May 9, 2017

Ocera Therapeutics Reports First Quarter 2017 Financial Results and Provides Clinical Update

Post-hoc per protocol analysis demonstrates OCR-002 achieved primary endpoint with statistical significance, p=0.034

Company to host conference call and webcast today at 4:30 p.m. ET

REDWOOD CITY, Calif. and RESEARCH TRIANGLE PARK, N.C., May 09, 2017 (GLOBE NEWSWIRE) -- Ocera Therapeutics, Inc. (NASDAQ:OCRX), a clinical stage biopharmaceutical company focused on acute and chronic orphan liver diseases, today reported financial results for the quarter ended March 31, 2017 and provided updates on its clinical development programs of OCR-002 for the treatment of hepatic encephalopathy (HE), a debilitating liver disorder and significant burden on the healthcare system.

"To date, 2017 has been very eventful for Ocera with a successful Phase 1 study of oral OCR-002 in cirrhotic patients in January followed by the completion of our STOP-HE Phase 2b clinical trial of IV OCR-002 and subsequent data read out," said Linda Grais, M.D., Chief Executive Officer of Ocera. "The data from STOP-HE confirmed that hyperammonemia is correlated with the severity of HE symptoms and that OCR-002 correlates with faster reduction of ammonia, and with clinical improvement."

Previously, the company reported top-line data from STOP-HE based on an intent to treat (ITT) population of patients with elevated plasma ammonia levels at screening. Patients receiving OCR-002 demonstrated a 17-hour reduction in time to improvement in HE symptoms over placebo (47 *versus* 64 hours, respectively) for the primary endpoint, p=0.129.

Today, the company reported new data from STOP-HE. A post-hoc analysis of the same primary endpoint revealed patients with confirmed hyperammonemia at randomization (baseline) improved faster on OCR-002 than placebo (42 *versus* 63 hours, respectively), with statistical significance, p=0.034.

The findings are based on a retrospective analysis of baseline ammonia levels drawn at time of randomization and determined by a central laboratory. Of the 231 patients in the ITT analysis, 201 were confirmed as hyperammonemic at time of randomization; some patients' ammonia levels had normalized between screening and randomization under standard of care. This post-hoc per protocol population represents the study's target population given the ammonia-scavenging mechanism of action of OCR-002.

"We are very encouraged by this additional analysis of the data which reaffirms the clinical benefits attributable to the mechanism of action of OCR-002," said Stan Bukofzer, M.D., Chief Medical Officer. "STOP-HE demonstrated that rapid reduction of ammonia in hyperammonemic patients leads to faster clinical improvement, which we believe will translate to better outcomes for these patients. We look forward to continuing to develop OCR-002 with the hope of bringing these benefits to patients, their families, and to the healthcare system."

Select First Quarter Financial Results

- As of March 31, 2017, Ocera had cash, cash equivalents and marketable securities of $25.2 million.
- Net loss for the quarter was $6.7 million compared to a net loss of $7.5 million for the same period in 2016. Basic and diluted net loss per share were $0.28 for the quarter compared to basic and diluted net loss per share of $0.36 for the same period in 2016.
- Research and development (R&D) expense for the quarter decreased to $3.9 million, from $4.7 million for the same period in 2016 due primarily to a decrease in clinical development costs.
- General and administrative (G&A) expense for the quarter is $2.5 million, essentially flat compared with $2.6 million for the same period in 2016.
- Net interest expense of $0.3 million for the quarter was primarily attributable to interest and amortization associated with the debt facility which closed in July 2015.

- Net cash proceeds generated from the Company's "at the market" equity facility totaled approximately $3.5 million for the quarter.

Financial Guidance

Ocera expects net use of cash for 2017 to be in the range of $24.0 million to $27.0 million, including $3.1 million in scheduled principal repayments on notes payable, and reiterates its previous guidance that it will have sufficient cash to fund operations into the second quarter of 2018 based on its current operating plan.

Conference Call and Webcast

Ocera's financial results conference call and webcast for the quarter ended March 31, 2017 will take place at 4:30 p.m. Eastern Time today, May 9, 2017. The audio webcast can be accessed under "Presentations & Events" in the Investor Relations section of the Company's website at www.oceraine.com.

Domestic investors wishing to participate in the call should dial (844) 419-1758 and international investors should dial (209) 905-5955. The conference ID is 17133971. Investors can also access the call at http://edge.media-server.com/m/p/mkgis75d.

Replays of the call will be available on the company's website through June 9, 2017. Domestic investors can access the replay by dialing (844) 419-1758 and international investors can access the replay by dialing (209) 905-5955. The conference ID to access the reply is 17133971.

About Ocera

Ocera Therapeutics, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of OCR-002 (ornithine phenylacetate) in both intravenous and oral formulations. OCR-002 is an ammonia scavenger and has been granted orphan drug designation and Fast Track status by the U.S. Food and Drug Administration (FDA) for the treatment of hyperammonemia and resultant hepatic encephalopathy in patients with acute liver failure and acute-on-chronic liver disease. For additional information, please see www.oceraine.com.

Forward-Looking Statements

This press release contains "forward-looking" statements, including, without limitation, all statements related to the OCR-002 clinical development program, including but not limited to the potential benefits of OCR-002 to help patients with hepatic encephalopathy, our ability to identify a development path forward for OCR-002, whether any future studies of OCR-002 we may conduct will demonstrate similar results to our Phase 2b study, the timing and nature of our future clinical development plans, and the company's financial projections. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "believe," "expected," "hope," "plan," "potential," "will" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Ocera's current expectations. Forward-looking statements involve risks and uncertainties and Ocera's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, including the risk that we may need to conduct one or more additional studies in light of the fact our Phase 2b trial did not meet its clinical endpoints, including related cost and timing issues associated with future studies, if any, the risk that the FDA or other regulatory authorities may not attribute significance to the data from the post hoc analysis of our Phase 2b clinical trial, including the per protocol analysis relative to the data observed in the ITT population, when we discuss potential development pathways forward for OCR-002, our ability to raise sufficient capital or consummate other strategic transactions to enable the continued development of OCR-002, and those risks and uncertainties discussed under the heading "Risk Factors" in Ocera's Annual Report on Form 10-K for the year ended December 31, 2016 and subsequent filings with the SEC. All information in this press release is as of the date of the release, and Ocera undertakes no duty to update this information unless required by law.

Susan Sharpe
Ocera Therapeutics, Inc.
contact@oceraine.com
919-328-1109

Ocera Therapeutics, Inc.
Condensed Consolidated Statement of Operations
(Unaudited)

(In thousands, except per share data)

	Three Months Ended March 31,	
	2017	2016
Revenue:		
Royalty revenue	$ —	$ 33
Operating expenses:		
Research and development	3,904	4,747
General and administrative	2,524	2,554
Total operating expenses	6,428	7,301
Loss from operations	(6,428)	(7,268)
Net interest expense	(255)	(246)
Net loss	$ (6,683)	$ (7,514)
Net loss per share, basic and diluted	$ (0.28)	$ (0.36)
Shares used to compute net loss per share, basic and diluted	24,037,387	20,943,966

Ocera Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands)

	March 31, 2017	December 31, 2016
Cash, cash equivalents and marketable securities	$ 25,180	$ 28,360
Working capital	22,003	24,890
Total assets	26,594	29,639
Notes payable	9,148	9,703
Accumulated deficit	(165,011)	(158,328)
Total stockholders' equity	$ 13,524	$ 15,737