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Cerecor Inc. (CERC-NASDAQ)

CERC: Expansion in Rare and Orphan Diseases with Acquisition of Aevi Genomic Medicine …

Based on our probability adjusted DCF model that takes into account potential future revenues from the company's rare and orphan disease pipeline along with the sale of PRVs, and using a 13.5% discount rate CERC is valued at $8.00/share.

Current Price (12/13/19)	$4.40
Valuation	**$8.00**

OUTLOOK

On December 5, 2019, Cerecor Inc. (CERC) announced the acquisition of Aevi Genomic Medicine (GNMX), a move that will further strengthen the company's position in the rare and orphan disease space. Aevi has a pipeline of early stage assets focused on rare diseases with significant unmet needs that will complement Cerecor's rare and orphan portfolio. In addition, one of Aevi's programs may be eligible for a Priority Review Voucher (PRV), which will bring the total of potential PRV's from Cerecor's pipeline to four. The past few PRV's sold have done so for approximately $100 million each. The acquisition of Aevi comes after Cerecor sold off its Pediatric Portfolio to Aytu Bioscience, Inc. (AYTU), thus transitioning the company towards a pure R&D-focused strategy while also eliminating the $15 million debt obligation. With the focus now directed toward the rare and orphan disease space, Cerecor is evaluating strategic alternatives for its neurology assets as well as for Millipred®, which was retained following the Aytu transaction.

SUMMARY DATA

52-Week High	**$7.22**
52-Week Low	**$2.93**
One-Year Return (%)	**29.41**
Beta	**2.11**
Average Daily Volume (sh)	**79,911**
Shares Outstanding (mil)	**44**
Market Capitalization ($mil)	**$194**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**61**
Insider Ownership (%)	**64**
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 2018 Estimate	**-10.4**
P/E using 2019 Estimate	**-14.4**

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)
2018	4.5 A	4.8 A	4.1 A	5.0 A	18.3 A
2019	5.4 A	4.4 A	5.5 A	1.0 E	16.4 E
2020					0.0 E
2021					0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$0.12 A	-$0.19 A	-$0.71 A	-$0.18 A	-$1.20 A
2019	-$0.13 A	-$0.11 A	-$0.07 A	-$0.23 E	-$0.65 E
2020					-$0.52 E
2021					-$0.55 E

WHAT'S NEW

Business Update

Acquisition of Aevi Genomic Medicine Strengthens Rare and Orphan Disease Pipeline

On December 5, 2019, Cerecor, Inc. (CERC) announced the acquisition of Aevi Genomic Medicine (GNMX) in an all-stock transaction valued at approximately $16.1 million plus contingent value rights (CVRs) for up to an additional $6.5 million based on subsequent clinical or regulatory milestones. In addition to the acquisition of Aevi, the company also disclosed that it is seeking strategic alternatives for its neurological assets and its one commercial product, Millipred®, which was not included in the sale of the company's Pediatric Portfolio (discussed below).

The rationale behind the acquisition of Aevi centers on Cerecor's desire to expand its rare disease pipeline, which will now include three clinical-stage programs from Aevi in addition to the 800-series programs. In addition, the CEO and CMO from Aevi, Mike Cola and Dr. Garry Neil, will join Cerecor as the company did not have anyone in either position prior to the acquisition.

The three programs that Cerecor will acquire from Aevi are:

AEVI-007: This is an anti-interleukin (IL)-18 fully human monoclonal antibody that will developed for the treatment of Adult Onset Stills Disease (AOSD) and multiple myeloma (MM). We anticipate proof-of-concept clinical trials initiating in 2020.

- AOSD is an inflammatory disease in which patients suffer from high fevers, sore throat, joint pain, swollen lymph nodes, and weight loss. The cause is unknown and no risk factors have been identified. Approximately 1 in 100,000 people develop AOSD each year and it becomes a chronic condition in approximately 1/3rd of those affected (Medlineplus).

- MM is a cancer of monoclonal plasma cells that derive from post-germinal-center B cells. The disease is characterized by an infiltration of these cells into the bone marrow causing anemia, lytic bone disease, hypercalcemia, and kidney damage from the accumulation of monoclonal immunoglobulins (Kumar *et al*., 2017). The disease is most common in the elderly, with a median age of onset of 69 years (NCI SEER). Elevated IL-18 serum levels are associated with poor overall survival in MM patients (Alexandrakis *et al*., 2004) and IL-18 drives the generation of myeloid-derived suppressor cells (MDSCs) that accelerate disease progression (Nakamura *et al*., 2018).

AEVI-006: This is a small molecule inhibitor of the mTORC1/2 complexes that is being developed for the treatment of complex lymphatic malformation (LM). LMs are rare, non-malignant masses composed of fluid-filled channels or spaces caused by the improper formation of the lymphatic system. The abnormal lymphatic vessels cause the slow transfer of lymphatic fluid back into the venous system, thus excessive fluid accumulates and dilates the lymphatic channels. LMs form prior to birth and are typically identified within the first two years of life. They most commonly affect the head and neck area but can occur anywhere in the body.

The cellular receptor TIE2 plays a key role in vascular maturation through the PI3K/AKT/mTOR signaling pathway, and up to 60% of venous malformations are caused by mutations in TIE2 (Hammer *et al*., 2018) while another 20% are due to mutations in PIK3CA, which encodes the catalytic subunit of PI3K (Limaye *et al*., 2015).

Sirolimus is an allosteric inhibitor of mTOR, the catalytic subunit of two distinct complexes: mTORC1 and mTORC2. It inhibits mTORC1 (Tsang *et al*., 2007) but only inhibits mTORC2 in certain cell types after prolonged exposure (Sarbassov *et al*., 2006).

A systematic review identified twenty studies that included 71 patients with vascular malformations (45 patients with LM) treated with sirolimus (Wiegand *et al*., 2018). Despite dosing and duration of treatment differences, 60 patients experienced a partial remission of disease. Thus, we believe these data provide compelling justification for testing an mTORC1/2 inhibitor for the treatment of LM. Cerecor intends to start a Phase 1b proof-of-concept trial in 2020.

AEVI-002: This is a fully human monoclonal antibody targeting LIGHT (**L**ymphotoxin-like, exhibits **I**nducible expression, and competes with HSV **G**lycoprotein D for **H**VEM, a receptor expressed by **T** lymphocytes [part of the Tumor Necrosis Super Family 14]). The compound is currently in a Phase 1 clinical trial in adult patients with Crohn's disease (CD), and the company is planning to initiate a clinical trial for pediatric Crohn's disease.

Crohn's disease is chronic type of inflammatory bowel disease of the digestive tract in which patients experience diarrhea, cramping and pain in the abdomen, and weight loss (NIDDK). The cause of CD is unknown but is thought to be an interplay between various genetic and environmental factors. Current treatment options work to decrease the inflammation and to prevent its recurrence, however there is no cure for the disease. Corticosteroids, immunomodulators, and biologic therapies that targets tumor necrosis factor-alpha, IL-12, or IL-23 are examples of currently available treatments.

Previous preclinical research showed that LIGHT expression caused similar pathological features and cytokine characterization that is observed in CD (Wang *et al*., 2005), which forms the basis for potentially treating Crohn's patients with an anti-LIGHT antibody. Aevi has initiated a clinical trial of AEVI-002 in adult Crohn's disease patients (NCT03169894) and we anticipate initial data from this study in the first half of 2020.

Sale of Pediatric Assets Provides Capital to Advance R&D Portfolio

On October 14, 2019, Cerecor announced the sale of the company's Pediatric Portfolio to Aytu Bioscience, Inc. (AYTU) for a combination of cash and stock totaling $17 million ($4.5 million in cash and $12.5 million in shares of Aytu convertible preferred stock) along with the assumption of the $15 million debt obligation with Deerfield. The deal also includes the elimination of the existing royalty obligations and various commercial accruals totaling $11 million.

The Pediatric Portfolio includes five product lines: Aciphex® Sprinkle™, Cefaclor for Oral Suspension, Karbinal® ER, Flexichamber™, Poly-Vi-Flor®, and Tri-Vi-Flor™. Importantly, Millipred® was not included in the Pediatric Portfolio sold to Aytu. We believe Millipred® generates approximately $8-9 million in yearly net revenues and approximately $7 million in free cash flow. The company will look to monetize Millipred®, and using a 2-3x free cash flow multiple, we estimate that it could be sold for $15-20 million.

The $15 million debt obligation with Deerfield was assumed when Cerecor acquired Avadel US Holdings, which included Aciphex® Sprinkle™, Cefaclor for Oral Suspension, Karbinal® ER, Flexichamber™. Following the transaction Cerecor will be a debt-free company, and will also no longer be responsible for any license agreements associated with the Pediatric Portfolio, which are currently valued at $9.6 million.

In addition to the elimination of debt and existing royalty obligations, a significant cost savings of $7 to $9 million annually will occur due to no longer having a Pediatric commercial sales force and sales management team, which will be transitioned to Aytu.

CERC-800 Series Update

Cerecor is developing CERC-801 (D-galactose), CERC-802 (D-mannose), and CERC-803 (L-fucose) for the treatment of the congenital disorder of glycosylation (CDG) diseases phosphoglucomutase 1 (PGM1) deficiency, mannose-phosphate isomerase (MPI) deficiency, and leukocyte adhesion deficiency type II (LADII) or SLC35C1-CDG, respectively.

In July 2019, the company announced the first patient was enrolled in the CDG FIRST (Congenital Disorders of Glycosylation Formative Retrospective Study) trial. The purpose of the CDG FIRST trial is to collect natural history data from patients diagnosed with CDGs along with any treatment-related data whether or not they had been treated with D-galactose, D-mannose, or L-fucose. Earlier in 2019, the FDA issued draft guidance on the use of natural history studies for drug development in rare diseases. Since the natural history, or the course a disease would take with no intervention, is typically limited for rare diseases, these types of studies are important to help understand the most useful types of outcomes to monitor.

We believe the company is hoping to collect data from approximately 10 patients each for CERC-801 and CERC-802 while for CERC-803 only a few patients will likely be needed given that it is incredibly rare. The company has requested a meeting with the FDA, which we anticipate will occur in the first quarter of 2020, during which it will present the data collected thus far from the CDG FIRST trial along with Phase 1 data in healthy volunteers for both CERC-801 and CERC-802. In addition, we anticipate the company learning what type of prospective studies will be required for each of the CERC-800 compounds. This will determine the timeline for filing NDAs, and at this point we

anticipate the first NDA being filed in 2021. Which compound the first NDA is filed for will be determined by the size of the prospective studies the FDA requests. However, since each qualifies for a priority review voucher (discussed below), it doesn't make a difference which compound is approved first.

We don't believe any prospective study required by the FDA will be onerous and will likely only require up to 10 patients each for CERC-801 and CERC-802 and potentially only a couple of patients for CERC-803. Precedent for a very small prospective trial is provided by Xuriden® (uridine triacetate), which was approved by the FDA in 2015 following an open-label study in four patients with hereditary orotic aciduria. Three of the four patients had previously been treated with uridine before being switched to Xuriden®.

Potential for Priority Review Voucher

Given that the number of patients for each of the CERC-800 products is very small, the most important aspect for those products 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 $80.6 million in Aug. 2018, Eli Lilly (LLY) for $80 million in Nov. 2018, Biohaven Pharmaceutical Holding Company for $105 million in Mar. 2019, and AstraZeneca (AZN) for $95 million in Aug. 2019. While prices for PRVs have come down since AbbVie purchased one for $350 million in 2015, the price for them appears to have settled in the $80-$100 million range. The following table shows how many PRVs 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	Used for brolucizumab for wetAMD
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 $110 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	Sold to Novo Nordisk for undisclosed amt
2018	Rare Pediatric Disease	GW Pharma	Sold to Biohaven for $105 million on Mar. 18, 2019
2018	Material Threat Medical Countermeasure	SIGA Technologies	Sold to Eli Lilly for $80 million on Nov. 1, 2018
2018	Tropical Disease	GlaxoSmithKline	Used by ViiV Healthcare for NDA for HIV-1 infection
2018	Rare Pediatric Disease	Leadiant Bioscience Inc	Not used
2018	Rare Pediatric Disease	Sobi and Novimmune	Sold to AZN for $95 million in Aug 2019
2019	Tropical Disease	Novartis	Not used
2019	Rare Pediatric Disease	Vertex	Not used
2019	Rare Pediatric Disease	Alexion Pharmaceuticals	Not used
2019	Tropical Disease	Sanofi	Not used
2019	Rare Pediatric Disease	Novartis	Not used
2019	Tropical Disease	TB Alliance	Not used
2019	Material Threat Medical Countermeasure	Bavarian Nordic	Intending to sell it
2019	Rare Pediatric Disease	Vertex	Not used

Source: raps.org / Zacks SCR

Financial Update

On November 14, 2019, Cerecor announced financial results for the third quarter of 2019. The company reported revenues of $5.5 million for the third quarter of 2019, compared to $4.1 million for the third quarter of 2018. The increase was due to higher sales volume. Cost of product sales was $1.4 million for the three months ending Sep. 30, 2019, compared to $3.1 million for the three months ending Sep. 30, 2018. The decrease was driven by the lack of minimum obligations due pursuant to the Lachlan Agreement following a settlement agreement that fully released the company from all current and future liabilities related to the Lachlan Agreement. R&D expenses in the third quarter of 2019 were $1.7 million, compared to $1.0 million for the third quarter of 2018. The increase was primarily due to increased CMC expenses, clinical expenses, and salaries and related costs. G&A expenses for the third quarter of 2019 were $2.7 million, compared to $1.9 million for the third quarter of 2018. The increase was primarily due to an increase in legal, consulting, and professional fees. Sales and marketing expenses in the third quarter of

2019 were $2.6 million, compared to $2.3 million for the third quarter of 2018. The increase was primarily due to an increase in salaries and related costs. Net loss for the three months ended Sep. 30, 2019 was $4.0 million compared to a net loss of $24.6 million for the three months ended Sep. 30, 2018. The large decrease was the result of an $18.7 million charge for acquired in-process research and development recognized in the third quarter of 2018 while there was no such charge for the third quarter of 2019.

As of Sep. 30, 2019, Cerecor had cash and cash equivalents of approximately $5.3 million, which does not include the $4.5 million in cash received from Aytu for the sale of the Pediatric Portfolio in the fourth quarter of 2019. In addition, the company has $12.5 million in Aytu preferred stock (which has a lock-up period until June 2020) and will look to monetize Millipred®, which we believe could be sold for $15-20 million. As of Nov. 12, 2019, Cerecor had approximately 44.1 million shares outstanding and when factoring in stock options and warrants a fully diluted share count of 54 million shares.

Conclusion and Valuation

Following the acquisition of Aevi and the sale of the Pediatric Portfolio, Cerecor is now fully focused on a diverse pipeline of assets targeting rare and orphan diseases. Unfortunately, the Pediatric Portfolio never performed as originally expected, and we believe that pivoting to an R&D-focused organization was the right move. The company now has no debt on its balance sheet and a number of options available to fund the company to an expected PRV in 2022, with three other PRV's possible over the following few years.

For the CERC-800 series, the majority of the valuation comes from the potential PRVs to be issued upon approval of each of the compounds. However, the company will be commercializing the products as well and we estimate that the CERC-800 series compounds could generate peak sales of $75 million. We model for three PRVs to be issued in 2021, 2022, and 2023 and currently use a 70% probability of approval. We also model for each PRV to be sold a year after being issued. Using a 13.5% discount rate leads to a net present value for the CERC-800 series of $161 million.

For the Aevi assets, we currently estimate that Cerecor will commercialize each of the assets in the U.S., although if AEVI-007 is advanced in MM, we believe that will be done through a partnership. For sales outside the U.S., we estimate that each compound will be partnered and the company will receive a 15% royalty on net sales.

For AEVI-007 in AOSD, we estimate there are approximately 4,000 individuals in the U.S. and approximately 6,000 in the rest of the world with the condition. Based on the literature, approximately 30% of patients are refractory to front-line methotrexate therapy and thus would be the target population for treatment with AEVI-007. Based on approval in 2025, a $250,000 yearly cost, peak sales of $250 million in the U.S. and $150 million in the rest of the world, and using a 13.5% discount rate and a 20% probability of approval leads to a net present value for AEVI-007 in AOSD of approximately $16 million.

For AEVI-007 in MM, we estimate there are approximately 30,000 and 39,000 individuals with the disease in the U.S. and E.U., respectively. We estimate for approval in 2027, peak sales of $700 million in the U.S. and $400 million in the E.U., and using a 13.5% discount rate and a 20% probability of approval leads to a net present value for AEVI-007 in MM of approximately $35 million.

For AEVI-006 in LM, we estimate there are approximately 50,000 and 60,000 individuals with the condition in the U.S. and E.U., respectively. We estimate for approval in 2024 in the U.S. and 2025 in the E.U., peak sales of $600 million in the U.S. and $700 million in the E.U., and using a 13.5% discount rate and a 20% probability of approval leads to a net present value for AEVI-006 in LM of approximately $68 million.

For AEVI-002 for pediatric Crohn's, we estimate there are approximately 50,000 and 75,000 individuals with the condition in the U.S. and E.U., respectively. We estimate for approval in 2026 in the U.S. and 2027 in the E.U., peak sales of $400 million in both the U.S. and E.U., and using a 13.5% discount rate and a 20% probability of approval leads to a net present value for AEVI-002 in pediatric Crohn's of approximately $26 million.

Combining the net present value for the CERC-800 series, the Aevi assets, a $15 million valuation for Millipred®, a $20 million valuation for the legacy neurology assets, and the company's current cash total and dividing by the current share count of approximately 44.1 million shares leads to a valuation for Cerecor of $8 per share.

PROJECTED FINANCIALS

Cerecor, Inc.	2018 A	Q1 A	Q2 A	Q3 A	Q4 E	2019 E	2020 E	2021 E
Commercial Group	$18.3	$5.4	$4.4	$5.5	$1.0	$16.4	$0.0	$0.0
Rare Disease Portfolio	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
PRV Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Grant Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$18**	**$5.4**	**$4.4**	**$5.5**	**$1.0**	**$16.4**	**$0.0**	**$0.0**
Cost of Sales	$7.5	$1.9	($0.1)	$1.4	$0.2	$3.4	$0.0	$0.0
Product Gross Margin	*59%*	*64%*	*103%*	*74%*	*80%*	*79%*	*#DIV/0!*	*#DIV/0!*
Research & Development	$5.8	$3.4	$3.7	$1.7	$4.2	$13.1	$13.0	$14.0
Acquired in-process R&D	$18.7	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
General & Administrative	$10.7	$2.7	$2.4	$2.7	$2.5	$10.3	$10.5	$11.0
Sales and Marketing	$8.5	$3.1	$2.9	$2.6	$3.0	$11.7	$0.0	$0.0
Amortization Expense	$4.5	$1.1	$1.1	$1.0	$1.2	$4.4	$1.3	$1.3
Impairment of Intangible Assets	$1.9	$0.0	$1.4	$0.0	$0.0	$1.4	$0.0	$0.0
Change in fair value of contingent consideration	$0.1	$0.2	($1.0)	($0.2)	$0.0	($1.0)	$0.0	$0.0
Operating Income	($39.3)	($7.0)	($6.0)	($3.8)	($10.1)	($26.9)	($24.8)	($26.3)
Operating Margin	*-215%*	-	-	-	-	*-164%*	*#DIV/0!*	*#DIV/0!*
Other (expense) income	($0.8)	($0.3)	($0.2)	($0.2)	($0.3)	($1.2)	($1.2)	($1.2)
Pre-Tax Income	($40.1)	($7.3)	($6.2)	($4.0)	($10.4)	($28.1)	($26.0)	($27.5)
Income Taxes Paid	($0.0)	$0.2	$0.1	$0.0	$0.0	$0.3	$0.1	$0.1
Net Income	**($40.1)**	**($7.5)**	**($6.2)**	**($4.0)**	**($10.4)**	**($28.4)**	**($26.1)**	**($27.6)**
Net Margin		-	-	-	-			
Reported EPS	**($1.20)**	**($0.13)**	**($0.11)**	**($0.07)**	**($0.23)**	**($0.65)**	**($0.52)**	**($0.55)**
YOY Growth		-	-	-	-			
Basic Shares Outstanding	34.8	42.0	42.8	43.2	46.0	43.5	50.0	50.0

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

HISTORICAL STOCK PRICE

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