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Cerecor Inc

(CERC-NASDAQ)

CERC: Phase 1 Trial of CERC-301 in nOH Underway…

Based on our probability adjusted DCF model that takes into account potential future revenues from CERC-301 and CERC-611 using a 12% discount rate along with a 4x sales valuation for commercial operations, CERC is valued at $6.00/share.

Current Price (08/15/18)	$3.92
Valuation	**$6.00**

OUTLOOK

Cerecor Inc. (CERC) is a pediatric-focused healthcare company with a diverse group of marketed products, including prescribed dietary supplements Poly-Vi-Flor® and Tri-Vi-Flor® and prescribed medications that treat a variety of pediatric conditions, including Millipred®, Veripred®, Ulesfia®, Karbinal™ ER, AcipHex® Sprinkle™, and Cefaclor.

The company's strategy involves utilizing the revenue generated from commercial operations to fund the development of new development products. The lead product candidate is CERC-301, which the company recently initiated a Phase 1 clinical trial for in neurogenic orthostatic hypotension and for which we anticipate data for in the first half of 2019.

SUMMARY DATA

52-Week High	**$5.66**
52-Week Low	**$0.56**
One-Year Return (%)	**569.86**
Beta	**1.28**
Average Daily Volume (sh)	**47,531**
Shares Outstanding (mil)	**34**
Market Capitalization ($mil)	**$133**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**53**
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	**18.6**
P/E using 2018 Estimate	**-6.3**
P/E using 2019 Estimate	**-6.1**

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)
2017	0 A	0 A	25 A	2 A	28 A
2018	4.5 A	4.8 A	4.8 E	4.9 E	19.0 E
2019					22.0 E
2020					25.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.19 A	-$0.14 A	-$0.52 A	-$0.11 A	-$0.42 A
2018	-$0.12 A	-$0.19 A	$0.12 E	-$0.12 E	$0.55 E
2019					-$0.34 E
2020					-$0.28 E

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WHAT'S NEW

Cerecor, Inc. (CERC) is a fully integrated pharmaceutical company with a diversified offering of commercial products and a development product portfolio. The commercial portfolio consists of products intended to treat pediatric-focused conditions and includes the prescribed dietary supplements Poly-Vi-Flor® (a multivitamin and fluoride chewable tablet) and Tri-Vi-Flor® (a multivitamin and fluoride suspension) along with the prescribed medications Millipred®, Veripred®, Ulesfia®, Karbinal™ ER, AcipHex® Sprinkle™, and Cefaclor. The company's goal is to use cash flow from commercial operations to fund the development of the clinical product candidates.

Financial Update

On August 9, 2018, Cerecor announced financial results for the second quarter of 2018. The company recorded net revenues of $4.8 million in the second quarter of 2018 compared to $0.2 million in the second quarter of 2017. The increase in net revenues was due to the acquisition of TRx Pharmaceuticals and the pediatric products from Avadel U.S. Holdings, Inc. In the second quarter of 2018, cost of product sales was $1.4 million, sales and marketing expenses were $2.0 million, and amortization expense was $1.2 million. There were no expenses related to those three categories in the second quarter of 2017 as they are all related to the acquisition of TRx Pharmaceuticals and the pediatric products from Avadel U.S. Holdings, Inc. R&D expenses were $1.1 million in the second quarter of 2018 compared to $0.5 million for the second quarter of 2017. The increase was due to increased costs associated with the development of CERC-301. G&A expenses were $3.0 million for the second quarter of 2018 compared to $1.4 million in the second quarter of 2017. The increase was due to increased employee costs, legal expenses, and stock-based compensation. Net loss for the second quarter of 2018 was $6.0 million compared to $1.8 million in the second quarter of 2017. The net loss was driven in part by a non-cash intangible asset impairment charge due to the termination of the PAI sales and marketing agreement along with amortization of intangible assets, stock-based compensation, and acquisition and integration related charges.

Adjusted EBITDA, which excludes highly variable items and additional non-cash charges, for the second quarter of 2018 was ($1.3) million compared to ($1.5) million in the second quarter of 2017. We forecast for the company to have positive adjusted EBITDA by the end of the year. As of June 30, 2018, Cerecor had approximately $2.2 million in cash and cash equivalents. In August 2018, we anticipate the company receiving $3.75 million that had been held in escrow for the past year related to the sale of CERC-501 to Jannsen. In addition, the company has approximately $3.3 million in accounts receivable. We believe the company currently has sufficient capital to fund operations through the second quarter of 2019.

As of August 6, 2018, Cerecor had approximately 33.8 million shares outstanding and when factoring in stock options and reasonably priced warrants a fully diluted share count of approximately 57.3 million.

Business Update

Developing CERC-301 for Neurogenic Orthostatic Hypotension

On August 1, 2018, Cerecor announced the first patient has been enrolled in a Phase 1 study of its lead compound, CERC-301, for the treatment of neurogenic orthostatic hypotension (nOH) associated with Parkinson's disease. We anticipate topline data from the Phase 1 study of CERC-301 in nOH in the first half of 2019.

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 beneft. 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).

Expansion of Leadership Team

On July 16, 2018, Cerecor announced the appointment of Joe Miller as Chief Financial Officer, Pericles Calias, PhD as Chief Scientific Officer, and Jaime Harrell as Executive Vice President of Marketing and Investor Relations. We believe each of these individuals brings important leadership and executive experience that will be invaluable to the company as it transitions to a fully-integrated pharmaceutical company.

Mr. Miller has over 20 years of experience as a senior executive across the health sciences, biotech, and pharmaceutical sectors. Previously, he was at Sucampo Pharmaceuticals where he led the expansion of the finance organization that ultimately ended up in the $1.2 billion merger with Mallinckrodt in early 2018. Previous to Sucampo, Mr. Miller was employed in various finance and management roles at Qiagen, Eppendorf, and KPMG LLP.

Dr. Calias has over 25 years of biopharmaceutical experience in clinical development across multiple disciplines in the healthcare sector. Previously, Dr. Calias was Vice President of Global CMC and Product Development at Sucampo. Prior to that, he held a variety of positions in both clinical and non-clinical R&D at Shire HGT and Genzyme.

Mr. Harrell has over 25 years of biopharmaceutical experience in various commercial and marketing positions. He was previously the Vice President and General Manager of Specialty Pharmaceuticals for Covidien, which included heading a 350-member commercial operations group. Prior to that, he held various commercial and leadership positions at Covidien, Medimmune, Centocor, Inc., and Rhone Poulenc Rorer. He has helped commercialize over 25 products, including three blockbusters in Lovenox®, Remicade®, and Synagis®.

Conclusion

We are pleased to see that Cerecor is continuing to execute on its strategy as it transitions to a fully-integrated pharmaceutical company. Looking ahead to the second half of the year, we believe revenues will trend slightly higher and we are forecasting for approximately $19 million in net revenues for the full year and for the company to have positive adjusted EBITDA in the fourth quarter of 2018. We also believe the commercial group will become cash flow positive in 2019, an important milestone for the company as it looks to use the proceeds from commercial operations to fund the clinical pipeline. Our current valuation, derived from a mixed model approach employing a DCF model for the development pipeline and a 4x sales multiple for the commercial business, is $6.00 per share.

PROJECTED FINANCIALS

Cerecor, Inc.	2017 A	Q1 A	Q2 A	Q3 E	Q4 E	2018 E	2019 E	2020 E
Commercial Group	$2.2	$4.5	$4.8	$4.8	$4.9	$19.0	$22.0	$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	$25.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Grant Revenue	$0.6	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$27.8**	**$4.5**	**$4.8**	**$4.8**	**$4.9**	**$19.0**	**$22.0**	**$25.0**
Cost of Sales	$1	$0.9	$1.4	$1.4	$1.4	$5.1	$5.3	$6.0
Product Gross Margin	-	*81%*	*70%*	*71%*	*71%*	*73%*	*76%*	*76%*
Research & Development	$4.4	$1.6	$1.1	$1.1	$1.2	$5.0	$5.2	$5.5
General & Administrative	$7.9	$2.9	$3.0	$3.0	$3.0	$12.0	$10.2	$10.5
Sales and Marketing	$1	$1.5	$2.0	$2.0	$2.0	$7.6	$8.0	$8.0
Amortization Expense	$0	$1.0	$1.2	$1.0	$1.0	$4.3	$4.0	$4.0
Impariment of Intangible Assets	$0	$0.0	$1.7	$0.0	$0.0	$1.7	$0.0	$0.0
Operating Income	$13.9	($3.5)	($5.7)	($3.7)	($3.7)	($16.6)	($10.7)	($9.0)
Operating Margin	*50%*	-	-	-	-	*-88%*	*-49%*	*-36%*
Other (expense) income	($0.1)	($0.4)	($0.3)	($0.3)	($0.3)	($1.2)	($1.2)	($1.2)
Pre-Tax Income	$13.8	($3.9)	($6.0)	($4.0)	($4.0)	($17.9)	($11.9)	($10.2)
Income Taxes Paid	$2	$0	$0	$0	$0	$0	$0	$0
Net Income	**$11.9**	**($3.9)**	**($6.0)**	**($4.0)**	**($4.0)**	**($18.0)**	**($11.9)**	**($10.2)**
EBITDA	**-**	**($2.7)**	**($4.4)**	**($2.8)**	**($2.8)**	**($12.8)**	**($7.0)**	**($5.3)**
Adjusted EBITDA	**-**	**($1.4)**	**($1.3)**	**($0.9)**	**$0.1**	**($3.5)**	**$2.0**	**$3.5**
Net Margin	-	-	-	-	-			
Reported EPS	**$0.64**	**($0.12)**	**($0.19)**	**($0.12)**	**($0.12)**	**($0.55)**	**($0.34)**	**($0.28)**
YOY Growth	-	-	-	-	-			
Basic Shares Outstanding	18.4	31.3	32.2	33.9	34.0	32.9	35.0	36.0

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

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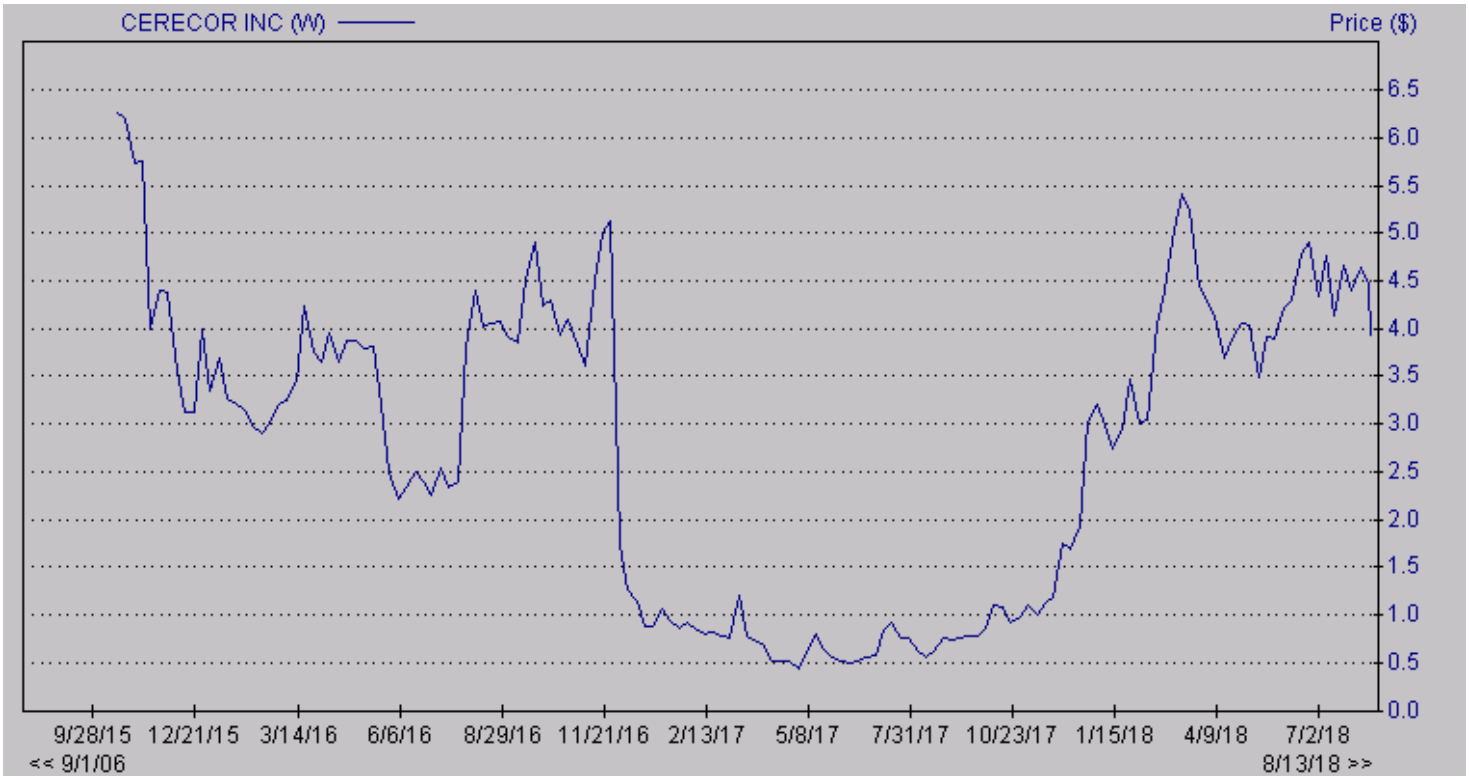

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