

August 2, 2021



# Cerecor Reports Second Quarter 2021 Financial Results and Provides Business Updates

- **Announced positive results for low-dose cohort of CERC-002 (1.0 mg/kg) in moderate-to-severe Crohn's disease patients who had previously failed three or more lines of biologic therapies, including anti-TNF alpha treatments**
- **Announced plans to explore CERC-002 in patients with moderate-to-severe ulcerative colitis refractory to anti-TNF alpha therapies**
- **Completed \$35 million debt financing that extends cash runway and supports multiple clinical catalysts anticipated in the second half of 2021**

ROCKVILLE, Md. and CHESTERBROOK, Pa., Aug. 02, 2021 (GLOBE NEWSWIRE) -- Cerecor Inc. (NASDAQ: CERC), a biopharmaceutical company focused on becoming a leader in the development and commercialization of treatments for immunologic, immunoncologic and rare genetic disorders, today announced recent business progress and second quarter 2021 financial results.

*"We are pleased with the progress made in the second quarter," said Mike Cola, Chief Executive Officer of Cerecor. "In addition to strengthening our cash position with the debt financing, we expanded our pipeline with an exciting collaboration with Sanford Burnham, and announced favorable results in one of our key programs, CERC-002 in moderate-to-severe Crohn's disease. We are excited to continue the advancement of our programs, including the expansion of CERC-002 into moderate-to-severe ulcerative colitis refractory to anti-TNF alpha therapies. We look forward to the second half of 2021 with multiple data readouts including the second cohort of CERC-002 in Crohn's disease."*

## **Business Updates:**

- Announced positive results from Cohort 1 of its open-label proof-of-concept Phase 1b study of CERC-002 in patients with moderate-to-severe Crohn's disease who had previously failed three or more lines of biologics therapies, including anti-TNF alpha treatments. Data demonstrated a rapid and dramatic mean reduction of LIGHT levels of approximately 80% compared to baseline that correlated to the pharmacodynamic effect of CERC-002 (1.0 mg/kg). A clinically meaningful benefit in mucosal healing as determined by colonoscopy (SES-CD score) was observed in 75% of the patients in Cohort 1 (3 of 4). CERC-002 was well-tolerated with no drug-related severe adverse events. The Company has completed enrollment of Cohort 2 (3.0 mg/kg) and anticipates data in the second half of 2021.
- Cerecor entered into an exclusive license agreement with Sanford Burnham Prebys for

the worldwide development and commercialization of an immune checkpoint program. The license further enhances the Company's development pipeline of novel biologics that address immunology and immuno-oncology targets.

- Cerecor strengthened and extended its financial resources with a \$35 million debt financing agreement with Horizon Technology Finance. The Company received the initial tranche of \$20 million at the loan closing in the second quarter and an additional \$10 million in the third quarter (following the positive results from Cohort 1 of its open-label proof-of-concept Phase 1b study of CERC-002 in moderate-to-severe Crohn's disease). The remaining \$5 million may be funded upon achieving certain predetermined milestones.

### **Program Updates and Milestones:**

- **CERC-002:** Anti-LIGHT monoclonal antibody in clinical development for COVID-19 acute respiratory distress syndrome (ARDS), moderate-to-severe Crohn's disease, and moderate-to-severe ulcerative colitis (UC) refractory to anti-TNF alpha therapies.
  - The Company announced the completion of enrollment in Cohort 2 (3.0 mg/kg) of its Phase 1b proof-of-concept study of CERC-002 in moderate-to-severe Crohn's disease and anticipates data in the second half of 2021.
  - Based on the positive data from Cohort 1 (1.0 mg/kg) of its Phase 1b trial of CERC-002 in moderate-to-severe Crohn's disease, the Company announced its plans to expand CERC-002 to include patients with moderate-to-severe UC who are refractory to anti-TNF alpha therapies.
  - The Company remains in dialogue with the FDA and is working through feedback to determine the trial design for a registrational study of CERC-002 in COVID-19 ARDS and accompanying timelines, including the potential expansion to a larger patient population in broader ARDS.
- **CERC-007:** Anti-IL-18 monoclonal antibody for the treatment of multiple myeloma (MM) and Still's disease (adult onset Still's disease (AOSD) and systemic juvenile idiopathic arthritis (sJIA)).
  - Top-line data anticipated from the Phase 1b clinical trial in patients with relapsed or refractory MM in the second half of 2021.
  - Initial data anticipated from the Phase 1b clinical trial in AOSD in the third quarter of 2021.
- **CERC-006:** Dual mTORc1/c2 small molecule inhibitor for complex lymphatic malformations.
  - Initial data anticipated from the Phase 1b proof-of-concept clinical study in the third 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 from the pivotal trial evaluating the safety and efficacy of D-galactose in patients suffering from Phosphoglucosyltransferase-1 deficiency related CDG (PGM1-CDG) are anticipated in the first quarter of 2022.

- CERC-802 – Data from the pivotal trial evaluating the safety and efficacy of D-mannose in patients suffering from Mannose phosphate isomerase deficiency related CDG (MPI-CDG) are anticipated in the second half of 2021.
- CERC-803 – Data from the pivotal trial evaluating the safety and efficacy of L-fucose in patients suffering from Leukocyte Adhesion Deficiency II (LAD II) are anticipated in the second half of 2021.

## Second Quarter 2021 Financial Update:

As of June 30, 2021, Cerecor had \$40.4 million in cash and cash equivalents, representing a \$21.5 million increase as compared to December 31, 2020. The increase was driven by gross proceeds of \$20 million from a debt financing agreement entered into in June 2021 and net proceeds of \$37.7 million from an underwritten public offering completed in January 2021, partially offset by operating expenditures, the majority of which related to pipeline development. In the third quarter, the Company achieved a milestone triggering receipt of an additional \$10 million debt tranche.

Net product revenue of the Company's commercialized product, which the Company considers non-core, increased \$1.4 million for the three months ended June 30, 2021 as compared to the three months ended June 30, 2020, which was driven by increased demand to backfill the short-dated inventory sold in the prior quarter.

Total operating expenses increased \$7.3 million for the three months ended June 30, 2021 as compared to the three months ended June 30, 2020, which was the largest driver of the increase in net loss period over period. The increased operating expenses were largely driven by a \$6.7 million increase in research and development expenses as a result of Cerecor's continued advancement of its maturing pipeline, particularly as it relates to clinical and manufacturing expenses.

## Condensed Consolidated Balance Sheets

*(In thousands, except share and per share data)*

	June 30, 2021 (unaudited) (a)	December 31, 2020 (a)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 40,435	\$ 18,919
Accounts receivable, net	4,120	2,177
Other receivables	998	2,208
Inventory, net	20	3
Prepaid expenses and other current assets	1,750	2,660
Restricted cash, current portion	41	38
Total current assets	47,364	26,005
Property and equipment, net	1,431	1,607
Intangible assets, net	732	1,585

Goodwill	14,409	14,409
Restricted cash, net of current portion	149	149
Total assets	<u>\$ 64,085</u>	<u>\$ 43,755</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 3,965	\$ 2,574
Accrued expenses and other current liabilities	17,611	11,310
Current liabilities of discontinued operations	98	1,341
Total current liabilities	<u>21,674</u>	<u>15,225</u>
Notes payable	17,143	—
Royalty obligation	2,000	2,000
Deferred tax liability, net	122	90
Other long-term liabilities	1,558	1,878
Total liabilities	<u>42,497</u>	<u>19,193</u>
Stockholders' equity:		
Common stock—\$0.001 par value; 200,000,000 shares authorized at June 30, 2021 and December 31, 2020; 96,008,951 and 75,004,127 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	96	75
Preferred stock—\$0.001 par value; 5,000,000 shares authorized at June 30, 2021 and December 31, 2020; 0 and 1,257,143 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	—	1
Additional paid-in capital	247,067	202,276
Accumulated deficit	(225,575)	(177,790)
Total stockholders' equity	<u>21,588</u>	<u>24,562</u>
Total liabilities and stockholders' equity	<u>\$ 64,085</u>	<u>\$ 43,755</u>

(a) The condensed consolidated balance sheets as of June 30, 2021 and December 31, 2020 have been derived from the reviewed and audited financial statements, respectively, but do not include all of the information and footnotes required by accounting principles accepted in the United States for complete financial statements.

## Condensed Consolidated Statements of Operations

(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021 (a)	2020 (a)	2021 (a)	2020 (a)
Revenues:				
Product revenue, net	\$ 2,730	\$ 1,338	\$ 3,204	\$ 4,092
License revenue	625	—	625	—

Total revenues, net	<u>3,355</u>	<u>1,338</u>	<u>3,829</u>	<u>4,092</u>
Operating expenses:				
Cost of product sales	83	78	159	144
Research and development	12,569	5,917	37,774	10,685
Acquired in-process research and development	—	—	—	25,549
General and administrative	6,618	6,101	11,530	8,777
Sales and marketing	786	653	1,221	1,330
Amortization expense	428	404	853	834
Total operating expenses	<u>20,484</u>	<u>13,153</u>	<u>51,537</u>	<u>47,319</u>
	(17,129)	(11,815)	(47,708)	(43,227)
Other (expense) income:				
Change in fair value of Investment in Aytu	—	(1,872)	—	5,208
Other income (expense), net	(5)	398	(5)	410
Interest (expense) income, net	(239)	9	(222)	18
Total other (expense) income, net from continuing operations	<u>(244)</u>	<u>(1,465)</u>	<u>(227)</u>	<u>5,636</u>
Loss from continuing operations before taxes	(17,373)	(13,280)	(47,935)	(37,591)
Income tax benefit	(199)	(454)	(188)	(2,611)
Loss from continuing operations	<u>\$(17,174)</u>	<u>\$(12,826)</u>	<u>\$(47,747)</u>	<u>\$(34,980)</u>
Income (loss) from discontinued operations, net of tax	69	(455)	(38)	582
Net loss	<u>\$(17,105)</u>	<u>\$(13,281)</u>	<u>\$(47,785)</u>	<u>\$(34,398)</u>
Net (loss) income per share of common stock, basic and diluted:				
Continuing operations	\$ (0.18)	\$ (0.18)	\$ (0.50)	\$ (0.53)
Discontinued operations	—	(0.01)	—	0.01
Net loss per share of common stock, basic and diluted	<u>\$ (0.18)</u>	<u>\$ (0.19)</u>	<u>\$ (0.50)</u>	<u>\$ (0.52)</u>
Net (loss) income per share of preferred stock, basic and diluted:				
Continuing operations	\$ (0.88)	\$ (0.93)	\$ (2.49)	\$ (2.66)
Discontinued operations	—	(0.03)	—	0.04
Net loss per share of preferred stock, basic and diluted	<u>\$ (0.88)</u>	<u>\$ (0.96)</u>	<u>\$ (2.49)</u>	<u>\$ (2.62)</u>

(a) The unaudited condensed consolidated statements of operations for the three and six months ended June 30, 2021 and 2020 have been derived from the reviewed 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 immunologic, immuno-oncologic and rare genetic disorders. 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 inflammatory bowel 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](http://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; the risk that preliminary findings from our clinical studies may not be indicative of subsequent study results; 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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