Zacks Small-Cap Research

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David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Cerecor Inc.

(CERC-NASDAQ)

CERC: Encouraging Proof-of-Concept Data for CERC-002 in COVID-19 ARDS…

Based on our probability adjusted DCF model that takes into account potential future revenues from the company's rare and orphan disease pipeline along with the sale of PRVs, and using a 13.5% discount rate CERC is valued at $9.00/share.

Current Price (02/08/21)	$3.44
Valuation	**$9.00**

OUTLOOK

In January 2021, Cerecor Inc. (CERC) announced encouraging proof-of-concept data for CERC-002 for the treatment of hospitalized patients with COVID-19 ARDS. CERC-002 is a monoclonal antibody that targets LIGHT (TNSF14), a pro-inflammatory cytokine. A single dose of CERC-002 increased the proportion of patients alive and free of respiratory failure over the 28-day study period (OR = 2.62; *P*=0.059). A prespecified subgroup analysis of patients ≥60 years of age showed that treatment with CERC-002 resulted in a 3-fold increase in the likelihood of avoiding respiratory failure and death compared to placebo (OR = 3.38; *P*=0.054). We anticipate 60-day safety data being reported in the first quarter of 2021 along with a meeting with the FDA to discuss the initiation of a registration trial and filing for Breakthrough Therapy Designation.

SUMMARY DATA

52-Week High	**$4.27**
52-Week Low	**$1.70**
One-Year Return (%)	**-19.44**
Beta	**1.63**
Average Daily Volume (sh)	**1,407,301**
Shares Outstanding (mil)	**89**
Market Capitalization ($mil)	**$306**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**66**
Insider Ownership (%)	**58**
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 2020 Estimate	**-7.5**
P/E using 2021 Estimate	**-8.1**

Risk Level	**Above Avg.**
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)
2019	5.4 A	4.4 A	5.5 A	-8.6 A	6.8 A
2020	2.8 A	1.3 A	1.1 A	2.0 E	7.2 E
2021					8.0 E
2022					108.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	-$0.13 A	-$0.11 A	-$0.07 A	$0.03 A	-$0.38 A
2020	-$0.13 A	-$0.11 A	-$0.07 A	-$0.15 E	-$0.90 E
2021					-$0.51 E
2022					$0.46 E

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WHAT'S NEW

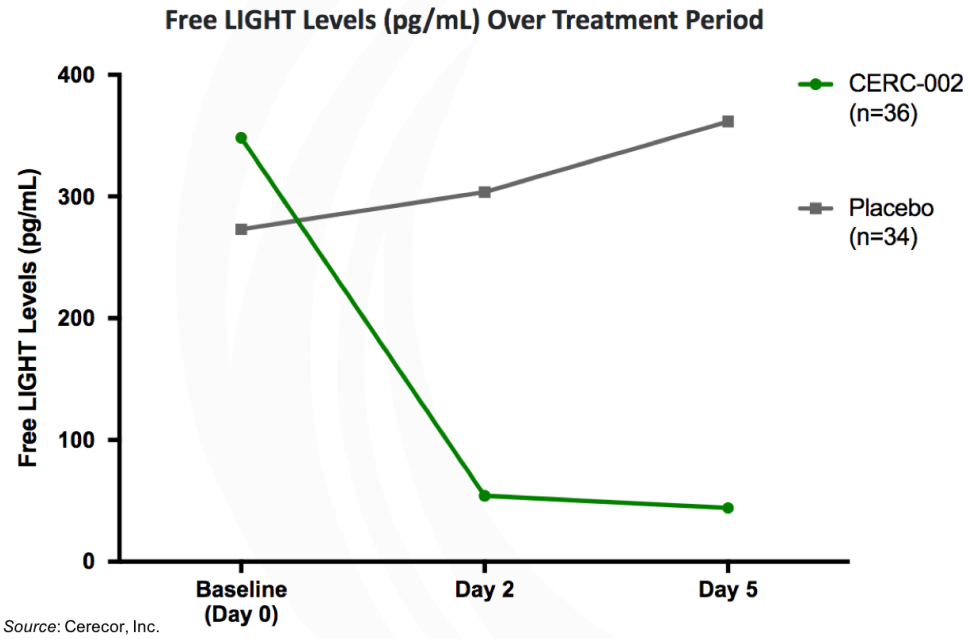
Business Update

Encouraging Proof-of-Concept Data for CERC-002 in ARDS

In January 2021, Cerecor, Inc. (CERC) announced proof-of-concept data from the exploratory Phase 2 clinical trial of CERC-002 in hospitalized patients with COVID-19 ARDS (NCT04412057). A total of 83 patients (82 treated) were randomized 1:1 to receive standard of care plus either a single dose of CERC-002 (16 mg/kg, maximum 1200 mg) or placebo. Since the protocol allowed for the use of high-flow oxygen prior to randomization (which was part of the definition of 'respiratory failure', the primary outcome), the intent-to-treat (ITT) population included 62 patients for analysis of the primary endpoint.

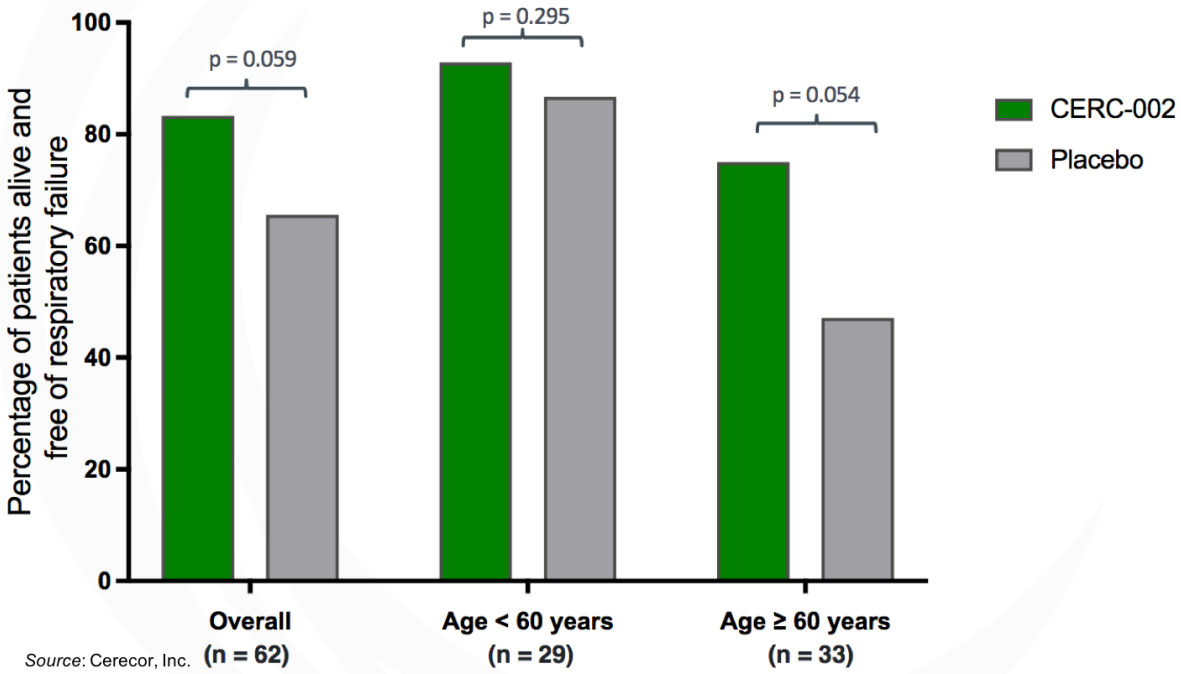
CERC-002 is a monoclonal antibody targeted against LIGHT (**L**ymphotoxin-like, exhibits **I**nducible expression, and competes with HSV **G**lycoprotein D for **H**VEM, a receptor expressed by **T** lymphocytes [part of the Tumor Necrosis Super Family 14]), an inflammatory cytokine that is involved in stimulating T cells and the innate immune response (Ward-Kavanagh *et al*., 2016). It is known to induce the expression of other proinflammatory cytokines such as IL-6 and GM-CSF (Antunes *et al*., 2018). In addition, its expression is induced by rhinovirus infection and it is involved in airway remodeling driven by allergens (Mehta *et al*., 2018).

The following graph shows the change in free LIGHT levels in patients over the treatment period. The average LIGHT levels were similar between cohorts, with LIGHT levels approximately 100 pg/mL higher in patients ≥60 years of age. The reduction in light levels by CERC-002 is particularly impressive as it was administered in addition to corticosteroids, which approximately 90% of patients received. We anticipate additional data on LIGHT levels out to Day 28 at the next update.



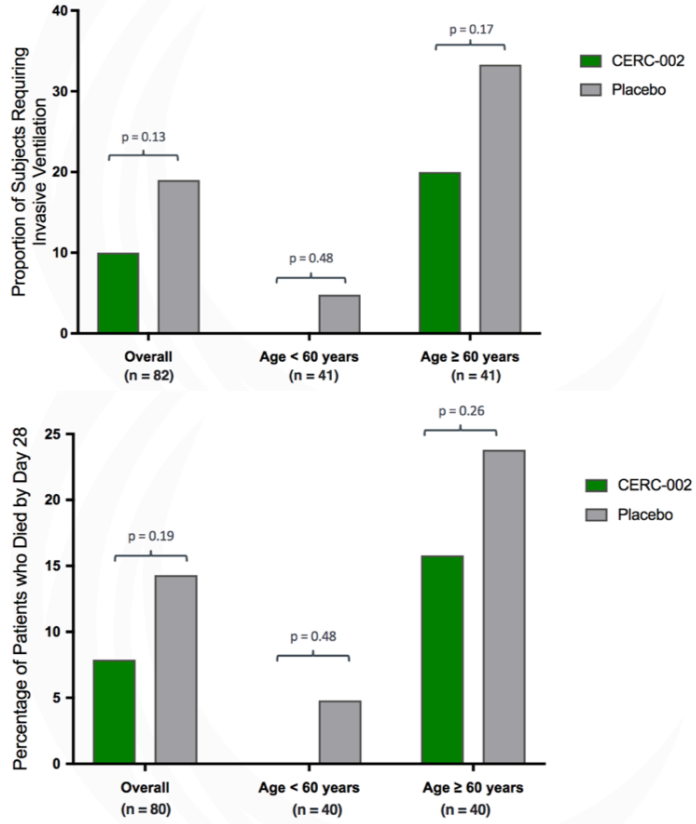
Source: Cerecor, Inc.

The primary endpoint of the trial was the proportion of patients alive and free of respiratory failure over the 28-day study period, with respiratory failure defined as endotracheal intubation and mechanical ventilation, oxygen delivered by high-flow nasal cannula, noninvasive positive pressure ventilation, or extracorporeal membrane oxygenation. The results showed that a single treatment of CERC-002 increased the proportion of patients alive and free of respiratory failure over the 28-day study period compared to placebo (OR = 2.62; *P*=0.059), particularly in patients ≥60 years of age (OR = 3.38; *P*=0.054) as shown in the following figure.



Source: Cerecor, Inc.

In addition to showing a positive trend for the primary endpoint, there were clear trends evident for CERC-002 to decrease the need for invasive ventilation and reduce the risk of 28-day mortality, as shown in the following figures. Both of these effects were driven by results in patients ≥60 years of age. While the results did not hit statistical significance, likely due to the low number of events, the data will serve as a guide for properly powering a pivotal trial.



Source: Cerecor, Inc.

Regarding safety, CERC-002 was well tolerated at a single dose of 16 mg/kg (1,200 mg maximum dose) with no drug-related serious adverse events. In addition, there was no evidence of increased infections or other adverse events related to immunosuppression, with the majority of adverse events reported as mild or moderate.

	CERC-002 N = 40	Placebo N = 42
Subjects with ≥1 AE (%)	16 (40%)	21 (50%)
Subjects with ≥ Drug-related AE	8 (20%)	6 (14.3%)
AEs > 5%		
Leukocytosis	6 (15%)	4 (9.5%)
Anemia	4 (10%)	3 (7.1%)
Hepatic enzyme increase	4 (10%)	2 (4.8%)
Acute kidney injury	3 (7.5%)	2 (4.8%)
Respiratory failure	3 (7.5%)	3 (7.1%)

Source: Cerecor, Inc.

Looking ahead, we anticipate 60-day follow up data to be reported during the first quarter of 2021, with the full data set presented a scientific conference later this year. In addition, the company will conduct an 'End-of-Phase 2' meeting with the FDA to discuss the design of a registration trial as well as filing for Breakthrough Therapy Designation.

Financial Update

Cerecor recently completed a public offering that included the exercise by the underwriters of their option to purchase an additional approximately 1.6 million shares, which increased the total offered through the public offering to approximately 14.0 million and approximately 1.7 million prefunded warrants. This resulted in gross proceeds to the company of approximately $40.7 million. Following the offering, we estimate that the company has approximately $60 million in cash and cash equivalents and approximately 89 million shares outstanding, with a fully diluted share count of approximately 111 million.

Conclusion

We are excited about the data for CERC-002 in COVID-19 ARDS patients, particularly since the drug appears to exert the greatest effect in patients ≥60 years of age, a cohort that is desperately in need of more effective therapies. In addition to providing proof-of-concept data as a COVID-19 treatment, we believe the data presented by Cerecor also serves as excellent proof-of-concept as a potential treatment for non-COVID-19 ARDS patients, which is also a critical situation as there are no pharmacological treatments specifically for ARDS and approximately 40% of hospitalized patients die from it. Outside of ARDS, we anticipate initial data from a trial of CERC-002 in severe pediatric onset Crohn's disease in the first quarter of 2021. Based on the CERC-002 results and its potential in ARDS we have increased our valuation to $9 per share.

PROJECTED FINANCIALS

Cerecor, Inc.	2019 A	Q1 A	Q2 A	Q3 A	Q4 E	2020 E	2021 E	2022 E
Commercial Group	$6.7	$2.8	$1.3	$1.1	$2.0	$7.2	$8.0	$8.0
Rare Disease Portfolio	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$100.0
PRV Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Grant Revenue	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$6.8**	**$2.8**	**$1.3**	**$1.1**	**$2.0**	**$7.2**	**$8.0**	**$108.0**
Cost of Sales	($0.6)	$0.1	$0.1	$0.1	$0.3	$0.5	$1.0	$1.0
Product Gross Margin	*108%*	*98%*	*94%*	*93%*	*88%*	*93%*	*88%*	*99%*
Research & Development	$11.8	$4.8	$5.9	$8.9	$10.0	$29.6	$34.0	$40.0
Acquired in-process R&D	$0.0	$25.5	$0.0	$0.0	$0.0	$25.5	$0.0	$0.0
General & Administrative	$10.1	$2.7	$6.1	$4.6	$3.1	$16.5	$18.0	$20.0
Sales and Marketing	$1.5	$0.7	$0.7	$0.5	$0.0	$1.8	$0.0	$0.0
Amortization Expense	$1.3	$0.4	$0.4	$0.4	$0.0	$1.2	$0.0	$0.0
Impariment of Intangible Assets	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Change in fair value of contingent consideration	($1.3)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($16.1)	($31.4)	($11.8)	($13.3)	($11.4)	($67.9)	($45.0)	$47.0
Operating Margin	*-239%*	-	-	-	-	*-942%*	*-563%*	*44%*
Other (expense) income	$0.1	$7.1	($1.5)	$0.0	$0.0	$5.7	($1.2)	($1.2)
Pre-Tax Income	($16.0)	($24.3)	($13.3)	($13.3)	($11.4)	($62.2)	($46.2)	$45.8
Income Taxes Paid	$0.3	($2.2)	($0.5)	$0.0	$0.1	($2.5)	$0.1	$0.1
Net Income	**($16.3)**	**($22.2)**	**($12.8)**	**($13.3)**	**($11.5)**	**($59.7)**	**($46.3)**	**$45.7**
Net Margin		-	-	-	-			
Reported EPS	**($0.38)**	**($0.13)**	**($0.11)**	**($0.07)**	**($0.15)**	**($0.90)**	**($0.51)**	**$0.46**
YOY Growth		-	-	-	-			
Basic Shares Outstanding	42.9	53.9	62.8	74.9	75.0	66.7	90.0	100.0

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

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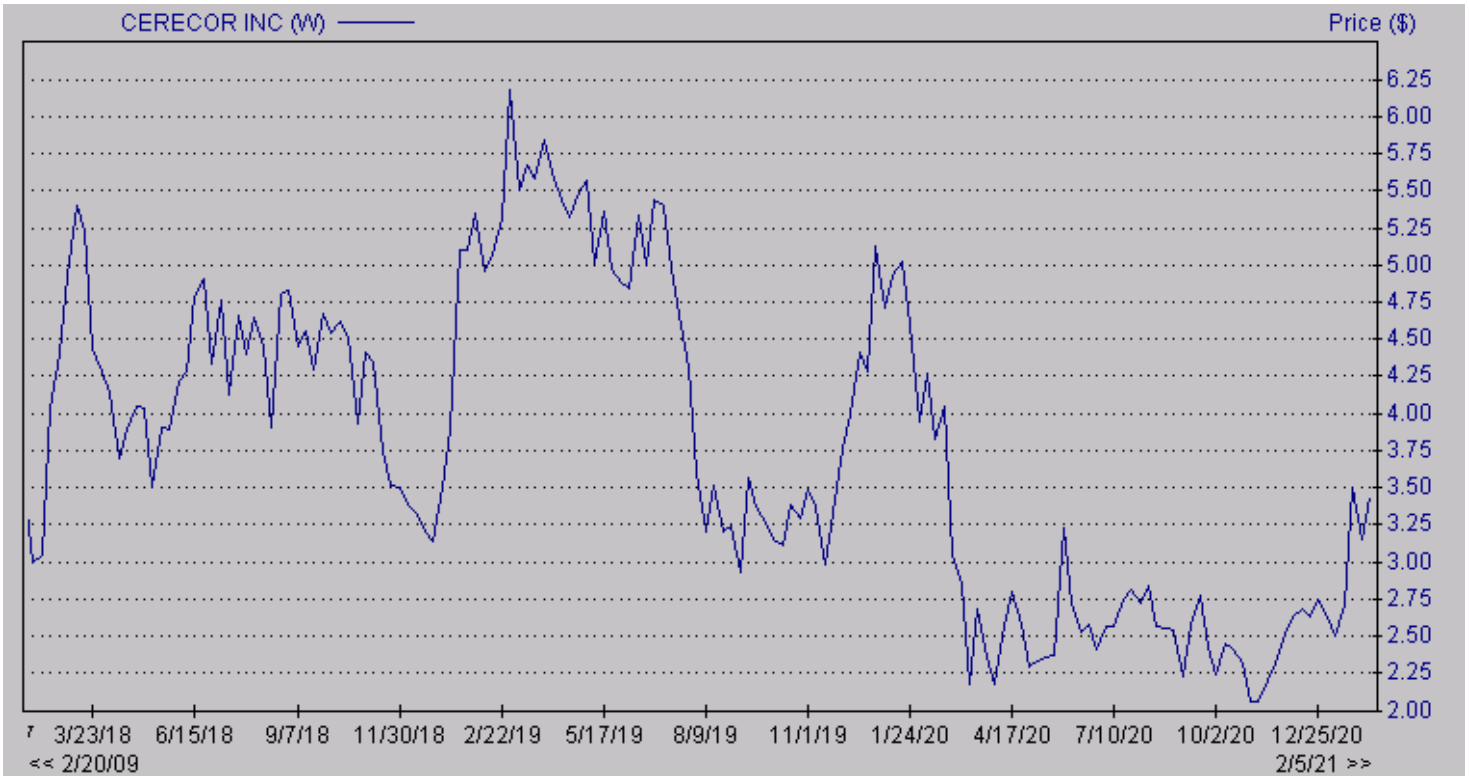
HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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