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Cerecor Inc.

(CERC-NASDAQ)

CERC: Topline Data from COVID ARDS Trial in 4Q20…

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 $7.00/share.

Current Price (08/13/20)	$2.60
Valuation	**$7.00**

OUTLOOK

On August 6, 2020, Cerecor Inc. (CERC) announced financial results for the second quarter of 2020 and provided a business update. The company has a number of catalysts upcoming over the next six to 12 months, including a data readout from the proof-of-concept trial of CERC-002 in patients with ARDS caused by COVID-19 in the fourth quarter of 2020 and proof-of-concept data for CERC-007 in both multiple myeloma and AOSD. The company exited the second quarter of 2020 with $45.4 million in cash due in part to a recently completed $35 million public offering and divesting its equity stake in Aytu Biosciences for $12.8 million. We estimate the company's current cash will fund operations into the second quarter of 2021.

SUMMARY DATA

52-Week High	**$5.71**
52-Week Low	**$1.70**
One-Year Return (%)	**-24.85**
Beta	**1.83**
Average Daily Volume (sh)	**947,445**
Shares Outstanding (mil)	**75**
Market Capitalization ($mil)	**$195**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**60**
Insider Ownership (%)	**64**
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	**-5.5**
P/E using 2021 Estimate	**-4.0**

Risk Level	**Above Avg.**
Type of Stock	**Small-Blend**
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	2.0 E	2.0 E	8.1 E
2021					8.0 E
2022					8.0 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 E	-$0.09 E	-$0.72 E
2021					-$0.38 E
2022					-$0.39 E

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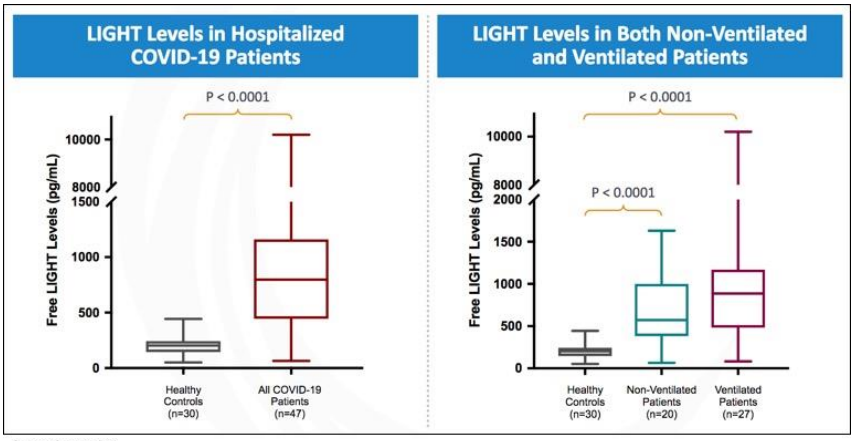
WHAT'S NEW

Business Update

Proof-of-Concept Data for CERC-002 in ARDS in 4Q20

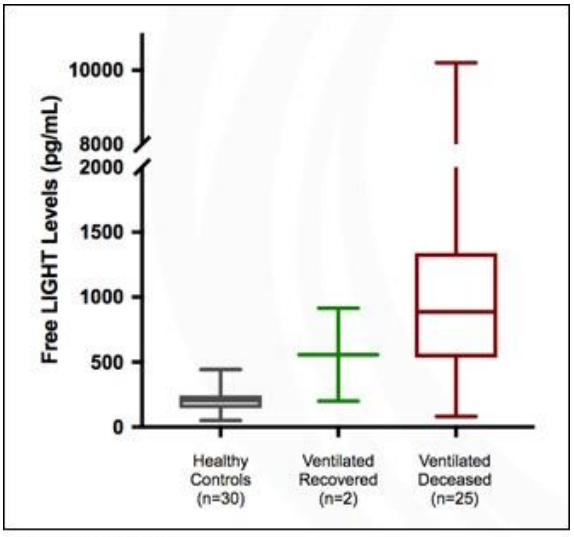
Cerecor, Inc. (CERC) is currently conducting a proof-of-concept clinical trial of CERC-002 (anti-LIGHT monoclonal antibody) in patients suffering from cytokine storm as a result of COVID-19. It is a randomized, double blind, placebo controlled trial in hospitalized patients with confirmed COVID-19 infection and clinical evidence of pneumonia and acute lung injury. Patients will be randomized 1:1 to receive a single injection of CERC-002 (16 mg/kg up to 1200 mg maximum) on Day 1 or placebo along with standard of care. The primary endpoint is the proportion of patients treated with CERC-002 compared to placebo that are alive and free of respiratory failure at Day 28. Key secondary outcomes are one-month mortality, the change in PaO_2/FiO_2 ratio, the time to and duration of invasive ventilation, markers of inflammation, and viral load. We anticipate initial data in the fourth quarter of 2020.

The company had previously announced that hospitalized COVID-19 patients had significantly elevated levels of the inflammatory cytokine LIGHT. The following figure shows the serum levels of LIGHT compared to a group of healthy controls and that the levels of LIGHT are highest in ventilated patients.



Source: Cerecor, Inc.

Elevated LIGHT levels are also linked to increased mortality in ventilated patients. The following figure shows that LIGHT levels were highest in ventilated patients that ultimately died compared to those that recovered. The observed mortality rate in ventilated patients (93%) was much higher compared to non-ventilated patients (20%).



Source: Cerecor, Inc.

Background on LIGHT and ARDS

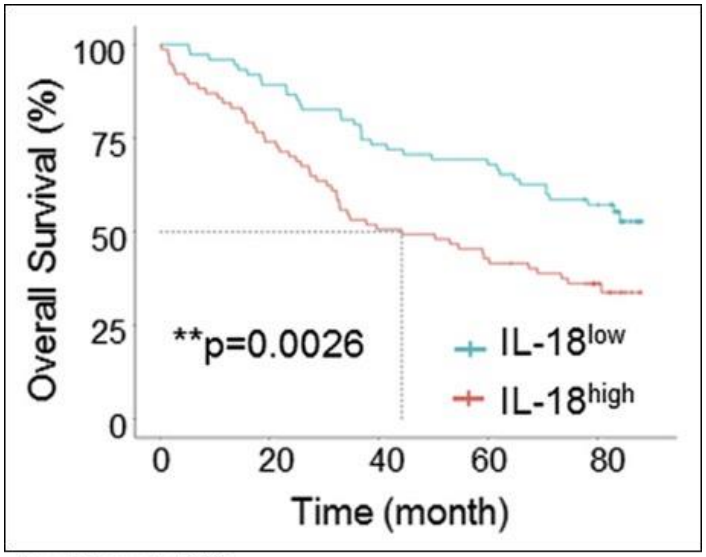
LIGHT (**L**ymphotoxin-like, exhibits **I**nducible expression, and competes with HSV **G**lycoprotein D for **H**VEM, a receptor expressed by **T** lymphocytes [part of the Tumor Necrosis Super Family 14]) is an inflammatory cytokine that is involved in stimulating T cells and the innate immune response (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).

ARDS results in the small blood vessels of the lung leaking fluid that fills up the alveoli, thus preventing proper oxygen exchange (Stevens *et al*., 2018). It is caused by a number of different conditions, including infections (e.g., pneumonia), severe burns, pancreatitis, inhalation of smoke or chemicals, or other serious illnesses. An excessive inflammatory response appears to be involved in the pathogenesis of ARDS (Li *et al*., 2019). Current treatment options involve supportive care while the lungs heal, which involves oxygen therapy supplied through a ventilator. There are no pharmacological treatments specifically for ARDS and approximately 40% of hospitalized patients die from it (Siegel *et al*., 2020).

Update on CERC-007

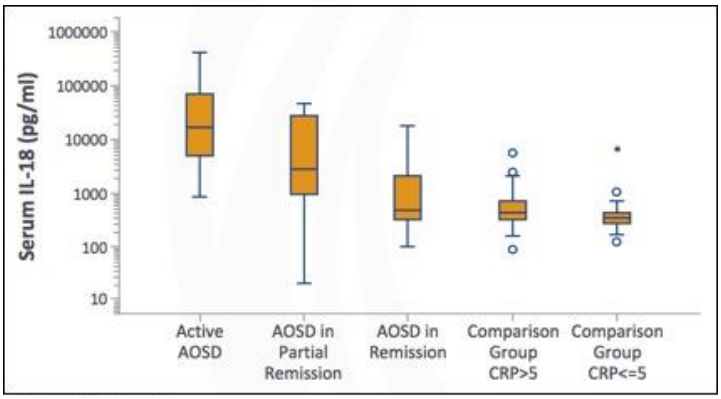
CERC-007 is an anti-interleukin (IL)-18 fully human monoclonal antibody that is being developed for the treatment of multiple myeloma (MM) and Adult Onset Stills Disease (AOSD). We anticipate proof-of-concept clinical trials initiating in both indications in the fourth quarter of 2020.

- MM is a cancer of monoclonal plasma cells that derive from post-germinal-center B cells. The disease is characterized by an infiltration of these cells into the bone marrow causing anemia, lytic bone disease, hypercalcemia, and kidney damage from the accumulation of monoclonal immunoglobulins (Kumar *et al*., 2017). The disease is most common in the elderly, with a median age of onset of 69 years (NCI SEER). Elevated IL-18 serum levels are associated with poor overall survival in MM patients (Alexandrakis *et al*., 2004) and IL-18 drives the generation of myeloid-derived suppressor cells (MDSCs) that accelerate disease progression (Nakamura *et al*., 2018). The following graph shows that MM patients with low levels of IL-18 have improved overall survival compared with patients that have high levels of IL-18, thus suggesting that decreased IL-18 levels may improve MM treatment.



Source: Nakamura *et al*., 2018

- AOSD is an inflammatory disease in which patients suffer from high fevers, sore throat, joint pain, swollen lymph nodes, and weight loss. The cause is unknown and no risk factors have been identified. Approximately 1 in 100,000 people develop AOSD each year and it becomes a chronic condition in approximately 1/3rd of those affected (Medlineplus). We estimate there are approximately 4,000 patients in the U.S. with AOSD. The following figure shows that IL-18 levels are highest in patients with active AOSD when compared with to those with high or low levels of CRP.



Source: Cerecor, Inc.

Update on CERC-006

CERC-006 is a small molecule inhibitor of the mTORC1/2 complexes that is being developed for the treatment of complex lymphatic malformation (LM). LMs are rare, non-malignant masses composed of fluid-filled channels or spaces caused by the improper formation of the lymphatic system. The abnormal lymphatic vessels cause the slow transfer of lymphatic fluid back into the venous system, thus excessive fluid accumulates and dilates the lymphatic channels. LMs form prior to birth and are typically identified within the first two years of life. They most commonly affect the head and neck area but can occur anywhere in the body. They affect approximately 50,000 individuals in the U.S.

The cellular receptor TIE2 plays a key role in vascular maturation through the PI3K/AKT/mTOR signaling pathway, and up to 60% of venous malformations are caused by mutations in TIE2 (Hammer *et al*., 2018) while another 20% are due to mutations in PIK3CA, which encodes the catalytic subunit of PI3K (Limaye *et al*., 2015).

Sirolimus is an allosteric inhibitor of mTOR, the catalytic subunit of two distinct complexes: mTORC1 and mTORC2. It inhibits mTORC1 (Tsang *et al*., 2007) but only inhibits mTORC2 in certain cell types after prolonged exposure (Sarbassov *et al*., 2006).

A systematic review identified twenty studies that included 71 patients with vascular malformations (45 patients with LM) treated with sirolimus (Wiegand *et al*., 2018). Despite dosing and duration of treatment differences, 60 patients experienced a partial remission of disease. Thus, we believe these data provide compelling justification for testing an mTORC1/2 inhibitor for the treatment of LM.

Cerecor recently announced the CERC-006 has been granted both Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPDD). ODD includes seven years of market exclusivity upon FDA approval, an exemption of FDA application fees, and tax credits for qualified clinical trials. RPDD allows for the issuance of a priority review voucher (PRV) upon FDA approval.

Cerecor has completed a pre-IND meeting with the FDA that included concurrence on inclusion criteria and the outline for a proof-of-concept trial. We anticipate the study initiating in the first quarter of 2021.

CERC-800 Series Update

Cerecor is developing CERC-801 (D-galactose), CERC-802 (D-mannose), and CERC-803 (L-fucose) for the treatment of the congenital disorder of glycosylation (CDG) diseases phosphoglucomutase 1 (PGM1) deficiency, mannose-phosphate isomerase (MPI) deficiency, and leukocyte adhesion deficiency type II (LADII) or SLC35C1-CDG, respectively.

The company initiated the CDG First (Congenital Disorders of Glycosylation Formative Retrospective Study) trial in July 2019 and recently announced its completion. The purpose of the CDG FIRST trial was to collect natural history data from patients diagnosed with CDGs along with any treatment-related data whether or not they had been treated with D-galactose, D-mannose, or L-fucose to help guide confirmatory trials.

We anticipate pivotal trials for CERC-801 and CERC-802 initiating in the fourth quarter of 2020. For CERC-801, an estimated 10 patients will be enrolled into a six-month study with the primary endpoint of surrogate biomarkers. For CERC-802, an estimated five patients will be enrolled into a three-month study with the primary endpoint of the

maintenance of antithrombin III. For CERC-803, an IND submission is planned for the fourth quarter of 2020. We anticipate approval for -801 and -802 in 2022.

Potential for Priority Review Voucher

CERC-600 and the 800 Series products have RPDD and thus are eligible for PRVs. A PRV allows the holder of the voucher to receive an expedited six-month review from the FDA for an NDA or biologics license application (BLA) instead of the usual ten-month review. The Food and Drug Administration Safety and Innovation Act (FDASIA) created the rare pediatric voucher in 2012 to specifically target the need for additional therapies for rare pediatric subsets of diseases (affect fewer than 200,000 individuals in the U.S.). PRVs are also awarded for the development of treatments for certain tropical diseases and medical countermeasures.

PRVs are fully transferrable, and a number of companies that have been issued the vouchers in the past have sold them, including one that was sold to AbbVie (ABBV) in Aug. 2015 for $350 million. The four most recent purchases are by Biohaven Pharmaceutical Holding Company for $105 million in Mar. 2019, AstraZeneca (AZN) for $95 million in Aug. 2019, an undisclosed buy for $95 million in Dec. 2019, and Vifor for $111 million in Feb. 2020. While prices for PRVs have come down since AbbVie purchased one for $350 million in 2015, the price for them appears to have settled to approximately $100 million. The following table shows how many PRVs have been issued along with the current status of the voucher, if known.

Priority Review Vouchers

Voucher Award Date	Voucher Type	Voucher Awardee	Voucher Status
2009	Tropical Disease	Novartis	Used for BLA for canakinumab
2012	Tropical Disease	Janssen	Used to accelerate approval of Tremfya (guselkumab) for plaque psoriasis
2014	Rare Pediatric Disease	BioMarin	Sold to Sanofi for $67.5M in Jul 2014; used for approval of Praluent
2014	Tropical Disease	Knight Therapeutics	Sold to Gilead for $125M in Nov 2014; used for approval of Odefsey
2015	Rare Pediatric Disease	United Therapeutics	Sold to AbbVie for $350M in Aug 2015
2015	Rare Pediatric Disease	Asklepion Pharmaceuticals	Transferred to Retrophin and sold to Sanofi for $245M in May 2015
2015	Rare Pediatric Disease	Wellstat Therapeutics	Transferred to AstraZeneca
2015	Rare Pediatric Disease	Alexion Pharmaceuticals	Used for approval of ALXN1210
2015	Rare Pediatric Disease	Alexion Pharmaceuticals	Not used
2016	Tropical Disease	PaxVax Bermuda	Not used (possibly sold to Gilead for ~$200M in 2Q16)
2016	Rare Pediatric Disease	Sarepta Therapeutics	Sold to Gilead for $125M in Feb 2017; used for approval of HIV treatment
2016	Rare Pediatric Disease	Ionis Pharmaceuticals	Not used
2017	Rare Pediatric Disease	Marathon Pharmaceuticals	Not used
2017	Rare Pediatric Disease	BioMarin	Sold for $125 million in Nov 2017
2017	Tropical Disease	Chemo Research, S.L.	Not used
2017	Rare Pediatric Disease	Novartis	Used for brolucizumab for wetAMD
2017	Rare Pediatric Disease	Ultragenyx Pharmaceutical	Sold to Novartis for $130 million in Dec. 2017; used for approval of siponimod
2017	Rare Pediatric Disease	Spark Therapeutics	Sold to Jazz Pharmaceuticals for $110 million in Apr 2018
2018	Rare Pediatric Disease	Ultragenyx Pharmaceutical	Sold to Gilead for $80.6 million in Aug. 2018
2018	Rare Pediatric Disease	Medicines Development	Sold to Novo Nordisk for undisclosed amt
2018	Rare Pediatric Disease	GW Pharma	Sold to Biohaven for $105 million on Mar. 18, 2019
2018	Material Threat Medical Countermeasure	SIGA Technologies	Sold to Eli Lilly for $80 million on Nov. 1, 2018
2018	Tropical Disease	GlaxoSmithKline	Used by ViiV Healthcare for NDA for HIV-1 infection
2018	Rare Pediatric Disease	Leadiant Bioscience Inc	Not used
2018	Rare Pediatric Disease	Sobi and Novimmune	Sold to AZN for $95 million in Aug 2019
2019	Tropical Disease	Novartis	Used for BLA fr ofatumumab
2019	Rare Pediatric Disease	Vertex	Not used
2019	Rare Pediatric Disease	Alexion Pharmaceuticals	Not used
2019	Tropical Disease	Sanofi	Not used
2019	Rare Pediatric Disease	Novartis	Used for BLA for secukinumab
2019	Tropical Disease	TB Alliance	Not used
2019	Material Threat Medical Countermeasure	Bavarian Nordic	Sold to undisclosed buyer for $95 million in Dec. 2019
2019	Rare Pediatric Disease	Vertex	Not used
2019	Rare Pediatric Disease	Sarepta Therapeutics	Sold to Vifor in Feb. 2020 for $111 million
2019	Tropical Disease	Merck	Not used

Source: raps.org / Zacks SCR

Financial Update

On August 6, 2020, Cerecor announced financial results for the second quarter of 2020. The company reported net revenues of $1.3 million for the second quarter of 2020, which was in line with the revenue reported in the second quarter of 2019. R&D expenses were $5.9 million for the second quarter of 2020, compared to $3.7 million for the second quarter of 2019. The increase was primarily due to the expanded pipeline that was a result of the Aevi merger. G&A expenses for the second quarter of 2020 were $6.1 million, compared to $2.3 million for the second quarter of 2019. The increase was primarily due to increased stock-based compensation and increased salaries and benefits.

Cerecor exited the second quarter of 2020 with approximately $45.4 million in cash and cash equivalents. In June 2020, the company announced the closing of a $35.4 million public offering in which 15.18 million shares of common stock were sold for $2.50 per share. During the second quarter of 2020, Cerecor sold its stake in Aytu Biosciences for approximately $12.8 million.

As of August 4, 2020, Cerecor had approximately 74.9 million shares outstanding and, when factoring in options and warrants, a fully diluted share count of approximately 88.9 million.

Conclusion

Cerecor has a number of data readouts and infection points coming up over the next six to 12 months, including data from the proof-of-concept trial of CERC-002 in COVID-19 patients, which could lead to emergency use authorization if successful, initial data from CERC-007 proof-of-concept trials in the first half of 2020, and the initiation of trials for CERC-801 and -802 in the fourth quarter of 2020. Our valuation remains at $7 per share.

PROJECTED FINANCIALS

Cerecor, Inc.	2019 A	Q1 A	Q2 A	Q3 E	Q4 E	2020 E	2021 E	2021 E
Commercial Group	$6.7	$2.8	$1.3	$2.0	$2.0	$8.1	$8.0	$8.0
Rare Disease Portfolio	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
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**	**$2.0**	**$2.0**	**$8.1**	**$8.0**	**$8.0**
Cost of Sales	($0.6)	$0.1	$0.1	$0.3	$0.3	$0.6	$1.0	$1.0
Product Gross Margin	*108%*	*98%*	*94%*	*88%*	*88%*	*92%*	*88%*	*88%*
Research & Development	$11.8	$4.8	$5.9	$5.0	$5.3	$21.0	$24.0	$26.0
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	$3.0	$3.1	$14.9	$12.0	$12.5
Sales and Marketing	$1.5	$0.7	$0.7	$0.0	$0.0	$1.3	$0.0	$0.0
Amortization Expense	$1.3	$0.4	$0.4	$0.0	$0.0	$0.8	$0.0	$0.0
Impairment 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)	($6.3)	($6.7)	($56.1)	($29.0)	($31.5)
Operating Margin	*-239%*	-	-	-	-	*-694%*	*-363%*	*-394%*
Other (expense) income	$0.1	$7.1	($1.5)	$0.0	$0.0	$5.6	($1.2)	($1.2)
Pre-Tax Income	($16.0)	($24.3)	($13.3)	($6.3)	($6.7)	($50.5)	($30.2)	($32.7)
Income Taxes Paid	$0.3	($2.2)	($0.5)	$0.1	$0.1	($2.4)	$0.1	$0.1
Net Income	**($16.3)**	**($22.2)**	**($12.8)**	**($6.4)**	**($6.8)**	**($48.1)**	**($30.3)**	**($32.8)**
Net Margin		-	-	-	-			
Reported EPS	**($0.38)**	**($0.13)**	**($0.11)**	**($0.07)**	**($0.09)**	**($0.72)**	**($0.38)**	**($0.39)**
YOY Growth		-	-	-	-			
Basic Shares Outstanding	42.9	53.9	62.8	75.0	75.0	66.7	80.0	85.0

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

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HISTORICAL STOCK PRICE



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