Zacks Small-Cap Research

May 10, 2017
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 Results from Proof-of-Concept 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 $2/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 (05/10/17)	$0.82
Valuation	**$2.00**

OUTLOOK

On May 1, 2017, Cerecor, Inc. (CERC) announced encouraging results from a proof-of-concept trial of CERC-501 in treatment-resistant depression. Treatment with CERC-501 resulted in a clinically meaningful 2.0-point difference from placebo on the HAM-D-6 scale change from baseline to 72 hours. Clinically meaningful differences were also observed across multiple secondary outcome measurements.

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. Cerecor recently raised $5 million in a private placement with Armistice Capital that will allow the company to complete preparations for clinical trials of CERC-501 and CERC-611.

SUMMARY DATA

52-Week High	**$5.23**
52-Week Low	**$0.44**
One-Year Return (%)	**-77.84**
Beta	**1.39**
Average Daily Volume (sh)	**390,099**
Shares Outstanding (mil)	**14**
Market Capitalization ($mil)	**$12**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**7**
Insider Ownership (%)	**11**
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	0.4 A	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	-$0.19 A	-$0.22 E	-$0.24 E	-$0.23 E	-$0.86 E
2018					-$0.86 E
2019					-$0.88 E

© Copyright 2017, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Financial Update

On May 9, 2017, Cerecor, Inc. (CERC) announced financial results for the first quarter of 2017. The company recorded $0.4 million in revenue during the quarter from the grant from the National Institute on Alcohol Abuse and Alcoholism (NIAAA) to support the Phase 2 clinical trial of CERC-501. The company did not report any grant revenue in the first quarter of 2016. Net loss for the first quarter of 2017 was $2.0, or $0.19 per share, and consisted of $1.0 million in R&D expenses and $1.2 million in G&A expenses. This compares with $2.3 million in R&D expenses and $2.6 million in G&A expenses for the first quarter of 2016. The decrease in R&D expenses was primarily due to the completion of the Phase 2 clinical trials of CERC-301 and CERC-501 in 2016. The decrease in G&A expenses was primarily due to a temporary reduction in executive salaries and stock-based compensation.

As of Mar. 31, 2017, Cerecor had cash and cash equivalents of approximately $3.0 million. Subsequent to the end of the quarter, the company raised net proceeds of $4.65 million from a private placement with Armistice Capital Master Fund Ltd. In addition, Cerecor entered into an equity distribution agreement with Maxim Group LLC, which allows for the sale of shares of common stock through Maxim. As of Mar. 31, 2017, the company has sold 501,859 shares of common stock for gross proceeds of $412,000 and may sell up to an additional $2.9 million of common shares. We estimate the company has sufficient capital to fund operations to the end of 2017.

As of May 9, 2017, Cerecor had approximately 14.1 million shares of common stock outstanding. In addition, there were approximately 11.9 million shares from the conversion of Series A Preferred Stock, 2.1 million stock options, and 14.3 million warrants with an exercise price of $0.40 for a fully diluted share count of approximately 42.4 million.

Encouraging Results from Proof-of-Concept Trial of CERC-501 in Treatment-Resistant Depression

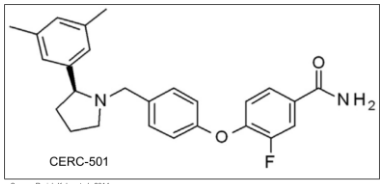
On May 1, 2017, Cereceor announced encouraging results from a small proof-of-concept study of CERC-501 in treatment-resistant depression. The study was conducted by the National Institute of Mental Health (NIMH), a division of the National Institutes of Health (NIH), under the direction of Dr. Maurizio Fava of Massachusetts General Hospital (NCT01913535).

This was a Phase 2 randomized, double blind, placebo controlled SPCD designed study that enrolled 8 subjects with treatment resistant depression currently on stable antidepressant therapy. Subjects participated in two sequential 72 hour periods and received either CERC-501 (10 mg or 20 mg) or placebo. Placebo non-responders in Period 1 were re-randomized to either CERC-501 (10 mg or 20 mg) or placebo for Period 2. The trial was terminated early due to recruitment issues, and no statistical analysis was performed due to the small sample size.

The primary outcome of the study was the Hamilton Rating Scale for Depression – 6 Items (HAM-D-6). There was a clinically meaningful 2.0 point difference from placebo in the HAM-D-6, which is comparable to a 4.0 point difference on the Hamilton Depression Rating Scale-17 (HDRS-17). In addition, a number of secondary endpoints showed clinically meaningful differences including: number of responders on HAM-D-6 at 72 hours, change in Montgomery-Asberg Depression Rating Scale (MADRS), change in clinical global impression severity (CGI-S), and change in the Perceived Stress Scale (PSS). The results on the PSS (3.5 point decrease for CERC-501 treated patients and 0.5 point increase in placebo treated patients) have not been seen before in only three days of treatment with standard antidepressants. We anticipate additional results from the study being presented at a scientific conference in 2017.

Planning Continues for Phase 2/3 Trial of CERC-501 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.



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.

Beginning Preparations for CERC-611 Phase 1 Study

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.

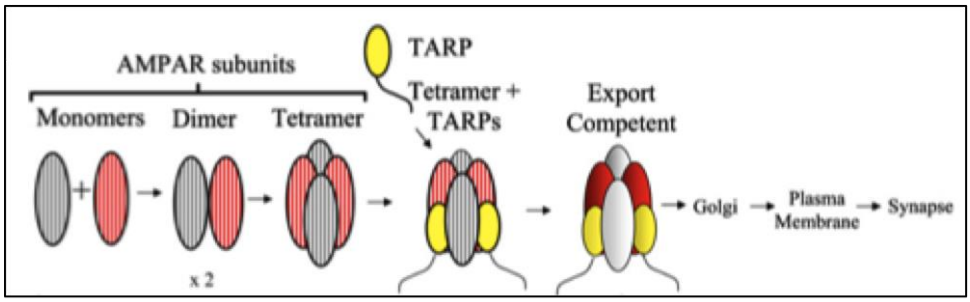
Standard of care treatment currently consists of anti-epileptic drugs (AEDs), of which there are a number of different options. The AEDs that are available do help some patients by decreasing the frequency and magnitude of seizures, however a significant proportion of epileptics (30-40%) are resistant 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 ongoing preparation during 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. In addition, although only eight subjects completed the trial, the data from the proof-of-concept study is encouraging.

Following the private placement with Armistice, the company has sufficient funds to get through 2017 and to lay the groundwork for the Phase 2/3 clinical trial of CERC-501 in MDD, however additional funding will be necessary to complete the trial. Assuming additional 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 probability adjusted discounted cash flow model currently yields a valuation of $2/share.

PROJECTED FINANCIALS

Cerecor, Inc.
Income Statement

Cerecor, Inc.	2016 A	Q1 A	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	$1.3	$1.2	$1.2	$1.3	$5.0	$7.0	$8.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($16.1)	($1.9)	($2.7)	($3.2)	($3.3)	($11.10)	($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)	($2.0)	($2.8)	($3.3)	($3.4)	($11.5)	($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)**	**($2.0)**	**($2.8)**	**($3.3)**	**($3.4)**	**($11.5)**	**($16.4)**	**($19.4)**
Net Margin	-	-	-	-	-	-		
Reported EPS	**($1.87)**	**($0.19)**	**($0.22)**	**($0.24)**	**($0.23)**	**($0.88)**	**($0.86)**	**($0.88)**
YOY Growth	-	-	-	-	-	-		
Basic Shares Outstanding	8.8	10.2	13.0	14.0	15.0	13.1	19.0	22.0

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

© Copyright 2017, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE



© Copyright 2017, Zacks Investment Research. All Rights Reserved.

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, David Bautz, PhD, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.