OCERA THERAPEUTICS, INC.

FORM 8-K
(Current report filing)

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Address	555 TWIN DOLPHIN DRIVE SUITE 615 REDWOOD CITY, CA 94065
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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): **August 1, 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.)

555 Twin Dolphin Drive, Suite 615 **Redwood City, CA** (Address of principal executive offices)	**94065** (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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). 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 August 1, 2017, Ocera Therapeutics, Inc. issued a press release announcing its financial results and other information for the quarter ended June 30, 2017. 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 August 1, 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.

August 1, 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 Second Quarter 2017 Financial Results

REDWOOD CITY, Calif., and RESEARCH TRIANGLE PARK, N.C., August 1, 2017 – Ocera Therapeutics, Inc. (NASDAQ:OCRX), a clinical stage biopharmaceutical company focused on the development of OCR-002 for the treatment and prevention of hepatic encephalopathy (HE), a debilitating complication of liver disease and significant burden on the healthcare system, today reported financial results for the quarter ended June 30, 2017 .

“We’ve enjoyed a busy quarter preparing to meet with the U.S. Food and Drug Administration (FDA) later this year regarding the design of the next clinical study for our ammonia scavenger OCR-002,” said Linda Grais, M.D., Chief Executive Officer of Ocera. “The meeting with FDA will focus on the intravenous formulation of OCR-002 which we are developing to treat hospitalized patients with elevated ammonia and neurocognitive symptoms of HE. In addition, our Phase 2a study with oral OCR-002 in patients with cirrhosis is progressing well, and we remain on track to report top-line results by the end of the year.”

Select Second Quarter Financial Results

- As of June 30, 2017 , Ocera had cash, cash equivalents and marketable securities of $20.6 million .
- Net loss for the three and six months ended June 30, 2017 was $6.1 million and $12.8 million , respectively. Net loss for the three and six months ended June 30, 2016 was $7.1 million and $14.6 million , respectively. Basic and diluted net loss per share for the three and six months ended June 30, 2017 was $0.23 and $0.51 , respectively. Basic and diluted net loss for the three and six months ended June 30, 2016 was $0.33 and $0.69 , respectively.
- Research and development (R&D) expense for the three months ended June 30, 2017 was $3.4 million , compared to $3.9 million for the same period in 2016. R&D expense for the six months ended June 30, 2017 was $7.3 million , compared to $8.7 million for the same period in 2016. The decrease in R&D expense for both the three and six month periods was due primarily to a decrease in clinical development costs.
- General and administrative (G&A) expense for the three months ended June 30, 2017 was $2.5 million , compared to $3.0 million for the same period in 2016. G&A expense for the six months ended June 30, 2017 was $5.0 million , compared to $5.5 million for the same period in 2016. The decrease in G&A expense for both the three and six -month periods was due primarily to decreases in headcount and related expenses, and professional services fees partially offset by an increase in business development costs.
- Net interest expense of $0.2 million and $0.5 million for the three and six months ended June 30, 2017 , respectively, was primarily attributable to interest and amortization associated with the Company’s debt facility.

- Net cash proceeds generated from the Company's "at the market" equity facility totaled approximately $0.8 million for the three -month period ended June 30, 2017 .

Financial Guidance

Ocera reiterates its previous guidance and 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 expectation that it will have sufficient cash to fund operations into the second quarter of 2018 based on its current operating plan.

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, our expected timing for release of clinical data, 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 be unable 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.

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Susan Sharpe
Ocera Therapeutics, Inc.
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919-328-1109

Ocera Therapeutics, Inc.

Condensed Consolidated Statement of Operations

(Unaudited)

(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	**2016**	**2017**	**2016**
Revenue:				
Royalty revenue	$ —	$ 26	$ —	$ 59
Operating expenses:				
Research and development	3,409	3,909	7,313	8,656
General and administrative	2,500	2,970	5,024	5,524
Total operating expenses	5,909	6,879	12,337	14,180
Loss from operations	(5,909)	(6,853)	(12,337)	(14,121)
Interest expense, net	(224)	(250)	(479)	(496)
Net loss	$ (6,133)	$ (7,103)	$ (12,816)	$ (14,617)
Net loss per share, basic and diluted	$ (0.23)	$ (0.33)	$ (0.51)	$ (0.69)
Shares used to compute net loss per share, basic and diluted	26,413,839	21,552,089	25,232,178	21,248,027

Ocera Therapeutics, Inc.

Condensed Consolidated Balance Sheets

(Unaudited)

(In thousands)

	June 30, 2017	**December 31, 2016**
Cash, cash equivalents and marketable securities	$ 20,562	$ 28,360
Working capital, excluding notes payable	16,902	24,890
Total assets	21,684	29,639
Notes payable	8,273	9,703
Accumulated deficit	(171,144)	(158,328)
Total stockholders' equity	$ 9,268	$ 15,737