Zacks Small-Cap Research

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Corbus Pharmaceuticals, Inc. (CRBP - NASDAQ)

CRBP: Three Phase 2 Clinical Trials Underway for Resunab™…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	01/06/2015
Current Price (11/13/15)	$1.71
Target Price	**$6.25**

UPDATE

On November 13, 2015, Corbus Pharmaceuticals announced financial results for the third quarter of 2015 and provided a corporate update. Net loss for the quarter was $2.3 million, or $0.06 per share. The company exited the quarter with approximately $13.2 million in cash and cash equivalents, which we believe will be sufficient to fund operations into the fourth quarter of 2016.

On the clinical side, Resunab is now being evaluated in three separate clinical trials for the treatment of dermatomyositis, cystic fibrosis, and scleroderma. We anticipate that results from the cystic fibrosis and scleroderma trials will be available in the fourth quarter of 2016 while results from the dermatomyositis trial will be available in the first half of 2017.

SUMMARY DATA

52-Week High	**$4.15**
52-Week Low	**$0.05**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**297,734**
Shares Outstanding (mil)	**38**
Market Capitalization ($mil)	**$64**
Short Interest Ratio (days)	**0.42**
Institutional Ownership (%)	**8**
Insider Ownership (%)	**13**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	0 A	0 A	0 A	0 A	0 A
2015	0 A	0 A	0 A	0 E	0 E
2016					0 E
2017					0 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.02 A	-$0.02 A	-$0.03 A	-$0.05 A	-$0.13 A
2015	-$0.06 A	-$0.10 A	-$0.06 A	-$0.10 E	-$0.30 E
2016					-$0.31 E
2017					-$0.35 E

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WHAT'S NEW

Financial Update

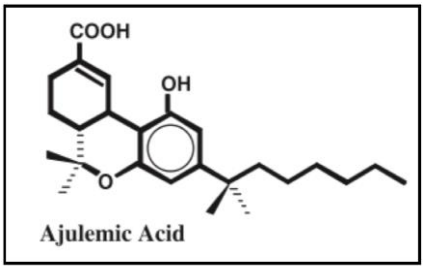
On November 12, 2015, Corbus Pharmaceuticals, Inc. (CRBP) announced financial results for the third quarter of 2015 and provided a corporate update. The company recorded revenue of $0.17 million for the quarter. In May 2015, the company received $1.25 million from the Cystic Fibrosis Foundation as part of the Development Award to support the Phase 2 clinical trial of Resunab™ in patients with cystic fibrosis. For accounting purposes, the company recorded the $1.25 million as deferred revenue and is amortizing the deferred revenue on a straight-line basis over the performance period. In October 2015, the company dosed the first patient in the cystic fibrosis clinical trial and thus is due to receive an additional $1.25 million.

Net loss for the quarter was $2.3 million, or $0.06 per share, and was comprised of $0.8 million in G&A and $1.6 million in R&D expenses. The company exited the third quarter of 2015 with approximately $13.2 million in cash and cash equivalents. In July 2015, the company announced a call notice for the redemption of certain outstanding warrants. These 11.3 million warrants were issued in April and May 2014 in conjunction with the company's private placement and had an exercise price of $1.00 per share. As a reminder, the warrants were callable if the stock traded at $2.50 or above for 20 consecutive trading days, which occurred during March 2015. The company received net proceeds of $10.8 million from the exercise of these warrants.

Business Update

Corbus is developing Resunab™ (ajulemic acid, AJA) for the treatment of rare, chronic life-threatening inflammatory conditions, including cystic fibrosis, scleroderma, and dermatomyositis. The company has a large amount of preclinical and clinical data showing the compound is well tolerated and exhibits anti-inflammatory properties.

Resunab™



Source: Zurier *et al*., 2009

Corbus is developing Resunab™ (ajulemic acid, AJA) for the treatment of rare, chronic life-threatening inflammatory conditions. Resunab™ is a synthetic small molecule that selectively binds to the CB2 receptor while having minimal penetration across the blood brain barrier (Burstein *et al*., 1992). Resunab™ was designed to have increased anti-inflammatory / anti-fibrotic properties without the CNS-related side effects seen with other cannabinoid receptor targeting drugs. This places it in a potentially unique position; it is the only CB2 binding drug that is a "pure" anti-inflammatory / anti-fibrotic agent and could therefore be used chronically in a wide variety of indications, eliciting potent anti-inflammatory effects with minimal CNS-related side effects that limit its peers.

Resunab™ has been well tolerated in a number of toxicity studies in mice, rats, and dogs with assessments of the central nervous system, cardiovascular and respiratory systems, renal system, and gastrointestinal system showing no adverse effects. In addition, 13-week toxicology studies have been completed in rats and dogs and showed no major toxicological concerns and an excellent safety margin based on drug exposure levels. Resunab™ has previously been evaluated in two Phase 1 and one Phase 2 clinical trials, which were conducted by prior licensees Atlantic Pharmaceuticals and Indevus Pharmaceuticals, Inc.

Resunab™ for the Treatment of Cystic Fibrosis

Cystic Fibrosis (CF) is an autosomal recessive genetic inflammatory disorder that affects close to 30,000 individuals in the U.S. and a total of 70,000 people worldwide. The hallmark of CF is thick, sticky mucus in various organs

throughout the body. Typically, mucus is a slippery, water substance produced by tissues that line organs and body cavities, such as the lungs and nose. However, due to abnormal sodium and chloride transport in the lungs, pancreas, liver, and digestive tract, patients suffering from CF have mucus that is thick and sticky and leads to blockages of the airways in the lungs and ducts in the pancreas (Boucher, 2004). The name cystic fibrosis refers to the characteristic scarring (fibrosis) and cyst formation seen in the pancreas. The disease is incurable with the life expectancy of an infant born today with CF projected to be just 40 years. Pulmonary and gastrointestinal abnormalities are noticeable within days of birth.

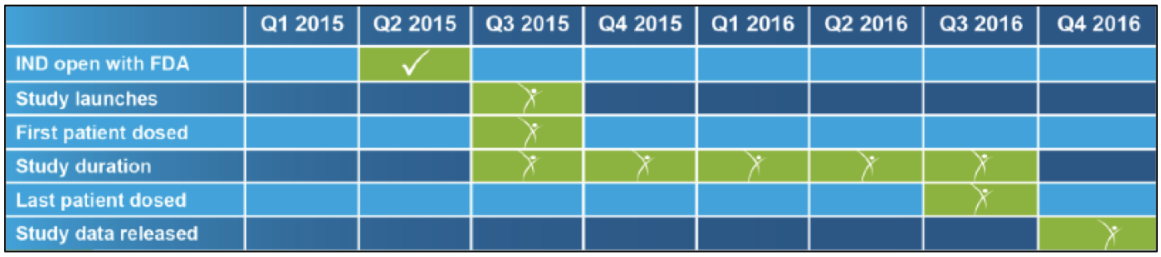
The most serious complication associated with the disease is a chronic underlying inflammation that leads to recurrent lung infections that then cause excessive inflammation leading to fibrosis. There is an increasing body of evidence indicating that the inflammatory defect is at the core of this disease that results in abnormally high levels of pro-inflammatory mediators and little or no presence of anti-inflammatory mediators. Patients with cystic fibrosis suffer from a continual cycle of airway obstruction, infection, and inflammation that are intimately linked. Airway inflammation begins early in life with persistent inflammation leading to irreversible damage of the airways and progressive decline of lung function.

For a detailed overview of preclinical data showing the potential for Resunab™ as a CF treatment, please see our previous report.

CF Clinical Trial Gets Underway

On October 15, 2015, Corbus announced that the first patient has been dosed in the Phase 2 clinical trial of Resunab™ for the treatment of CF. The CF clinical trial is a randomized, double blind, placebo-controlled study at 20 sites in the U.S. and EU (NCT02465450). The primary endpoints of the study are safety and tolerability, with a target enrollment of 70 adults with CF. Secondary endpoints will include pharmacokinetic (PK) and efficacy analysis such as FEV1, Lung Clearance Index (LCI), and CFQ-R Respiratory Domain. Exploratory endpoints will include metabolipidomic profile for MOA and biomarkers of disease activity in the blood and sputum.

The company is planning to study four doses in the Phase 2 study. Initially, patients will be dosed with 1 mg Resunab™, 5 mg Resunab™, or placebo once per day for the first 28 days. Patients will then be switched to 20 mg Resunab™ or placebo once or twice per day up to Day 84 with the final analyses taking place on Day 85. The reason for the low dose during the first month is for safety purposes, as this will be a first in CF patients trial for Resunab™. The 20 mg dose for the last two months of the study was chosen to examine the upper end of the dose-response curve. Thus, the response data generated from treating patients once a day with 1 mg to twice a day with 20 mg will help guide dose selection for future clinical trials. A timeline for the study is given below, and topline results should be available at the end of 2016.



Source: Corbus Pharmaceuticals

Resunab™ for the Treatment of Scleroderma

Scleroderma is a group of rare diseases that involve the hardening and tightening of the skin and connective tissues. Localized scleroderma only affects the skin with limited internal organ damage while systemic sclerosis affects the skin and always involves extensive internal organs damage.

According to the Scleroderma Foundation, approximately 300,000 Americans have scleroderma with one-third of those having the systemic form. The disease typically affects adults (80% of patients are female), with onset usually occurring in midlife.

Systemic scleroderma is a highly complex condition with multiple clinical forms ranging from limited cutaneous systemic sclerosis (mainly confined to the skin) to diffuse cutaneous systemic sclerosis (diffuse skin sclerosis coupled with progressive internal organ development). The limited and diffuse forms of systemic sclerosis each

make up approximately 50% of systemic sclerosis cases. Patients with limited scleroderma have skin thickening of the fingers, hands, and face that develops over a number of years. Patients with diffuse scleroderma develop skin thickening more quickly over a broader area of the body with the disease potentially affecting the gastrointestinal tract, lungs, kidneys, heart, and other internal organs.

Survival, which is highly dependent upon the degree of internal organ development, has improved over the past few decades with the 10-year survival rate now 70-80% (Korn, 2003). Diffuse systemic scleroderma has a highly variable but unfavorable survival rate with death typically resulting from progressive pulmonary fibrosis, pulmonary hypertension, severe gastrointestinal involvement, or scleroderma heart disease.

Scleroderma Clinical Trial Gets Underway

On October 7, 2015, Corbus announced that the first patient has been dosed in the Phase 2 clinical trial of Resunab™ for the treatment of scleroderma. The scleroderma clinical trial is a randomized, double blind, placebo-controlled study at 8-10 sites in the U.S. (NCT02465437). The primary endpoints of the study are safety and tolerability, and the change in Combined Response Index in diffuse cutaneous Systemic Sclerosis (CRISS). Secondary endpoints include metabolipidomic profile, biomarkers of disease activity, and quality of life scores. Target enrollment is 36 adults with scleroderma. The company is planning to study three doses in the Phase 2 study: 5 mg/day, 20 mg/day, and 40 mg/day broken up between two 20 mg doses. Treatment duration will be three months with a one-month follow-up analysis. Below is a quick representation of the expected timeline for the Phase 2 Resunab™ scleroderma study, with data expected at the end of 2016.

	Q1 2015	Q2 2015	Q3 2015	Q4 2015	Q1 2016	Q2 2016	Q3 2016	Q4 2016
IND open with FDA	✓							
Study launches								
First patient dosed								
Study duration								
Last patient dosed								
Study data released								

Source: Corbus Pharmaceuticals

Dermatomyositis Trial Gets Underway

On July 13, 2015, Corbus announced the dosing of the first patient in a Phase 2 clinical trial of Resunab™ for the treatment of dermatomyositis, which is an uncommon, inflammatory muscle disease that is accompanied by skin rashes and affects up to approximately 25,000 individuals in the U.S. The disease shares many characteristics with automimmune disorders. Small blood vessels in muscle tissue are particularly affected by infiltration of inflammatory cells that leads to the eventual degeneration of the muscle fibers. The pathology can involve serious pulmonary, cardiovascular, and gastrointestinal involvement, has a significant burden of illness, and impairs daily functioning and quality-of-life. There are currently no FDA-approved therapies specific for dermatomyositis, and physicians commonly treat manifestations of the disease with immunosuppressive therapies that have significant toxicities.

The Phase 2 clinical trial of Resunab™ for the treatment of skin-predominant dermatomyositis is being funded by a grant from the National Institutes of Health (NIH) to the University of Pennsylvania School of Medicine and is being led by Dr. Victoria Werth, a Professor of Medicine at the University of Pennsylvania School of Medicine and Chief, Dermatology, Philadelphia V.A. Hospital (NCT02466243).

The primary outcomes of the study are the safety and tolerability of Resunab™ along with the change in Cutaneous Dermatomyositis Disease Area and Severity Index (CDASI) from baseline. The CDASI, which was developed by Dr. Werth and colleagues, is a clinician-scored single page instrument that separately measures activity and damage in the skin of dermatomyositis patients and is used both in clinical practice and for clinical/therapeutic studies (Klein *et al*., 2008). The modified CDASI (version 2) is the one in current use (Yassaee *et al*., 2010). The modified CDASI has 3 activity measures (erythema, scale, and erosion/ulceration) and 2 damage measures (poikiloderma and calcinosis) that are assessed over 15 body areas. In addition, Gottron's papules (raised purple patches) on the hands are evaluated both for activity and damage. Lastly, the activity of periungual (area around the fingernails and toenails) changes and alopecia is assessed.

The study plans to enroll 22 adults whose skin disease is refractory to standard-of-care. These adults will receive 20 mg Resunab™ or placebo once a day for 28 days, then twice a day for the next 56 days, for a total treatment duration of 84 days, with 28 days follow-up. We anticipate results from the study in the first half of 2017.

Resunab™ Has Fast Track Status and Orphan Drug Designation for Cystic Fibrosis and Scleroderma

The FDA has granted Resunab™ both Fast Track status and Orphan Drug designation for the treatment of both CF and scleroderma. The Fast Track program was put into place under the FDA Modernization Act of 1997 and is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. Since there are currently no treatments available for scleroderma, Resunab™ would obviously fill an unmet medical need. A company with a drug that receives Fast Track designation is eligible for the following:

- More frequent meetings with the FDA to discuss the drug's development plan and ensure that the appropriate data is being collected to support drug approval.
- More frequent written communication from the FDA about things such as clinical trial design.
- Eligibility for accelerated approval and priority review, including the submission of a New Drug Application (NDA) or a Biologics License application (BLA) on a rolling basis. What this means is that a company can submit completed sections of an NDA or BLA as they are completed and have them reviewed by the FDA, rather than waiting until every section of the application is completed before the entire application can be reviewed.

Orphan drug designation carries a number of other incentives for the company, including increased feedback from the FDA regarding clinical trial design, seven years of market exclusivity following approval for the treatment of CF and/or scleroderma, tax credits, and a waiver of PDUFA fees.

Conclusion and Recommendation

Current anti-inflammatory medications have a number of serious side effects with no therapies that are known to reverse the inflammatory response; they only attempt to halt it. Thus, there is a serious unmet medical need for safer and more efficacious anti-inflammatory medications. The preclinical data for Resunab™ is intriguing and points to a potential safe and novel therapeutic for a number of inflammatory conditions and we are quite interested to see how the compound performs in clinical testing.

Corbus currently has a market cap of approximately $64 million. This valuation is perplexingly low, both in terms of the potential for Resunab™ as well as on a comparable basis. For example, Vertex Pharmaceuticals and Parion Sciences announced a collaboration deal in June 2015 that included $80 million up front and the potential for up to $1.2 billion in milestone payments as well as royalties for a set of compounds that maintain normal mucus viscosity in the lungs, with one of those compounds currently in a Phase 2 clinical trial in CF patients (NCT02343445). What is so remarkable about Corbus' current valuation is that the pipeline is valued at less than the up-front payment that Parion received from Vertex! This signifies that Corbus' value is not accurately reflected by the company's current stock price and represents a great buying opportunity for investors.

In terms of Corbus' valuation, if Resunab™ is shown to be effective in CF and/or scleroderma it could easily have peak U.S. sales of over $1 billion. In fact, we model for peak sales in CF and scleroderma of over $4 billion – admittedly a large number, but investors need to understand that both the size of the market and the potential for very aggressive pricing allows for the arrival at large numbers rather quickly. For example, Vertex Pharma's Kalydeco® posted sales of $464 million in 2014, and the drug only targets less than 10% of CF patients with certain mutations. If effective, Resunab™ would target the entire CF population with no limitations based on patient-specific mutations. Using a probability-adjusted discounted cash flow model, we believe the shares are worth $6.25. While an investment in Corbus is high-risk, it offers a substantial potential return.

PROJECTED FINANCIALS

Corbus Pharmaceuticals, Inc.
Income Statement

Corbus Pharmaceuticals, Inc.	2014 A	Q1 A	Q2 A	Q3 A	Q4 E	2015 E	2016 E
Resunab Scleroderma	$0	$0	$0	$0	$0	$0	$0
Resunab Cystic Fibrosis	$0	$0	$0	$0	$0	$0	$0
Resunab Dermatomyositis	$0	$0	$0	$0	$0	$0	$0
Collaboration Revenue	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-
Cost of Sales	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-
General & Administration	$1.39	$0.81	$0.97	$0.79	$0.90	$3.47	$4.25
Research & Development	$1.26	$0.72	$1.71	$1.63	$2.00	$6.07	$7.50
Other Operating Expenses	$0	$0	$0	$0	$0	$0	$0
Operating Income	($2.65)	($1.54)	($2.56)	($2.25)	($2.90)	($9.25)	($11.75)
Operating Margin	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.11	($0.00)	$0.00	$0.00	($0.20)	($0.20)	($0.50)
Pre-Tax Income	($2.54)	($1.54)	($2.56)	($2.25)	($3.10)	($9.45)	($12.25)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($2.54)	($1.54)	($2.56)	($2.25)	($3.10)	($9.45)	($12.25)
Net Margin	-	-	-	-	-	-	-
Reported EPS	**($0.13)**	**($0.06)**	**($0.10)**	**($0.06)**	**($0.08)**	**($0.30)**	**($0.31)**
YOY Growth	-	-	-	-	-	-	-
Basic Shares Outstanding	20.16	25.87	26.90	34.77	37.00	31.14	40.00

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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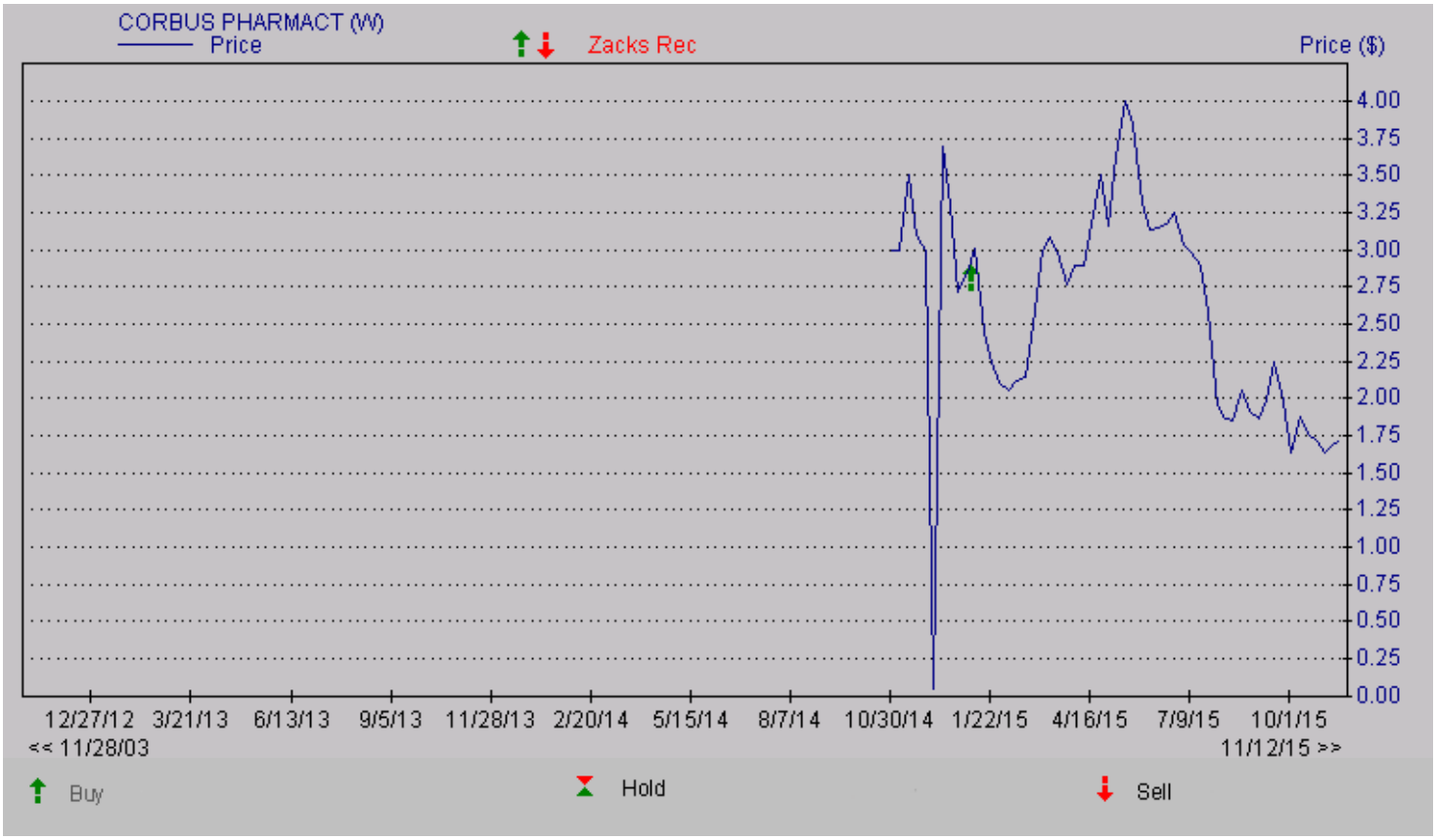
HISTORICAL ZACKS RECOMMENDATIONS



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Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 25.4%, Hold/Neutral- 56.2%, Sell/Underperform – 14.6%. Data is as of midnight on the business day immediately prior to this publication.