

# **Cerecor Reports 2019 Results**

-Company Transformed Into Orphan and Rare Disease Biotech -Clear Corporate Strategy with New Leadership -Significant Advancement in Pipeline and Regulatory Milestones

ROCKVILLE, Md., March 11, 2020 (GLOBE NEWSWIRE) -- Cerecor Inc. (NASDAQ: CERC), a biopharmaceutical company focused on becoming a leader in development and commercialization of treatments for rare pediatric and orphan diseases, today announced full-year results for 2019. The Company achieved significant research, development and regulatory milestones while transforming the organization through significant business development activities.

"We believe the Company made aggressive steps to transform itself over the second half of 2019. The first being the divestiture of the commercial pediatric portfolio to AYTU, providing near term cash flow, eliminating the debt overhang and improving the Company's balance sheet. The second being the merger with Aevi Genomic Medicine, which more than doubled the Company's pipeline and refined the focus of the organization as a rare pediatric and orphan disease biotech," said Mike Cola, Chief Executive Officer of Cerecor. "At the same time, we continued to advance our pipeline achieving numerous clinical and regulatory milestones."

#### 2019 Highlights

### **Clinical and Regulatory Highlights**

- The FDA granted Orphan Drug Designation to CERC-801, CERC-802 and CERC-803 as therapies in development for Congenital Disorders of Glycosylation ("CDGs")
- Received Fast Track Designation from the FDA for CERC-801 for the treatment of PGM1 Deficiency and for CERC-802 for the treatment of Mannose-Phosphate Isomerase Deficiency
- The FDA accepted the IND application for Cerecor's investigational drugs CERC-801 for the treatment of PGM1 Deficiency and CERC-802 for the treatment of MPI-CDG
- Announced positive Phase I data for CERC-801 and CERC-802 in Healthy Volunteers
- First patient enrolled into the CDG FIRST Trial; a retrospective trial looking at the natural history of the disease and the current treatment paradigm of patients with specific CDGs

#### **Corporate and Financial Highlights**

- Announced Company headquarters move to the pharmaceutical corridor of Rockville, Maryland
- Closed a \$10 million Common Stock offering

- The Company was added to the Russell 3000 Index<sup>®</sup>
- Sold the pediatric portfolio and underlying commercial infrastructure to AYTU BioScience, Inc. ("AYTU") in a deal valued in excess of \$43 million and removed debt associated with Deerfield agreement on commercial assets ("Aytu Divestiture")
- Signed, then subsequently closed deal in February 2020, to merge with Aevi Genomic Medicine
- Mike Cola announced as Chief Executive Officer and Garry Neil announced as Chief Medical Officer effective upon closing of the Aevi Merger
- Merger doubled the number of near-term clinical assets from the three CERC-800s programs to six total programs; honing the organizational strategy as a rare pediatric and orphan disease biotech
  - CERC-002 an anti-LIGHT MAb for Pediatric-onset Crohn's Disease
  - CERC-006 a dual mTor inhibitor for complex Lymphatic Malformations
  - CERC-007 an anti-IL 18 MAb for Adult-onset Still's Disease and Multiple Myeloma
  - CERC-801 D Galactose substrate replacement therapy for PGMI-CDG
  - CERC-802 D Mannose substrate replacement therapy for MPI-CDG
  - CERC-803 L Fucose substrate replacement therapy for (LADII), also known as SLC35C1-CDG

Dr. Garry Neil, Chief Medical Officer for Cerecor commented, 'We have a rich pipeline with near-term approvals possible in 2022 and/or 2023. All of our assets have novel mechanisms of action and have the potential to be high value, first-in-class medicines for patient populations suffering from orphan and rare diseases. At Cerecor we are committed to developing and delivering medicines to help these underserved patient populations."

#### 2019 Financial Update

Cerecor significantly improved its working capital from a negative \$4.3 million as of December 31, 2018 to a positive \$5.6 million as of December 31, 2019, largely as a result of the Aytu Divestiture. Additionally, the Company avoided future cash outflows by eliminating long-term debt and contingent consideration, also as a result of the Aytu Divestiture. Operating expenses declined largely as a result of acquired in-process research and development expense of \$18.7 million recognized as part of the Ichorion acquisition in 2018, which did not repeat in 2019. Net loss and net loss per share improved largely as a result of the decrease in operating expenses.

#### **Condensed Consolidated Balance Sheets**

	D	December 31,		
	2019		2018	
Assets	(in thousands)			
Current assets:				
Cash and cash equivalents	\$ 3,6	9 \$	10,646	
Accounts receivable, net	1,0	2	822	
Other receivables	4,2	1	5,262	
Inventory, net		<u> 1</u>	318	

Prepaid expenses and other current assets		707		732
Restricted cash, current portion		17		19
Investment in Aytu		7,629		-
Current assets of discontinued operations		498		4,133
Total current assets		17,724		21,932
Property and equipment, net		1,448		587
Intangibles assets, net		2,426		3,765
Goodwill		14,409		14,409
Restricted cash, net of current portion		102		82
Long-term assets of discontinued operations		-		29,476
Total assets	\$	36,109	\$	70,251
Liabilities and stockholders' equity	<u> </u>	00,100	<u>Ψ</u>	70,201
Current liabilities:				
Accounts payable	\$	2,078	\$	1,446
Accounts payable  Accrued expenses and other current liabilities	Ψ	5,640	Ψ	14,329
Income taxes payable		552		2,032
Contingent consideration, current portion		-		860
Current liabilities of discontinued operations		3,891		7,550
Total current liabilities		12,161		26,217
Contingent consideration, net of current portion		12,101		397
Deferred tax liability, net		86		69
License obligations		00		00
2.001100 obligations		-		1,250
Other long-term liabilities		1,112		385
Long-term liabilities of discontinued operations		1,755		21,025
Total liabilities		15,114		49,343
Stockholders' equity:				
Common Stock—\$0.001 par value; 200,000,000 shares authorized at				
December 31, 2019 and 2018; 44,384,222 and 40,804,189 shares issued and outstanding at December 31, 2019 and 2018, respectively		44		41
Preferred Stock—\$0.001 par value; 5,000,000 shares authorized at December 31,		44		41
2019 and 2018; 2,857,143 shares issued and outstanding at December 31, 2019				
and 2018, respectively		3		3
Additional paid-in capital		135,239		119,082
Accumulated deficit		(114,291)		(98,218)
Total stockholders' equity		20,995		20,908
Total liabilities and stockholders' equity	\$	36,109	\$	70,251
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The condensed consolidated balance sheets at December 31, 2019 and 2018 have been derived from the financial statements but do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements

## **Condensed Consolidated Statements of Operations**

Year Ended D	ecember 31,
2019	2018

		(in thousands, except per share data)			
Revenues					
Product revenue, net	\$	6,650	\$	6,572	
Sales force revenue		-		456	
License and other revenue		100		-	
Total revenues, net		6,750		7,028	
Operating expenses:					
Cost of product sales		(567)		3,261	
Research and development		11,764		5,786	
Acquired in-process research and development		-		18,724	
General and administrative		10,124		10,511	
Sales and marketing		1,484		545	
Amortization expense		1,339		1,828	
mpairment of intangible assets		-		1,862	
Change in fair value of contingent consideration		(1,256)		(111)	
Total operating expenses		22,888		42,406	
oss from continuing operations		(16,138)		(35,378)	
Other (expense) income:					
Change in fair value of Investment in Aytu		54		-	
Change in fair value of warrant liability and unit purchase option liability		(4)		25	
Other (expense) income, net		(24)		13	
nterest income, net		121		16	
Total other income, net from continuing operations		147		54	
Loss from continuing operations before taxes		(15,991)		(35,324)	
ncome tax expense (benefit)		280		(49)	
Loss from continuing operations	\$	(16,271)	\$	(35,275)	
ncome (loss) from discontinued operations, net of tax (inclusive of	Ψ	(10,271)	Ψ	(33,273)	
gain on sale)		198		(4,778)	
Net loss	\$	(16,073)	\$	(40,053)	
vet 1033	<u> </u>	(10,010)	<u> </u>	(40,000)	
Net (loss) income per share of common stock, basic and diluted:			-		
Continuing operations	\$	(0.28)	\$	(1.06)	
Discontinued operations		0.00		(0.14)	
Net loss per share of common stock, basic and diluted	\$	(0.28)	\$	(1.20)	
Net (loss) income per share of preferred stock, basic and diluted:					
Continuing operations	\$	(1.42)			
Discontinued operations	•	0.01			
Net loss per share of preferred stock, basic and diluted	\$	(1.41 )			

The condensed consolidated statements of operations for the years ended December 31, 2019 and 2018 have been derived from the financial statements but do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

The 2020 organizational focus is driving clinical development programs towards key milestones:

- CERC-800s (CERC-801, CERC-802 and CERC-803) anticipate initial data readout from the CDG-FIRST Trial within the 1 Half 2020
- CERC-002 (anti-LIGHT mAb) being developed for Pediatric-onset Crohn's Disease expects initial data readout 2 Half 2020
- CERC-007 (anti-IL-18 mAb) being developed for auto-inflammatory diseases (AOSD, MM) is expecting initial data readout Q4 2020 to Q1 2021
- CERC-006 (dual mTOR inhibitor) being developed for complex Lymphatic Malformations anticipates initial data readout 1 Half 2021

Actual results might vary materially, whether as a result of market conditions, or other factors, including those described in the "Risk Factors" sections of our SEC filings.

#### **About Cerecor**

Cerecor is a biopharmaceutical company focused on becoming a leader in development and commercialization of treatments for rare pediatric and orphan diseases. The Company is advancing an emerging clinical-stage pipeline of innovative therapies. The Company's pediatric rare disease pipeline is led by CERC-801, CERC-802 and CERC-803 ("CERC-800 programs"), which are therapies for inborn errors of metabolism, specifically disorders known as Congenital Disorders of Glycosylation ("CDGs"). The FDA granted Rare Pediatric Disease Designation and Orphan Drug Designation ("ODD") to all three CERC-800 programs, thus potentially qualifying the Company to receive a Priority Review Voucher ("PRV") upon approval of a new drug application ("NDA"). The Company is also developing CERC-002, CERC-006 and CERC-007. CERC-007 is an anti-IL-18 monoclonal antibody being developed for the treatment of autoimmune inflammatory diseases such as Adult Onset Stills Disease ("AOSD") and Multiple Myeloma ("MM"). CERC-006 is a dual mTOR inhibitor being developed for the treatment of complex Lymphatic Malformations. CERC-002 is an anti-LIGHT monoclonal antibody being developed for the treatment of Pediatric-onset Crohn's Disease.

For more information about Cerecor, please visitwww.cerecor.com.

#### **Forward-Looking Statements**

This press release may include forward-looking statements made pursuant to the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts. Such forward-looking statements are subject to significant risks and uncertainties that are subject to change based on various factors (many of which are beyond Cerecor's control), which could cause actual results to differ from the forward-looking statements. Such statements may include, without limitation, statements with respect to Cerecor's plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects," "may," "will," "could," "would," "should," "continue," "seeks," "aims," "predicts," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential," or similar expressions (including their use in the negative), or by discussions of future matters such as: the integration of the companies and their personnel; the development of product candidates or products; timing and success of trial results and regulatory review; potential attributes and benefits of product candidates; the expansion of

Cerecor's drug portfolio; strategic alternatives for the neurological assets and Millipred; and other statements that are not historical. These statements are based upon the current beliefs and expectations of Cerecor's management but are subject to significant risks and uncertainties, including: risks related to integration of the combined company; drug development costs, timing and other risks, including reliance on investigators and enrollment of patients in clinical trials; regulatory risks; reliance on and the need to attract, integrate and retain key personnel; Cerecor's cash position and the need for it to raise additional capital; risks related to potential strategic alternatives for the Company's neurology assets and Millipred; and those other risks detailed in Cerecor's filings with the Securities and Exchange Commission. Actual results may differ from those set forth in the forward-looking statements. Except as required by applicable law, Cerecor expressly disclaims any obligations or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Cerecor's expectations with respect thereto or any change in events, conditions or circumstances on which any statement is based.

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Source: Cerecor Inc.