
**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) November 14, 2019

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

Delaware

(State or other jurisdiction of incorporation)

001-37590
(Commission File Number)

45-0705648
(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 November 14, 2019, Cerecor Inc. issued a press release announcing its financial results for the quarter ended September 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 November 14, 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: November 14, 2019

/s/ Joseph M. Miller

Joseph M. Miller

Chief Financial Officer



Cerecor Reports Third Quarter 2019 Results

- Sale of Pediatric Portfolio in a Deal Valued in Excess of \$43 Million
- First Patient Enrolled in Diabetic OH Trial with CERC-301
- Completed Phase 1 Healthy Volunteer Study with CERC-802
- CERC-802 IND Accepted by FDA and Received Fast Track Designation

Rockville, MD, November 14, 2019 — Cerecor Inc. (NASDAQ: CERC), a biopharmaceutical company focused on becoming a leader in development and commercialization of treatments for orphan diseases and neurology, announced today its financial results for the third quarter ended September 30, 2019 and provided additional corporate highlights.

“It’s been a transformational start to the back-half of the year for Cerecor. We continue to execute on our plan to increase shareholder value by advancing our clinical pipeline and executing transformative business development deals. CERC-802 achieved several regulatory milestones and had encouraging results from its Phase I Safety Study in Healthy Volunteers. CERC-301 final results were reported from its neurogenic Orthostatic Hypotension (nOH) trial in patients with Parkinson’s disease and is preparing to advance into a proof-of-concept trial investigating its use in Orthostatic Hypotension (OH) associated with Diabetes. Diabetic OH is a significantly larger patient population (15-fold greater than nOH with ~3 million U.S. patients) ; and there are no approved therapies. Additionally, the sale of the Pediatric Portfolio strengthens our balance sheet by providing non-dilutive capital for R&D helping us to advance CERC-801 towards NDA approval, allowing us to obtain a PRV for potential monetization.,” said Dr. Simon Pedder, Executive Chairman of the Board.

Corporate Update

- On October 10, 2019, the Company entered into, and subsequently closed on, an asset purchase agreement with Aytu BioScience, Inc. (Aytu) to sell its Pediatric Portfolio with the overall deal valued in excess of \$43 million
 - The Pediatric Portfolio includes the following five product lines: Aciphex® Sprinkle™, Cefaclor for Oral Suspension, Karbinal® ER, Flexichamber™, Poly-Vi-Flor® and Tri-Vi-Flor™
 - Composite of \$17 million in cash and preferred stock (\$4.5 in cash & 12.5 million of Aytu stock)
 - Assumption of Cerecor’s outstanding payment obligations payable to Deerfield CSF, LLC (“Deerfield Note”) and other liabilities in excess of \$15 million
 - Elimination of existing royalty obligations & various commercial accruals of \$11 million
 - Estimated annual expense reduction of \$7 to \$9 million associated with Commercial Sales organization transfer to Aytu
 - The Company retained all rights to Millipred®, which is the Company’s most profitable product. Millipred® profits will assist the Company in funding its pipeline assets and may provide future optionality towards monetization and further pipeline funding
- James Harrell, EVP of Marketing and Investor Relations, was promoted to Chief Commercial Officer
- Private Placement of ~\$3.7 million from Armistice Capital in September 2019

Research and Development Update

Orphan Pipeline

- The CDG FIRST trial enrolled its first patient in July 2019. The purpose of the trial is to investigate the natural course of disease and current treatment approaches for Congenital Disorders of Glycosylation (CDGs). The data acquired through the CDG FIRST study is expected to be used to support regulatory filings for the CERC-800s series (CERC-801, CERC-802 and CERC-803), and may help to expedite the first approved treatment(s) for CDGs
- The U.S. Food and Drug Administration (“FDA”) communicated that the Company may proceed under the IND for CERC-802 in MPI-CDG (Mannose-Phosphate Isomerase)
- CERC-802 obtained fast-track designation (FTD) from the FDA. Both CERC-801 and CERC-802 now have fast-track designation from the FDA
- CERC-802 completed its Phase I Safety Study in healthy volunteers. The single-center, US-based safety, tolerability and pharmacokinetic study was an open-label, randomized, single-dose, 4-way crossover study in 16 healthy adult volunteers. Pharmacokinetic (PK) data is expected in early 2020

Neurological Pipeline

- CERC-301 completed and reported its final results from its Phase I trial in nOH
 - The 20mg dose group (the highest dose tested) demonstrated rapid, robust and sustained increases in blood pressure over baseline and placebo with a maximum improvement of 29.1 mmHg throughout the study
 - 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 has the potential to be used in a broader Orthostatic Hypotension patient population
- Initiated a Phase I Proof-of-Concept trial in diabetic orthostatic hypotension (DOH)
 - The purpose of this study is to assess the single dose effects of CERC-301 in patients with symptomatic DOH
 - This study is a randomized, double-blind, placebo-controlled, two-way cross-over trial over two 24-hour in-clinic visits. At each visit, subjects will receive a single 20 mg dose of CERC-301 or placebo then undergo a series of orthostatic challenge tests over the 24 hour in-clinic period
 - Patients will also complete an OH symptomatic assessment following each orthostatic challenge. Safety, tolerability, PK data will also be collected. As part of the routine laboratory tests, particular interest will be paid to the patient’s plasma glucose levels over the course of the study

Third Quarter 2019 Financial Results

Net product revenue increased \$1.4 million to \$5.5 million for the three months ended September 30, 2019 as compared to the same period in 2018. The increase was due to improved product mix and higher sales volume during the current period.

Total operating expenses were \$9.3 million for the three months ended September 30, 2019, compared to operating expenses of \$28.4 million for the three months ended September 30, 2018. The significant decrease was due to \$18.7 million of in-process research and development costs as a result of the Ichorion acquisition in 2018.

Net loss for the three months ended September 30, 2019 was \$4.0 million compared to net loss of \$24.6 million for the three months ended September 30, 2018. The significant decrease was largely a result of the 2018 in-process research and development costs highlighted above.

The cash balance was \$5.3 million for the quarter ended September 30, 2019. The company received \$4.5 million in cash from Aytu from the sale of the pediatric portfolio in the fourth quarter of 2019.

Unaudited Condensed Consolidated Statements of Operations

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2019 (a), (b)	2018 (a)	2019 (a), (b)	2018 (a)
	(in thousands, except per share data)		(in thousands, except per share data)	
Revenues:				
Product revenue, net	\$ 5,513	\$ 4,075	\$ 15,374	\$ 13,046
License and other revenue	100	—	100	—
Sales force revenue	—	—	—	297
Total revenues, net	5,613	4,075	15,474	13,343
Operating expenses:				
Cost of product sales	1,435	3,111	3,241	5,398
Research and development	1,743	1,048	8,857	3,780
Acquired in-process research and development	—	18,724	—	18,724
General and administrative	2,679	1,884	7,779	7,834
Sales and marketing	2,631	2,311	8,676	5,889
Amortization expense	1,037	1,065	3,195	3,316
Impairment of intangible assets	—	160	1,449	1,861
Change in fair value of contingent consideration	(197)	85	(1,009)	361
Total operating expenses	9,328	28,388	32,188	47,163
Loss from operations	(3,715)	(24,313)	(16,714)	(33,820)
Other (expense) income:				
Change in fair value of warrant liability and unit purchase option liability	35	(3)	7	(23)
Other (expense) income, net	(15)	—	(24)	19
Interest expense, net	(206)	(235)	(614)	(578)
Total other expense, net	(186)	(238)	(631)	(582)
Net loss before taxes	(3,901)	(24,551)	(17,345)	(34,402)
Income tax expense	115	52	349	92
Net loss	\$ (4,016)	\$ (24,603)	\$ (17,694)	\$ (34,494)
Net loss per share of common stock, basic and diluted	\$ (0.07)	\$ (0.71)	\$ (0.31)	\$ (1.05)
Net loss per share of preferred stock, basic and diluted	\$ (0.35)	\$ —	\$ (1.56)	\$ —

(a) The unaudited condensed consolidated statements of operations for the three and nine months ended September 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.

(b) The unaudited condensed consolidated statements of operations for the three and nine months ended September 30, 2019 do not include the impact of the Aytu transaction because the transaction was entered into and subsequently closed in the fourth quarter of 2019.

Condensed Consolidated Balance Sheets

	September 30, 2019 (a), (b)	December 31, 2018 (a)
	(unaudited)	
Assets	(in thousands)	
Current assets:		
Cash and cash equivalents	\$ 5,251	\$ 10,646
Accounts receivable, net	4,956	3,158
Other receivables	208	5,469
Inventory, net	402	1,111
Prepaid expenses and other current assets	1,670	1,529
Restricted cash, current portion	102	19
Total current assets	12,589	21,932
Property and equipment, net	1,497	587
Intangible assets, net	26,595	31,239
Goodwill	16,411	16,411
Restricted cash, net of current portion	102	82
Total assets	\$ 57,194	\$ 70,251
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 826	\$ 1,446
Accrued expenses and other current liabilities	13,134	19,731
Income taxes payable	1,015	2,032
Long-term debt, current portion	1,050	1,050
Contingent consideration, current portion	1,237	1,957
Total current liabilities	17,262	26,216
Long-term debt, net of current portion	14,255	14,328
Contingent consideration, net of current portion	6,236	7,094
Deferred tax liability, net	98	69
License obligations	—	1,250
Other long-term liabilities	1,122	386
Total liabilities	38,973	49,343
Stockholders' equity:		
Common stock—\$0.001 par value; 200,000,000 shares authorized at September 30, 2019 and December 31, 2018; 44,106,794 and 40,804,189 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	44	41
Preferred stock—\$0.001 par value; 5,000,000 shares authorized at September 30, 2019 and December 31, 2018; 2,857,143 shares issued and outstanding at September 30, 2019 and December 31, 2018	3	3
Additional paid-in capital	134,086	119,082
Accumulated deficit	(115,912)	(98,218)
Total stockholders' equity	18,221	20,908
Total liabilities and stockholders' equity	\$ 57,194	\$ 70,251

(a) The condensed consolidated balance sheets as of September 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.

(b) The condensed consolidated balance sheet as of September 30, 2019 do not include the impact of the Aytu transaction because the transaction was entered into and subsequently closed in the fourth quarter of 2019.

Outlook

Cerecor was on track to achieve its 2019 revenue guidance in a range of \$20 to \$22 million. However, as a result of the sale of the pediatric portfolio to Aytu, Cerecor will no longer be providing revenue guidance.

About Cerecor

Cerecor is a biopharmaceutical company focused on becoming a leader in development and commercialization of treatments for orphan diseases and neurological conditions. The Company is building a robust pipeline of innovative therapies in orphan diseases and neurology. 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. 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 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 one marketed product, Millipred®, an oral prednisolone indicated across a wide variety of inflammatory conditions and indications. 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, 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 potential need for it to raise additional capital; 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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