Zacks Small-Cap Research

August 17, 2015
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Corbus Pharmaceuticals, Inc. (CRBP - NASDAQ)

CRBP: All Set to Initiate Phase 2 Clinical Trials of Resunab™ for Cystic Fibrosis and Scleroderma…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	01/06/2015
Current Price (08/17/15)	$1.85
Target Price	**$6.25**

UPDATE

On August 13, 2015, Corbus Pharmaceuticals announced financial results for the second quarter of 2015 and provided a business update. Net loss for the quarter was $2.6 million, or $0.10 per share. The company exited the quarter with approximately $9.4 million. When including the money expected from warrant exercises and the development award from the Cystic Fibrosis Foundation the company should have sufficient funds to last into the fourth quarter of 2016.

On the clinical side, the dermatomyositis clinical trial has initiated and the cystic fibrosis and scleroderma trials are expected to initiate and dose the first patients during 3Q15.

SUMMARY DATA

52-Week High	**$4.15**
52-Week Low	**$0.05**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**155,821**
Shares Outstanding (mil)	**26**
Market Capitalization ($mil)	**$48**
Short Interest Ratio (days)	**0.43**
Institutional Ownership (%)	**0**
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 E	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	-$0.08 E	-$0.10 E	-$0.30 E
2016					-$0.31 E
2017					-$0.35 E

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WHAT'S NEW

Financial Update

On August 13, 2015, Corbus Pharmaceuticals, Inc. (CRBP) announced financial results for the second quarter of 2015. During the quarter, 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, which is expected to conclude in the first quarter of 2017. Thus, the company recorded revenue of $113,636 for the three months ended June 30, 2015. Net loss for the quarter was $2.6 million, or $0.10 per share, and was comprised of $0.97 million in G&A and $1.71 million of R&D expenses.

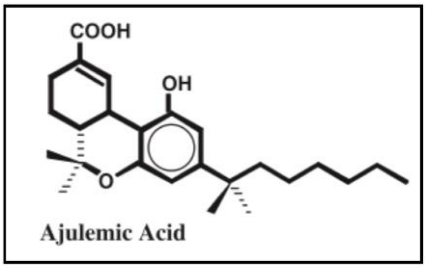
The company exited the second quarter of 2015 with $9.2 million. Subsequent to the end of the quarter, the company announced a call notice for the redemption of certain outstanding warrants. These 11.3 million warrants were issued in April and May 2014 in conjunction with the company's private placement and have 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. Since December 2014, the company had raised approximately $5.1 million from the exercise of these warrants, and we estimate that the remainder of the warrants will bring in an additional $6.2 million.

The exercise of these warrants was an important step for the company, as it: 1) increases the company's cash position such that we estimate there is now sufficient capital to fund the company through the end of 2016, and 2) it cleans up the company's capital structure. Having both of these issues resolved should make the stock more attractive to institutional investors and help in aligning the company's current stock price with its fair value.

Business Update

Corbus is developing Resunab™ (ajulemic acid, AJA) for the treatment of rare, chronic life-threatening inflammatory conditions, including cystic fibrosis (CF), 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 been evaluated in two Phase 1 and one Phase 2 clinical trials, which were conducted by prior licensees Atlantic Pharmaceuticals and Indevus Pharmaceuticals, Inc.

- Phase 1 Study #1: This study evaluated the safety, tolerability, and pharmacokinetics of a single oral dose of Resunab™ in healthy adult males over a dose range of 1 to 10 mg in four dose groups of eight subjects each. Resunab™ had satisfactory bioavailability, was well tolerated, and exhibited linear pharmacokinetics over the dose range tested. There were no life-threatening or serious adverse events in the study. Two subjects in the 3 mg group and one subject in the 6 mg group out of a total of 24 subjects reported adverse events of mild to moderate intensity. The two subjects in the 3 mg group reported blurred vision, difficulty in remembering, mild euphoria, impression of slower movements, dry mouth, and difficulty in concentrating. The subject in the 6 mg group reported orthostatic vagal fainting, feeling dizzy, and nausea immediately after the first blood draw, which occurred prior to the administration of the drug. Since the adverse events were not dose dependent, study investigators concluded that the AEs were not treatment related.

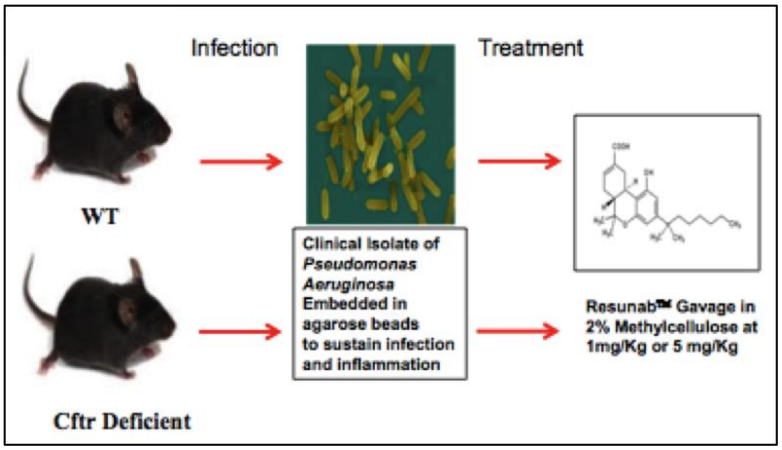
- Phase 1 Study #2: This study evaluated the safety, tolerability, and pharmacokinetics of single and multiple ascending doses of Resunab™ at higher doses. Each dose level had eight subjects, six receiving Resunab™ and two receiving placebo. Doses ranged from 10 to 240 mg single dose, and 20, 40, and 80 mg three times a day (tid) for seven days multi-dose. Resunab™ showed good tolerability at single doses up to 120 mg and multiple doses up to 40 mg three times a day for 7 days. The most frequent adverse events (AEs) were dizziness, nausea, vomiting, pallor, dry mouth, headache, somnolence, tremor, and disorientation. All the AEs were mild to moderate with the majority of them occurring at doses of 120 mg and above for the single dose groups and at the highest multi-dose level of 80 mg tid for seven days.

- Phase 2a: This was a crossover study performed with refractory neuropathic pain (NP) patients. A total of 21 NP patients were treated with either Resunab™ or placebo at 20 or 40 mg twice a day for one week followed by a one-week washout and a cross over. Resunab™ reduced the three hour pain index by up to 28% ($P < 0.03$) in one cohort and was effective at reducing pain by > 30% in half the patients of this same cohort ($P < 0.03$). Resunab™ was well tolerated with no safety issues noted in the study. However, the analgesic effect wore off between three and eight hours post-dose.

Pre-Clinical Data Shows Potential For Resunab™ in CF

On June 1, 2015, Corbus announced the presentation of preclinical data for Resunab™. The compound was tested in a mouse model of CF where the mice have the same ΔF508 mutation that affects 90% of CF patients in the U.S. (Zeiher *et al*., 1995). The mice also have an additional transgene inserted into their genome that allows for expression of a functional CFTR protein in the intestines, since loss of the CFTR protein results in intestinal obstruction and death in a large number of CFTR-deficient mice during the first month of life (Zhou *et al*., 1994).

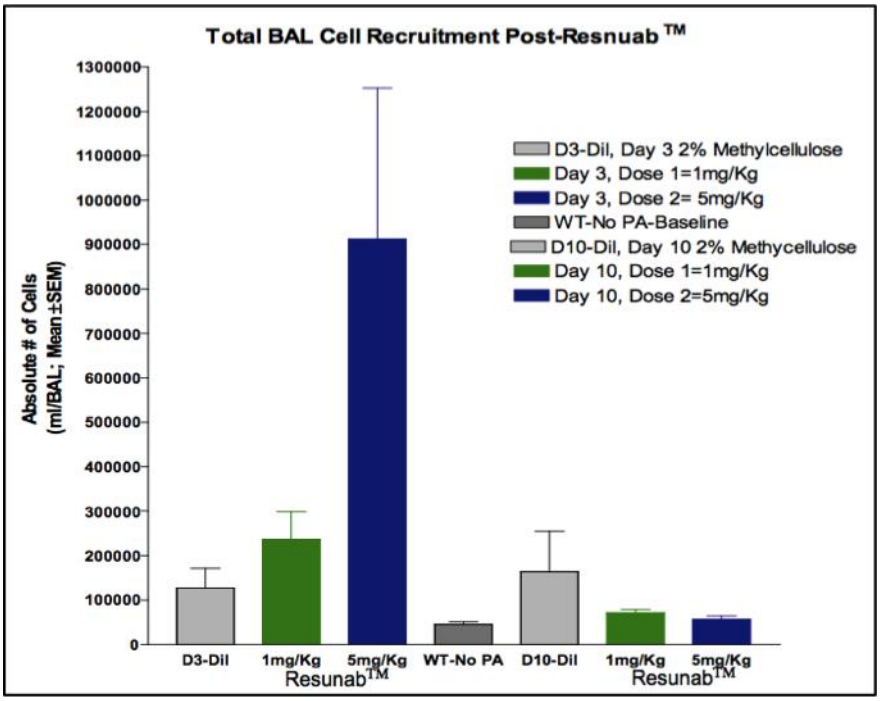
The data presented by Corbus involved two studies: 1) the safety and efficacy of Resunab™ in wild-type mice after infection with *Pseudomonas aeruginosa*, the most common lung pathogen found in CF patients, and 2) the effect of Resunab™ on resolution of inflammation and infection in wild-type and CFTR-deficient mice.



Source: Bonfield *et al*., 2015

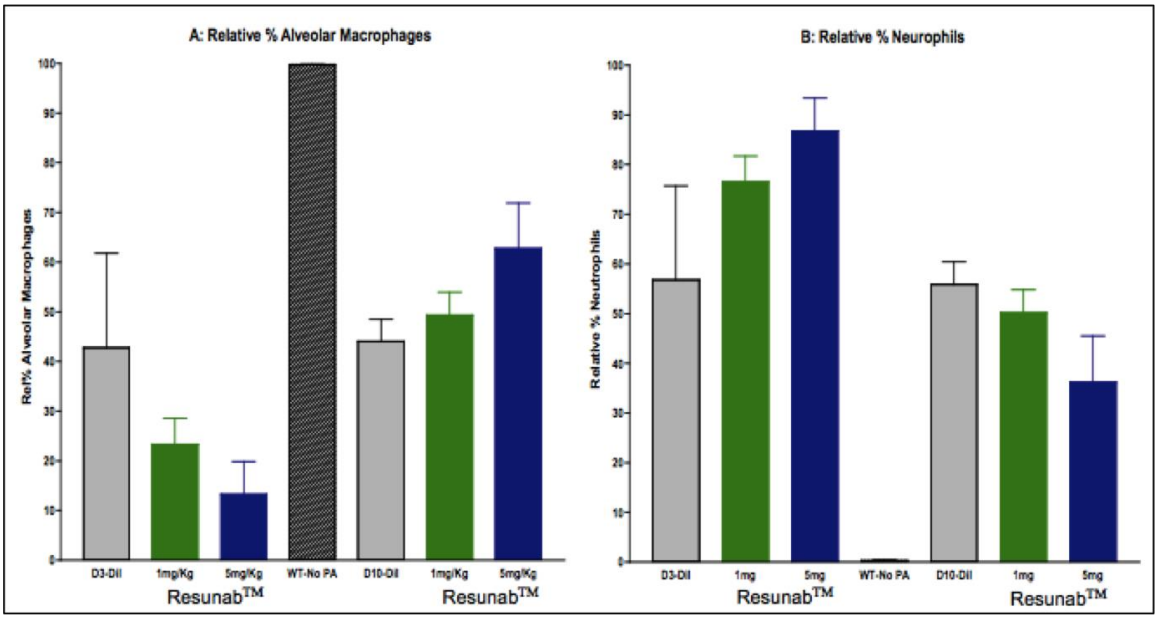
Mice were infected with *P. aeruginosa* on Day 0 and Resunab™ treatment was initiated on Day 1. Mice were treated with either 1 mg/kg or 5 mg/kg Resunab™ twice a day (eight hours apart). A subset of mice were

euthanized on Day 3 to assess the earlier impact of Resunab™ on the infection/inflammation process while the rest of the animals were euthanized on Day 10 to examine the effects of infection/inflammation resolution. The following figure shows the effect of Resunab™ on the inflammatory response to infection with *P. aeruginosa* as assessed by bronchoalveolar lavage (BAL), which is used to examine cell populations in the lungs. While treatment with Resunab™ results in a significant increase in total cell counts on Day 3, this was quickly resolved by Day 10. Resunab™ was delivered to the mice in 2% methylcellulose, thus control mice were given 2% methylcellulose only.



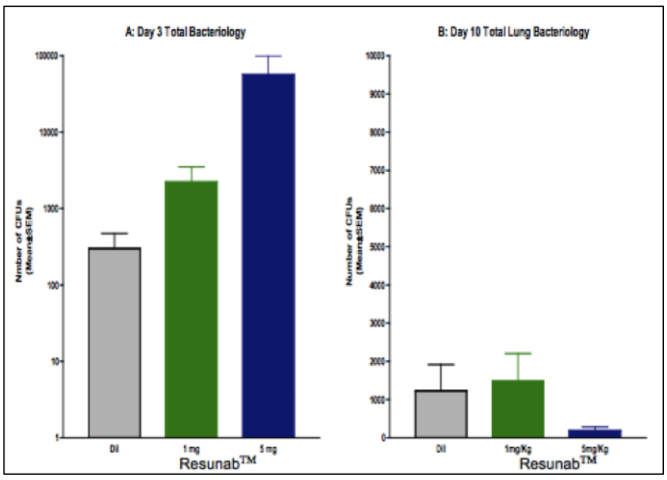
Source: Bonfield *et al.*, 2015

Consistent with the white blood cell counts (shown above), there were elevated levels of neutrophils in all treatment groups relative to control on Day 3 after infection. By Day 10, Resunab™-treated mice showed a decrease in the percentage of neutrophils, with a corresponding increase in the level of macrophages. This decrease in the percentage of neutrophils is indicative of the resolution of the inflammatory response. The company reported that there were no significant differences or levels of lymphocytes or eosinophils in any of the groups.



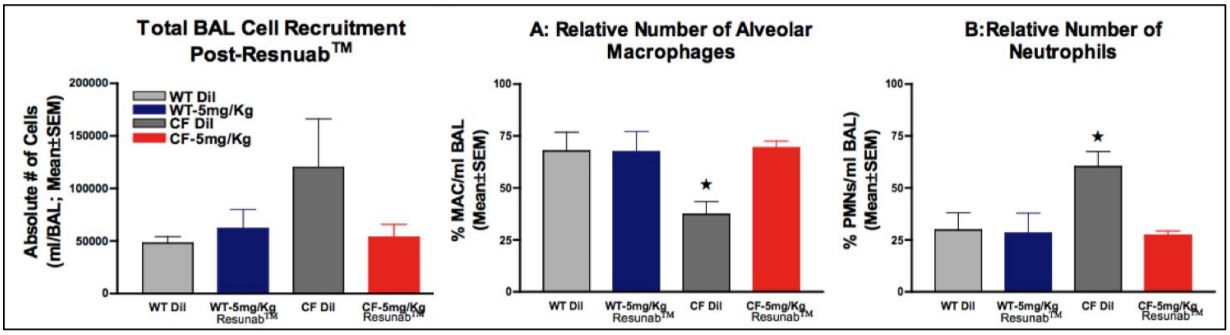
Source: Bonfield *et al.*, 2015

The next figure shows an interesting phenomenon in that treatment with 5 mg/kg Resunab™ resulted in a significant increase in bacterial cell counts by Day 3 after infection. We are unsure as to the likely mechanism behind this increase, however there was an approximately 3-log reduction in the number of bacterial cells by Day 10. Also, the increase in bacterial cell counts on Day 3 was not accompanied by any change in clinical parameters. Readers should note the following graph on the left is in log-scale while the graph on the right is linear scale.



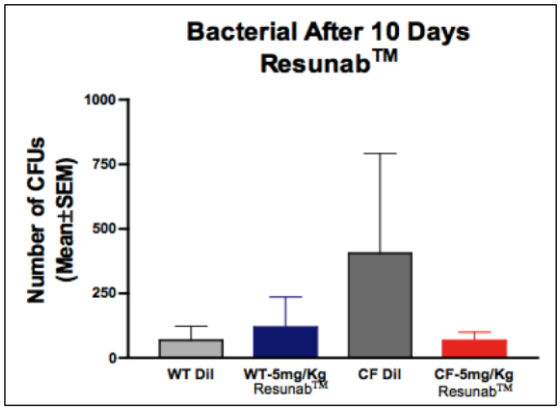
Source: Bonfield *et al.*, 2015

The previous data was generated with wild type mice. When the same studies were performed with CFTR-deficient mice ("CF mice") the results showed that those mice were less able to clear bacterial infections even though they had a heightened immune response, as shown by an increase in the percentage of neutrophils obtained from BAL at Day 10. However, treatment of CF mice with Resunab™ caused a reduction in the inflammatory response similar to what was seen in wild-type mice.



Source: Bonfield *et al.*, 2015

This reduction in inflammatory response was coupled with an increased ability for CF mice treated with Resunab™ to clear the *P. aeruginosa* infection similarly to wild-type mice, while CF mice not treated with Resunab™ were not able to clear the infection effectively. The company reported that 5/5 CF mice treated with Resunab™ survived the experiment to Day 10, while only 3/5 CF mice not treated with Resunab™ survived the full 10 days.



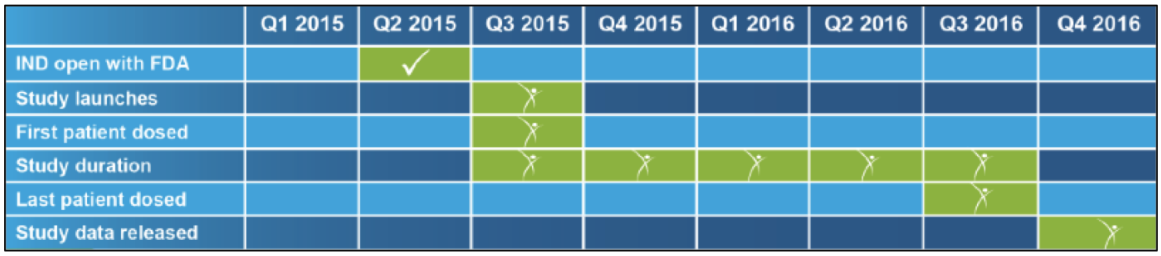
Source: Bonfield *et al.*, 2015

Cystic Fibrosis and Scleroderma Trials to Get Underway in 3Q15

Corbus is planning to initiate the Phase 2 trials of Resunab™ for the treatment of scleroderma and cystic fibrosis (CF) during the third quarter of 2015.

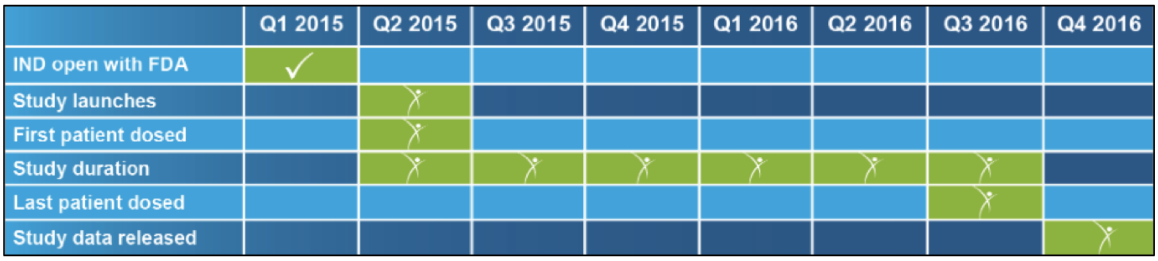
The CF clinical trial will be a randomized, double blind, placebo-controlled study at 20 sites in the U.S. and EU (NCT02465450). The primary endpoints of the study are safety and tolerability, with a target enrollment of 70 adults with CF. Secondary endpoints will include pharmacokinetic (PK) and efficacy 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.



Source: Corbus Pharmaceuticals

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. We estimate the study will take approximately 18 months from initiation to data release. Below is a quick representation of the expected timeline for the Phase 2 Resunab™ scleroderma study.



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.

Conclusion

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.

When taking into account the exercise of the 11.3 million warrants, Corbus currently has a market cap of approximately $80 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 recently announced a collaboration deal 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 $200 million in the first twelve months after launch and the drug only targets the 4% of CF patients with the G551D mutation. 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

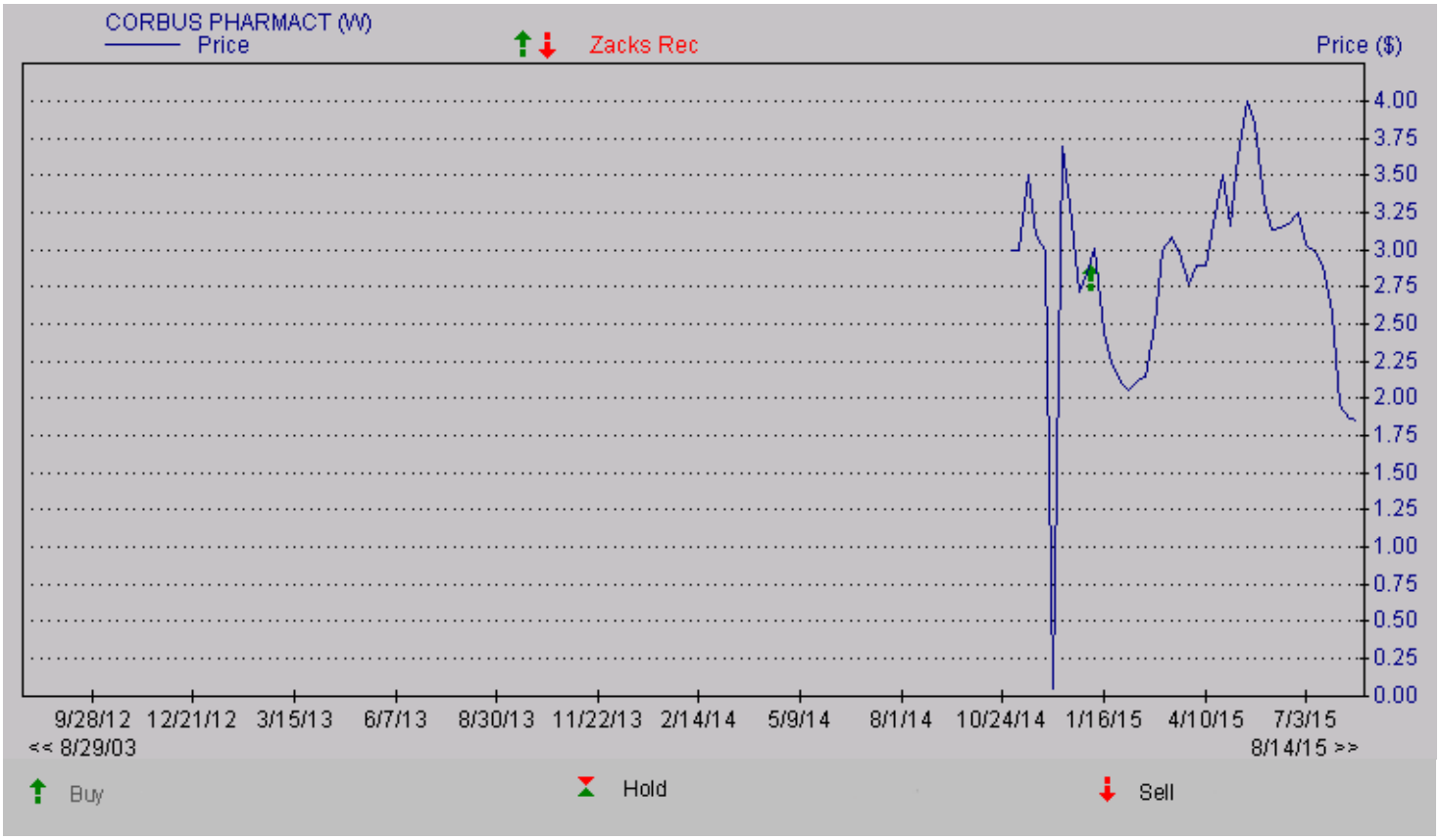
Corbus Pharmaceuticals, Inc.
Income Statement

Corbus Pharmaceuticals, Inc.	2014 A	Q1 A	Q2 A	Q3 E	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	$0.85	$0.90	$3.53	$4.25
Research & Development	$1.26	$0.72	$1.71	$1.25	$2.00	$5.68	$7.50
Other Operating Expenses	$0	$0	$0	$0	$0	$0	$0
Operating Income	($2.65)	($1.54)	($2.56)	($2.10)	($2.90)	($9.10)	($11.75)
Operating Margin	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.11	($0.00)	$0.00	($0.15)	($0.20)	($0.35)	($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)**	**($0.08)**	**($0.10)**	**($0.34)**	**($0.31)**
YOY Growth	-	-	-	-	-	-	-
Basic Shares Outstanding	20.16	25.87	26.90	29.00	30.00	27.94	40.00

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

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Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
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- 28.0%, Hold/Neutral- 50.3%, Sell/Underperform – 18.5%. Data is as of midnight on the business day immediately prior to this publication.