UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 13, 2021

CERECOR INC.
(Exact name of registrant as specified in its charter)

Delaware		
(State or other jurisdiction of incorporation)		
001-37590		**45-0705648**
(Commission File Number)		**(IRS Employer Identification No.)**

540 Gaither Road, Suite 400, Rockville, Maryland 20850
(Address of principal executive offices) (Zip Code)

Registrant's Telephone Number, Including Area Code: (410) 522-8707

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 Par Value	CERC	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging Growth Company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On May 13, 2021, Cerecor Inc. issued a press release announcing its financial results for the quarter ended March 31, 2021. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein in its entirety by reference.

The information in this Item 2.02 (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release, dated May 13, 2021.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CERECOR INC.

Date: May 13, 2021

By: /s/ Schond L. Greenway
Schond L. Greenway
Chief Financial Officer

Cerecor Reports First Quarter 2021 Financial Results and Provides Business Updates

- **Announced CERC-002 received Fast Track Designation from the U.S. Food and Drug Administration, following positive Phase 2 clinical trial for the treatment of patients hospitalized with COVID-19 ARDS**
- **Secured exclusive, world-wide rights to develop, manufacture and commercialize CERC-002 for all indications**
- **Poised to deliver significant number of clinical and regulatory catalysts in 2021**

ROCKVILLE, Md. and CHESTERBROOK, Pa., May 13, 2021 -- Cerecor Inc. (NASDAQ: CERC), a biopharmaceutical company focused on becoming a leader in the development and commercialization of treatments for rare and orphan diseases, today announced recent business progress and first quarter 2021 financial results.

"It has been a productive start to the year," said Mike Cola, Chief Executive Officer of Cerecor. "Over the course of 2021, we anticipate multiple data readouts, including CERC-007 in multiple myeloma and adult onset Still's disease and CERC-006 in complex lymphatic malformations, that will demonstrate significant progress in developing treatments for immunology, oncology, and rare genetic disorders."

Business Updates:

- Cerecor announced an expanded agreement with Kyowa Kirin for the world-wide rights to develop, manufacture and commercialize the anti-LIGHT antibody CERC-002 for all indications, including severe pediatric onset inflammatory bowel disease and acute respiratory distress syndrome (ARDS) including COVID-19 ARDS. Kyowa Kirin has an option to retain the rights in Japan.
- The U.S. Food and Drug Administration (FDA) granted Fast Track designation to CERC-002 for the treatment of hospitalized COVID-19 patients.
- Cerecor announced that it has dosed its first patient in a Phase 1b proof-of-concept, multi-center, open-label dose-escalation, clinical trial of CERC-007, a fully human anti-IL-18 monoclonal antibody, in patients with adult onset Still's disease (AOSD).

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 hospitalized COVID-19 patients with mild-to-moderate ARDS.
  - Final analysis inclusive of the 60-day safety update in the randomized placebo-controlled study demonstrated a single dose of CERC-002 led to a statistically significant reduction in respiratory failure and mortality at Day 28 in patients hospitalized with COVID-19-associated pneumonia and mild to moderate 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 was safe and well-tolerated on top of standard of care including high dose steroids (>90%) and remdesivir (>65%).
  - CERC-002 was granted FDA Fast Track designation for the treatment of hospitalized patients with COVID-19.

- 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 systemic juvenile idiopathic arthritis (sJIA)).
  - The Company has successfully completed enrollment of the first cohort, and has begun to enroll patients in the second of the three cohorts, in the Phase 1b clinical trial in patients with relapsed or refractory MM.
  - The Company anticipates top-line data from the Phase 1b MM trial in the second half of 2021.
  - Initial data anticipated from 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 a 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 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 the 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 the second half of 2021.
  - CERC-803 – 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 the second half of 2021.

First Quarter 2021 Financial Update:

As of March 31, 2021, Cerecor had $38.3 million in cash and cash equivalents, which was a significant increase over the $18.9 million balance as of December 31, 2020. The increase was driven by 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.

Net product revenue of the Company's commercialized product, which the Company considers non-core and for which strategic alternatives are being explored, decreased $2.3 million for the three months ended March 31, 2021. The decrease was due to a full sales return allowance recorded on sales of product that became short-dated in February 2021 due to manufacturing delays. The Company received the delayed inventory lot in April 2021 and it therefore expects revenues to normalize over the remainder of the year.

Total operating expenses decreased $3.1 million for the three months ended March 31, 2021 as compared to the three months ended March 31, 2020. In 2020, there was a $25.5 million acquired in-process research and development (IPR&D) charge directly related to the Company's merger with Aevi Genomic Medicine, Inc. (the Aevi Merger), which led to the decrease compared to the prior period. This decrease was largely offset by a significant increase in research and development expenses. This increase was due partially to a full quarter of the expanded pipeline from the Aevi Merger as opposed to a partial quarter in the prior year and partially as a result of the focus on integration as opposed to pipeline development. Additionally, the increase in research and development expenses for the quarter includes the $10 million upfront license fee related to the expanded license agreement for CERC-002 entered into and expensed in March 2021. While the IPR&D charge in 2020 largely offset the increased research and development expenses in 2021, the net loss increased as compared to the prior year due to a $7.1 million increase in the fair value of an investment of the Company in the prior year that did not repeat in the current quarter. Loss per share was largely consistent with the prior year with an increase in shares, due to financings, offsetting the larger net loss.

Condensed Consolidated Balance Sheets

(In thousands, except share and per share data)

	March 31, 2021 (unaudited) (a)	December 31, 2020 (a)
Assets		
Current assets:		
Cash and cash equivalents	$ 38,292	$ 18,919
Accounts receivable, net	3,130	2,177
Other receivables	2,056	2,208
Inventory, net	—	3
Prepaid expenses and other current assets	2,465	2,660
Restricted cash, current portion	153	38
Total current assets	46,096	26,005
Property and equipment, net	1,530	1,607
Intangible assets, net	1,161	1,585
Goodwill	14,409	14,409
Restricted cash, net of current portion	149	149
Total assets	$ 63,345	$ 43,755
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 11,913	$ 2,574
Accrued expenses and other current liabilities	14,238	11,310
Current liabilities of discontinued operations	209	1,341
Total current liabilities	26,360	15,225
Royalty obligation	2,000	2,000
Deferred tax liability, net	111	90
Other long-term liabilities	1,719	1,878
Total liabilities	30,190	19,193
Stockholders' equity:		
Common stock—$0.001 par value; 200,000,000 shares authorized at March 31, 2021 and December 31, 2020; 89,104,816 and 75,004,127 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	89	75
Preferred stock—$0.001 par value; 5,000,000 shares authorized at March 31, 2021 and December 31, 2020; 1,257,143 shares issued and outstanding at March 31, 2021 and December 31, 2020	1	1
Additional paid-in capital	241,535	202,276
Accumulated deficit	(208,470)	(177,790)
Total stockholders' equity	33,155	24,562
Total liabilities and stockholders' equity	$ 63,345	$ 43,755

(a) The condensed consolidated balance sheets as of March 31, 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 March 31,	
	2021 (a)	2020 (a)
Revenues:		
Product revenue, net	$ 473	$ 2,754
Total revenues, net	473	2,754
Operating expenses:		
Cost of product sales	77	66
Research and development	25,206	4,768
Acquired in-process research and development	—	25,549
General and administrative	4,911	2,676
Sales and marketing	435	677
Amortization expense	424	431
Total operating expenses	31,053	34,167
	(30,580)	(31,413)
Other income:		
Change in fair value of Investment in Aytu	—	7,080
Other income	—	11
Interest income	17	10
Total other income, net from continuing operations	17	7,101
Loss from continuing operations before taxes	(30,563)	(24,312)
Income tax expense (benefit)	11	(2,157)
Loss from continuing operations	$ (30,574)	$ (22,155)
(Loss) income from discontinued operations, net of tax	(106)	1,038
Net loss	$ (30,680)	$ (21,117)
Net (loss) income per share of common stock, basic and diluted:		
Continuing operations	$ (0.32)	$ (0.36)
Discontinued operations	(0.00)	0.02
Net loss per share of common stock, basic and diluted	$ (0.32)	$ (0.34)
Net (loss) income per share of preferred stock, basic and diluted:		
Continuing operations	$ (1.61)	$ (1.78)
Discontinued operations	(0.01)	0.08
Net loss per share of preferred stock, basic and diluted	$ (1.62)	$ (1.70)

(a) The unaudited condensed consolidated statements of operations for the three months ended March 31, 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 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 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

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