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Cerecor Inc

(CERC-NASDAQ)

CERC: Completion of Phase 1 Trial of CERC-801…

Based on our probability adjusted DCF model that takes into account potential future revenues from CERC-301, CERC-611, commercial operations, and sales of PRVs, using a 12% discount rate CERC is valued at $8.50/share.

Current Price (05/13/19)	$5.02
Valuation	**$8.50**

OUTLOOK

On April 29, 2019, Cerecor Inc. (CERC) announced the completion of the Phase 1 study for CERC-801. It was an open label, single dose, 4-way crossover study in 16 health adult subjects. CERC-801 was safe and well tolerated and there were no reports of serious adverse events. We anticipate pharmacokinetic (PK) data will be reported in the summer of 2019. In addition to the Phase 1 study, the company has also initiated a retrospective study to collect natural history, efficacy, and safety data from patients with congenital disorders of glycosylation (CDG) treated with monosaccharide substrate replacement therapy. That information will be necessary to obtain approval of all three CERC-800 programs.

SUMMARY DATA

52-Week High	**$7.22**
52-Week Low	**$3.02**
One-Year Return (%)	**43.43**
Beta	**2.14**
Average Daily Volume (sh)	**80,062**
Shares Outstanding (mil)	**43**
Market Capitalization ($mil)	**$215**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**50**
Insider Ownership (%)	**80**
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 2018 Estimate	**-7.7**
P/E using 2019 Estimate	**-6.6**

Risk Level	**High**
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)
2018	4.5 A	4.8 A	4.1 A	5.0 A	18.3 A
2019	5.4 A	5.1 E	5.3 E	5.6 E	21.0 E
2020					23.0 E
2021					25.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$0.12 A	-$0.19 A	-$0.71 A	-$0.18 A	-$1.20 A
2019	-$0.13 A	-$0.18 E	-$0.18 E	-$0.17 E	-$0.70 E
2020					-$0.64 E
2021					-$0.65 E

WHAT'S NEW

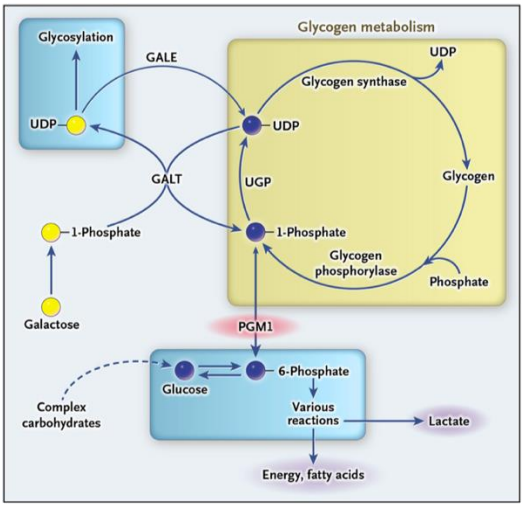
Business Update

CERC-801 Phase 1 Study Complete

On April 29, 2019, Cerecor Inc. (CERC) announced dosing has completed in the Phase 1 clinical trial of CERC-801 (D-galactose), which is being developed for the treatment of Phosphoglucomutase 1 (PGM1) deficiency. a recently characterized congenital disorder of glycosylation (CDG). The open label, randomized, single dose, 4-way crossover study in 16 healthy adult volunteers showed CERC-801 to be safe and well tolerated with no reports of serious adverse events. We anticipate pharmacokinetic (PK) data from this study to be reported in the summer of 2019. The company has also initiated a natural history study to collect efficacy and safety data from CDG patients treated with monosaccharide replacement therapy, which will be an important part of the application for approval using the 505(b)(2) pathway.

Patients with PGM1 deficiency have multiple clinical phenotypes, including dilated cardiomyopathy, exercise intolerance, and hepatopathy (Tegtmeyer *et al*., 2014). The multisystem deficiencies are a result of a lack of protein glycosylation, which is dependent upon the important metabolic intermediate glucose-1-phosphate.

PGM1 is responsible for the interconversion of glucose-1-phosphate and glucose-6-phosphate. In between meals, PGM1 drives the production of glucose-6-phosphate from glucose-1-phosphate, which is the product of glycogen breakdown. Following a meal, when glucose concentration is high, PGM1 drives the production of glucose-1-phosphate such that excess glucose can be stored as glycogen. The loss of PGM1 leads to a decreased amount of glucose-1-phosphate, which ultimately results in decreased protein glycosylation. The following figure shows the role of PGM1 in metabolism.



Source: Tegtmeyer *et al*., 2014

Galactose supplementation (1.5 g/kg/day) was recently tested in nine patients with PGM1 deficiency (Wong *et al*., 2017). Results of the study showed that supplementation was well tolerated, abnormal baseline results in liver enzymes normalized, and increases in protein glycosylation were noted.

Potential for Priority Review Voucher

Given that the number of patients for each of the CERC-800 products is very small, the most important aspect for those products is likely the fact that they are eligible for a priority review voucher (PRV) upon approval. 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.). Priority review vouchers are also awarded for the development of treatments for certain tropical diseases and medical countermeasures.

Priority review vouchers 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 Novartis (NVS) for $130 million in Dec. 2017, Jazz Pharmaceuticals for $125 million in Apr. 2017, an undisclosed buyer for $80.6 million in Aug. 2018, and Biohaven Pharmaceutical Holding Company for $105 million in Mar. 2019. While prices for PRVs have come down since AbbVie purchased one for $350 million in 2015, the price for them has appeared to settle in the $80-$100 million range. The following table shows how many priority review vouchers have been issued along with the current status of the voucher, if known.

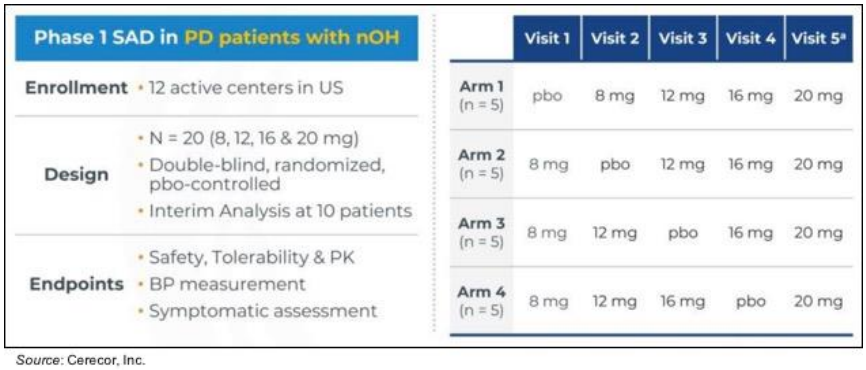
Priority Review Vouchers

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	Not used
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 undisclosed buyer for $80.6 million in Aug. 2018
2018	Rare Pediatric Disease	Medicines Development	Not used
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	Not used
2019	Tropical Disease	Novartis	Not used
2019	Rare Pediatric Disease	Vertex	Not used
2019	Rare Pediatric Disease	Alexion Pharmaceuticals	Not used
2019	Tropical Disease	Sanofi	Not used

Source: raps.org / Zacks SCR

Positive Interim Results for CERC-301 in nOH

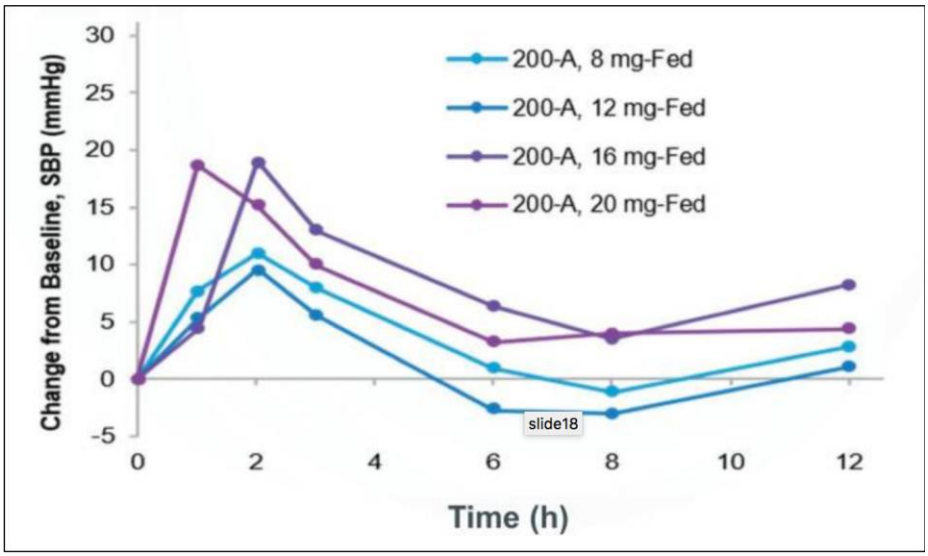
On April 15, 2019, Cerecor, Inc. (CERC) announced positive interim results for the Phase 1 study of CERC-301 in Parkinson's Disease (PD) patients suffering from neurogenic orthostatic hypotension (nOH). The Phase 1 trial is a double blind, randomized, placebo controlled trial with a target enrollment of 20 Parkinson's patients with nOH. Each patient will have five visits in which they will receive four single escalating doses of drug (8, 12, 16, or 20 mg) or placebo. Patients then complete six orthostatic standing tests over a six hour period: blood pressure is recorded while in supine position with the head elevated, immediately before standing, and then one minute, three minutes, and five minutes after standing. This is repeated every hour for six hours. While the primary endpoints of the study are safety, tolerability, and pharmacokinetics, a key secondary endpoint is the effect of CERC-301 on blood pressure. An overview of the trial is given below.



Source: Cerecor, Inc.

The company reported interim data from half of the patients that are intended to enroll. The data showed that the highest dose demonstrated an improvement in systolic blood pressure (SBP) of 15.6 mmHg at one-hour post-dose that ultimately reached 26.7 mmHg in SBP over baseline at the 6-hour timepoint. Whether the company will test additional doses above 20 mg will be determined after the trial is complete. Importantly, all doses tested were safe and well tolerated, just as was seen in previous trials of the drug. We anticipate the trial completing and topline data being reported by the end of the second quarter of 2019.

CERC-301 is an orally available specific antagonist against the NMDA receptor subunit 2B (NR2B). It has previously been studied in approximately 400 patients and healthy volunteers. The following chart shows the rapid and sustained change in systolic blood pressure that occurs upon taking CERC-301, which is the basis for its use in nOH.



Source: Cerecor, Inc.

Background on nOH

Orthostatic hypotension (OH) occurs due to an inability to maintain blood pressure upon standing. The technical definition of OH is a sustained reduction in systolic blood pressure of at least 20 mm Hg or diastolic blood pressure of at least 10 mm Hg within three minutes of standing. OH can result from either non-neurogenic or neurogenic causes and be either acute or chronic. Non-neurogenic causes include dehydration, cardiac abnormalities (bradycardia/tachyarrhythmia/myocardial infarction), and prolonged standing.

nOH is caused by decreased release of norepinephrine from sympathetic vasomotor neurons that can result in both inadequate vasoconstriction and heart rate upon standing (Freeman *et al*., 2011). The disorder occurs mostly in those with specific diseases caused by accumulation of alpha-synuclein, including Parkinson's disease (PD), multiple system atrophy (MSA), Lewy body dementia, and pure autonomic failure (PAF). It can also occur in patients with peripheral neuropathies, including diabetic neuropathy, amyloidosis, and Guillan-Barre syndrome.

In contrast to OH, which is relatively common in elderly patients (prevalence of 15% in those aged 65 to 69 to 26% in those aged 85 years or older, Rutan *et al*. 1992), nOH is a rare disorder and is considered as an orphan disease, affecting approximately 80,000 individuals with PD, MSA, and PAF in the U.S. (FDA briefing documents for Northera®).

Few studies have examined the prognosis for patients with nOH, however a study of 104 nOH patients over a 14-year period in Italy showed that the condition increased the risk of death three-fold compared to the general population in that area (Maule *et al*., 2012). On a day to day basis, the condition can result in severe morbidity for patients that includes significant drops in blood pressure during the day. This can lead to an interference in normal daily activities, with the increased debilitation potentially leading to a poor quality of life (QOL).

Non-pharmacological therapies for nOH include drinking more water (to help increase blood volume), increase salt in the diet, avoid carbohydrate-heavy meals, elevating the head of the bed, slowly rising when standing, and getting

regular exercise. There are currently two therapies approved in the U.S. for the treatment of nOH: midodrine, which was approved in 1996, and droxidopa (Northera®), which was approved in 2014.

- Midodrine (ProAmatine®): This is a peripherally acting α-andrenergic agonist. The drug was originally approved based on clinical data showing an effect on the surrogate endpoint of increase in standing blood pressure, which is thought to confer clinical benefit. It is currently available as a generic.

- Droxidopa (Northera®): This is a synthetic amino acid precursor for norepinephrine that is capable of crossing the blood-brain barrier. Droxidopa was originally approved in Japan for the treatment of hypotension and nOH in 1989. Chelsea Therapeutics acquired the rights to droxidopa and following approval of the compound by the FDA the company was acquired by Lundbeck for $658 million. Lundbeck reported 2017 revenues for Northera® of DKK 1,644 (approximately $270 million).

Financial Update

On May 9, 2019, Cerecor announced financial results for the first quarter of 2019. The company recorded revenues of $5.4 million in the first quarter of 2019, which was a $1.2 million increase over the first quarter of 2018. The increase was due to unit growth driven by the sales force expansion as well as there being a full quarter of sales of products that were acquired during the prior year quarter. Cost of product sales were $1.9 million in the first quarter of 2019 compared to $0.9 million for the first quarter of 2018. The increase was driven by an increase in net product revenue. R&D expenses in the first quarter of 2019 were $3.4 million compared to $1.6 million for the first quarter of 2018. The increase was the result of increased clinical and CMC expenses along with increased salaries, benefits, and related costs. G&A expenses for the first quarter of 2019 were $2.7 million compared to $3.8 million for the first quarter of 2018. The decrease was primarily due to a decrease in consulting fees, as the consulting costs incurred during 2018 were related to the integration of the acquisitions of TRx and Avadel's pediatric products. Sales and marketing expenses were $3.1 million for the first quarter of 2019 compared to $1.5 million for the first quarter of 2018. The increase was due to increased salaries, benefits, and related costs along with increased commercial operations expenses and advertising and marketing expenses. Net loss for the first quarter of 2019 was $7.5 million compared to a net loss of $3.9 million in the first quarter of 2018.

As of March 31, 2018, Cerecor had cash and cash equivalents of approximately $16.1 million, which was due in part to an underwritten offering of 1,818,182 shares of common stock at a price of $5.50 per share, with Armistice Capital (the company's largest shareholder) purchasing 363,637 of the shares. Net proceeds were approximately $9.0 million. We believe the company has sufficient capital to fund operations through the end of 2019.

As of May 3, 2019, Cerecor had approximately 42.8 million shares outstanding and when factoring in stock options and warrants a fully diluted share count of approximately 51.4 million.

Conclusion and Valuation

Cerecor continues to execute on its business transformation strategy as it transitions to a fully-integrated pharmaceutical company. We're encouraged by the interim data announced by the company regarding CERC-301 in nOH patients as well as the safety data for CERC-801 in healthy volunteers and we look forward to additional updates on these programs later in the year. Our valuation remains at $8.50.

PROJECTED FINANCIALS

Cerecor, Inc.	2018 A	Q1 A	Q2 E	Q3 E	Q4 E	2019 E	2020 E	2021 E
Commercial Group	$18.3	$5.4	$5.1	$5.3	$5.6	$21.4	$23.0	$25.0
CERC-301	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
CERC-611	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
CERC-406	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
LIcense Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Grant Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$18.3**	**$5.4**	**$5.1**	**$5.3**	**$5.6**	**$21.4**	**$23.0**	**$25.0**
Cost of Sales	$7.5	$1.9	$2.1	$2.1	$2.2	$8.3	$8.9	$9.8
Product Gross Margin	*59%*	*64%*	*59%*	*60%*	*61%*	*61%*	*61%*	*61%*
Research & Development	$5.8	$3.4	$3.8	$4.0	$4.2	$15.4	$17.0	$19.0
Acquired in-process R&D	$18.7	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
General & Administrative	$10.7	$2.7	$2.3	$2.4	$2.5	$9.9	$10.0	$10.5
Sales and Marketing	$8.5	$3.1	$3.0	$3.0	$3.0	$12.1	$13.0	$14.0
Amortization Expense	$4.5	$1.1	$1.2	$1.2	$1.2	$4.7	$4.8	$4.8
Impariment of Intangible Assets	$1.9	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Change in fair value of contingent consideration	$0.1	$0.2	$0.0	$0.0	$0.0	$0.2	$0.0	$0.0
Operating Income	($39.3)	($7.0)	($7.3)	($7.4)	($7.5)	($29.2)	($30.7)	($33.1)
Operating Margin	*-215%*	-	-	-	-	*-136%*	*-133%*	*-132%*
Other (expense) income	($0.8)	($0.3)	($0.3)	($0.3)	($0.3)	($1.2)	($1.2)	($1.2)
Pre-Tax Income	($40.1)	($7.3)	($7.6)	($7.7)	($7.8)	($30.4)	($31.9)	($34.3)
Income Taxes Paid	($0.0)	$0.2	$0.0	$0.0	$0.0	$0.3	$0.1	$0.1
Net Income	**($40.1)**	**($7.5)**	**($7.6)**	**($7.8)**	**($7.8)**	**($30.7)**	**($32.0)**	**($34.4)**
Net Margin		-	-	-	-			
Reported EPS	**($1.20)**	**($0.13)**	**($0.18)**	**($0.18)**	**($0.17)**	**($0.70)**	**($0.64)**	**($0.65)**
YOY Growth		-	-	-	-			
Basic Shares Outstanding	34.8	42.0	43.0	43.5	46.0	43.6	50.0	53.0

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

HISTORICAL STOCK PRICE

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