November 2, 2016

Ocera Therapeutics Reports Third Quarter 2016 Financial Results and Company Update

PALO ALTO, Calif. and RESEARCH TRIANGLE PARK, N.C., Nov. 02, 2016 (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 September 30, 2016, 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.

"We are pleased to report significant progress in our clinical programs. Enrollment in our STOP-HE Phase 2b study for acute hepatic encephalopathy has now surpassed 220 patients and, consistent with previous guidance, we expect to complete full enrollment of approximately 230 patients by year-end and publish top-line results of the study in the first quarter of 2017," said Linda Grais, M.D., Chief Executive Officer of Ocera. "In addition, dosing has commenced with our oral formulation of OCR-002 in a Phase 1 study in patients with cirrhosis as a chronic use option to maintain remission of HE. We remain on track to report results of part one of this study by year-end and initiate part two in the first half of 2017."

Select Third Quarter Financial Results

- As of September 30, 2016, Ocera had cash, cash equivalents and investments of $32.5 million.
- Net loss for the three and nine months ended September 30, 2016 was $7.1 million and $21.7 million, respectively. Net loss for the three and nine months ended September 30, 2015 was $6.6 million and $19.4 million, respectively. Basic and diluted net loss per share for the three and nine months ended September 30, 2016 was $0.32 and $1.01, respectively. Basic and diluted net loss per share for the three and nine months ended September 30, 2015 was $0.33 and $0.98, respectively.
- Research and development (R&D) expense for the three months ended September 30, 2016 was $4.3 million, compared to $4.2 million for the same period in 2015. R&D expense for the nine months ended September 30, 2016 was $12.9 million, compared to $12.0 million for the same period in 2015. The increase in R&D expense for both the three and nine month periods was due primarily to an increase in headcount and related costs.
- General and administrative (G&A) expense for the three months ended September 30, 2016 was $2.6 million, compared to $2.4 million for the same period in 2015. G&A expense for the nine months ended September 30, 2016 was $8.1 million, compared to $7.5 million for the same period in 2015. The increase in G&A expense for the three and nine month periods was due primarily to an increase in personnel-related costs, including stock-based compensation expense, as well as costs associated with professional service fees.
- Net interest expense of $262,000 and $758,000 for the three and nine months ended September 30, 2016, respectively, 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 $6.0 million for the nine month period ended September 30, 2016.

Financial Guidance

Ocera reiterates its previous guidance and expects net use of cash for 2016 to be in the range of $22 million to $26 million, and updates its expectation that it will have sufficient cash to fund operations into the first quarter of 2018 based on its current operating plan. The Company previously estimated its cash runway into the fourth quarter of 2017. This improvement in projected cash runway is due primarily to the deferral of certain external development costs for OCR-002, lower than expected internal operating expenses, and cash proceeds generated from the "at the market" equity facility.

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.ocerainc.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 and other indications, the timing of clinical and enrollment milestones, the timing and availability of study data, 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 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, 2015 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.

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Ocera Therapeutics, Inc.
Condensed Consolidated Statement of Operations
(Unaudited)
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	**2015**	**2016**	**2015**
Revenue:				
Royalty revenue	$ 38	$ 35	$ 97	$ 109
Total revenue	38	35	97	109
Operating expenses:				
Research and development	4,283	4,235	12,939	12,050
General and administrative	2,618	2,372	8,142	7,460
Amortization of intangibles	-	41	-	123
Total operating expenses	6,901	6,648	21,081	19,633
Loss from operations	(6,863)	(6,613)	(20,984)	(19,524)
Net interest expense	(262)	(180)	(758)	(142)
Net loss from continuing operations	(7,125)	(6,793)	(21,742)	(19,666)
Net income from discontinued operations	-	219	-	219
Net loss	$ (7,125)	$ (6,574)	$ (21,742)	$ (19,447)
Net loss per share from continuing operations-basic and diluted	$ (0.32)	$ (0.34)	$ (1.01)	$ (0.99)
Net income per share from discontinued operations-basic and diluted	-	0.01	-	0.01
Net loss per share-basic and diluted	$ (0.32)	$ (0.33)	$ (1.01)	$ (0.98)
Shares used to compute net loss per share-basic and diluted	22,096,610	20,183,939	21,532,953	19,902,815

Ocera Therapeutics, Inc.
Condensed Consolidated Balance Sheets

(Unaudited)
(In thousands)

	September 30, 2016	December 31, 2015
Cash, cash equivalents and investments	$ 32,464	$ 43,336
Working capital[(1)]	25,964	40,188
Total assets	33,931	44,737
Notes payable - long term	7,689	9,508
Accumulated deficit	(153,175)	(131,433)
Total stockholders' equity	$ 18,846	$ 31,394

[(1)] includes $1.96 million of short-term notes payable in the period ended September 30, 2016.