Cerecor To Sell Pediatric Portfolio to AYTU BioScience

-Deal Valued in Excess of $32 Million
-Eliminates Debt Associated with Avadel / Deerfield Agreement
-Provides Non-Dilutive Cash Generation to Fund R&D
-Extends Runway Towards NDA Submission of CERC-801

ROCKVILLE, Md., Oct. 14, 2019 (GLOBE NEWSWIRE) -- Cerecor Inc. (NASDAQ: CERC), a biopharmaceutical company focused on becoming a leader in development and commercialization of treatments for pediatric rare diseases and neurology, announced today that it has entered into an asset purchase agreement with AYTU BioScience, Inc. (“AYTU”) to sell Cerecor’s Pediatric Portfolio in a deal valued in excess of $32 million. The consideration includes a combination of cash and Aytu preferred stock totaling $17 million and the assumption of Cerecor’s outstanding payment obligations payable to Deerfield CSF, LLC (“Deerfield Note”) and certain other liabilities in excess of $15 million, providing non-dilutive cash generation for the Cerecor. The funds from the transaction extend the runway towards NDA submission of CERC-801 and its associated Priority Review Voucher (PRV).

Dr. Simon Pedder, Executive Chairman of the Board, commented, “We believe this a positive deal for both the business and our shareholders. In totality, it improves our cash position, and removes our debt obligations. It allows the organization to focus on, and invest in, our fast-to-market pipeline in rare orphan diseases with the CERC-800s series. It also accelerates our build toward the launch of CERC-801 which will deliver the first approved product for Congenital Disorders of Glycosylation. Currently there are no FDA approved treatments for this underserved patient population. Lastly, it enables us to further CERC-301 into the clinic in both Diabetic Orthostatic Hypotension and Intradialytic Hypotension, two therapeutic areas with significant market size and unmet medical need.”

Deal Components

- Overall deal valued in excess of $43 million as a composite of $17 million in cash and preferred stock ($4.5 million in cash and 12.5 million in shares of Aytu convertible preferred stock), the assumption of the Deerfield note of $15M, the elimination of the existing royalty obligations coupled with various commercial accruals of $11 million

- Cash will be paid, and the Shares will be issued upon closing; the Shares will convert to shares of Aytu common stock following Aytu shareholder approval

- 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™
• Aytu will retain Cerecor’s Pediatric commercial infrastructure and sales force, inclusive of hiring Matt Phillips, Cerecor’s Chief Commercial Officer, as Aytu’s Executive Vice President of Commercial Operations

• Aytu will assume all obligations under the Deerfield Note, associated with the Pediatric Portfolio of products acquired from Avadel in 2018

• Aytu will assume all contractual obligations under the existing license agreements and the assumption of certain liabilities associated with the Pediatric Portfolio

Benefits of the Transaction

• **Aligns with Cerecor’s Pipeline Innovation Strategy:** Cerecor’s strategy is focused on advancing its clinical pipeline and compounds through development and to regulatory approval. We believe the $17 million in near-term value received as part of the transaction will allow the Company to fund its portfolio of development assets focusing on long term value drivers, which includes the near-term development of our CERC-800 series of assets and the advancement and expansion of the CERC-301 program.

• **Enables a Debt-Free Company:** The transaction extinguishes the $15 million debt obligation with Deerfield CSF, LLC, which was due in January of 2021. Further, it extinguishes future financial obligations under the Company’s license agreements associated with the Pediatric Portfolio, currently valued at approximately $9.6 million. We believe the extinguishment of these obligations allows the Company to continue to develop its pipeline assets.

• **Cost Savings from Reduction in Commercial Sales Organization:** We estimate an approximate annual expense reduction of $7 to $9 million associated with the Pediatric commercial sales force and sales management transfer to Aytu. The retention of the customer-facing sales organization by Aytu should help to maintain consistency in the market and minimize customer and product disruption.

• **Optionality to Continue to Grow Sales of Most Profitable Product:** The Company will retain all rights to Millipred®, which is the Company’s most profitable product. The cash inflows from Millipred® will assist the Company in funding its portfolio of pipeline assets and may provide future optionality towards monetization and further pipeline funding.

“This deal, coupled with the income generation from Millipred®, significantly extends our financial runway. The combination allows us to aggressively develop our rare disease pipeline over the next 18 months, when we expect our first FDA approval. The CERC-800’s are three late-stage assets targeted to launch in 2021 and 2022 for the treatment of the orphan rare disease referred to as Congenital Disorders of Glycosylation. We believe the approvals will allow the Company to launch its highly profitable rare disease products, while maintaining optionality around the granted Priority Review Vouchers (“PRV”) that accompany each of the three rare disease assets currently under development. Each PRV may be sold or transferred an unlimited number of times and have recently been monetized
for values between $85 and $110 million,” stated Joseph Miller, Cerecor's Chief Financial Officer.

At the close of the transaction Cerecor was on track to achieve its 2019 revenue guidance. However, as a result of the transaction, Cerecor will no longer be providing revenue guidance.

Concurrent with the transaction Matt Phillips, Chief Commercial Officer, and Patrick Crutcher, Chief Strategy Officer, will transition out of the organization, with Mr. Phillips joining Aytu as the Executive Vice President of Commercial Operations. James Harrell will assume their roles and responsibilities in his new position as Chief Commercial Officer.

“We would like to thank Matt and Patrick for their leadership and contribution to Cerecor over the past years and wish them the best in their new endeavors,” stated Dr. Simon Pedder, Executive Chairman of the Board, Cerecor.

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 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 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. Giving effect to the Aytu asset sale, the Company will also have 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: risks that the transaction does not close or that Aytu stockholder approval for conversion of the preferred stock is delayed or not received; risks of owning a large amount of relatively illiquid Aytu stock even once converted to common; 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,
Chief Commercial Officer
Cerecor Inc.
jharrell@cerecor.com
623.439.2220 office

Source: Cerecor Inc.