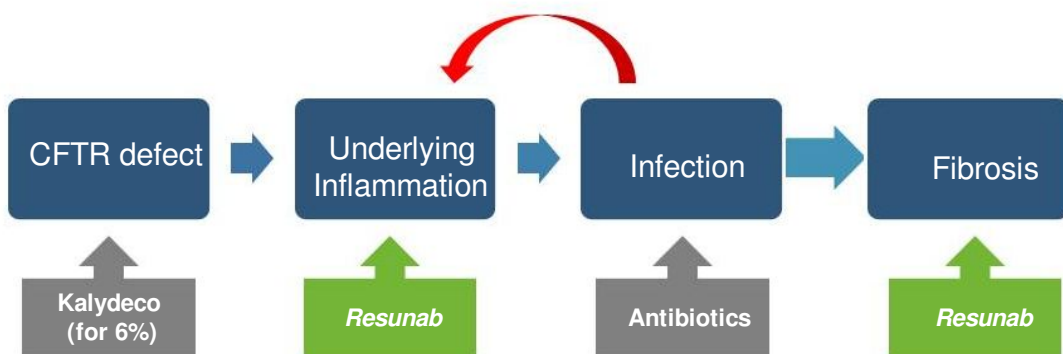
Overview: Cystic Fibrosis

- Inflammatory orphan disease (30,000 patients in USA, 75,000 WW)
- Average life expectancy of CF patients is approximately 40 years
- Inflammation at core of disease's morbidity and mortality (pulmonary fibrosis)
- Very high doses of steroids/ibuprofen effective but rarely used due to toxicity
- Need for safe, chronic anti-inflammatory drug is unmet and universally recognized
- Pharmaco-economics support premium pricing (e.g. Kalydeco by Vertex priced at \$320,000/yr)

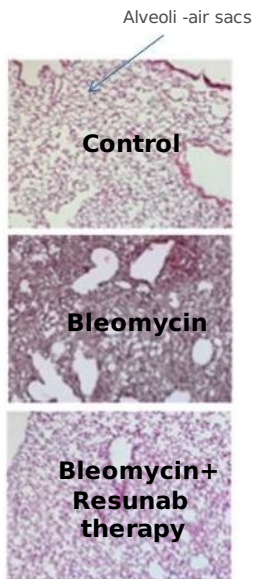


Resunab targets key CF inflammatory players

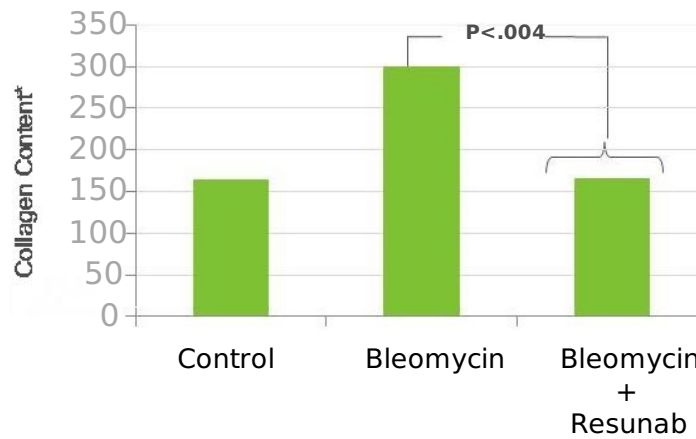
↓ TGFβ	↑ Lipoxin-A4
<ul style="list-style-type: none"> • Genetically linked to disease • Associated with worsening symptoms 	<ul style="list-style-type: none"> • Absent in CF lungs • Replacement therapy effective in animal models



Resunab Reduces Pulmonary Fibrosis In Animal Models



Fibrosis-inducing agent (Bleomycin) administered to lungs day 1 followed by daily oral *Resunab* for 21 days



Gonzales et.al., *Annals of Rheumatic Diseases*, 2012. 71:1545-51
 * Measured by hydroxyproline



Resunat Planned Cystic Fibrosis Phase 2 Trial

- Double blind placebo control study in the USA under IND from FDA
- **Primary endpoints** Safety/tolerability PK
- **Secondary endpoints** Inflammatory biomarkers MOA + change in clinical outcome measures
- **Patient number** 70 adults with CF in 15-20 sites
- **Treatment duration** 3 months + 1 month follow-up
- **Dose response** 1mg/day 5mg/day 20mg/day and 20mg/2X/day

	Q1 2015	Q2 2015	Q3 2015	Q4 2015	Q1 2016	Q2 2016	Q3 2016	Q4 2016
Protocol filed with FDA	X							
Study launches		X						
First patient dosed		X						
Study duration		X	X	X	X	X	X	
Last patient dosed							X	
Study data released								X

Diffuse Systemic Sclerosis (“Scleroderma”)

Relief for a disease with no effective long-term therapy

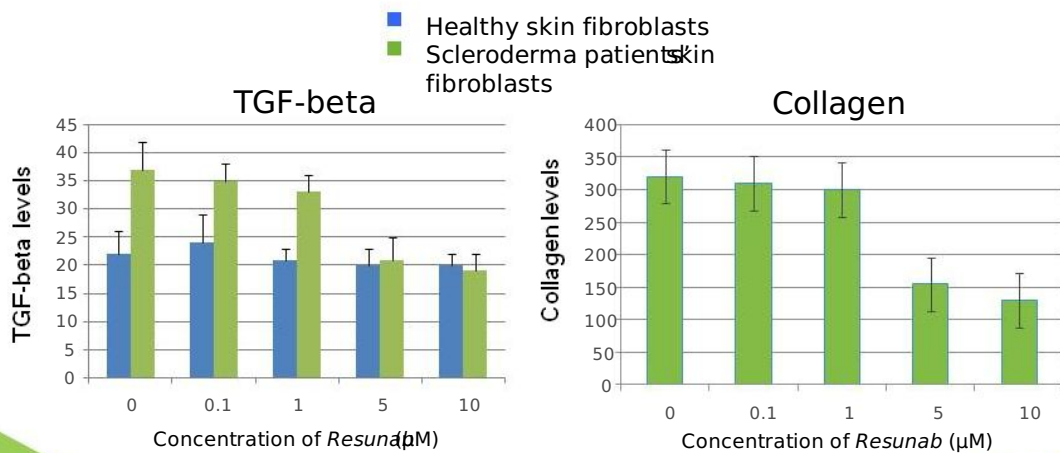


Overview: Diffuse Systemic Sclerosis (Scleroderma)

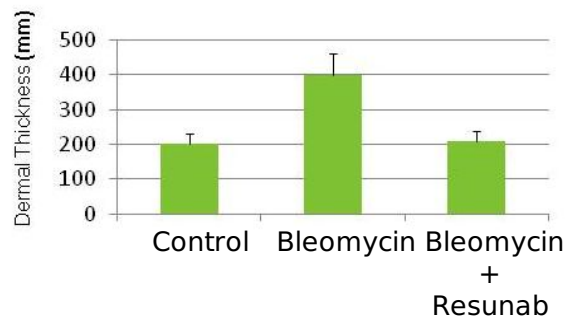
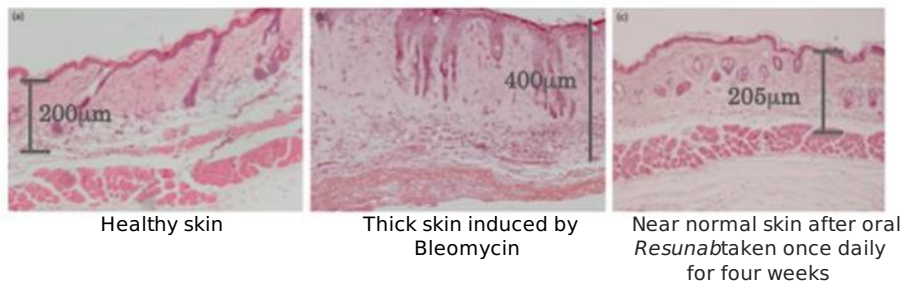
- Chronic inflammatory disease causing fibrosis of skin, joints and internal organs
- Orphan disease (50,000 patients in USA)
- 80% of patients are women in their 30's and 40's
- Common cause of death: lung fibrosis (50% mortality in 10 years)
- Early stage of disease responds to steroids/methotrexate but with serious side effects
- No effective and safe long-term therapy available
- Pipelines often target Idiopathic Pulmonary Fibrosis (IPF) in conjunction to SSC

Resunab Inhibits Key Factors in SSC

- TGF-beta plays key role in SSC progression (same in CF and IPF)
- Elevated TGF-beta levels associated with disease progression
- Strong Resunab efficacy data in animal models
- Resunab reduces TGF-beta and collagen in skin fibroblasts from SSC patients



Resunab Inhibits Skin Thickening In Mouse SSC Model



Gonzales et.al., *Annals of Rheumatic Diseases*, April 4, 2012

Resunab Planned SSC Phase 2 Clinical Trial

- Double blind placebo control study in USA under IND from FDA
- **Primary endpoints** Safety/tolerability PK+ Change in clinical outcomes
- **Secondary endpoints** Inflammatory biomarkers + quality of life (QOL)
- **Patient number** 35 adults with SSC with 8-10 sites
- **Treatment duration** 3 months + 1 month follow-up
- **Dose response** 5mg/day 20mg/day and 20mg/2X/day

	Q1 2015	Q2 2015	Q3 2015	Q4 2015	Q1 2016	Q2 2016	Q3 2016	Q4 2016
Protocol filed with FDA	X							
Study launches	X							
First patient dosed		X						
Study duration		X	X	X	X	X	X	
Last patient dosed							X	
Study data released								X

Management Team

Yuval Cohen, Ph.D.- Chief Executive Officer

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

Mark Tepper, Ph.D.- President & Chief Scientific Officer

- Former VP USA Research & Operations, EMD Serono; Sr. Investigator, Bristol-Myers Squibb
- Key member of project teams which developed the following marketed drugs: Taxol® (Ovarian Cancer, 2000 peak sales of \$1.6B), Orenda® (RA, 2013 sales of \$1.4B), Rebif® (MS, 2013 sales of \$2.59B), Gonal-F® (Fertility, 2013 sales of \$815MM)

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)

Barbara White, M.D.- Chief Medical Officer

- Former VP Clinical & Medical Director at Amgen, UCB and Medimmune. Expert rheumatologist in scleroderma with decades of experience in clinical trial development.



Board of Directors

Yuval Cohen, Ph.D.- Chief Executive Officer

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 Inspire Pharma (sold to Merck for \$430m in 2011)
- Chairman of the Board of the Metropolitan Washington, D.C. Chapter of the Cystic Fibrosis Foundation

David Hochmann

- Managing Partner of Orchestra Medical Ventures
- Over 17 years of venture capital and investment banking experience
- Former Managing Director of Spencer Trask Ventures, Inc. securing over \$420 million in equity capital

Renu Gupta, MD

- 25 years of development, regulatory and senior management experience in the biopharm industry
- Former CMO of Insmed, a specialty CF company and current advisor to the CEO
- Former Vice President and Head of US Clinical Research and Development at Novartis (2003-2006)

Avery W. (Chip) Caitlin

- CFO Celldex Therapeutics (CLDX) since 2000
- Raised over \$415MM financing
- 20 years experience in industry: Repligen (CFO) and Endogen (CFO)



World Class Scientific Advisors

Sumner Burstein, Ph.D. - UMass Medical School

Professor of Biochemistry and Pharmacology; inventor of Resunab

Michael Knowles, M.D., Ph.D. - UNC Chapel Hill

Professor of Pulmonary and Critical Care Medicine

James Chmiel, M.D. - Case Western Reserve Medical School

Professor Medicine, National PI on largest ever anti-inflammatory CF study

Robert Simms, M.D. - Boston University School of Medicine

Chairman of International Clinical Scleroderma Consortium

Daniel Furst, M.D. - UCLA School of Medicine

Director of UCLA Scleroderma Program

Robert Zurier, M.D. - UMass Medical School

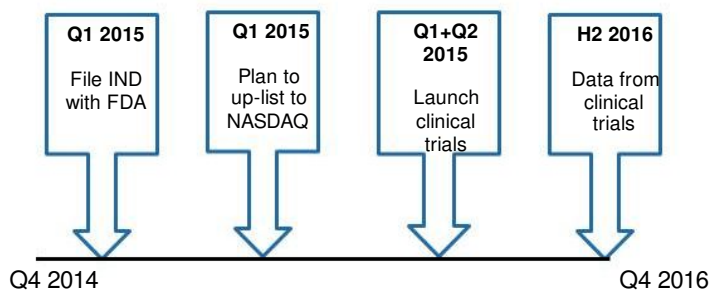
Ex-Chair of Rheumatology



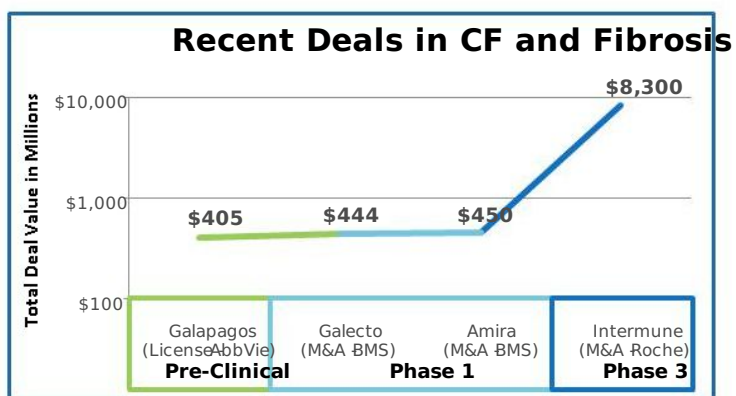
Financial Profile

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Stock Ticker:	CRBP:OTCQB
\$77,400,000	Market capitalization as of November 30, 2014
\$10,300,000	Raise from successful private placement (Q2 2014) from institutional and retail base
25,800,000	Common shares outstanding
41,500,000	Fully diluted shares outstanding (including warrants and stock options)
\$11,400,000	Available from exercise of callable warrants
NASDAQ	Up-listing to NASDAQ planned by Q-1 2015



Corbus Poised for Significant Upside

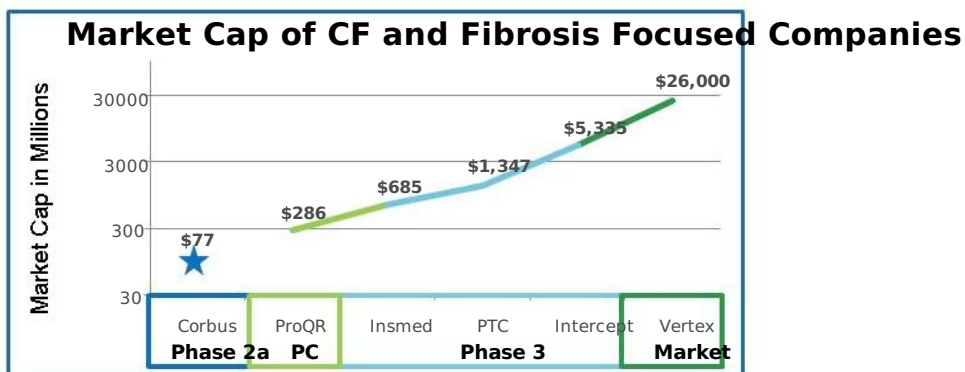


Recent Deals								
Date	Company	Partner	Type	Drug	Indication	Stage	Up-Front	Deal Total
11/14	Galecto	BMS	Option to acquire	TD139	Idiopathic pulmonary fibrosis	Phase 1	NA	\$444M*
8/14	InterMune	Roche	Acquisition	Esbriet	Idiopathic pulmonary fibrosis	Approved	NA	\$8.3B*
9/2013	Galapagos	AbbVie	License	GLPG1837	Mutations in CF patients, including F508del and G551D	Pre-clinical	\$45M*	\$405M*
7/2011	Amira	BMS	Acquisition	AM152	Idiopathic pulmonary fibrosis and systemic sclerosis	Phase 1	\$325M*	\$475M*

* Figures from company press releases



Potential Value Indicators



Recent IPO					
Date	Company	Lead Compound	Indication	Stage	Market Cap
9/2014	ProQR	QR-010	Cystic Fibrosis RNA repair	Pre-clinical	\$284.11M

Approved Products					
Company	Drug	Indication	Cost per Year	2018 Sales Est.	
Vertex	Kalydeco	Cystic Fibrosis mutations of CFTR gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R	\$294,000	\$1.2B**	

* Figures from company press releases
 ** Leerink analyst report



Conclusions

- Lead Product *Resunab* is a novel, safe and promisingly potent clinical stage anti-inflammatory/anti-fibrotic drug which acts to resolve inflammation
- Targets multiple rare inflammatory indications
- Proven safe in two Phase 1 trials
- Promising potency in multiple pre-clinical models
- Launch two Phase 2 trials in 2015 (Cystic Fibrosis and Scleroderma)
- Completion of studies in 2016
- Strong patent portfolio until 2033





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