March 8, 2021

Cerecor Reports 2020 Financial Results and Provides Business Updates

- Announced CERC-002 significantly reduced respiratory failure and mortality in Phase 2 clinical trial in patients hospitalized with COVID-19 ARDS
- Improved financial position with $18.9M of cash on hand as of December 31, 2020 and $37.6M of net proceeds raised in January 2021 Poised to deliver significant number of clinical and regulatory catalysts in 2021
- Poised to deliver significant number of clinical and regulatory catalysts in 2021

ROCKVILLE, Md. and CHESTERBROOK, Pa., March 08, 2021 (GLOBE NEWSWIRE) -- Cerecor Inc. (NASDAQ: CERC), a biopharmaceutical company focused on becoming a leader in development and commercialization of treatments for rare and orphan diseases, today announced recent business progress and year-end financial results for 2020.

"Looking back, 2020 was a very productive and transformative year for Cerecor highlighted by swift transition post the merger with Aevi Genomic Medicine, improving the financial position of the company and initiating clinical trials across our pipeline," said Mike Cola, Chief Executive Officer of Cerecor*. "2021 started strong with positive Phase 2 data from CERC-002, our novel anti-LIGHT drug candidate in development for the treatment of COVID-19 ARDS. We have recently filed both Breakthrough Therapy and Fast Track Designations and anticipate meeting with the FDA to discuss next steps in this program soon. Overall, we believe 2021 will be a breakout year for Cerecor and look forward to building on early momentum with important pipeline updates across our immunology, oncology, and rare disease assets."*

Business Updates:

- Cerecor announced CERC-002 significantly reduced respiratory failure and mortality in Phase 2 clinical trial in Patients hospitalized with COVID-19 ARDS.
- The Company closed an underwritten public offering for net proceeds of approximately $37.6 million in January.
- Dr. Gilla Kaplan was appointed to the Board of Directors in October of 2020 bringing decades of experience in rare diseases and immune-inflammatory disorders.
- Schond Greenway was appointed as Chief Financial Officer, with an established focus on investor relations to further help capitalize the company.

Program Updates:

- **CERC-002:** Anti-LIGHT monoclonal antibody in clinical development for COVID-19 ARDS and severe pediatric onset Crohn's disease.
  - Completed double-blinded, placebo-controlled Phase 2 proof-of-concept study of CERC-002 in cytokine storm-induced COVID-19 ARDS.
  - Final analysis inclusive of the 60-day safety update in the randomized placebo-controlled study demonstrated CERC-002 was statistically significant in reducing respiratory failure and mortality at Day 28 in patients hospitalized with COVID-19-associated pneumonia and mild to moderate acute respiratory distress syndrome (ARDS), the primary endpoint, (n=62, p=0.044)
  - At both the 28-day and the 60-day final timepoints, an approximately 50% trend in mortality reduction (22.5% vs 10.8%) was observed. CERC-002 appeared safe and well-tolerated on top of standard of care including high dose steroids (>90%) and remdesivir (>65%).
  - Cerecor has submitted applications to the FDA for Breakthrough Therapy and Fast Track Designations and plans to meet with FDA to discuss the path to Emergency Use Authorization (EUA) and full approval.
  - The company is continuing to enroll patients in its Phase 1b trial in severe pediatric-onset Crohn's disease with initial data expected in the second quarter and is exploring the applicability of CERC-002 in non-COVID-19 ARDS.

- **CERC-007**: Anti-IL-18 monoclonal antibody for the treatment of multiple myeloma (MM) and Still's disease (AOSD and sJIA).
  - In December 2020, announced FDA Acceptance of two Investigational New Drug Applications for CERC-007 for the treatment of Still's disease and for the treatment of relapsed or refractory multiple myeloma (MM).
  - Following the first patient dosed in the Phase 1b clinical trial in patients with relapsed or refractory MM in December, the Company has successfully completed enrollment of the first patient cohort and looks to begin dosing cohort two.
  - Initial data anticipated from Phase 1b clinical trial in adult onset Still's disease in the second quarter of 2021.

- **CERC-006:** Dual mTORC1 and mTORC2 small molecule inhibitor for complex lymphatic malformations.
  - Initial data anticipated from proof-of-concept study in the second quarter of 2021.

- **CERC-800 programs (CERC-801, CERC-802, and CERC-803):** Therapeutic doses of monosaccharide therapies for congenital disorders of glycosylation (CDGs).
  - CERC-801 – In collaboration with the Frontiers in Congenital Disorders of Glycosylation Consortium clinical program, data are anticipated from the pivotal trial evaluating the safety and efficacy of D-galactose in patients suffering from Phosphoglucomutase-1 deficiency related congenital disorders of glycosylation (PGM1-CDG) in second half of 2021.
  - CERC-802 – Data anticipated from the pivotal trial evaluating the safety and efficacy of D-mannose in patients suffering from Mannose phosphate isomerase deficiency related CDG (MPI-CDG) in second half of 2021.

- CERC-803 – Clearance to proceed on the Investigational New Drug Application and received Fast Track Designation from the FDA in the fourth quarter 2020. Data anticipated from the pivotal trial evaluating the safety and efficacy of L-fucose in patients suffering from Leukocyte Adhesion Deficiency II (LAD II) in second half of 2021.

2020 Financial Update:

As of December 31, 2020, Cerecor had $18.9 million in cash and cash equivalents which is a significant increase over the prior year balance of $3.6 million. Furthermore, in January 2021, the Company closed an underwritten public offering for net proceeds of approximately $37.6 million.

There were significant increases to most operating expenses, net loss and net loss per share related to the merger with Aevi Genomic Medicine that occurred in February 2020 (the Aevi Merger). Notably, research and development expense for the year ended December 31, 2020 significantly increased to $32.2 million, which was driven by activities to advance the Company's expanded pipeline as a result of the Aevi Merger. There was a $25.5 million acquired in-process research and development (IPR&D) charge in 2020 directly related to the Aevi Merger. General and administrative expense increased to $17.4 million; the largest driver of such increase was stock-based compensation and other expenses related to leadership changes as a result of the Aevi Merger.

We believe these significant investments in our expanded pipeline and leadership team will lead to value driving milestones as our pipeline progresses toward commercialization.

Condensed Consolidated Balance Sheets

	December 31,	
	2020	**2019**
Assets	*(in thousands)*	
Current assets:		
Cash and cash equivalents	$ 18,919	$ 3,609
Accounts receivable, net	2,177	1,002
Other receivables	2,208	4,241
Inventory, net	3	21
Prepaid expenses and other current assets	2,660	707
Restricted cash, current portion	38	17
Investment in Aytu	-	7,629
Current assets of discontinued operations	-	498
Total current assets	26,005	17,724
Property and equipment, net	1,607	1,448
Intangible assets, net	1,585	2,426
Goodwill	14,409	14,409
Restricted cash, net of current portion	149	102
Total assets	$ 43,755	$ 36,109

Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,574	$ 2,078
Accrued expenses and other current liabilities	11,310	5,640
Income taxes payable	-	552
Current liabilities of discontinued operations	1,341	3,891
Total current liabilities	15,225	12,161
Royalty obligation	2,000	-
Deferred tax liability, net	90	86
Other long-term liabilities	1,878	1,112
Long-term liabilities of discontinued operations	-	1,755
Total liabilities	19,193	15,114
Stockholders' equity:		
Common stock—$0.001 par value; 200,000,000 shares authorized at December 31, 2020 and 2019; 75,004,127 and 44,384,222 shares issued and outstanding at December 31, 2020 and 2019, respectively	75	44
Preferred stock—$0.001 par value; 5,000,000 shares authorized at December 31, 2020 and 2019; 1,257,143 and 2,857,143 shares issued and outstanding at December 31, 2020 and 2019, respectively	1	3
Additional paid-in capital	202,276	135,239
Accumulated deficit	(177,790)	(114,291)
Total stockholders' equity	24,562	20,995
Total liabilities and stockholders' equity	$ 43,755	$ 36,109

The condensed consolidated balance sheets at December 31, 2020 and 2019 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 December 31,	
	2020	**2019**
	(in thousands, except per share data)	
Revenues:		
Product revenue, net	$ 6,699	$ 6,650
License and other revenue	-	100
Total revenues, net	6,699	6,750

Operating expenses:		
Cost of product sales	300	(567)
Research and development	32,193	11,764
Acquired in-process research and development	25,549	-
General and administrative	17,418	10,124
Sales and marketing	2,341	1,484
Amortization expense	1,741	1,339
Change in fair value of contingent consideration	-	(1,256)
Total operating expenses	79,542	22,888
	(72,843)	(16,138)
Other income:		
Change in fair value of Investment in Aytu	5,208	54
Other income (expense), net	409	(28)
Interest income, net	49	121
Total other income, net from continuing operations	5,666	147
Loss from continuing operations before taxes	(67,177)	(15,991)
Income tax (benefit) expense	(2,793)	280
Loss from continuing operations	$ (64,384)	$ (16,271)
Income from discontinued operations, net of tax	884	198
Net loss	$ (63,500)	$ (16,073)
Net (loss) income per share of common stock, basic and diluted:		
Continuing operations	$ (0.87)	$ (0.28)
Discontinued operations	0.01	0.00
Net loss per share of common stock, basic and diluted	$ (0.86)	$ (0.28)
Net (loss) income per share of preferred stock, basic and diluted:		
Continuing operations	$ (4.38)	$ (1.42)
Discontinued operations	0.06	0.01
Net loss per share of preferred stock, basic and diluted	$ (4.32)	$ (1.41)

The condensed consolidated statements of operations for the years ended December 31, 2020 and 2019 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.

About Cerecor

Cerecor is a biopharmaceutical company focused on becoming a leader in the development and commercialization of treatments for rare and orphan diseases. The company is advancing its clinical-stage pipeline of innovative therapies that address unmet patient needs within rare and orphan diseases. The company's rare disease pipeline includes CERC-801,

CERC-802 and CERC-803, which are in development for congenital disorders of glycosylation and CERC-006, an oral mTORc1/c2 inhibitor in development for the treatment of complex lymphatic malformations. The company is also developing two monoclonal antibodies, CERC-002, and CERC-007. CERC-002 targets the cytokine LIGHT (TNFSF14) and is in clinical development for treatment of severe pediatric-onset Crohn's disease, and COVID-19 acute respiratory distress syndrome. CERC-007 targets the cytokine IL-18 and is in clinical development for the treatment of Still's disease (adult onset Still's disease (AOSD) and systemic juvenile idiopathic arthritis (sJIA)), and multiple myeloma (MM). CERC-006, 801, 802 and 803 have all received Orphan Drug Designation and Rare Pediatric Disease Designation, which makes all four eligible for a priority review voucher upon FDA approval.

For more information about Cerecor, please visit www.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," "might," "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 development of product candidates or products; timing and success of trial results and regulatory review; potential attributes and benefits of product candidates; 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: drug development costs, timing and other risks, including reliance on investigators and enrollment of patients in clinical trials, which might be slowed by the COVID-19 pandemic; regulatory risks; Cerecor's cash position and the potential need for it to raise additional capital; general economic and market risks and uncertainties, including those caused by the COVID-19 pandemic; 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.

For media and investor inquiries

Chris Brinzey
Westwicke, an ICR Company
chris.brinzey@westwicke.com
339-970-2843

or

Schond L. Greenway
Investor Relations
Chief Financial Officer
Cerecor Inc.
sgreenway@cerecor.com
610-522-6200 office

Source: Cerecor Inc.