OCERA THERAPEUTICS, INC.

FORM 10-Q
(Quarterly Report)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2017

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number 001-35119

Ocera Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

DELAWARE	**63-1192270**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
555 Twin Dolphin Drive, Suite 615 Redwood City, CA	**94065**
(Address of principal executive offices)	(Zip Code)

(650) 475-0158

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer ☐	Accelerated Filer ☐
Non-Accelerated Filer ☒ (Do not check if a smaller reporting company)	Smaller Reporting Company ☐
	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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The number of shares outstanding of the registrant's Common Stock as of April 30, 2017 was 26,510,051 .

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would," or the negative of these words or other comparable terminology.

These forward-looking statements include, but are not limited to, statements about:

- the timing of our planned meeting with the United States Food and Drug Administration, or FDA, to inform development paths forward for IV OCR-002;
- our ability to identify a development path forward for OCR-002;
- any additional studies of OCR-002 that we may be required to conduct in light of the fact our Phase 2b clinical trial did not meet its clinical endpoints, including related cost and timing issues associated with future studies;
- whether any future studies of OCR-002 we may conduct will demonstrate similar results to our Phase 2b clinical trial;
- our ability to raise sufficient capital or consummate other strategic transactions to enable the continued development of OCR-002 and our ability to continue as a going concern;
- our ability to enroll patients, and the timing of enrollment, in our planned Phase 2a clinical trial of oral OCR-002 in cirrhotic patients;
- the number, timing, design, results and implementation of any additional future clinical trials and nonclinical activities for OCR-002 and the timing of the availability of data from these trials and activities;
- our ability to obtain U.S. and foreign regulatory approval for OCR-002 and the ability of OCR-002 to meet existing or future regulatory standards;
- the progress, timing and amount of expenses associated with our research, development and commercialization activities for OCR-002;
- our expectations regarding federal, state and foreign regulatory requirements;
- the therapeutic benefits, effectiveness and safety of OCR-002;
- the commercial success and market acceptance of OCR-002, if approved;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- the accuracy of our estimates of the size and characteristics of the markets that may be addressed by OCR-002;
- our ability to manufacture sufficient amounts of OCR-002 for clinical trials and commercialization activities;
- our ability to comply with the covenants in our credit facility;
- our intention to seek, and our ability to establish strategic collaborations or partnerships for the development or sale of OCR-002 and the effectiveness of such collaborations or partnerships;
- our expectations as to future financial performance, cash and expense levels and liquidity sources; and
- other risks and uncertainties, including those described in Part II, Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q, Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2016 and our other filings with the SEC.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part II, Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q, Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2016 and our other filings with the SEC. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

Unless the context requires otherwise, references in this Quarterly Report to "we," "us" and "our" refer to Ocera Therapeutics, Inc. and its subsidiary.

OCERA THERAPEUTICS, INC.
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PART I. FINANCIAL INFORMATION
Item 1. Condensed Consolidated Financial Statements

Ocera Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(In Thousands, Except Share and Per Share Amounts)

	March 31, 2017	December 31, 2016
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 25,180	$ 24,611
Short-term marketable securities	—	3,749
Prepaid expenses and other current assets	745	584
Total current assets	25,925	28,944
Property and equipment, net	54	64
Deposits	20	36
Goodwill	595	595
Total assets	$ 26,594	$ 29,639
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,228	$ 1,215
Accrued liabilities	2,694	2,839
Notes payable, short-term (Note 5)	9,148	9,703
Total current liabilities	13,070	13,757
Other liabilities	—	145
Total liabilities	13,070	13,902
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.00001 par value, 5,000,000 shares authorized and no shares issued or outstanding.	—	—
Common stock, $0.00001 par value, 100,000,000 shares authorized, 25,962,848 issued and outstanding at March 31, 2017 and 23,600,242 shares issued and outstanding at December 31, 2016.	—	—
Additional paid-in capital	178,535	174,065
Accumulated deficit	(165,011)	(158,328)
Total stockholders' equity	13,524	15,737
Total liabilities and stockholders' equity	$ 26,594	$ 29,639

See the accompanying notes to the unaudited consolidated financial statements.

Ocera Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In Thousands, Except Share and Per Share Amount)

	Three Months Ended March 31,	
	2017	**2016**
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
Other income (expense):		
Interest and other income	27	33
Interest and other expense	(282)	(279)
Other expense, net	(255)	(246)
Net loss	$ (6,683)	$ (7,514)
Net loss per share:		
Net loss per share, basic and diluted	$ (0.28)	$ (0.36)
Weighted average number of shares used to compute net loss per share of common stock, basic and diluted	24,037,387	20,943,966
Comprehensive loss:		
Net loss	$ (6,683)	$ (7,514)
Unrealized gain on investments	—	6
Comprehensive loss	$ (6,683)	$ (7,508)

See the accompanying notes to the unaudited consolidated financial statements.

Ocera Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In Thousands)

	Three Months Ended March 31,	
	2017	**2016**
Operating activities		
Net loss	$ (6,683)	$ (7,514)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	10	12
Stock-based compensation	951	1,106
Amortization of premiums on marketable securities, net	(1)	22
Amortization of debt discount	50	47
Changes in operating assets and liabilities:		
Accounts receivable	—	(34)
Prepaid expenses and other assets	(145)	94
Accounts payable	(17)	544
Accrued liabilities	(594)	498
Net cash used in operating activities	(6,429)	(5,225)
Investing activities		
Purchase of marketable securities	—	(3,754)
Maturities of marketable securities	3,750	3,733
Net cash provided by (used in) investing activities	3,750	(21)
Financing activities		
Proceeds from sale of common stock, net of underwriting commissions and issuance cost	3,549	1,746
Repayments on notes payable	(301)	—
Proceeds from exercise of common stock options	—	11
Net cash provided by financing activities	3,248	1,757
Net increase (decrease) in cash and cash equivalents	569	(3,489)
Cash and cash equivalents, beginning of period	24,611	35,921
Cash and cash equivalents, end of period	$ 25,180	$ 32,432
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 207	$ 207
Supplemental schedule of non-cash investing and financing activities		
Issuance cost related to at the market equity program in accounts payable	$ 30	$ 40

See the accompanying notes to the unaudited consolidated financial statements.

1. Description of Business

Ocera Therapeutics, Inc. (the "Company") is a clinical stage biopharmaceutical company targeting acute and clinical orphan liver disease. The Company's initial focus is on the development and commercialization of OCR-002 (ornithine phenylacetate) in both intravenous and oral formulations for the treatment and prevention of hepatic encephalopathy (“HE”). HE is a serious complication of liver cirrhosis, or liver failure, marked by mental changes including confusion, impaired motor skills, disorientation in time and space, and, in its more severe form, stupor, coma and even death.

OCR-002 is a novel molecule, ornithine, phenylacetate, which functions as an ammonia scavenger and which the Company believes is the only direct ammonia scavenger currently in clinical development for the treatment and prevention of HE. OCR-002 has been granted orphan drug designation and Fast Track status by the FDA for the treatment of hyperammonemia and resultant HE in patients with acute liver failure and acute-on-chronic liver disease. Orphan drug designation is given to a drug candidate intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States. OCR-002 has also been granted orphan drug designation in the European Union for the treatment of acute liver failure. Fast Track designation is available for certain new drug products if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation does not change the standards for approval but may expedite the development or approval process.

On July 15, 2013 , Terrapin Acquisition, Inc., a Delaware corporation (“Merger Sub”), a wholly owned subsidiary of Tranzyme, Inc., a Delaware corporation (“Tranzyme”), completed its merger (the “Merger”) with and into Ocera Therapeutics, Inc., a private Delaware corporation (“Private Ocera”). Private Ocera was considered the acquiring company in the Merger for accounting purposes. In connection with the Merger, the combined company changed its name to Ocera Therapeutics, Inc. and the name of Private Ocera was changed to Ocera Subsidiary, Inc. ("Ocera Subsidiary").

The Company has a limited operating history and the sales and income potential of its business and market are unproven. As of March 31, 2017 , the Company has an accumulated deficit of $165.0 million and has experienced net losses each year since its inception. The Company anticipates that it will continue to incur net losses into the foreseeable future and will need to raise additional capital as it continues the development and commercialization of OCR-002. The Company's cash and cash equivalents may not be sufficient to fund its operations beyond the second quarter of 2018. These factors raise substantial doubt about the Company's ability to continue as a going concern within twelve months following the date of the filing of this Form 10-Q. The Company's ability to continue as a going concern and finance operations beyond its current resources will depend heavily on the value investors see in the data from previous clinical trials of OCR-002 and favorable results from any future clinical trials of OCR-002 the Company may conduct.

The Company plans to raise additional capital through collaboration, licensing or similar arrangements, private and public equity offerings or debt financing, or a combination thereof. Additional financing may not be available when the Company needs it or may not be available on terms that are favorable to the Company. Collaboration, licensing or similar arrangements may require the Company to relinquish valuable rights to its potential products or proprietary technologies. To the extent that the Company raises additional capital through the sale of equity or convertible debt securities, the ownership interest of existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, as is the case with the Company's loan facility, results in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring debt, making capital expenditures or declaring dividends. Without additional funds, the Company may be forced to delay, scale back or eliminate some of its research and development activities or operations and potentially delay product development of OCR-002.

The condensed consolidated financial statements included in this report have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of the uncertainty related to our ability to continue as a going concern.

2. Summary of Significant Accounting Policies

Basis of Accounting

The accompanying unaudited condensed consolidated financial statements of the Company and our wholly-owned subsidiary have been prepared in accordance with United States of America generally accepted accounting principles ("U.S. GAAP") for interim financial statements and pursuant to the rules and regulations of the Securities and Exchange Commission. For interim reporting the financial statements and related notes do not include all information and footnotes required by U.S. GAAP for annual reports. This quarterly report should be read in conjunction with the consolidated financial statements included in the Company's annual report on Form 10-K for the year ended December 31, 2016 .

Unaudited Interim Financial Information

The accompanying interim condensed consolidated financial statements and related disclosures are unaudited, have been prepared on the same basis as the annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the results of operations for the periods presented. The year-end condensed consolidated balance sheets were derived from audited consolidated financial statements, but does not include all disclosures required by U.S. GAAP for complete financial statements. The consolidated results of operations for any interim period are not necessarily indicative of the results to be expected for the full year or for any other future year or interim period.

Use of Estimates

The preparation of financial statements in conformity with the U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Recent Accounting Pronouncements

Occasionally, new accounting standards are issued or proposed by the Financial Accounting Standards Board (the "FASB"), or other standards-setting bodies, that the Company adopts by the effective date specified within the standard.

(i) New Accounting Updates Recently Adopted

In March 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-09, Improvements to Employee Share-Based Payment Accounting (Topic 718), Compensation - Stock Compensation. The ASU simplifies several aspects of the accounting for share-based payments, including the income tax consequences, changing the threshold to qualify for equity classification to the employees' maximum statutory tax rates, allowing an entity-wide accounting policy election to either estimate the number of awards that are expected to vest or account for forfeitures as they occur, and clarifying the classification on the statement of cash flows for the excess tax benefit and employee taxes paid when an employer withholds shares for tax-withholding purposes. As a result of the adoption of this ASU, the Company recognized additional deferred tax assets of $0.3 million . There was no change to beginning retained earnings for previously unrecognized tax benefits, as the increase to deferred tax assets was fully offset by an increase to the valuation allowance as the Company determined that it was not more likely than not that the Company will realize the benefit of these deferred tax assets. The Company has elected to maintain its practice of estimating forfeitures when recognizing expense for share-based payment awards.

(ii) Recent Accounting Updates Not Yet Effective

In January 2017, the FASB issued ASU No. 2017-04, Simplifying the Test for Goodwill Impairment, which removes the second step of the two-step goodwill impairment test. Under ASU No. 2017-04, an entity will apply a one-step quantitative test and record the amount of goodwill impairment as the excess of a reporting unit's carrying amount over its fair value, not to exceed the total amount of goodwill allocated to the reporting unit. ASU No. 2017-04 does not amend the optional qualitative assessment of goodwill impairment. Additionally, an entity should consider income tax effects from any tax-deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable. ASU No. 2017-04 is effective for annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2019; early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company is currently evaluating the impact of the adoption of this standard and does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, Classification of Certain Cash Receipts and Cash Payments, which aims to eliminate diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows under Topic 230, Statement of Cash Flows, and other Topics. ASU No. 2016-15 is effective for annual reporting periods, and interim periods therein, beginning after December 15, 2017. The Company continues to assess the potential impact of this standard, but currently does not expect the adoption of this standard to have a material impact on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases, to increase transparency and comparability among organizations by requiring recognition of lease assets and lease liabilities on the balance sheet and disclosure of key information about leasing arrangements. The standard will become effective for interim and annual periods beginning after December 15, 2018, with early adoption permitted. The guidance is required to be adopted at the earliest period presented using a modified retrospective approach. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers. The standard's core principle is that a reporting entity will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard will become effective for the Company beginning in the first quarter of 2018. Early adoption is permitted in 2017. Entities have the option of using either a full retrospective or a modified retrospective approach to adopt this new guidance. In March and April 2016, the FASB issued ASU No. 2016-08 Revenue From Contracts With Customers: Principal vs. Agent Considerations and ASU No. 2016-10 Revenue From Contracts with Customers: Identifying Performance Obligations and Licensing to provide supplemental adoption guidance and clarification to ASU No. 2014-09. The Company plans to adopt this guidance as of January 1, 2018, using the modified retrospective method and is in the process of evaluating its arrangements where it has licensed or sold intellectual property. The Company has not yet completed its full assessment and is not yet able to estimate the anticipated impact to the condensed consolidated financial statements from the application of the new standard.

The Company reviewed all other recently issued accounting pronouncements and concluded that they were either not applicable or not expected to have a significant impact to the condensed consolidated financial statements. Additionally, the adoption of accounting pronouncements in the first quarter of this year did not have an impact on the Company's consolidated financial position or results of operations.

3. Fair Value Measurements

The following tables present information about the Company's financial assets measured at fair value on a recurring basis as of March 31, 2017 , and December 31, 2016 , and indicate the fair value hierarchy of the valuation techniques utilized by the Company to determine such fair value. As a basis for categorizing inputs, the Company uses a three-tier fair value hierarchy, which prioritizes the inputs used to measure fair value from market-based assumptions to entity specific assumptions:

Level 1: Inputs which include quoted prices in active markets for identical assets or liabilities;

Level 2: Inputs, other than level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and

Level 3: Unobservable inputs that are supported by little or no market activity, which require the reporting entity to develop its own assumptions.

No transfers between levels have occurred during the periods presented.

Assets measured at fair value on a recurring basis as of March 31, 2017 are as follows (in thousands):

	Total	Level 1	Level 2	Level 3
Money market funds	$ 25,163	$ 25,163	$ —	$ —

The estimated fair value of the Company's notes payable, considering level 2 inputs, approximates their carrying value based upon the borrowing terms and conditions available to the Company at March 31, 2017 .

Assets measured at fair value on a recurring basis as of December 31, 2016 are as follows (in thousands):

	Total	Level 1	Level 2	Level 3
Money market funds	$ 24,593	$ 24,593	$ —	$ —
Commercial paper	1,498	—	1,498	—
Corporate debt securities	2,251	—	2,251	—
Total assets	$ 28,342	$ 24,593	$ 3,749	$ —

The estimated fair value of the Company's notes payable, considering level 2 inputs, approximates their carrying value based upon the borrowing terms and conditions available to the Company at December 31, 2016 .

4. Balance Sheet Components

Investments

The following table summarizes the Company's cash equivalents as of March 31, 2017 (in thousands):

	Maturity (In Years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Money market funds	n/a	$ 25,163	$ —	$ —	$ 25,163

The following table summarizes the Company's cash equivalents and marketable securities as of December 31, 2016 (in thousands):

	Maturity (In Years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Money market funds (1)	n/a	$ 24,593	$ —	$ —	$ 24,593
Commercial paper	1 or less	1,498	—	—	1,498
Corporate debt securities	1 or less	2,251	—	—	2,251
Total cash equivalents and marketable securities		$ 28,342	$ —	$ —	$ 28,342

(1) Money market funds are included in cash and cash equivalents on our condensed consolidated balance sheets.

At each reporting date, the Company reviews its investments for impairment to determine if the unrealized losses are other-than-temporary. There have been no other-than-temporary impairments on these securities as of March 31, 2017 and December 31, 2016 . Realized gains or losses on available-for-sale securities were immaterial for the periods presented. The Company does not intend to and believes it is not more likely than not that it will be required to sell these securities before their maturities.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	March 31, 2017	December 31, 2016
Clinical trials	$ 1,500	$ 1,519
Compensation and related expenses	504	1,124
Professional services	123	102
Principal payment due on notes payable	304	—
Interest expense on notes payable	237	69
Other	26	25
Total accrued liabilities	$ 2,694	$ 2,839

5. Notes Payable

On July 30, 2015 , the Company and Ocera Subsidiary entered into a Loan and Security Agreement (the “Loan Agreement”) with Oxford Finance LLC (“Oxford”) and Silicon Valley Bank (“SVB”) (collectively, the “Lenders”). The Loan Agreement provides for up to $20.0 million in new term loans (the “Term Loan Facility”), $ 10.0 million of which was funded on July 30, 2015 . The remaining $10.0 million was not drawn and expired at December 31, 2016 due to non-achievement of certain financial and clinical milestones.

The annual interest rate for the initial $10.0 million funding is 8.275% . Loan payments were interest-only until February 1, 2017, followed by 30 equal monthly payments of principal and interest through the scheduled maturity date of August 1, 2019. In addition, a final payment equal to 3% of the aggregate amount drawn will be due at maturity or on earlier repayment. If the Company prepays all or a portion of the loans, a prepayment fee of between 1% and 3% of the principal amount prepaid will also be due depending on the timing of the prepayment.

The Company received net proceeds of $9.7 million after fees and expenses from the Term Loan Facility. These fees and expenses are being accounted for as a debt discount and classified within notes payable on the Company’s condensed consolidated balance sheets. Related legal and consulting fees are presented in the condensed consolidated balance sheets as a direct deduction from the carrying amount of notes payable, consistent with the debt discount. The debt discount, issuance costs and the final payment are being amortized or accreted as interest expense over the term of the loan using the effective interest method.

In connection with the Loan Agreement, the Company issued to the Lenders warrants to purchase an aggregate of 97,680 shares of the Company's common stock at an exercise price of $4.10 per share. The Company recorded $0.3 million for the warrants as debt discount within notes payable and an increase to additional paid-in capital on the Company's balance sheet. As of March 31, 2017 , the warrants remained outstanding and exercisable. The debt discount is being amortized as interest expense over the term of the loan using the effective interest method.

The Term Loan Facility is secured by substantially all of the Company's assets and the assets of Ocera Subsidiary, Inc., except that the collateral does not include any intellectual property held by the Company or Ocera Subsidiary, Inc. However, pursuant to the terms of a negative pledge arrangement, the Company has agreed not to encumber any of the intellectual property of the Company or its subsidiaries. The Loan Agreement contains customary representations, warranties and covenants by the Company, which limit the Company's ability to convey, sell, lease, transfer, assign or otherwise dispose of certain of our assets; engage in any business other than the businesses the Company currently engages in or reasonably related thereto; liquidate or dissolve; make certain management changes; undergo certain change of control events; create, incur, assume, or be liable with respect to certain indebtedness; grant certain liens; pay dividends and make certain other restricted payments; make certain investments; enter into any material transactions with any affiliates, with certain exceptions; make payments on any subordinated debt; and permit certain of the Company's subsidiaries to maintain, own or otherwise hold any material assets or conduct any business operations other than as disclosed to the Lenders. In addition, subject to certain exceptions, the Company and Ocera Subsidiary, Inc., are required to maintain with SVB their respective primary deposit accounts, securities accounts and commodity accounts.

The Loan Agreement also contains customary indemnification obligations and customary events of default, including, among other things, failure to fulfill certain of the Company's obligations under the Loan Agreement, the occurrence of a material adverse change in the Company's business, operations, or condition (financial or otherwise), a material impairment of the prospect of repayment of any portion of the loan, or a material impairment in the perfection or priority of the Lenders' lien in the collateral or in the value of such collateral. In the event of default by the Company under the Loan Agreement, the Lenders would be entitled to exercise their remedies thereunder, including the right to accelerate the debt, upon which the Company may be required to repay all amounts then outstanding under the Loan Agreement, which could harm the Company's financial condition. The Company was in compliance with all applicable covenants set forth in the Loan Agreement as of March 31, 2017 and December 31, 2016 . The principal and related interest payments due under the Loan Agreement have been classified as current liabilities at March 31, 2017 due to the considerations discussed in Note 1 and the assessment that a material adverse change under the Loan Agreement is not within the Company's control. The Company has not been notified of an event of default by the Lenders as of the date of the filing of this Form 10-Q.

The Company recorded interest expense related to the Term Loan Facility of $0.3 million for each of the three months ended March 31, 2017 and 2016 . The annual effective interest rate on the note payable, including the amortization of the debt discounts and accretion of the final payment, is 11.72% .

Future principal payments under the Loan Agreement as of March 31, 2017 are as follows (in thousands):

Years ending December 31,		
2017 (for the remaining nine months)	$	2,502
2018		4,022
2019		2,871
Total principal payments		9,395
Unamortized discount on notes payable		(247)
Notes payable, balance	$	9,148

Future interest payments under the Loan Agreement as of March 31, 2017 amount to $1.3 million .

6. Stockholders' Equity

On May 15, 2015 , the Company entered into a sales agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen"), pursuant to which the Company may issue and sell shares of its common stock having aggregate sales proceeds of up to $25.0 million from time to time through an "at the market" equity program under which Cowen acts as sales agent.

During the three months ended March 31, 2017 , the Company sold an aggregate of 2,341,812 shares of common stock under the Sales Agreement, at an average price of approximately $1.56 per share, for net proceeds of $3.5 million after deducting commissions and other transaction costs. As of March 31, 2017 , $10.1 million of common stock remained available to be sold under the Sales Agreement, subject to certain conditions specified therein.

In March 2017, the Company issued 20,794 shares of common stock pursuant to the cashless exercise of certain warrants at an exercise price of $0.67 per share.

7. Stock-Based Compensation

On July 15, 2013, in connection with the Merger, the Company assumed the existing Tranzyme 2011 Stock Option and Incentive Plan (the "2011 Plan"). The 2011 Plan provides for the granting of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units ("RSUs"), performance stock awards, performance cash awards and other stock awards to employees, officers, directors and consultants.

The Company recognized stock-based compensation expense within the condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended March 31,	
	2017	2016
Research and development	$ 201	$ 207
General and administrative	750	899
Total stock-based compensation	$ 951	$ 1,106

As of March 31, 2017 , there was unrecognized stock-based compensation expense of $6.0 million which the Company expects to recognize over a weighted average period of 1.88 years.

Stock-based compensation expense for stock options is estimated at the grant date based on the fair-value using the Black-Scholes option pricing model. The fair value of employee stock options is being amortized on a straight-line basis over the requisite service period of the awards. The fair value of all stock options granted was estimated using the following weighted-average assumptions:

	Three Months Ended March 31,	
	2017	2016
Expected dividend yield	—	—
Risk-free interest rates	—%	1.33% - 1.97%
Expected term in years	—	4.66 - 8.04
Expected volatility	—%	75% - 92%

Restricted Stock Units:

On March 29, 2017 , the Company granted 1,065,000 RSU's to certain employees and consultants. The RSUs vest according to the following schedule: 50% of the RSUs vests on December 31, 2017 and the remainder vests on December 31, 2018 , in each case subject to the recipient’s continued employment or service on each vesting date. Stock-based compensation expense recorded related to the RSUs during the three months ended March 31, 2017 was insignificant.

8. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and common stock equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. Potentially dilutive securities which include warrants and outstanding stock options have been excluded from the computation of diluted net loss per share as their effect would be anti-dilutive. For all periods presented, basic and diluted net loss were the same.

The following table presents the computation of net loss per share (in thousands, except share and per share data):

	Three Months Ended March 31,	
	2017	2016
Numerator		
Net loss	$ (6,683)	$ (7,514)
Denominator		
Weighted average common shares outstanding used to compute net loss per share, basic and diluted	24,037,387	20,943,966
Net loss per share of common stock, basic and diluted		
Net loss per share	$ (0.28)	$ (0.36)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share of common stock for the periods presented as the effect of their inclusion would have been anti-dilutive:

	Three Months Ended March 31,	
	2017	2016
Common stock warrants	965,240	1,026,249
Common stock options	3,928,511	3,630,529
Restricted stock units	1,065,000	—
Total potentially dilutive securities	5,958,751	4,656,778

9. Commitments and Contingencies

From time to time, the Company may be involved in disputes, including litigation, relating to claims arising out of operations in the normal course of business. Any of these claims could subject the Company to costly legal expenses and, while the Company generally believes that it has adequate insurance to cover many different types of liabilities, its insurance carriers may deny coverage or its policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on the Company's condensed consolidated results of operations and financial position. Additionally, any such claims, whether or not successful, could damage the Company's reputation and business. The Company is currently not a party to any legal proceedings, the adverse outcome of which, in management’s opinion, individually or in the aggregate, would have a material adverse effect on the Company's condensed consolidated results of operations or financial position.

UCL Business PLC

In December 2008, the Company licensed rights to OCR-002 from UCL Business PLC, an entity affiliated with the University College London (“UCL”), for the exclusive worldwide rights to develop and commercialize OCR-002 and related technologies for any use. The agreement was amended in July 2011, February 2013 and July 2015. The Company may be required to make future milestone payments to UCL totaling up to $20.0 million upon the achievement of various milestones related to clinical and regulatory events for OCR-002. The Company may also be required to pay milestone payments totaling up to $35.0 million upon the achievement of various milestones related to future net sales of OCR-002. The Company is also obligated to pay tiered royalties in the low to mid-single digits on potential future net sales of the licensed product candidate.

Purchase Commitments

In November 2016, the Company entered into an agreement with Evonik Industries (“Evonik”), under which Evonik will manufacture clinical supply of OCR-002 drug substance for the Company. Per the terms of the agreement, the Company will purchase clinical supply of OCR-002 totaling $1.3 million . As of March 31, 2017 , the Company has $0.5 million in non-cancelable purchase commitments under the agreement.

Rent

Rent expense was $0.1 million for each of the three months ended March 31, 2017 and 2016.

The following is a schedule of non-cancelable future minimum payments for operating leases as of March 31, 2017 (in thousands):

Years ending December 31,		
2017 (for the remaining nine months)	$	311
2018		109
2019 and beyond		8
Total future minimum payments for operating leases	$	428

10. Subsequent Event

Pursuant to the Company's "at the market" equity program, in April 2017, prior to the date of the filing of this Form 10-Q, the Company sold an aggregate of 547,203 shares of common stock under the Sales Agreement at an average price of approximately $1.51 per share, for net proceeds of approximately $0.8 million .

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion should be read in conjunction with the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2016 and the unaudited consolidated financial statements and notes thereto included elsewhere in this Quarterly Report on Form 10-Q. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" in Part II, Item 1 of this Quarterly Report on Form 10-Q, Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2016 and our other filings with the SEC, our actual results could differ materially from those anticipated in these forward-looking statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

Overview

We are a clinical-stage biopharmaceutical company targeting acute and chronic orphan liver diseases. Our initial focus is the development and commercialization of a clinical product candidate, OCR-002, in both intravenous, or IV, and oral formulations, for the treatment of acute and chronic hepatic encephalopathy, or HE. HE is a serious complication of liver cirrhosis, or liver failure, marked by mental changes including confusion, impaired motor skills, disorientation in time and space, and, in its more severe form, stupor, coma and even death. Although the exact cause of HE is not completely understood, there is growing evidence that elevated ammonia is a primary driver of HE, and that lowering ammonia may be beneficial to patients suffering from HE. Common causes of liver malfunction leading to elevated ammonia levels and HE include alcoholism, viral hepatitis and autoimmune diseases, non-alcoholic steatohepatitis, or NASH, as well as obesity, Type II diabetes, and acetaminophen overdose. It is estimated that there are between 30 to 35 million individuals in the United States with some form of chronic liver disease, of which approximately 5.5 million have cirrhosis. Of these 5.5 million individuals, approximately 1.5 to 2.0 million are at risk for developing HE. Approximately 200,000 of these individuals are hospitalized with overt HE per year in the United States.

OCR-002 is a novel molecule, ornithine phenylacetate, which functions as an ammonia scavenger and which we believe is the only direct ammonia scavenger currently in clinical development for the treatment and prevention of HE. In January 2017, we announced the top-line results from our exploratory study, STOP-HE, a Phase 2b clinical trial evaluating the safety, tolerability and efficacy of intravenously-administered OCR-002 in hospitalized patients with HE. The data showed that OCR-002 was both safe and well-tolerated at all dose levels evaluated. Although not statistically significant, OCR-002 demonstrated a 17-hour reduction over placebo (47 versus 64 hours, respectively) for the primary endpoint, which was median time to improvement in HE symptoms, p=0.129, hazard ratio 1.25. In addition, OCR-002 demonstrated a 15-hour reduction over placebo (87 versus 102 hours, respectively) for the secondary endpoint, which was median time to complete response in HE symptoms, p=0.361, hazard ratio 1.16. Notwithstanding that the clinical endpoints did not reach statistical significance, the patients at the higher doses (15 and 20 grams) had greater complete response rates compared to the patients on the lowest dose (10 grams) and those on placebo. In addition, consistent with its mechanism of action and the data we observed in pre-clinical studies, OCR-002 exhibited a statistically significant ammonia reduction over placebo for the study's pre-specified exploratory endpoint which was time to achieve normal plasma ammonia levels, p=0.028, hazard ratio 1.69.

In March 2017, we announced data from additional analyses that showed plasma ammonia reduction correlates with clinical improvement. Related to plasma ammonia levels, patients who responded had a greater change in plasma ammonia from baseline than patients who did not respond, (-28.2 and -9.2 μg/mL, respectively), p=0.0006. With regard to clinical improvement, patients on OCR-002 had a higher response rate at 48 hours than placebo, (51 and 37%, respectively), p=0.026. In addition, while not the primary endpoint patient-improvement measure, when patient improvement was measured by the pre-defined endpoint, Physician Overall Treatment Evaluation, a greater proportion of patients on OCR-002 demonstrated improvement over placebo, p=0.026. Rifaximin, although not indicated for hospitalized patients with overt HE, was widely used in the hospital resulting in a significant percentage of study patients having rifaximin concomitantly administered during OCR-002 therapy. Post hoc analysis of the time to improvement in HE symptoms excluding patients who used rifaximin indicates the primary endpoint of the study would have been achieved with high statistical significance, p=0.004. Other study data indicate OCR-002 provided clinical benefit over placebo as observed by improvement in Model for End-Stage Liver Disease, or MELD scores, p=0.051, and improvement in renal function as measured by the change from baseline in Blood Urea Nitrogen, or BUN levels, p=0.04. We currently plan to meet with the United States Food and Drug Administration, or FDA, to discuss next steps regarding future development for the IV formulation of OCR-002. While we prepare for our meeting with the FDA, we continue to evaluate pathways forward for the continued development of OCR-002.

In May 2017, we reported new data from STOP-HE following additional post-hoc analysis of the same primary endpoint from the trial - median time to improvement in HE symptoms. This analysis revealed that patients with confirmed

hyperammonemia, or excess ammonia levels in the blood, at randomization (baseline) improved faster on OCR-002 than placebo (42 versus 63 hours, respectively), with statistical significance, p=0.034. These 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 intent to treat (ITT) analysis population, 201 were confirmed as hyperammonemic at time of randomization, which indicates that some patients' ammonia levels had normalized between screening and randomization under standard of care. This post-hoc per protocol population represents the trial's target population given the ammonia-scavenging mechanism of action of OCR-002.

We currently plan to meet with the FDA in the third quarter of 2017 to discuss next steps regarding future development for the IV formulation of OCR-002. While we prepare for our meeting with the FDA, we continue to evaluate pathways forward for the continued development of OCR-002.

We are also developing an oral form of OCR-002 with the goal of providing continuity of care for HE patients post discharge in order to prevent subsequent episodes of acute HE. In January 2017, we completed a Phase 1 clinical trial with an orally administered liquid formulation of OCR-002 in patients with cirrhosis. In this open-label crossover study, OCR-002 was observed to be safe and well-tolerated with favorable pharmacokinetics, or pK, including absolute bioavailability of greater than 95%. In the fourth quarter of 2015, we completed a Phase 1 clinical trial with oral formulations of OCR-002 in healthy subjects. This open label, single-dose, five treatment, five-period crossover trial evaluated the pK, safety and tolerability of three prototype, extended-release oral formulations of OCR-002 compared to an immediate release oral solution of OCR-002 and the FDA-approved ammonia-lowering agent, glycerol phenylbutyrate (RAVICTI). Glycerol phenylbutyrate is a pre-pro-drug of phenylacetate, or PAA, a component of OCR-002. The results of this trial demonstrated a robust, extended-release pattern for all three pilot OCR-002 extended-release formulations, with mean plasma phenylacetate concentrations exceeding those achieved with RAVICTI at all time points for at least 12 hours post-dose. In addition, the concentration of phenylacetylglutamine, or PAGN, the end-product responsible for clearing ammonia, was greater in both plasma and urine for all three OCR-002 extended-release dosage forms than RAVICTI at an approximately equivalent molar PAA dose. We plan to initiate a Phase 2a clinical trial with a tablet formulation of OCR-002 in cirrhotic patients during the second quarter of 2017.

Our strategy is to focus clinical development activities on the IV formulation of OCR-002 to treat overt HE in hospitalized patients and on the oral form of OCR-002, which will be directed to chronic care of HE patients. Based on third party analysis of Healthcare Cost and Utilization Project, or HCUP, and Medicare data, we estimate that there are approximately 200,000 patients accounting for approximately 260,000 hospitalizations for overt HE in the United States annually. Additional third-party data from Centers for Medicare and Medicaid Services, or CMS, indicate that approximately 60% of patients suffering from HE are hospitalized for over four days. Utilizing this incidence data and a combination of third-party information and market research commissioned by us regarding pricing, we believe the combined annual market potential for intravenous and oral OCR-002 is approximately $1.5 to $2.0 billion in the United States alone. If intravenous OCR-002 is able to reduce the time to clinical improvement, and thereby shorten hospital stay, we believe it has an annual market potential of $600 to $800 million and if the oral formulation can reduce the frequency of overt HE episodes, we believe it has an annual market potential of $900 million to $1.2 billion.

OCR-002 has been granted orphan drug designation and Fast Track status by the FDA for the treatment of hyperammonemia and resultant HE in patients with acute liver failure and acute-on-chronic liver disease. Orphan drug designation is given to a drug candidate intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States. OCR-002 has also been granted orphan drug designation in the European Union for the treatment of acute liver failure. Fast Track designation is available for certain new drug products if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation does not change the standards for approval but may expedite the development or approval process.

In December 2008, we licensed rights to OCR-002 from UCL Business PLC, an entity affiliated with University College London, or UCL, for the exclusive worldwide rights to develop and commercialize OCR-002 and related technologies for any use. The agreement was amended in July 2011, February 2013 and July 2015. As consideration for the license, we paid an up-front fee of $1.0 million. We may be required to make future milestone payments to UCL totaling up to $20.0 million upon the achievement of various milestones related to clinical and regulatory events for OCR-002. We may also be required to pay milestone payments totaling up to $35.0 million upon the achievement of various milestones related to future net sales of OCR-002. We are also obligated to pay tiered royalties in the low to mid-single digits on future net sales of the licensed product candidate.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United

States. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments related to each of our critical accounting areas. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We discussed accounting policies and assumptions that involve a higher degree of judgment and complexity within our Annual Report on Form 10-K for the year ended December 31, 2016 . For the three months ended March 31, 2017 , there have been no material changes to our critical accounting policies and estimates as disclosed in our Annual Report on Form 10-K.

Merger with Tranzyme, Inc.

On July 15, 2013, Terrapin Acquisition, Inc., a Delaware corporation and wholly owned subsidiary of Tranzyme, Inc., a Delaware corporation, or Tranzyme, completed its merger, or the Merger, with and into Ocera Therapeutics, Inc., a private Delaware corporation, or Private Ocera. Private Ocera is considered the acquiring company in the Merger for accounting purposes. In connection with the Merger, the combined company changed its name to Ocera Therapeutics, Inc. and the name of Private Ocera was changed to Ocera Subsidiary, Inc., or Ocera Subsidiary.

Results of Operations

The following table shows the amounts from our condensed consolidated statements of operations for the periods presented (in thousands):

	Three Months Ended March 31,		Change	
	2017	2016	$	%
Royalty revenue	$ —	$ 33	$ (33)	(100.0)%
Operating expenses:				
Research and development	3,904	4,747	(843)	(17.8)%
General and administrative	2,524	2,554	(30)	(1.2)%
Total operating expenses	6,428	7,301	(873)	(12.0)%
Other expense	(255)	(246)	(9)	3.7 %
Net loss	$ (6,683)	$ (7,514)	$ 831	(11.1)%

Revenues

No revenues were recorded during the three months ended March 31, 2017 . Royalty revenue for the three months ended March 31, 2016 was $33,000 . This revenue was attributable to a license agreement that we acquired from Tranzyme in connection with the Merger.

Operating Expenses

Research and Development Expenses

Research and development expenses consist of salaries and other personnel-related expenses, including stock-based compensation, lab supplies, materials and facility costs, as well as fees paid to other non-employees and entities that conduct certain research and development activities on our behalf.

Research and development expenses decreased by $0.8 million for the three months ended March 31, 2017 compared to the three months ended March 31, 2016 . The decrease in expenses was primarily due to decreased expenses incurred with contract research organizations related to the development of the IV formulation of OCR-002 as a result of the completion of our STOP-HE study.

General and Administrative Expenses

General and administrative expenses were flat for the three months ended March 31, 2017 compared to the three months ended March 31, 2016 . We observed an increase in expenses related to consulting and professional services offset by a decrease in personnel-related costs.

Other Expense

Other expense increased marginally for the three months ended March 31, 2017 , compared to the three months ended March 31, 2016 . Other expense represents interest expense related to the Loan Agreement offset by interest income earned on our investment portfolio.

Liquidity and Capital Resources

Cash Flows

The following table summarizes cash flows for the three months ended March 31, 2017 and 2016 (in thousands):

	Three Months Ended March 31,	
	2017	2016
Net cash provided by (used in):		
Operating activities	$ (6,429)	$ (5,225)
Investing activities	3,750	(21)
Financing activities	3,248	1,757
Net increase (decrease) in cash and cash equivalents	$ 569	$ (3,489)

Comparison of the Three Months Ended March 31, 2017 and 2016

Cash used in operating activities for the three months ended March 31, 2017 was attributable to our net loss from operations of $6.7 million adjusted for changes in operating assets and liabilities of $0.8 million and non-cash charges of $1.0 million which consisted primarily of stock-based compensation expense.

Cash used in operating activities for the three months ended March 31, 2016 was attributable to our net loss from operations of $7.5 million adjusted for changes in operating assets and liabilities of $1.1 million and non-cash charges of $1.2 million which consisted primarily of stock-based compensation expense.

Cash provided by investing activities for the three months ended March 31, 2017 consisted of proceeds of $3.8 million from maturities of marketable securities.

Cash used in investing activities for the three months ended March 31, 2016 related to purchases of marketable securities which were largely offset by proceeds from maturities of marketable securities.

Cash provided by financing activities during the three months ended March 31, 2017 and 2016 related to proceeds from the issuance of common stock pursuant to the “at the market” equity program of $3.5 million and $1.7 million , respectively, partially offset by a repayment on notes payable of $0.3 million during the three months ended March 31, 2017 .

Notes Payable

On July 30, 2015, we entered into the Loan Agreement with the Lenders. The Loan Agreement provides up to $20.0 million principal in new term loans, $10.0 million of which was funded on July 30, 2015. The remaining $10.0 million was not drawn and expired at December 31, 2016.

The term loan repayment schedule provides for interest only payments through February 1, 2017 with respect to the first $10.0 million of the term loans, followed by 30 equal monthly payments of principal and interest through the scheduled maturity date of August 1, 2019. The Loan Agreement provides for an interest rate equal to 8.275% on the first $10.0 million funding. The Loan Agreement also provides for a final interest payment equal to 3.0% of the original principal amount of the first $10.0 million in term loans which is due when the term loan becomes due or upon the prepayment of the facility. We have the option to prepay the outstanding balance of the term loan in full, subject to a prepayment fee of 1% to 3% depending upon when the prepayment occurs. The Term Loan Facility matures on August 1, 2019.

The Term Loan Facility is secured by substantially all of our assets and the assets of Ocera Subsidiary, Inc., except that the collateral does not include any intellectual property held by us or our subsidiary, Ocera Subsidiary, Inc. However, pursuant to the terms of a negative pledge arrangement, we have agreed not to encumber any of the intellectual property of ours or our subsidiaries. The Loan Agreement contains customary representations, warranties and covenants by us, which limit our ability to convey, sell, lease, transfer, assign or otherwise dispose of certain of our assets; engage in any business other than the businesses we currently engage in or reasonably related thereto; liquidate or dissolve; make certain management changes; undergo certain change of control events; create, incur, assume, or be liable with respect to certain indebtedness; grant certain liens; pay dividends and make certain other restricted payments; make certain investments; enter into any material transactions with any affiliates, with certain exceptions; make payments on any subordinated debt; and permit certain of our subsidiaries to maintain, own or otherwise hold any material assets or conduct any business operations other than as disclosed to the Lenders. In addition, subject to certain exceptions, we and Ocera Subsidiary, Inc. are required to maintain with SVB their respective primary deposit accounts, securities accounts and commodity accounts.

The Loan Agreement also contains customary indemnification obligations and customary events of default, including, among other things, our failure to fulfill certain of our obligations under the Loan Agreement, the occurrence of a material adverse change in our business, operations, or condition (financial or otherwise), a material impairment of the prospect of repayment of any portion of the loan, or a material impairment in the perfection or priority of the Lenders' lien in the collateral or in the value of such collateral. In the event of default by us under the Loan Agreement, the Lenders would be entitled to exercise their remedies thereunder, including the right to accelerate the debt, upon which we may be required to repay all amounts then outstanding under the Loan Agreement, which could harm our financial condition. We have not been notified of an event of default by the Lenders as of the date of the filing of this Form 10-Q.

Capital Resources and Funding Requirements

We will require significant additional funds to support future operations including our development activities associated with the intravenous and oral formulations of OCR-002. Our future funding requirements depend on many factors, including, but not limited to the progress, timing, scope and costs of our nonclinical studies and clinical trials including the ability to enroll patients on a timely basis in our planned and potential future clinical trials, the size, complexity and duration of such clinical trials, the time and cost necessary to respond to technological, market or governmental developments, the cost of manufacturing adequate supplies of drug substance and drug product and the cost of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights.

We expect to fund our operations with our current cash and cash equivalents and proceeds from potential additional financing transactions and possible strategic opportunities. We believe that our current cash and cash equivalents may not be sufficient to fund our operations beyond the second quarter of 2018.

On May 15, 2015, we filed a shelf registration statement on Form S-3 under which we may offer shares of our common stock and preferred stock, various series of warrants to purchase common stock or preferred stock and debt securities, either individually or in units, in one or more offerings, up to a total dollar amount of $150.0 million. On May 15, 2015, we entered into a Sales Agreement, or the Sales Agreement, with Cowen and Company, LLC, or Cowen, pursuant to which we may issue and sell shares of our common stock for which we included a prospectus to our shelf registration statement on Form S-3, having aggregate sales proceeds of up to $25.0 million, from time to time, through an "at the market" equity program under which Cowen acts as sales agent. During the three months ended March 31, 2017 , we sold an aggregate of 2,341,812 shares of common stock under the Sales Agreement, at an average price of approximately $1.56 per share, for net proceeds of $3.5 million after deducting commissions and other transactions costs. As of March 31, 2017 , common stock valued at $10.1 million remained available to be sold under the Sales Agreement, subject to certain conditions specified therein.

We have based our estimates of our cash needs on a number of assumptions that may prove to be wrong, and changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. Because of the numerous risks and uncertainties associated with the development and commercialization of OCR-002, particularly in light of the failure of our Phase 2b clinical trial of OCR-002 to meet the primary endpoint, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with the continued development of OCR-002. If adequate funds are not available to us on a timely basis, or at all, we may be required to terminate or delay clinical trials or other development activities for OCR-002.

Off-Balance Sheet Arrangements

We do not currently have, and did not have during the periods presented, any off-balance sheet arrangements, as defined under SEC rules.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

For quantitative and qualitative disclosures about market risk affecting our company, see Item 7A: "Quantitative and Qualitative Disclosures about Market Risk" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 . Our exposure to foreign currency risk and market risk has not materially changed from that disclosed in our Annual Report.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our principal executive officer and principal financial and accounting officer, evaluated the effectiveness of our disclosure controls and procedures as of the period covered by this report. Based on that evaluation, our principal executive officer and principal financial and accounting officer concluded that, as of March 31, 2017 , our disclosure controls and procedures were effective at the reasonable assurance level.

We continue to review and document our disclosure controls and procedures, including our internal controls and procedures for financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) or 15d-15(f) under the Exchange Act) during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors

We operate in a rapidly changing environment that involves a number of risks that could materially affect our business, financial condition or future results, some of which are beyond our control. In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2016 , as filed with the Securities and Exchange Commission, which could materially affect our business, financial condition or future results. During the quarterly period covered by this Quarterly Report on Form 10-Q, there were no material changes to the risk factors described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 .

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

(a) Exhibits required by Item 601 of Regulation S-K.

Exhibit Number	Description
10.1†	Amendment to Amended and Restated Agreement for Employment by and between the Company and Linda Grais dated March 29, 2017 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 31, 2017).
10.2†	Amendment to Amended and Restated Agreement for Employment by and between the Company and Michael Byrnes dated March 29, 2017 (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on March 31, 2017).
10.3*†	Ocera Therapeutics, Inc. Fourth Amended and Restated Non-Employee Director Compensation Policy.
31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS+	XBRL Instance Document
101.SCH+	XBRL Taxonomy Extension Schema Document
101.CAL+	XBRL Taxonomy Calculation Linkbase Document
101.LAB+	XBRL Taxonomy Label Linkbase Document
101.PRE+	XBRL Taxonomy Presentation Linkbase Document
101.DEF+	XBRL Taxonomy Definitions Linkbase Document

*Filed herewith
**Furnished herewith
†Indicates a management contract or compensation plan, contract or arrangement.
+Attached as Exhibits 101 to this report are the following financial statements from our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 , formatted in XBRL (eXtensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Loss, (iii) the Condensed Consolidated Statements of Cash Flows and (iv) related notes to these financial statements tagged as blocks of text.

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 thereunto duly authorized.

OCERA THERAPEUTICS, INC.
(Registrant)

Date: May 9, 2017

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

Date: May 9, 2017

By: /s/ Michael Byrnes
Michael Byrnes
Chief Financial Officer and Treasurer

Exhibit 10.3

OCERA THERAPEUTICS, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

As Amended and Restated

March 29, 2017

The purpose of this Non-Employee Director Compensation Policy, as amended and restated (this "Policy"), of Ocera Therapeutics, Inc., a Delaware corporation (the "Company"), is to provide a total compensation package that enables the Company to attract and retain, on a long-term basis, high caliber directors on the Company's Board of Directors (the "Board") who are not employees or officers of the Company or its subsidiaries. This Policy will become effective as of the date this Policy is approved by the Board (the "Effective Date").

In furtherance of this purpose, following the Effective Date, all non-employee Directors shall be paid cash compensation for services provided to the Company as set forth below.

	Annual Amount
Annual Retainer for each Board Member:	$35,000
Additional Retainer for the Chairman of the Board:	$25,000
Additional Retainer for Lead Independent Director	$25,000
Audit Committee Chair:	$17,500
Other Audit Committee Members:	$7,500
Compensation Committee Chair:	$10,000
Other Compensation Committee Members:	$5,000
Nominating and Corporate Governance Committee Chair:	$8,000
Other Nominating and Corporate Governance Committee Members:	$4,000

Additionally, the non-employee Directors shall be eligible to receive the following equity grants under the Company's equity incentive plans:

(a) Welcome Grants . Following the Effective Date, each person who is thereafter first appointed or first elected to the Board as a non-employee Director, is or will be eligible to receive a one-time grant of 20,000 restricted stock units (the "Welcome Grant"). Each non-employee Director who is first appointed or first elected to the Board after the Effective Date shall receive his or her Welcome Grant promptly following the date that he or she is so appointed or elected to the Board, upon Board approval thereof. All Welcome Grants shall vest, as to 25% of the restricted stock units, on the first anniversary date of the date of grant thereof with the balance of the restricted stock units vesting in equal monthly installments over the next

succeeding three year period, provided, in all cases, that the non-employee Director is, as of such vesting date, then a director of the Company.

(b) Annual Grants . Annual grants of 12,500 restricted stock units (the "Annual Grants") shall be made to non-employee Directors in addition to the Welcome Grants, which grants shall vest in equal monthly installments over one year, with the first tranche vesting on the one month anniversary of the date of the grant, provided, in all cases, that the non-employee Director is, as of each such vesting date, then a director of the Company.

(c) Exercise Period Upon Departure . If a recipient of an option grant or grants under this Policy (the "Optionee") ceases to be a Director for any reason, any portion of a stock option granted pursuant to this Policy that is outstanding on such date may be exercised, to the extent exercisable on the date the Optionee ceased to be a Director, for a period of three (3) years from the date the Optionee ceased to be a Director or until the expiration date of the applicable option grants, if earlier. Any portion of a stock option granted pursuant to this Policy that is not exercisable on the date the Optionee ceases to be a Director shall terminate immediately and be of no further force or effect.

The foregoing compensation will be in addition to reimbursement of all out-of-pocket expenses incurred by non-employee Directors in attending meetings of the Board.

Exhibit 31.1

CERTIFICATION PURSUANT TO
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Linda S. Grais, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ocera Therapeutics, Inc. (the registrant);

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2017

By: /s/ Linda S. Grais, M.D.

Linda S. Grais, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Michael Byrnes, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ocera Therapeutics, Inc. (the registrant);

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2017

By: /s/ Michael Byrnes

Michael Byrnes

Chief Financial Officer and Treasurer

(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Ocera Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Linda S. Grais, M.D., President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that: (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated in the Report.

Date: May 9, 2017

By: /s/ Linda S. Grais, M.D.

Linda S. Grais, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Ocera Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael Byrnes, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that: (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated in the Report.

Date: May 9, 2017

By: /s/ Michael Byrnes

Michael Byrnes

Chief Financial Officer and Treasurer

(Principal Financial and Accounting Officer)