Zacks Small-Cap Research

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Cerecor, Inc.

(CERC-NASDAQ)

CERC: CERC-501 Not Successful in Nicotine Withdrawal; Preparing for 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 (12/05/16)	$1.75
Valuation	**$7.00**

OUTLOOK

On December 5, 2016, Cerecor, Inc. (CERC) announced topline results for the Phase 2 clinical trial of CERC-501 in nicotine withdrawal. The trial did not meet the primary outcome in nicotine withdrawal. However, CERC-501 was generally well tolerated with a favorable side-effect profile, and the company is going to continue development of CERC-501 in major depressive disorder (MDD), as they had previously disclosed. We anticipate a Phase 2/3 trial of CERC-501 in MDD getting underway in the second half of 2017.

SUMMARY DATA

52-Week High	**$5.23**
52-Week Low	**$1.75**
One-Year Return (%)	**-50.70**
Beta	**2.37**
Average Daily Volume (sh)	**176,961**
Shares Outstanding (mil)	**9**
Market Capitalization ($mil)	**$16**
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)
2015	0.0 A	0.0 A	0.0 A	0.0 A	0.3 A
2016	0.0 A	0.7 A	0.3 A	0.0 E	1.0 E
2017					0.0 E
2018					0.0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	- A	- A	- A	- A	-$4.71 A
2016	-$0.59 A	-$0.41 A	-$0.70 A	-$0.52 E	-$2.23 E
2017					-$1.88 E
2018					-$1.77 E

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WHAT'S NEW

CERC-501 Not Effective in Nicotine Withdrawal Trial; Company will Move Forward in MDD

On December 5, 2016, Cerecor, Inc. (CERC) announced topline results from the Phase 2 study of CERC-501 in nicotine withdrawal. The study did not achieve the primary objective in symptoms of tobacco withdrawal and smoking behaviors as measured by improvement in time to start smoking and number of cigarettes smoked following abstinence. However, CERC-501 was generally well tolerated and there were no serious adverse events reported and no discontinuations due to adverse events.

The Clin501-201 study was a randomized, double blind, placebo controlled trial to evaluate the effects of 15 mg of CERC-501 on tobacco withdrawal and reinstatement and to assess craving, mood, and anxiety during 18 hours of abstinence in 66 heavy cigarette smokers (NCT02641028). Cerecor received a $1 million grant from the National Institute on Drug Abuse to help fund the study. The company had previously stated that it did not intend to continue development of CERC-501 in nicotine withdrawal regardless of the results, thus the fact that the drug was generally well tolerated is the most important data to come out of the study as the company pivots to developing CERC-501 as a treatment for major depressive disorder (MDD).

Cerecor is currently planning a Phase 2/3 trial of CERC-501 in adjunctive MDD, which would likely initiate in the second half of 2017. 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 focusing resources on this opportunity.

Conclusion and Valuation

Cerecor has had a tough week, first with the disappointing results announced for CERC-301 in MDD and then with the CERC-501 trial failing to achieve the primary objective in nicotine withdrawal. While investors have initially chosen to focus on the fact that the nicotine trial failed, we believe that the most important data from that trial is the fact that CERC-501 was well tolerated with no serious adverse events reported, and thus Cerecor can now shift gears with CERC-501 and focus on its development in MDD.

Preparations are currently underway for a Phase 2/3 clinical trial 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 the third quarter of 2016 with $8.8 million, however there is a $15 million stock purchase agreement in place with Aspire Capital Fund, LLC. While the company will need to raise additional funds for the Phase 2/3 trial of CERC-501, there are multiple options available for how that money can be raised.

As noted in our previous report, we have made significant adjustments to our model. We have removed CERC-301 from our valuation model, and replaced it with CERC-501 as a treatment for adjunctive MDD. We model for potential regulatory filings in 2021 and approval in 2022. Our model estimates a price of $20 per day in the U.S. and $16 per day in the rest of the world and assume that patients would take the drug for approximately nine months out of the year. We model for potential peak sales of CERC-501 in MDD of $1.8 billion worldwide. With a 40% probability of success and an 18% discount rate, we arrive at a net present value 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 $30 million we arrive at a net present value for the company of $78.9 million. Dividing this by the company's fully diluted (common stock and options) share count of approximately 11.1 million shares leads to a valuation of $7/share.

PROJECTED FINANCIALS

Cerecor, Inc.
Income Statement

Cerecor, Inc.	2015 A	Q1 A	Q2 A	Q3 A	Q4 E	2016 E	2017 E	2018 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	$0	$0	$1	$0	$0	$1	$0	$0
YOY Growth	-	-	-	-	-	-	-	
Total Revenues	**$0**	**$0**	**$1**	**$0**	**$0**	**$1**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	
Research & Development	$6.6	$2.3	$2.5	$4.6	$2.3	$11.7	$11.0	$13.0
General & Administrative	$4.4	$2.6	$1.6	$1.7	$2.7	$8.7	$12.0	$14.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($11.0)	($4.9)	($3.5)	($6.0)	($5.0)	($19.4)	($23.0)	($27.0)
Operating Margin	-	-	-	-	-	-	-	
Non-Operating Expenses (Net)	$0.5	($0.2)	($0.0)	($0.2)	$0.2	($0.2)	$0.5	$0.5
Pre-Tax Income	($10.5)	($5.1)	($3.5)	($6.2)	($4.8)	($19.6)	($22.5)	($26.5)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($10.5)**	**($5.1)**	**($3.5)**	**($6.2)**	**($4.8)**	**($19.6)**	**($22.5)**	**($26.5)**
Net Margin	-	-	-	-	-	-	-	
Reported EPS	**($4.71)**	**($0.59)**	**($0.41)**	**($0.70)**	**($0.52)**	**($2.23)**	**($1.88)**	**($1.77)**
YOY Growth	-	-	-	-	-	-	-	
Basic Shares Outstanding	2.2	8.7	8.7	8.8	9.2	8.8	12.0	15.0

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

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