Zacks Small-Cap Research

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Cerecor, Inc.

(CERC-NASDAQ)

CERC: With An Infusion of Non-dilutive Capital, Cerecor Ready to Move the Pipeline Forward…

Based on our probability adjusted DCF model that takes into account potential future revenues from CERC-301 and CERC-611, CERC is valued at $1.50/share. This model is highly dependent upon the clinical success of CERC-301 and CERC-611 and will be adjusted accordingly based upon future clinical results.

Current Price (11/09/17)	$1.06
Valuation	**$1.50**

OUTLOOK

On November 6, 2017, Cerecor, Inc. (CERC) announced financial results for the third quarter of 2017. Following the sale of CERC-501 to Janssen Pharmaceuticals, Inc. for $25 million the company currently has approximately $24 million in cash and cash equivalents plus an additional approximately $3.8 million in an escrowed account. We believe this is sufficient to fund the operations at least through the end of 2018.

With a fresh infusion of cash, the company will now turn its attention to the development of CERC-301 as a treatment for orphan neurological indications, CERC-611 as a treatment for seizures in patients with epilepsy, and CERC-406 as a treatment for residual cognitive impairment.

SUMMARY DATA

52-Week High	**$5.23**
52-Week Low	**$0.44**
One-Year Return (%)	**-74.27**
Beta	**2.13**
Average Daily Volume (sh)	**210,683**
Shares Outstanding (mil)	**26**
Market Capitalization ($mil)	**$28**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**16**
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 A	25.0 A	0.0 E	25.6 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	-$0.14 A	$0.88 A	-$0.23 E	$0.83 E
2018					-$0.59 E
2019					-$0.61 E

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WHAT'S NEW

Financial Update

On November 6, 2017, Cerecor announced financial results for the third quarter of 2017. The company recorded $25.0 million in revenue from the sale of CERC-501 to Janssen Pharmaceuticals, Inc. along with $0.04 million in grant revenue, which was derived 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 had grant revenue of $0.3 million in the third quarter of 2016, which related to a grant from the National Institute of Drug Abuse for the development of CERC-501 in smoking cessation. The company sold CERC-501 to Janssen on August 14, 2017 and thus we do not anticipate any additional grant income related to CERC-501.

Net income for the third quarter of 2017 was $18.7 million, or $0.52 per share. R&D expenses totaled $1.0 million and G&A expenses totaled $2.2 million in the third quarter of 2017 compared to $4.6 million in R&D expenses and $1.7 million in G&A expenses for the third 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. Janssen has assumed all ongoing clinical trials and will be responsible for any new development or commercialization of CERC-501. The increase in G&A expenses was primarily due to costs associated with the sale of CERC-501 to Janssen.

As of Sep. 30, 2017, Cerecor had cash and cash equivalents of approximately $24.0 million. In August 2017 the company sold its world-wide rights to CERC-501 to Janssen for $25 million, of which $3.75 million was placed in a 12-month escrow to secure future indemnification obligations to Janssen. Based on the company's current cash position and the proceeds from the Janssen sale, we estimate the company has sufficient capital to fund operations at least through the end of 2018.

As of August 14, 2017, Cerecor had approximately 26.1 million shares of common stock outstanding. In addition, there were approximately 2.2 million stock options, and 14.3 million warrants with an exercise price of $0.40 for a fully diluted share count of approximately 42.5 million.

Business Update

CERC-501 Sold to Janssen for $25 Million

On August 14, 2017, Cerecor, Inc. (CERC) announced it has sold all the rights to CERC-501 to Janssen Pharmaceuticals, Inc. for $25 million, with $21.25 million paid in cash upon closing of the deal and $3.75 million placed into a 12-month escrow account to secure future indemnification obligations to Janssen. There is also a potential $20 million regulatory milestone payment. Janssen will assume the ongoing clinical trials and be responsible for any development and commercialization of CERC-501. We believe this infusion of non-dilutive capital will be sufficient to fund the company's operations at least through the end of 2018.

Focus Turns to CERC-301, CERC-611, and CERC-406

With the fresh infusion of capital, Cerecor is now turning its attention back to CERC-301, which had previously been tested in two Phase 2 clinical trials for major depressive disorder (MDD), along with preclinical candidates CERC-611 and CERC-406.

CERC-301

CERC-301 is an orally available specific antagonist against the N-methyl-D-aspartate (NMDA) glutamate receptors. These receptors are composed of various subunits to form three different subtypes: GluN1, GluN2, and GluN3 (or NR1, NR2, and NR3). There are eight variants of the NR1 subunit, four different NR2 subunits (referred to as NR2A through D), and two NR3 subunits (Paoletti *et al*., 2007). CERC-301 specifically targets the NR2B subunit.

Cerecor has evaluated CERC-301 in two separate Phase 2 clinical trials in patients with MDD. Neither study showed statistical efficacy in treating MDD. However, CERC-301 was shown to be safe and well tolerated in both studies. Since the compound is highly selective for the NR2B subunit of NMDA receptors, along with a having good

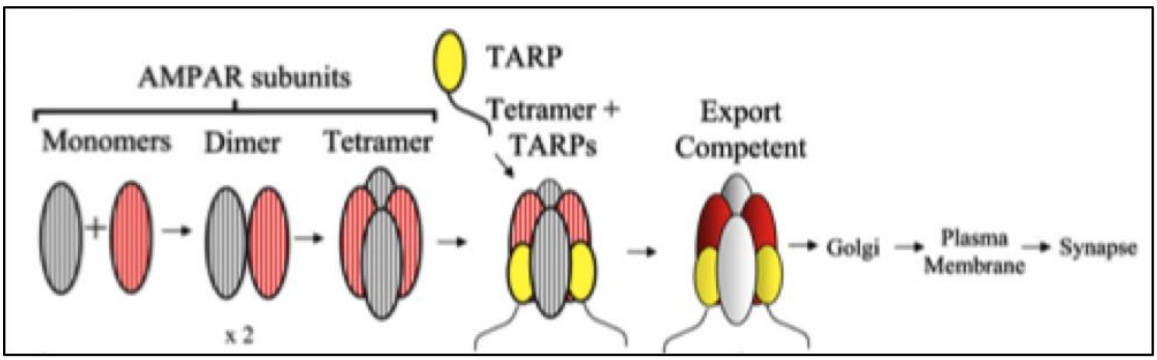
tolerability profile, Cerecor will be initiating a preclinical and clinical program to explore the use of CERC-301 in orphan neurological conditions. We anticipate learning more about the program in the coming months.

CERC-601

CERC-611 (formerly LY3130481) is a TARP-γ8-dependent α-amino-3-hydroxy-5-methyl-4-isoxazolepropionate (AMPA) receptor antagonist and is being developed as a treatment for epilepsy. Like NMDA receptors, AMPA receptors are a type of glutamate receptor. 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.

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. Even with their shortcomings, sales for AEDs totaled $5.1 billion in 2015 and are expected to increase to $8.5 billion in 2022 (Evaluate Pharma).

CERC-406

One of the primary mediators of functional impairment in patients suffering from MDD is cognitive dysfunction, which is a loss of basic intellectual functions such as memory, problem solving, reasoning, and learning. Most of those who suffer from MDD complain of some type of cognitive impairment. Criterion items for a diagnosis of MDD include a diminished ability to think or concentrate along with indecisiveness. Numerous studies have shown differences between healthy subjects and those with MDD in areas such as attention, executive function, learning, and memory along with cognitive affective bias, which results in focus moving away from positive stimuli and toward negative stimuli (Murrough *et al*., 2011).

While cognitive dysfunction may improve in those successfully treated for MDD, there is ample evidence to support the notion that certain cognitive deficits can persist. A 3-year study of those with MDD showed cognitive dysfunction in 94% of patients during acute depressive episodes and 44% during partial or full remission (Conradi *et al*., 2011). This suggests that cognitive dysfunction may be separate from mood symptoms in those suffering from MDD and that a subset of MDD patients would likely benefit from a treatment targeted to alleviate cognitive dysfunction.

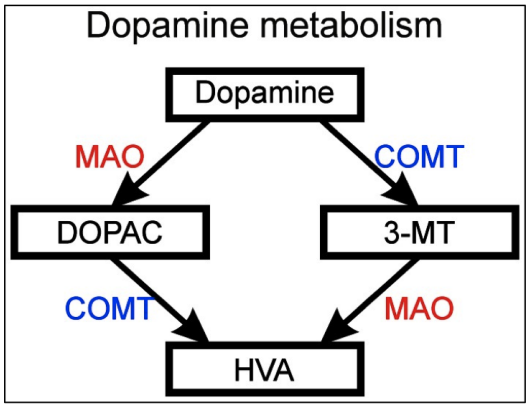
COMT as a Target for Treating Cognitive Dysfunction

Catechol-O-methyltransferase (COMT) is a promising candidate gene for modulating cognition function and dysfunction. The *COMT* gene encodes for two distinct isoforms: soluble-COMT (sCOMT) and membrane-bound COMT (mbCOMT) (Männistö *et al*., 1999). mbCOMT is expressed in the brain and has a much higher affinity for dopamine than sCOMT (Chen *et al*., 2011). Dopamine has a critical role in higher-order cognition in humans, impacting both thought and emotion, particularly in the pre-frontal cortex (PFC; Goldman-Rakic, 1999). COMT is responsible for the degradation of dopamine in the PFC. The level of dopamine in the brain is very tightly controlled, with too much or too little having negative consequences. Thus, since COMT is a key regulator of dopamine level, it has emerged as a prime target for augmenting cognitive function and COMT inhibition has been theorized to potentially impact executive function in patient's suffering from various ailments including Parkinson's disease and schizophrenia.

A couple of key characteristics of COMT inhibition are likely to facilitate drug development: genetic variability in the *COMT* gene and a readily available biomarker.

- **Genetic Variability**: Genetic studies have proven that a single nucleotide polymorphism in the *COMT* gene due to an adenine to guanine transition results in a methionine (Met) to valine (Val) substitution at amino acid 158 of the COMT protein (Lachman *et al*., 1996). The Val form of the enzyme leads to higher COMT protein levels and approximately 40% greater enzymatic activity compared to the Met form (Chen *et al*., 2004). These differences have real-world implications, as homozygous Val-COMT carriers have decreased performance on tests of executive control when compared to homozygous Met-COMT carriers (Malhotra *et al*., 2002). Drugs that target the dopaminergic system interact with these genetic variants, as shown by amphetamine improving cognitive performance in homozygous Val-COMT carriers but impairing it in homozygous Met-COMT carriers (Mattay *et al*., 2003). Thus, targeting those individuals that carry Val-COMT is likely to prove beneficial, as that group of patients appear most likely to benefit from pharmacological intervention.

- **Biomarker**: Inhibition of COMT is easily monitored through the quantification of the level of two compounds in the cerebrospinal fluid. The figure below shows that dopamine can be broken down via one of two pathways. The first step is catalyzed by either COMT to yield 3-methoxytyramine (3-MT) or monoamine oxidase aldehyde dehydrogenase (MAO) to yield 3,4-dihydroxyphenylacetic acid (DOPAC). The second step involves the conversion of DOPAC to homovanillic acid (HVA) by COMT or 3-MT to HVA by MAO. Thus, inhibition of COMT results in an accumulation of DOPAC (as no 3-MT is created from dopamine) and a decrease in HVA (as the DOPAC that was manufactured in step 1 can not be converted to HVA). The levels of each of the compounds can be correlated to the level of COMT inhibition.



Source: researchgate.net

COMTi Platform and CERC-406

In 2013, Cerecor acquired the rights to the COMT inhibitor (COMTi) platform from Merck. The platform comprises a group of COMT inhibitors that are selective for mbCOMT compared to sCOMT. The selectivity offered by these compounds is likely to lead to fewer off-target toxicities and side effects that were seen with previous COMT inhibitors such as tolcapone (liver toxicity) and entacapone (diarrhea). Cerecor's compounds are designed to fully penetrate the blood-brain barrier and to be highly selective for mbCOMT, potentially leading to higher efficacy with lower doses.

The lead compound from the COMTi platform is CERC-406, an orally available small molecule that has low inhibitory activity for sCOMT. The company is initially planning to develop CERC-406 as an adjunctive medication for patients with residual cognitive impairment due to MDD. CERC-406 was selected in part based on preclinical data showing a lower potential for periphery inhibition of COMT, rapid absorption and bioavailability, accessibility to the brain, and a favorable dose-dependent biomarker profile in rodents. The company is hopeful that CERC-406 will be effective in homozygous Val-COMT patients who have higher levels of COMT activity and lower levels of dopamine in the PFC, thus potentially restoring proper levels of dopamine and positively impacting cognitive function. CERC-406 is currently in preclinical testing.

Conclusion

Following disappointing clinical results for both CERC-301 and CERC-501, the company is looking to "start anew" with a large amount of cash, a renewed focus on the pipeline, and the eventual hiring of a new CEO. We are looking forward to learning more about the use of CERC-301 in orphan neurological indications, and what those indications might be. We anticipate the company moving ahead with an investigational new drug (IND) application for CERC-611 to begin development as an adjunctive treatment for seizures in patients with epilepsy, and additional details about the clinical path forward after that occurs. We anticipate CERC-406 is at least a couple of years away from the clinic as it is still early in preclinical development.

Cerecor currently has a little less than $28 million in cash (when including the $3.8 million in escrow) and a market cap very close to that. The stock has moved up since the company sold CERC-501, as it had been trading for well below the cash level following that transaction. However, at this point the market is assigning little to no value to the company's pipeline. Our valuation currently stands at $1.50.

PROJECTED FINANCIALS

Cerecor, Inc.
Income Statement

Cerecor, Inc.	2016 A	Q1 A	Q2 A	Q3 A	Q4 E	2017 E	2018 E	2019 E
CERC-301	$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 & License Revenue	$1	$0	$0	$25	$0	$26	$0	$0
YOY Growth	-	-	-	-	-	-		
Total Revenues	**$1**	**$0**	**$0**	**$25**	**$0**	**$26**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-		
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-		
Research & Development	$10.1	$1.0	$0.5	$1.0	$2.0	$4.4	$9.0	$11.0
General & Administrative	$7.1	$1.3	$1.4	$2.2	$1.3	$6.2	$7.0	$8.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($16.1)	($1.9)	($1.8)	$21.9	($3.3)	$14.9	($16.0)	($19.0)
Operating Margin	-	-	-	-	-	-		
Non-Operating Expenses (Net)	($0.4)	($0.1)	($0.0)	$0.0	($0.1)	($0.2)	($0.4)	($0.4)
Pre-Tax Income	($16.5)	($2.0)	($1.8)	$22.0	($3.4)	$14.8	($16.4)	($19.4)
Income Taxes Paid	$0	$0	$0	$3	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($16.5)**	**($2.0)**	**($1.8)**	**$18.7**	**($3.4)**	**$14.8**	**($16.4)**	**($19.4)**
Net Margin	-	-	-	-	-	-		
Reported EPS	**($1.87)**	**($0.19)**	**($0.14)**	**$0.88**	**($0.13)**	**$0.83**	**($0.59)**	**($0.61)**
YOY Growth	-	-	-	-	-	-		
Basic Shares Outstanding	8.8	10.2	13.3	21.4	26.2	17.8	28.0	32.0

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

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