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 September 30, 2016

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.)
525 University Avenue, Suite 610 **Palo Alto, CA**	**94301**
(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 ☐

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 October 31, 2016 was 23,143,938.

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 number, timing, design, results and implementation of our clinical trials and nonclinical activities for OCR-002 and the timing of the availability of data from these trials and activities;
- our ability to enroll patients, and the timing of enrollment, in our clinical trials, including our Phase 2b clinical trial of OCR-002;
- 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 or access additional proceeds under the 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, 2015 and our other prior 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, 2015 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. Unaudited Condensed Consolidated Financial Statements

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

	September 30, 2016 (unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 29,215	$ 35,921
Short-term investments, available-for-sale	3,249	7,415
Prepaid expenses and other current assets	773	686
Total current assets	33,237	44,022
Property and equipment, net	63	94
Deposits	36	26
Goodwill	595	595
Total assets	$ 33,931	$ 44,737
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,055	$ 701
Accrued liabilities	3,255	3,133
Notes payable - short term	1,963	—
Total current liabilities	7,273	3,834
Notes payable - long term	7,689	9,508
Other liabilities	123	1
Total liabilities	15,085	13,343
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, 23,075,831 issued and outstanding at September 30, 2016 and 20,695,160 shares issued and outstanding at December 31, 2015.	—	—
Additional paid-in capital	172,022	162,832
Accumulated other comprehensive loss	(1)	(5)
Accumulated deficit	(153,175)	(131,433)
Total stockholders' equity	18,846	31,394
Total liabilities and stockholders' equity	$ 33,931	$ 44,737

See the accompanying notes to the unaudited condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Royalty revenue	$ 38	$ 35	$ 97	$ 109
Operating expenses:				
Research and development	4,283	4,235	12,939	12,050
General and administrative	2,618	2,372	8,142	7,460
Amortization of intangibles	—	41	—	123
Total operating expenses	6,901	6,648	21,081	19,633
Other (expense) income:				
Interest and other income	20	23	83	71
Interest and other expense	(282)	(203)	(841)	(213)
Other (expense) income, net	(262)	(180)	(758)	(142)
Net loss from continuing operations	(7,125)	(6,793)	(21,742)	(19,666)
Net income from discontinued operations (See Note 8)	—	219	—	219
Net loss	$ (7,125)	$ (6,574)	$ (21,742)	$ (19,447)
Net loss per share:				
Net loss per share from continuing operations, basic and diluted	$ (0.32)	$ (0.34)	$ (1.01)	$ (0.99)
Net income per share from discontinued operations, basic and diluted	—	0.01	—	0.01
Net loss per share, basic and diluted	$ (0.32)	$ (0.33)	$ (1.01)	$ (0.98)
Weighted average number of shares used to compute net loss per share of common stock, basic and diluted	22,096,610	20,183,939	21,532,953	19,902,815
Comprehensive loss:				
Net loss	$ (7,125)	$ (6,574)	$ (21,742)	$ (19,447)
Unrealized (loss) gain on investments	(1)	4	4	30
Comprehensive loss	$ (7,126)	$ (6,570)	$ (21,738)	$ (19,417)

See the accompanying notes to the unaudited condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2016	**2015**
Operating activities		
Net loss	$ (21,742)	$ (19,447)
Adjustments to reconcile net loss to net cash used in operating activities:		
Net income from discontinued operations	—	(219)
Depreciation	34	23
Amortization of intangibles	—	123
Stock-based compensation	3,168	2,860
Amortization of premium on marketable securities	40	321
Amortization of debt discount	144	31
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(97)	354
Accounts payable	1,354	73
Accrued and other liabilities	244	531
Net cash used in continuing operating activities	(16,855)	(15,350)
Net cash provided by discontinued operating activities	—	219
Net cash used in operating activities	(16,855)	(15,131)
Investing activities		
Purchases of property and equipment	(3)	(71)
Purchases of marketable securities	(7,004)	(23,320)
Proceeds from maturities of marketable securities	11,134	38,952
Deposits on equipment	—	(18)
Net cash provided by investing activities	4,127	15,543
Financing activities		
Proceeds from sale of common stock, net of underwriting discounts and issuance cost	5,996	2,480
Proceeds from notes payable, net	—	9,748
Proceeds from exercise of common stock options	26	—
Net cash provided by financing activities	6,022	12,228
Net (decrease) increase in cash and cash equivalents	(6,706)	12,640
Cash and cash equivalents—beginning of period	35,921	10,127
Cash and cash equivalents—end of period	$ 29,215	$ 22,767
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 621	$ 71
Supplemental schedule of noncash investing and financing activities		
Fair value of warrants issued in connection with notes payable	$ —	$ 317
Issuance costs related to at the market equity program in accounts payable and accrued expenses	$ —	$ 23
Unrealized gain on investments	$ 4	$ 30

See the accompanying notes to the unaudited condensed consolidated financial statements.

1. The Company

Ocera Therapeutics, Inc. (the "Company") is a clinical-stage biopharmaceutical company focused on the development and commercialization of OCR-002 (ornithine phenylacetate). OCR-002 is an ammonia scavenger which has been granted orphan drug designation and Fast Track status by the U.S. Food and Drug Administration for the treatment of hyperammonemia and resultant hepatic encephalopathy in patients with liver cirrhosis, acute liver failure and acute-on-chronic liver disease.

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's business is subject to significant risks consistent with biopharmaceutical companies seeking to develop technologies and product candidates for human therapeutic use. These risks include, but are not limited to, uncertainties regarding research and development, access to capital, obtaining and enforcing patents, receiving regulatory approval and competition with other biotechnology and pharmaceutical companies.

The Company has a limited operating history and the sales and income potential of the Company's business and market are unproven. As of September 30, 2016 , the Company has incurred losses since inception of $ 153.2 million . The Company anticipates that it will continue to incur net losses into the foreseeable future as it continues its efforts to develop and commercialize OCR-002 and as it expands its corporate infrastructure. Based on the Company's current operating plan, the Company believes its working capital is sufficient to fund its operations through at least the next twelve months.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company and its 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. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. This quarterly report should be read in conjunction with the consolidated financial statements and related notes included in the Company’s annual report on Form 10-K for the year ended December 31, 2015.

Unaudited Interim Financial Information

The accompanying 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 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 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.

Investments in Marketable Securities

All investments in marketable securities have been classified as "available-for-sale" and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Unrealized gains and losses are excluded from earnings and are reported as a component of accumulated comprehensive income. Realized gains and losses and declines in fair value judged to be other than temporary, if any, on investments in marketable securities are included in interest and other income (expense), net. The cost of securities sold is based on the specific-identification method. Interest earned on investments in marketable securities is included in interest and other income.

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. Unless otherwise discussed, standards that do not require adoption until a future date are not expected to have a material impact on the Company's condensed consolidated financial statements upon adoption.

Recent Accounting Updates Not Yet Effective

In August 2016, the FASB issued Accounting Standards Update (“ASU”) 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 2016-15 is effective for annual reporting periods, and interim periods therein, beginning after December 15, 2017. The Company is currently evaluating the impact that the adoption of this standard will have on its condensed consolidated financial statements.

In March 2016, the FASB issued ASU 2016-06, Derivatives and Hedging (Topic 815), Contingent Put and Call Options in Debt Instruments. This ASU clarifies the requirements for assessing whether contingent call (put) options that can accelerate the payment of principal on debt instruments are clearly and closely related to their debt hosts. An entity performing the assessment under the amendments in this ASU is required to assess the embedded call (put) options solely in accordance with the four-step decision sequence. The new standard simplifies the embedded derivative analysis for debt instruments containing contingent call or put options by removing the requirement to assess whether a contingent event is related to interest rates or credit risks. This guidance should be applied on a modified retrospective basis to existing debt instruments as of the beginning of the fiscal year in which the amendments are effective, and is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The Company is currently evaluating the impact that the adoption of this standard will have on its condensed consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting (Topic 718), Compensation - Stock Compensation. The new guidance simplifies several aspects of the accounting for share-based payments, including immediate recognition of all excess tax benefits and deficiencies in the income statement, changing the threshold to qualify for equity classification up 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. ASU 2016-09 is effective for annual reporting periods beginning after December 15, 2016, and interim periods within that reporting period. The Company is currently evaluating the impact that the adoption of this standard will have on its condensed consolidated financial statements.

In February 2016, the FASB issued ASU 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 condensed consolidated financial statements.

In May 2014, the FASB issued ASU 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 2016-08 *Revenue From Contracts With Customers* : *Principal vs. Agent Considerations* and ASU 2016-10 *Revenue From Contracts with Customers: Identifying Performance Obligations and Licensing* to provide supplemental adoption guidance and clarification to ASU 2014-09. The Company is currently evaluating the impact that the adoption of this standard will have on its condensed consolidated financial statements.

3. Fair Value Measurements

Financial assets and liabilities are recorded at fair value. The carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents, prepaid expenses and other current assets, accounts payable, and accrued liabilities and deferred revenue, approximate their fair value due to their short maturities. Short-term and long-term debt are reported at their respective amortized cost on its condensed consolidated balance sheets. The remaining financial instruments are reported on its condensed consolidated balance sheets at amounts that approximate current fair values.

The following tables present information about the Company’s financial assets measured at fair value on a recurring basis as of September 30, 2016 , and December 31, 2015, 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.

None of the Company’s non-financial assets and liabilities are recorded at fair value on a non-recurring basis. No transfers between fair value hierarchy levels have occurred during the periods presented.

Assets measured at fair value on a recurring basis as of September 30, 2016 consisted of the following *(in thousands):*

	Balance as of September 30, 2016	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	$ 28,599	$ 28,599	$ —	$ —
Commercial paper	1,493	—	1,493	—
Corporate debt securities	3,008	—	3,008	—
	$ 33,100	$ 28,599	$ 4,501	$ —

Assets measured at fair value on a recurring basis as of December 31, 2015 consisted of the following *(in thousands):*

	Balance as of December 31, 2015	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	$ 34,806	$ 34,806	$ —	$ —
Corporate debt securities	7,415	—	7,415	—
	$ 42,221	$ 34,806	$ 7,415	$ —

The Company estimates the fair value of commercial paper and corporate debt securities by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker quotes on the same or similar securities; issuer credit spreads; benchmark securities; prepayment or default projections based on historical data; and other observable inputs.

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 currently available to the Company.

4. Balance Sheet Components

Investments in Marketable Securities

The following table summarizes the Company's available for sale investments as of September 30, 2016 *(in thousands):*

	Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Short-term investments:					
Commercial paper	1 or less	$ 1,493	$ —	$ —	$ 1,493
Corporate debt securities	1 or less	1,757	—	(1)	1,756
Total short-term investments		$ 3,250	$ —	$ (1)	$ 3,249

The following table summarizes the Company's available for sale investments as of December 31, 2015 *(in thousands):*

	Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Short-term investments:					
Corporate debt securities	1 or less	$ 7,420	$ —	$ (5)	$ 7,415
Total short-term investments		$ 7,420	$ —	$ (5)	$ 7,415

At each reporting date, the Company reviews its investments for impairment to determine if unrealized losses are other-than-temporary. For debt securities, management determines whether it intends to sell the impaired securities, and if there is no intent or expected requirement to sell, management considers whether it is likely that the amortized cost will be recovered. The Company does not consider unrealized losses on its debt investment securities to be credit-related. These unrealized losses relate to changes in interest rates and market spreads subsequent to purchase. The Company has not made a decision to sell securities with unrealized losses and believes it is more likely than not that it would not be required to sell such securities before recovery of its amortized cost. There have been no other-than-temporary losses recognized in earnings in any of the periods presented.

Accrued Liabilities

Accrued liabilities consisted of the following *(in thousands):*

	September 30, 2016	December 31, 2015
Clinical trials	$ 2,152	$ 1,666
Compensation and related expenses	832	993
Professional services	194	319
Interest expense and other	77	155
Total accrued liabilities	$ 3,255	$ 3,133

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 is available for draw until December 31, 2016 at the Company's discretion, subject to achievement of certain financial and clinical milestones. The milestones will be satisfied if the Company (a) has raised proceeds of at least $15.0 million from the sale of equity securities or upfront payments from a partnership agreement and (b) achieved positive data from its ongoing Phase 2b clinical trial of OCR-002.

The annual interest rate for the initial $10.0 million funding is 8.275% , and the interest rate for the second tranche will be fixed upon drawdown at an annual rate that is greater of 8.275% or 8.085% plus the 30-day U.S. LIBOR rate. Loan payments are 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 if the second tranche is not drawn. If the second tranche is drawn, the interest-only period continues to August 1, 2017, followed by 24 equal monthly payments. 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.

At the initial funding, the Company received net proceeds of $9.7 million after fees and expenses. These fees and expenses are being accounted for as a debt discount and classified within notes payable on the Company's condensed consolidated balance sheet. Legal and consulting fees are presented in the condensed consolidated balance sheet as a direct deduction from the carrying amount of the notes liability, consistent with debt discounts. Debt discounts, 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 the Lenders warrants to purchase an aggregate of 97,680 shares of the Company's common stock at an exercise price of $4.095 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 condensed consolidated balance sheet. As of September 30, 2016, the warrants remained outstanding and exercisable. The debt discount is being amortized as interest expense over the term of the Term Loan Facility using the effective interest method.

The Term Loan Facility is secured by substantially all of the assets of the Company and its subsidiaries, except that the collateral does not include any intellectual property held by the Company or its subsidiary. However, the Company has agreed not to encumber any of the intellectual property of the Company or its subsidiary. The Loan Agreement contains customary representations, warranties and covenants by the Company, and customary indemnification obligations and events of default. The Company was in compliance with all covenants set forth in the Loan Agreement as of September 30, 2016 .

The Company recorded interest expense related to the Term Loan Facility of $0.3 million for the three months ended September 30, 2016 , and $0.8 million for the nine months ended September 30, 2016 . The Company recorded $0.2 million of interest expense for the three and the nine months ended September 30, 2015. The annual effective interest rate on the note payable, including the amortization of the debt discounts and accretion of the final payments, is 11.72% .

Future minimum payments under the Loan Agreement as of September 30, 2016 are as follows (*in thousands):*

Years ending December 31:		
2016 (remaining three months)	$	207
2017		3,839
2018		4,442
2019		3,261
Total future minimum payments		11,749
Less amount representing interest		1,749
Notes payable, gross		10,000
Unamortized discount on notes payable		(348)
Notes payable, balance		9,652
Less current portion of notes payable		1,963
Non-current portion of notes payable	$	7,689

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 nine months ended September 30, 2016 , the Company sold an aggregate of 2,340,980 shares of common stock under the Sales Agreement, at an average price of approximately $2.68 per share, for gross proceeds of $6.3 million and net proceeds of $6.0 million after deducting commissions and other transactions costs. During the nine months ended September 30, 2015, proceeds from issuance of common stock under the Sales Agreement were $2.5 million after deducting commissions and other transaction costs.

As of September 30, 2016 , $15.0 million of common stock remained available to be sold under the Sales Agreement, subject to certain conditions specified therein.

In September 2016, the Company issued 15,753 shares of common stock pursuant to the cashless exercise of certain warrants at an exercise price of $0.67 price per share.

7. Stock-Based Compensation

The Company’s stock option awards activity and related information for the nine months ended September 30, 2016 were as follows *(in thousands, except share and per share data):*

	Shares Available for Grant	Stock Options Outstanding	Weighted-avg. Exercise Price Per Share	Weighted-avg. Remaining Contractual Life (in Years)	Aggregate Intrinsic Value
Balance at December 31, 2015	1,299,301	2,429,511	$ 7.00	8.01	$ 287
Additional shares authorized	1,400,000	—			
Stock options granted	(1,537,000)	1,537,000	$ 2.94		
Stock options canceled	354,951	(354,951)	$ 7.00		
Stock options exercised	—	(23,938)	$ 1.09		
Balance at September 30, 2016	1,517,252	3,587,622	$ 5.30	7.88	$ 230
At September 30, 2016:					
Vested and expected to vest		3,474,777	$ 5.36	7.84	$ 228
Exercisable		1,532,114	$ 7.16	6.48	$ 187

The aggregate intrinsic value of options exercised under all option plans was $42,000 for the nine months ended September 30, 2016 determined as of the date of option exercise. No options were exercised during the nine months ended September 30, 2015.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development	$ 139	$ 192	$ 516	$ 456
General and administrative	864	766	2,652	2,404
Total	$ 1,003	$ 958	$ 3,168	$ 2,860

At September 30, 2016 , there were 111,000 unvested options outstanding with performance conditions related to the achievement of certain clinical milestones. During the three and nine months ended September 30, 2016 , stock-based compensation expense recorded for theses performance-based options was insignificant to the interim condensed consolidated financial statements.

In April 2016, the Company's board of directors approved an amendment and restatement of the Company's Fourth Amended and Restated 2011 Stock Option and Incentive Plan (the "2011 Plan") to, among other things, increase the maximum number of shares that may be issued under the 2011 Plan from 3,602,328 to 5,002,328 shares. The amendment and restatement of the 2011 Plan was approved by the Company's stockholders on June 14, 2016 .

As of September 30, 2016 , there was unrecognized stock-based compensation expense of $6.2 million related to stock options. The Company expects to recognize those costs over a weighted average period of 2.16 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 ranges of weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Expected dividend yield	—	—	—	—
Risk-free interest rates	0.59% - 1.39%	1.59% - 1.64%	0.59% - 1.97%	1.52% - 2.08%
Expected term in years	0.95 - 4.43	5.52 - 6.08	0.95 - 8.14	5.49 - 8.06
Expected volatility	73% - 87%	78% - 80%	73% - 94%	78% - 92%

On January 6, 2016 , the Company granted certain of its executive officers non-qualified stock options to purchase 206,625 shares of the Company's common stock that vest on a monthly basis in equal installments over 48 months following the grant date if the Company's stock price equals or exceeds $6.00 for 20 consecutive trading days on or before June 30, 2017 . The options expire ten years from the date of the grant.

The fair values of these options were determined using a Monte Carlo simulation model incorporating the following ranges of weighted-average assumptions:

	Nine Months Ended September 30, 2016
Expected dividend yield	—
Risk-free interest rates	1.82% - 2.05%
Expected term in years	6.02 - 8.00
Expected volatility	77% - 89%
Weighted-average fair value per share	1.33 - 1.42

The estimated expense for these awards is being recognized on an accelerated basis over the estimated requisite service period, with no adjustments in the future periods based upon the Company's actual common stock price. The Company recorded $0.1 million in stock-based compensation expense during the nine months ended September 30, 2016 in connection with such awards. Stock-based compensation expense related to these awards was insignificant during the three months ended September 30, 2016 .

8. Discontinued Operations

On September 11, 2013, the Company announced a restructuring plan related to the operations of Tranzyme Pharma Inc. ("Tranzyme Pharma"). On December 13, 2013, the Company entered into a Technology Transfer and License Agreement with Genentech, Inc. ("Genentech"), and F. Hoffman-La Roche, Ltd. ("Roche") to sell certain Canadian fixed assets and materials, the MATCH technology and rights to the Genentech and Roche customer agreements and related intellectual property through licensing of patents for $4.0 million . The Company concluded that the operations of Tranzyme Pharma and related asset groups sold to Genentech and Roche would be accounted for as discontinued operations as the operations and cash flows of the discontinued component or asset group would be eliminated from ongoing operations of the Company and there would not be significant involvement in the component or asset group after the disposal transaction.

In 2014, the Company completed its obligations under the Technology Transfer and License Agreement with Genentech and Roche and recognized a gain on disposal of assets of $1.1 million within discontinued operations. There was $0.2 million in income recorded in discontinued operations for the three and nine months ended September 30, 2015 that relates to certain foreign research credits received.

9. 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 share 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 the effect of their inclusion would be anti-dilutive. For all periods presented, diluted and basic net loss per share were identical due to the Company's net loss position.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Numerator				
Net loss from continuing operations	$ (7,125)	$ (6,793)	$ (21,742)	$ (19,666)
Net income from discontinued operations	—	219	—	219
Net loss	$ (7,125)	$ (6,574)	$ (21,742)	$ (19,447)
Denominator				
Weighted average common shares outstanding used to compute net loss per share, basic and diluted	22,096,610	20,183,939	21,532,953	19,902,815
Net loss per share of common stock, basic and diluted				
Net loss per share from continuing operations	$ (0.32)	$ (0.34)	$ (1.01)	$ (0.99)
Net income per share from discontinued operations	—	0.01	—	0.01
Net loss per share	$ (0.32)	$ (0.33)	$ (1.01)	$ (0.98)

The following weighted average 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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Common stock warrants	1,021,651	997,839	1,024,705	954,345
Common stock options	3,646,426	2,340,054	3,652,762	2,134,428
Total	4,668,077	3,337,893	4,677,467	3,088,773

The Company has utilized the control number concept in the computation of diluted earnings per share to determine whether potential common stock instruments are dilutive. The control number used is loss from continuing operations. The control number concept requires that the same number of potentially dilutive securities applied in computing diluted earnings per share from continuing operations be applied to all other categories of income or loss, regardless of their anti-dilutive effect on such categories. Therefore, no dilutive effect has been recognized in the calculation of income from discontinued operations per share for the three and nine months ended September 30, 2015.

10. Subsequent Events

Pursuant to the Company's "at the market" equity program, since September 30, 2016, the Company has sold an aggregate of 68,107 shares of common stock under the Sales Agreement at an average price of approximately $2.60 per share for gross proceeds of approximately $0.2 million .

In September 2014, the Company entered into an asset license and purchase agreement for the sale and license of *ulimorelin* (the "Lyric Agreement"), the former lead compound of Tranzyme, to Lyric Pharmaceuticals, Inc. ("Lyric"). In October 2016, Lyric achieved a milestone under the Lyric Agreement, and accordingly, the Company will record $0.1 million in related milestone revenue during the fourth quarter of 2016.

In October 2016, the Company assigned its rights to certain non-core intellectual property acquired in the Merger with Tranzyme to GE Healthcare Dharmacon, Inc. ("GE"), formerly known as Open Biosystems, Inc. In connection with the assignment, the Company's existing license and marketing agreement with GE terminated and all future royalty payments payable from GE to the Company will cease. In consideration for the assignment, the Company will receive a one-time payment of $0.5 million from GE.

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, 2015 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, 2015 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 focused on acute and chronic orphan liver diseases. Our initial focus is on the development and commercialization of a clinical candidate, OCR-002, for the treatment of 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 in the United States there are approximately eight million individuals with some form of chronic liver disease, of which one million have cirrhosis. Of the one million individuals in the United States that have cirrhosis, it is estimated that approximately 500,000 are at risk for developing HE.

OCR-002 is a novel molecule, ornithine phenylacetate, which functions as an ammonia scavenger. In pre-clinical studies, OCR-002 significantly reduced arterial ammonia and cerebral edema in an animal model of chronic liver disease and significantly attenuated arterial ammonia, extracellular brain ammonia and intracranial pressure in a second animal model of acute liver failure.

We are currently conducting a randomized, placebo-controlled double blind Phase 2b clinical trial to evaluate the safety and efficacy of intravenous administration of OCR-002 in reducing the severity of HE symptoms among hospitalized HE patients. In March 2015, an independent data monitoring committee, or DMC, conducted an interim analysis, reporting that the trial was not futile and that no clinically significant safety concerns were observed. In addition, the DMC recommended that we continue the trial and increase target enrollment from 140 patients to approximately 230 patients. This sample size recommendation allows the trial to maintain 80% statistical power to observe the treatment effect at the conclusion of the trial that was observed by the DMC at the time of the interim analysis. The trial is currently being conducted in approximately 100 sites worldwide and as of October 31, 2016, over 220 patients have been enrolled in total. We expect to complete enrollment in the fourth quarter of 2016 and announce topline data in the first quarter of 2017.

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 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 pharmacokinetic, or 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. Based on the strength of these results and the prior clinical proof of concept established with RAVICTI® in preventing recurrent HE in patients suffering from liver cirrhosis and a prior history of HE, we plan to continue development of oral OCR-002. In September 2016 we initiated part one of a two-part Phase 1 clinical trial in patients with cirrhosis. Part 1 will evaluate the pK and bioavailability of a single oral dose of OCR-002 in cirrhotic patients dosed under certain conditions. Part 2 is expected to be a multi-dose study which will include the evaluation of steady state pK and the formation of PAGN. Data from Part 1 of this study is expected to be available by year-end 2016. We expect to complete Part 2 of this study, with data available, in the first half of 2017.

In 2012, we completed a Phase 1 pK and safety clinical trial of the intravenous form of OCR-002. A Phase 2a investigator-sponsored trial in Spain evaluated OCR-002 in patients with upper gastrointestinal bleeding associated with liver cirrhosis. These patients tend to have elevated ammonia levels because they swallow blood, which produces more ammonia as it is digested. In the first part of this trial, a 10-patient open label safety cohort, OCR-002 was shown to lower ammonia when administered as a continuous intravenous infusion of up to 10 grams per 24 hours. In February 2015, we announced the preliminary topline results of the second part of this trial, which was a randomized, placebo-controlled cohort of 38 patients. The data showed that over the first 12 hours of dosing, OCR-002 lowered ammonia by 19.6% compared to 3.2% in the placebo group, but this difference did not reach statistical significance. A statistically significant difference in urinary excretion of ammonia, as measured by PAGN, was observed and OCR-002 demonstrated a favorable safety profile and appeared to be well tolerated.

In addition, the investigator-sponsored Phase 2a clinical trial conducted by the National Institutes of Health, or NIH, to evaluate the safety and pK of OCR-002 in patients with hyperammonemia and HE due to acute liver failure or injury, was completed in September 2016. In November 2015, the NIH announced preliminary pK data on 24 patients and concluded that OCR-002 was safe and well-tolerated at the levels administered, up to 10 grams per 24 hours. A correlation was observed between the doses administered and the drug levels seen in the blood, but even at the 10 gram dose, the investigators deemed the exposure of the drug to be below the desired range. In September 2016, the NIH completed enrollment of an additional 12 patients at a higher dose of 20 grams per 24 hours. No drug-related serious adverse events were observed in this study and all doses were well tolerated. In addition, therapeutic serum levels of PAA were achieved at infusion rates of OCR-00 20g/24hrs, resulting in considerable ammonia excretion in urine as PAGN, even in patients with non-oliguric renal failure. Additional data from this study is expected to be available by the end of 2016.

Our strategy is to focus clinical development activities on the intravenous form of OCR-002 to treat acute HE in hospitalized patients and on the oral form of OCR-002, which will be directed to chronic care of HE patients.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated 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 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, 2015. For the nine months ended September 30, 2016, 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

Three Months and Nine Months Ended September 30, 2016 and 2015 (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2016	2015	$ Change	2016	2015	$ Change
Royalty revenue	$ 38	$ 35	$ 3	$ 97	$ 109	$ (12)
Operating expenses:						
Research and development	4,283	4,235	48	12,939	12,050	889
General and administrative	2,618	2,372	246	8,142	7,460	682
Amortization of intangibles	—	41	(41)	—	123	(123)
Total operating expenses	6,901	6,648	253	21,081	19,633	1,448
Total other income (expense)	(262)	(180)	(82)	(758)	(142)	(616)
Net loss from continuing operations	(7,125)	(6,793)	(332)	(21,742)	(19,666)	(2,076)
Net income from discontinued operations	—	219	(219)	—	219	(219)
Net loss	$ (7,125)	$ (6,574)	$ (551)	$ (21,742)	$ (19,447)	$ (2,295)

Revenues

We generated $38,000 in royalty revenue for the three months ended September 30, 2016 compared to $35,000 in royalty revenue for the three months ended September 30, 2015. We generated $97,000 in revenue for the nine months ended September 30, 2016 compared to $109,000 in revenue for the nine months ended September 30, 2015. The revenue in all periods was attributable to a license agreement that we acquired from Tranzyme in connection with the Merger.

Costs and Expenses

Research and Development Expenses

Research and development expenses increased marginally during the three months ended September 30, 2016 when compared with the same period in 2015. Research and development expense increased by $0.9 million , during the nine months ended September 30, 2016 , as compared to the same period ended in September 30, 2015 . The increase was primarily driven by an increase in headcount and related costs.

Expenses related to clinical trials are based on estimates of patient enrollment and related expenses at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that may be used to conduct and manage clinical trials on our behalf. We generally accrue expenses related to clinical trials based on contracted amounts applied to the level of patient enrollment and activity. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, we cannot reasonably estimate the cost to complete projects and development timelines for their completion. Enrollment in clinical trials might be delayed or occur faster than anticipated for reasons beyond our control, requiring additional cost and time or accelerating spending. Results from clinical trials might not be favorable, or might require us to perform additional unplanned clinical trials, accelerating spending, requiring additional cost and time, or resulting in termination of the project. Regulatory reviews can also be delayed. Process development and manufacturing scale-up for production of clinical and commercial product supplies might take longer and cost more than our forecasts. As a result, clinical development and regulatory programs are subject to risks and changes that might significantly impact cost projections and timelines. We will need to raise significant additional capital to advance the development and commercialization of OCR-002, which may include entering into strategic alliances.

General and Administrative Expenses

Our general and administrative expenses increased by $0.2 million and $0.7 million during the three and nine months ended September 30, 2016 , respectively, as compared to the same periods in 2015. The increases were primarily due to increased personnel-related costs, including stock-based compensation expense, as well as costs associated with professional services fees.

We expect that general and administrative expenses may increase in the future as we expand our operating activities, maintain and expand our patent portfolio and potentially expand our infrastructure.

Other Income (Expense)

Our net other expense increased by $ 0.1 million and $0.6 million for the three and nine months ended September 30, 2016 , respectively, as compared to the same periods in 2015. The increases were primarily due to increases in interest expense and amortization of debt issuance costs related to the debt facility that closed in the third quarter of 2015.

Net income from discontinued operations

During the three and nine months ended September 30, 2015, $0.2 million of income was recorded within discontinued operations. This related to certain foreign research credits received in the third quarter 2015.

Liquidity and Capital Resources

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2016 and 2015 *(in thousands):*

	Nine Months Ended September 30,	
	2016	**2015**
Cash flow from:		
Continuing operating activities	$ (16,855)	$ (15,350)
Discontinued operating activities	—	219
Investing activities	4,127	15,543
Financing activities	6,022	12,228
Net decrease in cash and cash equivalents	$ (6,706)	$ 12,640

Comparison of the Nine Months Ended September 30, 2016 and 2015

Cash used in continuing operating activities for the nine months ended September 30, 2016 was attributable to our net loss from operations of $21.7 million partially offset by changes in operating assets and liabilities of $ 1.5 million and non-cash charges of $ 3.4 million including stock-based compensation expense, accretion of premiums on investment in marketable securities and amortization of debt discount. Cash used in continuing operating activities for the nine months ended September 30, 2015 was attributable to our net loss from continuing operations of $19.7 million partially offset by changes in operating assets and liabilities of $1.0 million and non-cash charges of $3.4 million including stock-based compensation expense and accretion of premium on investment of securities.

Cash provided by discontinued operating activities for the nine months ended September 30, 2015 primarily reflected certain foreign research credits received.

Cash provided by investing activities for the nine months ended September 30, 2016 consisted of $11.1 million of proceeds from investment maturities partially offset by purchases of investments of $7.0 million . Cash provided by investing activities for the nine months ended September 30, 2015 related to $39.0 million of proceeds from investment maturities partially offset by purchases of investments of $23.3 million.

Cash provided by financing activities for the nine months ended September 30, 2016 consisted of net proceeds from the issuance of common stock pursuant to the “at the market” equity program of $ 6.0 million . Cash provided by financing activities for the nine months ended September 30, 2015 related to net proceeds from the issuance of notes payable of $9.7 million and net proceeds from the issuance of common stock pursuant to the “at the market” equity program of $2.5 million.

Debt Facility

On July 30, 2015, we entered into a Loan and Security Agreement, or the Loan Agreement, with Oxford Finance LLC and Silicon Valley Bank, or collectively, the Lenders. The Loan Agreement provides up to $20 million principal in new term loans, $10 million of which was funded on July 30, 2015. The remaining $10 million is available for draw until December 31,

2016 at the Company's discretion, subject to achievement of certain financial and clinical milestones. We refer to this facility as the Term Loan Facility.

The term loan repayment schedule provides for interest only payments (i) through either February 1, 2017 or August 1, 2017 with respect to the first $10 million of the term loans, depending on whether the remaining term loans have been funded within a certain period set forth in the Loan Agreement, and (ii) through August 1, 2017 with respect to the remaining $10 million of term loans, in each case followed by consecutive equal monthly payments of principal and interest in arrears starting on such dates and continuing through the maturity date of August 1, 2019. The Loan Agreement provides for an interest rate equal to the greater of (i) 8.275% or (ii) the sum of the thirty-day U.S. LIBOR rate for five days prior to the funding date of the applicable term loan plus 8.085%. The Loan Agreement also provides for a final interest payment equal to 3.0% of the original principal amount of the first $10 million in term loans and 1.325% of the original principal amount of the remaining $10 million in term loans, or $432,500, 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 Ocera Subsidiary. 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 subsidiary. The Loan Agreement contains customary representations, warranties and covenants by us, which covenants 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 are required to maintain with Silicon Valley Bank 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, which is defined as 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.

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 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 will be sufficient to fund our operations for at least the next twelve months.

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 nine month period ended September 30, 2016, we sold an aggregate of 2,340,980 shares of common stock under the Sales Agreement, at an average sale price of approximately $2.68 per share for gross proceeds of $6.3 million and net proceeds of $6.0 million after deducting

commissions and other transaction costs. As of September 30, 2016 , $15.0 million of common stock 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. For example, our OCR-002 Phase 2b clinical trial may cost more than we expect, or development of the oral formulation of OCR-002 may involve the license of proprietary technology. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidate, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. 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.

Our ability to finance operations beyond our current resources will depend heavily on our ability to fully and timely enroll patients and obtain favorable results in clinical trials of OCR-002 and to develop and commercialize OCR-002 successfully. For example, we may not access the second tranche of the Term Loan Facility unless we satisfy the following milestones by December 31, 2016: (a) we have raised proceeds of at least $15.0 million from the sale of equity securities or upfront payments from a partnership agreement and (b) we have achieve positive data from its ongoing Phase 2b clinical trial of OCR-002. Based on our current projections, we do not expect to have topline data from our Phase 2b clinical trial of OCR-002 until the first quarter of 2017. As a result, unless the Term Loan Facility is amended, we may not be able to access the $10.0 million second tranche.

Additional financing may not be available when we need it or may not be available on terms that are favorable to us. We may elect to raise additional funds even before we need them if the conditions for raising capital are favorable. We may seek to raise additional capital through a combination of private and public equity offerings and debt financings. To the extent that we raise 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 our Term 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.

Contractual Obligations

The following table summarizes our future contractual obligations as of September 30, 2016 *(in thousands):*

	Payments due by period				
	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	Total
Note payable obligations, including interest (1)	$ 207	$ 8,281	$ 3,261	$ —	$ 11,749
Operating lease obligations	$ 111	$ 325	$ 8	$ —	$ 444
Other non-cancellable commitments (2)	$ 218	$ —	$ —	$ —	$ 218
Total	$ 536	$ 8,606	$ 3,269	$ —	$ 12,411

(1) Upon the occurrence of an event of default, as defined in the Loan Agreement, and during the continuance of an event of default, a default interest rate of an additional 5% will be applied to the outstanding loan balances, and the Lenders may declare all outstanding obligations immediately due and payable.

(2) Contractual obligations and commitments under clinical contracts that are non-cancellable.

We have license milestone obligation payments that are not included in the table above because the Company cannot determine when or if the payments will occur. In the normal course of business, we enter into various firm purchase commitments and other contractual obligations which are cancellable within ninety days or less and are not a part of the future contractual obligations table above.

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 the 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, 2015. 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 September 30, 2016, 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, 2015, 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, 2015.

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
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
+Attached as Exhibits 101 to this report are the following financial statements from our Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, 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: November 2, 2016

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

Date: November 2, 2016

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

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: November 2, 2016

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: November 2, 2016

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 June 30, 2016, 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.

Date: November 2, 2016

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 June 30, 2016, 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.

Date: November 2, 2016

By: /s/ Michael Byrnes

Michael Byrnes

Chief Financial Officer and Treasurer

(Principal Financial and Accounting Officer)