Zacks Small-Cap Research

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Cerecor, Inc.

(CERC-NASDAQ)

CERC: Ready to Move Ahead With Phase 2/3 Study of CERC-501 in MDD…

Based on our probability adjusted DCF model that takes into account potential future revenues from CERC-501 and CERC-611, CERC is valued at $7/share. This model is highly dependent upon the clinical success of CERC-501 and CERC-611 and will be adjusted accordingly based upon future clinical results.

Current Price (03/21/17)	$0.74
Valuation	**$4.50**

OUTLOOK

On March 14, 2017, Cerecor, Inc. (CERC) announced financial results for the fourth quarter and full year 2016. The company exited 2016 with approximately $5.1 million in cash and cash equivalents, and is currently exploring various financing arrangements to fund further development of its pipeline. Cerecor also recently retained SunTrust Robinson Humphrey Inc. as the exclusive financial advisor during an ongoing review of strategic alternatives.

Assuming funding is available, the company plans on moving CERC-501 into a Phase 2/3 clinical trial as an adjunct treatment for major depressive disorder. In addition, during 2017 the company is expected to file an IND to move CERC-611 into a Phase 1 study in support of its development as an adjunctive treatment for epilepsy.

SUMMARY DATA

52-Week High	**$5.23**
52-Week Low	**$0.73**
One-Year Return (%)	**-80.11**
Beta	**1.41**
Average Daily Volume (sh)	**562,601**
Shares Outstanding (mil)	**11**
Market Capitalization ($mil)	**$8**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**8**
Insider Ownership (%)	**7**
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 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**

Risk Level	**N/A,**
Type of Stock	**N/A**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	0.0 A	0.7 A	0.3 A	0.2 A	1.2 A
2017	0.0 E	0.0 E	0.0 E	0.0 E	0.0 E
2018					0.0 E
2019					0.0 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.59 A	-$0.41 A	-$0.70 A	-$0.18 A	-$1.87 A
2017	-$0.21 A	-$0.22 A	-$0.24 A	-$0.23 E	-$0.89 E
2018					-$0.86 E
2019					-$0.88 E

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WHAT'S NEW

Financial Update

On March 14, 2017, Cerecor, Inc. (CERC) announced financial results for the fourth quarter and full year 2016. Revenue in the fourth quarter of 2016 was $0.2 million, which was primarily earned from a research and development grant awarded by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) for the development of CERC-501 for the treatment of alcohol abuse. For the full year, revenue was $1.2 million, with $1.0 million of that from the NIAAA grant.

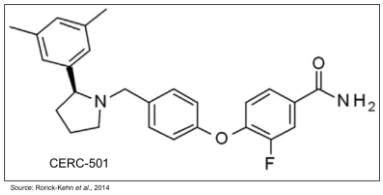
Net loss for the fourth quarter of 2016 was $1.6 million, or $0.18 per share, and was comprised of $0.8 million in R&D expenses and $1.1 million in G&A expenses. This compares to a net loss of $3.6 million for the fourth quarter of 2015. The decrease was driven mostly by the winding down of the Phase 2 trials for CERC-301 and CERC-501 during the fourth quarter of 2016.

For the full year, net loss was $16.5 million, or $1.87 per share, and was comprised of $10.2 million in R&D expenses and $7.1 million in G&A expenses. This compares to a net loss of $10.5 million, or $4.71 per share, in 2015. The increase in net loss for 2016 was driven by the $2.0 million initial payment for the license of CERC-611, the Phase 2 study of CERC-501 in smoking cessation, increases in costs associated with being a publicly traded company, and an increase in stock-based compensation.

Cerecor exited 2016 with approximately $5.1 million in cash and cash equivalents. Subsequent to the end of the quarter, the company sold $965,165 worth of stock under the purchase agreement with Aspire Capital Fund, LLC. In January 2017, Cerecor entered into an equity distribution agreement with Maxim Group and thus far has used it to raise gross proceeds of $287,000. The company is currently evaluating various financing arrangements to fund further development of its pipeline. Cerecor also recently retained SunTrust Robinson Humphrey Inc. as the exclusive financial advisor during an ongoing review of strategic alternatives.

CERC-501 to be Tested in Phase 2/3 Trial in MDD

Cerecor is developing CERC-501, an orally available, highly specific kappa opioid receptor (KOR) antagonist, as an adjunctive treatment for major depressive disorder (MDD). Cerecor acquired the rights to CERC-501, then LY2456302, through an exclusive, worldwide license from Eli Lilly and Company in February 2015.



CERC-501

Source: Rorick-Kehn et al., 2014

CERC-501 is highly selective for the KOR as it has 21-fold higher affinity for the kappa opioid receptor compared to the mu receptor and 135-fold higher affinity over the delta opioid receptor (Mitch *et al*., 2011). Preclinical studies showed that CERC-501 dose-dependently produced an antidepressant-like response in the forced swim test and significantly attenuated continuous ethanol self-administration in female rats with a history of high ethanol intake (Rorick-Kehn *et al*., 2014).

Provided the company is able to obtain financing, Cerecor is currently planning a Phase 2/3 trial of CERC-501 in adjunctive MDD. Validation for the use of a KOR antagonist as an adjunctive treatment to antidepressant therapy in MDD comes from recently released data from a Phase 3 study (FORWARD-5) conducted by Alkermes plc (ALKS) for ALKS-5461, which is a combination drug formulation of buprenorphine and samidorphan. FORWARD-5 was a randomized, double blind, placebo controlled, sequential parallel comparison design study that enrolled 407 patients with MDD who had an inadequate response to a stable dose of a selective serotonin reuptake inhibitor (SSRI) or a serotonin-norepinephrine reuptake inhibitor (SNRI). The results showed that ALKS 5461 2mg/2mg met the primary endpoint of significant reducing depression scores compared to placebo, as measured by the 6-item Montgomery-Asberg Depression Rating Scale (MADRS-6) scores (P=0.018) and the 10-item MADRS (MADRS-10)

scores (*P*=0.026). These results clearly show that a KOR antagonist, such as CERC-501, can have a positive effect in treating MDD, thus we believe Cerecor is fully justified in pursuing this opportunity.

IND to be Filed for CERC-611 Later in 2017

Last September, Cerecor, acquired CERC-611 (formerly LY3130481) from Eli Lilly for an upfront payment of $2 million, with $750,000 paid upon signing of the agreement and the other $1.25 million due when the first patient in a multiple ascending dose Phase 1 study is dosed. CERC-611 is a TARP-γ8-dependent AMPA receptor antagonist and is being developed as an adjunctive treatment for patients with epilepsy.

Epilepsy

Epilepsy is a neurological disorder that affects approximately 65 million individuals worldwide, including 3 million in the U.S. (Epilepsy Foundation). Every year, approximately 150,000 people in the U.S. are diagnosed with epilepsy. A diagnosis of epilepsy is made if someone suffers from two or more unprovoked seizures separated by at least 24 hours. Seizures are characterized by a sudden surge of electrical activity in the brain. They are potentially life-threatening and have a profoundly negative impact on a patients' life and well-being.

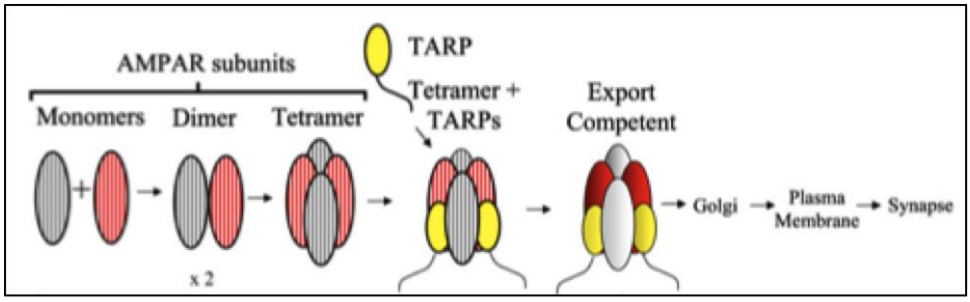
Standard of care treatment currently consists of anti-epileptic drugs (AEDs), of which there are a number of different options. The AEDs that are available do help some patients by decreasing the frequency and magnitude of seizures, however a significant proportion of epileptics (30-40%) are resistant to treatment. For those who respond to treatment there are number of side effects to AEDs, including sleepiness, fatigue, poor coordination, and nausea.

AMPA Receptor Antagonists as Epilepsy Treatments

Glutamate is a major neurotransmitter in the central nervous system. Glutamate receptors are classified into two groups: the α-amino-3-hydroxy-5-methyl-4-isoxazolepropionate (AMPA) receptor and the N-methyl-D-aspartate (NMDA) receptor are *ionotropic* receptors while metabolic and heterotrimeric GTP-binding protein-linked glutamate receptors (mGluRs) are *metabotropic* receptors (Palmada *et al*., 1998). The inhibition or down-regulation of AMPA receptors is seen as a potential therapy for central nervous system (CNS) disorders involving excessive neuronal activity, as the majority of fast synaptic transmission within the CNS is controlled by AMPA receptors.

Administration of glutamate receptor agonists is known to evoke seizures in rodents (Tang, 2005), while AMPA receptor antagonists are potent anticonvulsants and include a number of currently available anti-epileptic drugs, including perampanel and talampanel. Unfortunately, due to the non-specific nature of AMPA receptor binding by these drugs, they carry a number of side effects including dizziness, ataxia, and falling. This results in AMPA antagonists having a very narrow therapeutic window; too little drug and there is no anti-epileptic effect while too much drug results in excessive side effects (Rogawski, 2011).

AMPA receptors are composed of tetrameric combinations of subunits GluR1-4 (GluRA-D). In addition to the pore-forming subunits, there exist a class of proteins that bind to the cytoplasmic, C-terminal domains of the subunits and regulate trafficking of the AMPA receptors (Barry *et al*., 2002). The Transmembrane AMPA Receptor Regulatory Protein (TARP) family includes members (γ1-γ8) that bind to most, if not all, AMPA receptors in the brain and modulate their activity (Hashimoto *et al*., 1999). Several TARPs have brain-region specific expression, with TARP-γ8 being predominantly expressed in the hippocampus, with very little expression in the hindbrain, midbrain, or thalamus (Tomita *et al*., 2003). Thus, antagonism of AMPA receptors that are bound to TARP-γ8 offers the potential to affect conditions marked by excessive excitatory transmission within the hippocampus, such as temporal lobe epilepsy, while mitigating systemic side effects that would normally be found through non-selective AMPA receptor antagonism.



Source: Ziff, 2007

Scientists at Eli Lilly identified a compound (LY3130481) that selectively bound to and antagonized TARP-γ8 AMPA receptors (Gardinier *et al*., 2016). LY3130481 was shown to protect rats from clonic convulsions induced by subcutaneous administration of pentylenetetrazole with an ED_{50} of 1.7 mg/kg. This was in contrast to the currently available AED perampanel, which had an ED_{50} of 10.6 mg/kg in the same model. The effects on motor impairment in rats was tested in an inverted screen test, in which LY3130481 did not impair the ability of rats to climb to the top of an inverted screen at doses up to 100 mg/kg. Perampanel at a dose of 30 mg/kg fully impaired the ability of the rats to climb the inverted screen. These data support that hypothesis that a selective AMPA receptor antagonist is likely to have potent anti-seizure properties with minimal impact on motor function.

We anticipate an IND being filed before the end of 2017 such that Phase 1 development can be initiated for CERC-611 as an adjunctive treatment for seizures in patients with epilepsy.

Conclusion and Valuation

Preparations are currently underway for a Phase 2/3 clinical trial of CERC-501 in adjunctive MDD in patients that do not adequately respond to standard antidepressant therapies. Developing CERC-501 in adjunctive MDD makes sense with the positive Phase 3 data reported by Alkermes for ALKS-5461, which is also a KOR antagonist. The company exited 2016 with $5.1 million and is currently evaluating various opportunities to raise the funds necessary to move ahead with development of CERC-501, including the use of non-dilutive arrangements such as grants and collaborations. Assuming funding is available, the company will also be moving ahead with an IND for CERC-611 to begin development as an adjunctive treatment for seizures in patients with epilepsy. We anticipate more clarity on the trials for both CERC-501 and CERC-611 later in 2017.

Our current model only includes CERC-501 and CERC-611, as we have removed CERC-301 following the negative clinical trial results reported for it in 2016. We currently model for a regulatory filing for CERC-501 in 2022 and approval in 2023, with estimated peak sales of $1.8 billion. We also assign a 40% probability of success and an 18% discount rate to arrive at a net present value for the program of $100 million.

Combining the net present value for CERC-501 and CERC-611 along with the company's current cash total and expected operating burn of $50 million we arrive at a net present value for the company of approximately $55 million. Dividing this by the company's fully diluted (common stock and options) share count of approximately 12.5 million shares leads to a valuation of $4.50/share.

PROJECTED FINANCIALS

Cerecor, Inc.
Income Statement

Cerecor, Inc.	2016 A	Q1 E	Q2 E	Q3 E	Q4 E	2017 E	2018 E	2019 E
CERC-301	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-		
CERC-501	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-		
CERC-611	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-		
CERC-406	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-		
Grants & Collaborative Revenue	$1	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-		
Total Revenues	**$1**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-		
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-		
Research & Development	$10.1	$1.0	$1.5	$2.0	$2.0	$6.5	$9.0	$11.0
General & Administrative	$7.1	$1.1	$1.2	$1.2	$1.3	$4.8	$7.0	$8.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($16.1)	($2.1)	($2.7)	($3.2)	($3.3)	($11.30)	($16.0)	($19.0)
Operating Margin	-	-	-	-	-	-		
Non-Operating Expenses (Net)	($0.4)	($0.1)	($0.1)	($0.1)	($0.1)	($0.4)	($0.4)	($0.4)
Pre-Tax Income	($16.5)	($2.2)	($2.8)	($3.3)	($3.4)	($11.7)	($16.4)	($19.4)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($16.5)**	**($2.2)**	**($2.8)**	**($3.3)**	**($3.4)**	**($11.7)**	**($16.4)**	**($19.4)**
Net Margin	-	-	-	-	-	-		
Reported EPS	**($1.87)**	**($0.21)**	**($0.22)**	**($0.24)**	**($0.23)**	**($0.89)**	**($0.86)**	**($0.88)**
YOY Growth	-	-	-	-	-	-		
Basic Shares Outstanding	8.8	10.5	13.0	14.0	15.0	13.1	19.0	22.0

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

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