
**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) August 8, 2019**

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 August 8, 2019, Cerecor Inc. issued a press release announcing its financial results for the quarter ended June 30, 2019. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press release dated August 8, 2019.</u>

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: August 8, 2019

/s/ Joseph M. Miller

Joseph M. Miller

Chief Financial Officer



Cerecor Reports Second Quarter 2019 Results

- Positive Final Results with CERC-301 in nOH
- First Patient Enrolled in CDG FIRST Trial
- FDA Acceptance of IND Application of CERC-802

Rockville, MD, August 08, 2019 — Cerecor Inc. (NASDAQ: CERC), a biopharmaceutical company focused on becoming a leader in development and commercialization of treatments for rare and orphan diseases in pediatrics and neurology, announced today its financial results for the second quarter ended June 30, 2019 and provided additional corporate highlights.

“We are pleased with the ongoing success from our Research and Development efforts. We continued to meet our milestones across our Rare Orphan Disease pipeline with the CERC-800 series as well as our CNS pipeline with CERC-301. The first patient enrolled in CDG FIRST marks a significant milestone for all three assets in the CERC-800s clinical development program. Additionally, we received a Study May Proceed Letter from the FDA, confirming the FDA’s acceptance of the CERC-802 IND. Lastly, the positive final Phase I results for CERC-301 in nOH was consistent with the interim analysis and demonstrated both a rapid and sustained increase in blood pressure.” said Dr. Simon Pedder, Executive Chairman of the Board.

Corporate Update and Second Quarter 2019 Financial Result Highlights

- Announced positive final results from the Phase I study of CERC-301 in the treatment of Neurogenic Orthostatic Hypotension (“nOH”)
- Enrolled first patient in the Congenital Disorders of Glycosylation (“CDG”) FIRST Trial for the CERC-800 programs (a patient retrospective study with objective of collecting treatment related data and natural history of patients diagnosed and treated for MPI-CDG, PGM1-CDG and CDG-IIc)
- FDA accepted Investigational New Drug (“IND”) application for CERC-802 for the treatment of Mannose Phosphate Isomerase Deficiency (“MPI-CDG”)
- Added to the Russell 3000® Index
- Entered into settlement with Lachlan, which settled all future and historic minimum purchase and royalty obligations for Ulesfia and eliminated possible contingent milestone payments

Research and Development Update

The Company achieved several clinical and regulatory milestones in and following the second quarter in neurology, with CERC-301 completing its Phase I trial in nOH. The rapid, robust and sustained results were remarkable, demonstrating a maximum improvement of 29.1 mmHg in the 20mg dose group (the highest dose tested) throughout the study over baseline and placebo. Additionally, there was strong dose-related consistency of plasma concentrations across all doses studied. We believe this data may support a single daily dose and may allow for this compound to be used in a broader Orthostatic Hypotension (“OH”) patient population.

In the pediatric ultra-rare orphan diseases franchise, the CERC-800s series (CERC-801, CERC-802 and CERC-803), the CDG FIRST trial enrolled its first patient. The purpose of the trial is to investigate the natural course of disease and current treatment approaches for CDGs. The data acquired through the CDG FIRST study is expected to be used to support regulatory filings and may help to expedite the first approved treatment(s) for CDGs. Lastly, the U.S. Food and

Drug Administration (“FDA”) communicated that the Company may proceed with the IND acceptance for CERC-802 in MPI-CDG. The CERC-800 series have all received Orphan Drug Designation and CERC-801 has obtained fast-track designation from the FDA. By utilizing the 505(b)(2) pathway, published literature, as well as data from the CDG FIRST retrospective trial, these data will be used as part of the anticipated new drug application (NDA) filings for all three of the CERC-800s compounds. The NDA filings are targeted for late 2020 and into 2021, with possible approvals in 2021 and 2022.

Second Quarter 2019 Financial Results

Net product revenue decreased \$0.3 million to \$4.4 million for the three months ended June 30, 2019 as compared to the same period in 2018. The decrease was due to a less favorable product mix and lower sales volume during the current period.

Total operating expenses were \$10.4 million for the three months ended June 30, 2019, compared to operating expenses of \$10.5 million for the three months ended June 30, 2018.

Research and development expenses increased \$2.6 million to \$3.7 million for the three months ended June 30, 2019 as compared to the same period in 2018. The increase was due to increased spending on research and development and regulatory activities as the Company continues to advance its pipeline, specifically the CERC-800 programs in CDGs and CERC-301 in nOH. Additionally, sales and marketing expenses increased \$0.9 million over the same period as a result of the Company’s sales force expansion.

Operating expense increases were offset by a \$2.9 million gain recognized in cost of product sales and change in fair value of contingent consideration related to the successful settlement of the Lachlan litigation during the second quarter. The settlement fully released the Company of all future and historic minimum purchase and royalty obligations and eliminated possible contingent consideration milestone payments to Lachlan.

Net loss for the second quarter of 2019 was \$6.2 million as compared to the prior year quarter net loss of \$6.0 million.

The quarter-end cash balance was \$9.4 million, compared to a cash balance of \$10.6 million as of December 31, 2018.

Unaudited Condensed Consolidated Statements of Operations

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2019 (a)	2018 (a)	2019 (a)	2018 (a)
	(in thousands)		(in thousands)	
Revenues				
Product revenue, net	\$ 4,449	\$ 4,711	\$ 9,861	\$ 8,971
Sales force revenue	—	74	—	297
Total revenues, net	4,449	4,785	9,861	9,268
Operating expenses:				
Cost of product sales	(142)	1,423	1,806	2,287
Research and development	3,712	1,083	7,114	2,733
General and administrative	2,382	3,042	5,099	5,949
Sales and marketing	2,937	2,042	6,046	3,578
Amortization expense	1,079	1,233	2,158	2,250
Impairment of intangible assets	1,449	1,702	1,449	1,702
Change in fair value of contingent consideration	(992)	13	(812)	276
Total operating expenses	10,425	10,538	22,860	18,775
Loss from operations	(5,976)	(5,753)	(12,999)	(9,507)
Other (expense) income:				
Change in fair value of warrant liability and unit purchase option liability	19	4	(28)	(20)
Other (expense) income, net	—	—	(9)	19
Interest expense, net	(200)	(242)	(408)	(343)
Total other expense, net	(181)	(238)	(445)	(344)
Net loss before taxes	(6,157)	(5,991)	(13,444)	(9,851)
Income tax expense	66	16	233	40
Net loss	\$ (6,223)	\$ (6,007)	\$ (13,677)	\$ (9,891)
Net loss per share of common stock, basic and diluted	\$ (0.11)	\$ (0.19)	\$ (0.24)	\$ (0.31)
Net loss per share of preferred stock, basic and diluted	\$ (0.55)	\$ —	\$ (1.21)	\$ —

(a) The condensed consolidated statements of operations for the three and six months ended June 30, 2019 and 2018 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.

Condensed Consolidated Balance Sheets

	June 30, 2019 (a)	December 31, 2018 (a)
	(unaudited)	
(in thousands)		
Assets		
Current assets:		
Cash and cash equivalents	\$ 9,387	\$ 10,646
Accounts receivable, net	2,860	3,158
Other receivables	143	5,469
Inventory, net	618	1,111
Prepaid expenses and other current assets	865	1,529
Restricted cash, current portion	26	19
Total current assets	13,899	21,932
Property and equipment, net	1,526	587
Intangible assets, net	27,633	31,239
Goodwill	16,411	16,411
Restricted cash, net of current portion	152	82
Total assets	\$ 59,621	\$ 70,251
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,445	\$ 1,446
Accrued expenses and other current liabilities	13,348	19,731
Income taxes payable	1,393	2,032
Long-term debt, current portion	1,050	1,050
Contingent consideration, current portion	1,529	1,957
Total current liabilities	18,765	26,216
Long-term debt, net of current portion	14,279	14,328
Contingent consideration, net of current portion	6,330	7,094
Deferred tax liability, net	88	69
License obligations	1,250	1,250
Other long-term liabilities	1,212	386
Total liabilities	41,924	49,343
Stockholders' equity:		
Common stock—\$0.001 par value; 200,000,000 shares authorized at June 30, 2019 and December 31, 2018; 42,898,251 and 40,804,189 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	43	41
Preferred stock—\$0.001 par value; 5,000,000 shares authorized at June 30, 2019 and December 31, 2018; 2,857,143 shares issued and outstanding at June 30, 2019 and December 31, 2018	3	3
Additional paid-in capital	129,546	119,082
Accumulated deficit	(111,895)	(98,218)
Total stockholders' equity	17,697	20,908
Total liabilities and stockholders' equity	\$ 59,621	\$ 70,251

(a) The condensed consolidated balance sheets as of June 30, 2019 and December 31, 2018 have been derived from the reviewed and audited 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.

Outlook

The Company maintains its full-year 2019 net revenue guidance in a range of \$20 to \$22 million. These estimates are forward-looking statements that reflect management's current expectations for Cerecor's 2019 performance. Actual results may 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 fully integrated biopharmaceutical company with commercial operations and research and development capabilities. The Company is building a robust pipeline of innovative therapies in orphan diseases, neurology and pediatric healthcare. The Company's pediatric orphan 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. The FDA granted Rare Pediatric Disease Designation and Orphan Drug Designation ("ODD") to all three CERC-800 compounds, thus qualifying the Company to receive a Priority Review Voucher ("PRV") upon approval of a new drug application ("NDA"). The PRV may be sold or transferred an unlimited number of times. The Company plans to leverage the 505(b)(2) NDA pathway for all three compounds to accelerate development and approval. The Company is also in the process of developing one other preclinical pediatric orphan rare disease compound, CERC-913, for the treatment of mitochondrial DNA Depletion Syndrome. The Company's neurology pipeline is led by CERC-301, a Glutamate NR2B selective, NMDA Receptor antagonist, which Cerecor is currently exploring as a novel treatment for orthostatic hypotension. The Company is also developing CERC-406, a CNS-targeted COMT inhibitor for Parkinson's Disease. The Company also has a diverse portfolio of marketed products, led by our prescribed dietary supplements Poly-Vi-Flor® and Tri-Vi-Flor™, which are prescription vitamin and fluoride supplements used in infants and children to treat or prevent deficiency of essential vitamins and fluoride. The Company also markets a number of prescription drugs that treat a range of pediatric diseases, disorders and conditions. Cerecor's prescription drugs include Millipred®, Karbinal™ ER, AcipHex® Sprinkle™, and Cefaclor for Oral Suspension.

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," "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; the expansion of Cerecor's drug portfolio; 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; regulatory risks; reliance on and the need to attract, integrate and retain key personnel; Cerecor's cash position and the potential need for it to raise additional capital; risks associated with acquisitions, including the need to quickly and successfully integrate acquired assets and personnel; 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

James Harrell,
EVP Corporate Communications & Investor Relations
Cerecor Inc.
jharrell@cerecor.com
623.439.2220 *office*