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October 2, 2018
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Cerecor Inc

(CERC-NASDAQ)

CERC: Transformation Continues with Purchase of Ichorion Therapeutics, Inc…

Based on our probability adjusted DCF model that takes into account potential future revenues from CERC-301, CERC-611, commercial operations, and sales of PRVs, using a 12% discount rate CERC is valued at $7.50/share.

Current Price (10/02/18)	$4.66
Valuation	**$7.50**

OUTLOOK

On September 25, 2018, Cerecor Inc. (CERC) announced the acquisition of Ichorion Therapeutics, Inc., a private biotechnology company developing products for ultra-rare orphan indications caused by inborn errors of metabolism. Ichorion was acquired through issuing 5.8 million shares of common stock as well as potential development milestones worth up to an additional $15 million.

Ichorion has two lead products that could be developed through the 505(b)(2) pathway, and we expect INDs for those products to be filed in 2019. In addition, those two products have been granted Rare Pediatric Disease Designation, thus making them eligible for issuance of a Priority Review Voucher (PRV) upon approval. The past three PRVs to be sold have commanded an average price of over $100 million.

SUMMARY DATA

52-Week High	**$5.66**
52-Week Low	**$0.85**
One-Year Return (%)	**408.73**
Beta	**1.32**
Average Daily Volume (sh)	**48,340**
Shares Outstanding (mil)	**35**
Market Capitalization ($mil)	**$163**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**49**
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	**High**
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

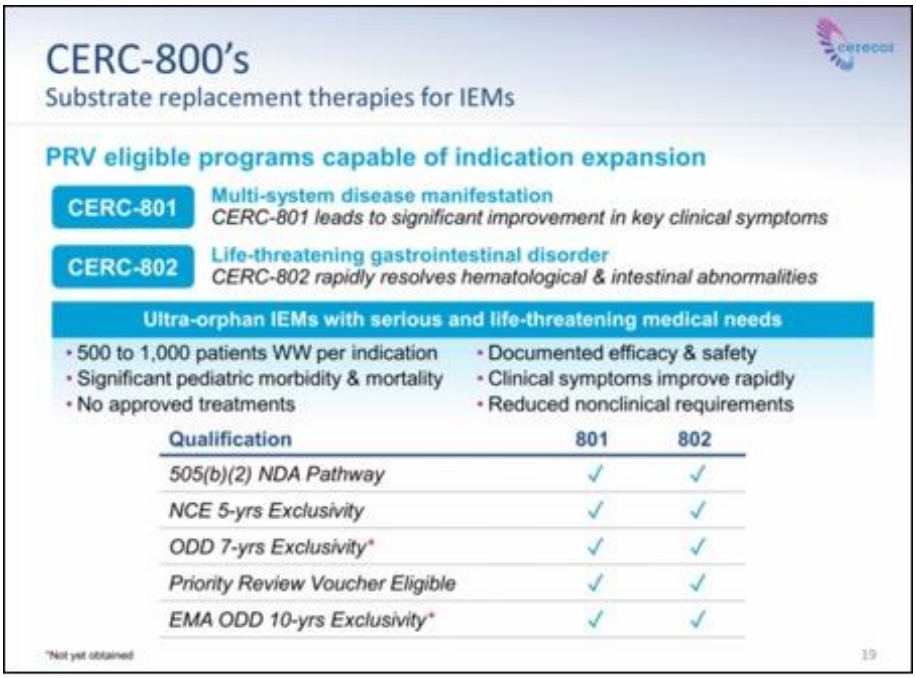
Business Update

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.

Purchases Ichorion Therapeutics, Inc.

On September 25, 2018, Cerecor announced the acquisition of privately-held Ichorion Therapeutics, Inc., a biotechnology company focused on ultra-rare orphan diseases caused by inborn errors of metabolism (IEM). In addition, Ichorion has a platform to target IEMs that are not amenable to substrate replacement therapy. Ichorion was acquired in exchange for 5.8 million shares of common stock and includes up to $15 million in development milestones that can be paid in either Cerecor stock or cash.

The lead development products acquired from Ichorion are CERC-801 and CERC-802. The company has not disclosed the exact indications for these products, but each of them will be developed along the 505(b)(2) new drug application (NDA) regulatory pathway. That pathway allows an applicant to use some information, including safety and efficacy information, from studies performed by others, thus potentially decreasing the time to market. The following slide gives an overview of CERC-801 and CERC-802.



Source: Cerecor, Inc.

Given that the number of patients for each of those products is in the hundreds, the most important aspect for CERC-801 and CERC-802 is likely the fact that they are eligible for a priority review voucher (PRV) upon approval. A PRV allows the holder of the voucher to receive an expedited six-month review from the FDA for an NDA or biologics license application (BLA) instead of the usual ten-month review. The Food and Drug Administration Safety and Innovation Act (FDASIA) created the rare pediatric voucher in 2012 to specifically target the need for additional therapies for rare pediatric subsets of diseases (affect fewer than 200,000 individuals in the U.S.). Priority review vouchers are also awarded for the development of treatments for certain tropical diseases and medical countermeasures.

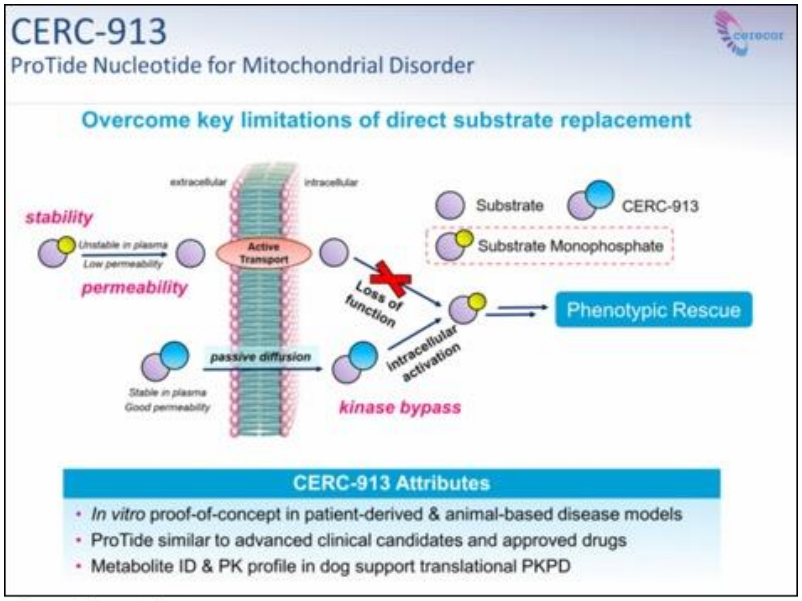
Priority review vouchers are fully transferrable, and a number of companies that have been issued the vouchers in the past have sold them, including one that was sold to AbbVie (ABBV) in Aug. 2015 for $350 million. The four most recent purchases are by an undisclosed buyer for $125 million in Nov. 2017, Novartis (NVS) for $130 million in Dec. 2017, Jazz Pharmaceuticals for $125 million in Apr. 2017, and an undisclosed buyer for $80.6 million in Aug. 2018. While prices for PRVs have come down since AbbVie purchased one for $350 million in 2015, the price for them has appeared to settle in the $100 million range. The following table shows how many priority review vouchers have been issued along with the current status of the voucher, if known.

Priority Review Vouchers

Voucher Award Date	Voucher Type	Voucher Awardee	Voucher Status
2009	Tropical Disease	Novartis	Used for BLA for canakinumab
2012	Tropical Disease	Janssen	Used to accelerate approval of Tremfya (guselkumab) for plaque psoriasis
2014	Rare Pediatric Disease	BioMarin	Sold to Sanofi for $67.5M in Jul 2014; used for approval of Praluent
2014	Tropical Disease	Knight Therapeutics	Sold to Gilead for $125M in Nov 2014; used for approval of Odefsey
2015	Rare Pediatric Disease	United Therapeutics	Sold to AbbVie for $350M in Aug 2015
2015	Rare Pediatric Disease	Asklepion Pharmaceuticals	Transferred to Retrophin and sold to Sanofi for $245M in May 2015
2015	Rare Pediatric Disease	Wellstat Therapeutics	Transferred to AstraZeneca
2015	Rare Pediatric Disease	Alexion Pharmaceuticals	Used for approval of ALXN1210
2015	Rare Pediatric Disease	Alexion Pharmaceuticals	Not used
2016	Tropical Disease	PaxVax Bermuda	Not used (possibly sold to Gilead for ~$200M in 2Q16)
2016	Rare Pediatric Disease	Sarepta Therapeutics	Sold to Gilead for $125M in Feb 2017; used for approval of HIV treatment
2016	Rare Pediatric Disease	Ionis Pharmaceuticals	Not used
2017	Rare Pediatric Disease	Marathon Pharmaceuticals	Not used
2017	Rare Pediatric Disease	BioMarin	Sold for $125 million in Nov 2017
2017	Tropical Disease	Chemo Research, S.L.	Not used
2017	Rare Pediatric Disease	Novartis	Not used
2017	Rare Pediatric Disease	Ultragenyx Pharmaceutical	Sold to Novartis for $130 million in Dec. 2017; used for approval of siponimod
2017	Rare Pediatric Disease	Spark Therapeutics	Sold to Jazz Pharmaceuticals for $125 million in Apr 2018
2018	Rare Pediatric Disease	Ultragenyx Pharmaceutical	Sold to undisclosed buyer for $80.6 million in Aug. 2018
2018	Rare Pediatric Disease	Medicines Development	Not used
2018	Rare Pediatric Disease	GW Pharma	Not used
2018	Material Threat Medical Countermeasure	SIGA Technologies	Not used
2018	Tropical Disease	GlaxoSmithKline	Not used

Source: raps.org / Zacks SCR

In addition to the substrate replacement therapy products acquired, Cerecor also received a platform technology for targeting diseases for which substrate replacement therapy is not feasible. The lead development candidate based on that technology is CERC-913. It is a molecule based on Ichorion's ProTide Nucleotide technology and is being developed to treat a mitochondrial disorder. The technology is based on the ability to get a phosphorylated substrate into the cell where it is needed. Typically, phosphorylated substrates will not passively diffuse through the cell membrane, thus a disease characterized by the lack of a phosphorylated substrate inside the cell is not able to be treated through substrate replacement therapy. The ProTide Nucleotide technology allows a phosphorylated substrate to diffuse into the cell, at which time it is activated such that the substrate can be used for phenotypic rescue. This is shown in the following slide.



Source: Cerecor, Inc.

CERC-913 has not been granted rare pediatric disease designation, however Cerecor will be applying for that status and is confident that it will be granted.

Conclusion and Valuation

Cerecor continues to execute on its business transformation strategy and the acquisition of Ichorion appears to fit well with the company's stated pediatric and rare disease focus. Based on the acquisition, we have updated our model to include the lead development candidates acquired from Ichorion. Instead of valuing them through their potential peak sales, and since we are unsure of the exact indication and market size, we believe it is more prudent to value them based on the value of the PRV issued upon approval. We model for three PRVs to be issued in 2020, 2021, and 2022 and currently use a 50% probability of approval. We also model for each PRV to be sold a year after being issued. Based on the average selling price for the previous four PRVs sold, we model for them to be sold for $100 million each. This leads to an NPV for the PRVs of approximately $1.50 per share, increasing our valuation for Cerecor to $7.50 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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