OCERA THERAPEUTICS, INC.

FORM 8-K
(Current report filing)

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Address	525 UNIVERSITY AVENUE SUITE 610 PALO ALTO, CA 94301
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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): **March 10, 2017**

OCERA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	**001-35119**	**63-1192270**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

525 University Avenue, Suite 610	
Palo Alto, CA	**94301**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code **(650) 475-0150**

Not applicable

(Former name or former address, if changed since last report)

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))

Item 2.02 Results of Operations and Financial Condition.

On March 10, 2017, Ocera Therapeutics, Inc. issued a press release announcing its financial results and other information for the quarter and year ended December 31, 2016. The full text of the press release and the related attachments are furnished as Exhibit 99.1 hereto and incorporated herein by reference.

The information under this Item 2.02, including Exhibit 99.1 attached hereto, is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (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, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Ocera Therapeutics, Inc. dated March 10, 2017, furnished hereto.

SIGNATURES

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.

March 10, 2017

Ocera Therapeutics, Inc.

By: /s/ Linda S. Grais, M.D.
Name: Linda S. Grais, M.D.
Title: President and Chief Executive Officer

Exhibit 99.1

PRESS RELEASE

Ocera Therapeutics Reports Fourth Quarter and Full Year 2016 Financial Results and Provides Corporate Update

PALO ALTO, Calif. and RESEARCH TRIANGLE PARK, N.C., March 10, 2017 - Ocera Therapeutics, Inc. (NASDAQ:OCRX), a clinical stage biopharmaceutical company focused on acute and chronic orphan liver diseases, today announced updates to its clinical development programs and reported financial results for the quarter and year ended December 31, 2016.

"2016 was a busy year for Ocera, culminating with the timely completion of enrollment in the fourth quarter of STOP-HE, a landmark study evaluating intravenous OCR-002 (ornithine phenylacetate) in patients hospitalized with acute hepatic encephalopathy (HE)," said Linda Grais, M.D., Chief Executive Officer of Ocera. "We also advanced our oral program testing orally-administered OCR-002 in patients with cirrhosis and developing a tablet formulation which is poised for clinical evaluation in 2017.

"In January 2017, we reported positive results from our Phase 1 study of orally-administered OCR-002 in patients with chronic liver cirrhosis. The study demonstrated robust bioavailability and promising pharmacokinetic and safety profiles in the intended use population. In addition, we recently announced the data from STOP-HE, including encouraging results demonstrating that OCR-002 is a potent ammonia scavenger, that the level of HE severity directly correlates with the level of ammonia, and that ammonia reduction correlates with clinical improvement in HE symptoms. Recent analyses support our belief that OCR-002 can become an important intervention in both the treatment and prevention of HE," added Dr. Grais.

Anticipated 2017 Activity

- Initiate Phase 2a multi-dose study of oral OCR-002 in cirrhotic patients in H1 2017
- Meet with the Food and Drug Administration in Q3 2017 regarding STOP-HE with goal of clarifying Phase 3 development plan

Fourth Quarter and Full Year 2016 Financial Results

- As of December 31, 2016, Ocera had cash, cash equivalents and investments of $28.4 million, compared with $43.3 million at December 31, 2015.

- Net use of cash for 2016 was $22.1 million, which was consistent with Ocera's most recent guidance of the low end of the range of $22.0 to $26.0 million. Net use of cash equals the difference of cash, cash equivalents and investments at December 31, 2016 and 2015, less cash provided by financing activities, consisting of net proceeds of $7.1 million generated by an "At-the-Market" equity program during 2016.

- Net loss for the three and twelve months ended December 31, 2016 was $5.2 million and $26.9 million, respectively. Net loss for the three and twelve months ended December 31, 2015 was $7.1 million and $26.5 million, respectively. Basic and diluted net loss per share for the three and twelve months ended December 31, 2016 was $0.22 and $1.22, respectively. Basic and diluted net

loss per share for the three and twelve months ended December 31, 2015 was $0.34 and $1.32, respectively.

- Revenue for the three and twelve months ended December 31, 2016 was $512,000 and $609,000, respectively. Revenue for the three and twelve months ended December 31, 2015 was $24,000 and $133,000, respectively. Revenue in all periods consisted of royalty and licensing revenue generated from certain clinical-stage assets acquired in connection with the 2013 reverse merger between Ocera and Tranzyme, Inc.

- Research and development (R&D) expense for the three and twelve months ended December 31, 2016 was $3.2 million and $16.1 million, respectively. R&D expense for the three and twelve months ended December 31, 2015 was $3.9 million and $16.0 million, respectively. The decrease in R&D expense for the three-month period was due primarily to a decrease in external development expenses, partially offset by personnel and related expenses.

- General and administrative (G&A) expense for the three and twelve months ended December 31, 2016 was $2.2 million and $10.4 million, respectively. G&A expense for the three and twelve months ended December 31, 2015 was $2.9 million and $10.3 million, respectively. The decrease in G&A expense for the three-month period was due primarily to lower personnel and related expenses.

Financial Guidance

Ocera anticipates it will have sufficient cash to fund operations into the second quarter of 2018 based on its current operating plan and re-prioritization of certain development activities.

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, the timing of our planned meeting with the FDA, 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 of our planned Phase 2a study of the oral formulation of OCR-002 in cirrhotic patients, 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, 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, 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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Susan Sharpe
Ocera Therapeutics, Inc.
contact@ocerainc.com
919-328-1109

Ocera Therapeutics, Inc.

Condensed Consolidated Statement of Operations

(Unaudited)

(In thousands, except per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2016	**2015**	**2016**	**2015**
Revenues:				
Royalty and licensing revenues	$ 512	$ 24	$ 609	$ 133
Operating expenses:				
Research and development	3,186	3,927	16,125	15,977
General and administrative	2,222	2,861	10,364	10,321
Amortization of intangibles	—	48	—	171
Total operating expenses	5,408	6,836	26,489	26,469
Loss from operations	(4,896)	(6,812)	(25,880)	(26,336)
Net interest income (expense)	(257)	(272)	(1,015)	(413)
Net loss from continuing operations	(5,153)	(7,084)	(26,895)	(26,749)
Net income from discontinued operations	—	8	—	227
Net loss	$ (5,153)	$ (7,076)	$ (26,895)	$ (26,522)
Net loss per share from continuing operations, basic and diluted	$ (0.22)	$ (0.34)	$ (1.22)	$ (1.33)
Net income per share from discontinued operations, basic and diluted	—	—	—	0.01
Net loss per share, basic and diluted	$ (0.22)	$ (0.34)	$ (1.22)	$ (1.32)
Shares used to compute net loss per share, basic and diluted	23,223,569	20,556,822	21,957,917	20,067,660

Ocera Therapeutics, Inc.

Condensed Consolidated Balance Sheets

(Unaudited)

(In thousands)

	December 31, 2016	December 31, 2015
Cash, cash equivalents and marketable securities	$ 28,360	$ 43,336
Working capital	24,890	40,188
Total assets	29,639	44,737
Notes payable	9,703	9,508
Accumulated deficit	(158,328)	(131,433)
Total stockholders' equity	$ 15,737	$ 31,394