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, 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, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer" "accelerated filer" "smaller reporting company" and "emerging growth 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 October 31, 2017, was 26,514,134.

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 closing of the Tender Offer (as defined in Note 10 to the Financial Statements) and the Merger (as defined in Note 10 to the Financial Statements) and the effects of its pendency on our operations and business;
- the timing of our planned meetings 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 complete our Phase 2a clinical trial of an oral formulation of 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)

	September 30, 2017 (Unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 14,352	$ 24,611
Short-term marketable securities	—	3,749
Prepaid expenses and other current assets	607	584
Total current assets	14,959	28,944
Property and equipment, net	35	64
Deposits	—	36
Goodwill	595	595
Total assets	$ 15,589	$ 29,639
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,684	$ 1,215
Accrued liabilities	2,687	2,839
Notes payable, short-term (Note 5)	7,373	9,703
Total current liabilities	11,744	13,757
Other liabilities	—	145
Total liabilities	11,744	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, 26,514,134 issued and outstanding at September 30, 2017 and 23,600,242 shares issued and outstanding at December 31, 2016.	—	—
Additional paid-in capital	181,258	174,065
Accumulated deficit	(177,413)	(158,328)
Total stockholders' equity	3,845	15,737
Total liabilities and stockholders' equity	$ 15,589	$ 29,639

See the accompanying notes to the unaudited condensed 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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Royalty revenue	$ —	$ 38	$ —	$ 97
Operating expenses:				
Research and development	3,776	4,283	11,089	12,939
General and administrative	2,301	2,618	7,325	8,142
Total operating expenses	6,077	6,901	18,414	21,081
Other income (expense):				
Interest and other income	40	20	104	83
Interest and other expense	(232)	(282)	(775)	(841)
Other expense, net	(192)	(262)	(671)	(758)
Net loss	$ (6,269)	$ (7,125)	$ (19,085)	$ (21,742)
Net loss per share:				
Net loss per share, basic and diluted	$ (0.24)	$ (0.32)	$ (0.74)	$ (1.01)
Weighted average number of shares used to compute net loss per share, basic and diluted	26,511,064	22,096,610	25,663,158	21,532,953
Comprehensive loss:				
Net loss	$ (6,269)	$ (7,125)	$ (19,085)	$ (21,742)
Unrealized (loss) gain on investments	—	(1)	—	4
Comprehensive loss	$ (6,269)	$ (7,126)	$ (19,085)	$ (21,738)

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

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

	Nine Months Ended September 30,	
	2017	**2016**
Operating activities		
Net loss	$(19,085)	$(21,742)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	29	34
Stock-based compensation	2,892	3,168
Amortization of premiums (discounts) on marketable securities, net	(2)	40
Amortization of debt discount	140	144
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	13	(97)
Accounts payable	469	1,354
Accrued liabilities	(615)	244
Net cash used in operating activities	(16,159)	(16,855)
Investing activities		
Purchases of property and equipment	—	(3)
Purchases of marketable securities	(399)	(7,004)
Maturities of marketable securities	4,150	11,134
Net cash provided by investing activities	3,751	4,127
Financing activities		
Proceeds from sale of common stock, net of underwriting commissions and issuance cost	4,301	5,996
Repayments on notes payable	(2,152)	—
Proceeds from exercise of common stock options	—	26
Net cash provided by financing activities	2,149	6,022
Net decrease in cash and cash equivalents	(10,259)	(6,706)
Cash and cash equivalents, beginning of period	24,611	35,921
Cash and cash equivalents, end of period	$ 14,352	$ 29,215
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 577	$ 621

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

Ocera Therapeutics, Inc.
Notes to Condensed 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, 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 September 30, 2017, the Company has an accumulated deficit of $177.4 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 into 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.

Further, as discussed in Note 10, on November 2, 2017, the Company announced that it had entered into a definitive agreement to be acquired by an affiliate of Mallinckrodt plc ("Mallinckrodt"). Should the proposed acquisition not be completed, the Company plans to fund its operations by raising 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 the Company's 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 the Company's 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 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. 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 do 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.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less at the date of purchase to be cash equivalents. Cash and cash equivalents may include money market funds, various deposit accounts, commercial paper and reverse repurchase agreements with original maturities of three months or less.

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. The Company adopted this ASU during the first quarter of 2017, and as a result of the adoption, 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 May 2017, the FASB issued ASU No. 2017-09, Compensation-Stock Compensation (Topic 718), Scope of Modification Accounting. ASU No. 2017-09 provides clarification on when modification accounting should be used for changes to the terms or conditions of a share-based payment award. The ASU does not change the accounting for modifications, but clarifies that modification accounting guidance should only be applied if there is a change to the value, vesting conditions, or award classification and would not be required if the changes are considered non-substantive. The standard will become effective for interim and annual periods beginning after December 15, 2017, with early adoption permitted. ASU 2017-09 is to be applied on a prospective basis to an award modified on or after the adoption date. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

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. In September 2017, the FASB issued ASU No. 2017-13, Revenue Recognition (Topic 605), Revenue from Contracts with Customers (Topic 606), Leases (Topic 840), and Leases (Topic 842), which provided additional implementation guidance on the previously issued ASU. 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. In September 2017, the FASB issued ASU No. 2017-13, Revenue Recognition (Topic 605), Revenue from Contracts with Customers (Topic 606), Leases (Topic 840), and Leases (Topic 842), which provided additional implementation guidance on the previously issued ASU. 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, but currently does not expect the adoption of this standard to have a material impact on its condensed consolidated financial statements.

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 the accounting pronouncement 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 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 September 30, 2017 are as follows (in thousands):

	Total	Level 1	Level 2	Level 3
Money market funds	$14,352	$14,352	$ —	$ —

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 September 30, 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 September 30, 2017 (in thousands):

	Maturity (In Years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Money market funds	n/a	$ 14,352	$ —	$ —	$ 14,352

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	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

At each reporting date, the Company reviews its investments for impairment to determine if the unrealized losses are other-than-temporary. The Company had no other-than-temporary impairments on these securities as of September 30, 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):

	September 30, 2017	December 31, 2016
Research and development	$ 888	$ 1,519
Compensation and related expenses	876	1,124
Professional services	315	102
Principal payment due on notes payable	316	—
Interest expense on notes payable	271	69
Other	21	25
Total accrued liabilities	$ 2,687	$ 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 September 30, 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 September 30, 2017 and December 31, 2016. The principal and related interest payments due under the Loan Agreement have been classified as current liabilities at September 30, 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 $0.2 million and $0.3 during the three months ended September 30, 2017 and 2016, respectively. Interest expense of $0.8 million were recorded during each of the nine months ended September 30, 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 September 30, 2017 were as follows (in thousands):

Years ending December 31,	
2017 (for the remaining three months) (1)	$ 639
2018	4,022
2019	2,871
Total principal payments	7,532
Unamortized discount on notes payable	(159)
Notes payable, balance	$7,373

(1) Amount does not include the principal amount payable at September 30, 2017, which was included in accrued liabilities (Note 4).

Future interest payments under the Loan Agreement as of September 30, 2017 amounted to $0.9 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 nine months ended September 30, 2017, the Company sold an aggregate of 2,889,015 shares of common stock under the Sales Agreement, at an average price of approximately $1.55 per share, for net proceeds of $4.3 million after deducting commissions and other transaction costs. As of September 30, 2017, $9.3 million of common stock remained available to be sold under the Sales Agreement, subject to certain conditions specified therein.

In September 2017, the Company issued a total of 4,083 shares of common stock pursuant to the cashless exercise of certain warrants at an exercise price of $0.67 per share. 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, which has since been amended and restated and is now referred to as the Ocera Therapeutics, Inc. Fourth Amended and Restated 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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Research and development	$ 246	$ 139	$ 712	$ 516
General and administrative	601	864	2,180	2,652
Total stock-based compensation	$ 847	$ 1,003	$ 2,892	$ 3,168

As of September 30, 2017, there was unrecognized stock-based compensation expense of $3.9 million, which the Company expects to recognize over a weighted average period of 2.03 years.

Stock Options

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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Expected dividend yield	—	—	—	—
Risk-free interest rates	— %	0.59% - 1.39%	— %	0.59% - 1.97%
Expected term in years	—	0.95 - 4.43	—	0.95 - 8.14
Expected volatility	— %	73% - 87%	— %	73% - 94%

Restricted Stock Units

On June 20, 2017, the Company granted its non-employee directors 75,000 RSUs. The RSUs shall vest in full on the earlier of the one year anniversary of the grant or the next annual meeting of shareholders, subject to the recipient's continued service as a director of the Company on each vesting date.

On March 29, 2017, the Company granted 1,065,000 RSUs 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.

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 outstanding warrants, stock options and restricted stock units 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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Numerator				
Net loss	$ (6,269)	$ (7,125)	$ (19,085)	$ (21,742)
Denominator				
Weighted average common shares outstanding used to compute net loss per share, basic and diluted	26,511,064	22,096,610	25,663,158	21,532,953
Net loss per share of common stock, basic and diluted				
Net loss per share	$ (0.24)	$ (0.32)	$ (0.74)	$ (1.01)

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

	September 30, 2017	
	2017	2016
Common stock warrants	863,686	1,003,984
Common stock options	3,644,856	3,587,622
Restricted stock units	1,140,000	—
Total potentially dilutive securities	5,648,542	4,591,606

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, July 2015 and October 2017. Pursuant to the October 2017 amendment, the Company made a non-refundable payment of $0.5 million in October 2017, which shall be credited against the future milestone payments related to clinical and regulatory events for OCR-002. The Company may be required to make future milestone payments to UCL totaling up to $19.5 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

As of September 30, 2017, the Company had $0.2 million in clinical contractual commitments that have not been recognized as a liability on the condensed consolidated balance sheets and are non-cancelable.

Rent

The following is a schedule of non-cancelable future minimum payments for operating leases as of September 30, 2017 (in thousands):

Years ending December 31,	
2017 (for the remaining three months)	$ 99
2018	109
2019 and beyond	8
Total future minimum payments for operating leases	$216

10. Subsequent events

Merger Agreement

On November 1, 2017, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") with MAK LLC, a Delaware limited liability company ("Parent"), MEH Acquisition Co., a Delaware Corporation and a direct wholly-owned subsidiary of Parent ("Purchaser"), and for limited purposes, Mallinckrodt plc, an Irish public limited company and the ultimate parent entity of Parent and Purchaser ("Mallinckrodt").

Pursuant to the terms and subject to the conditions of the Merger Agreement, Purchaser commenced a tender offer (the "Offer") on November 9, 2017 to acquire all of the outstanding shares of the Company's common stock (the "Shares"), at an offer price of (i) $1.52 per Share in cash (approximately $42 million in the aggregate) (the "Closing Amount"), plus (ii) one non-transferable contingent value right per Share (each, a "CVR"), which represents the contractual right under a Contingent Value Rights Agreement (the "CVR Agreement") to be entered into among Parent, Continental Transfer & Trust Company, as rights agent (the "Rights Agent"), and for limited purposes, Mallinckrodt, at or prior to the time that Purchaser accepts for payment all Shares tendered (and not validly withdrawn) pursuant to the Offer (the "Offer Acceptance Time") to receive one

or more payments in cash potentially totaling up to $2.58 per CVR (approximately $75 million in the aggregate) (the "Contingent Consideration"), contingent upon the achievement of certain milestones (one CVR together with the Closing Amount, or any higher amount per Share paid pursuant to the Offer, the "Offer Price"), in each case without any interest thereon and subject to any required tax withholdings. As a result, the maximum amount payable pursuant to the Merger Agreement is $4.10 per Share.

The obligation of Purchaser to purchase Shares tendered in the Offer is subject to the satisfaction or waiver of a number of conditions set forth in the Merger Agreement, including (i) that there shall have been validly tendered and not validly withdrawn Shares that, considered together with all other Shares, if any, beneficially owned by Parent and affiliated entities, represent one more Share than 50% of the total number of Shares outstanding at the time of the expiration of the Offer (calculated on a fully-diluted basis in accordance with the Merger Agreement) (the "Minimum Condition"), and (ii) those other conditions set forth in Annex I to the Merger Agreement.

The Offer will initially expire at one minute after 11:59 p.m. Eastern Time on December 8, 2017. Purchaser may, in its discretion and without the consent of the Company, extend the Offer on one or more occasions in accordance with the terms set forth in the Merger Agreement and the applicable rules and regulations of the Securities and Exchange Commission (the "SEC"). Purchaser is not required to extend the Offer beyond the earlier to occur of the valid termination of the Merger Agreement and the Outside Date (as defined below) (the "Extension Deadline"). Purchaser may not terminate the Offer, or permit the Offer to expire, prior to the Extension Deadline without the prior written consent of the Company.

As soon as practicable following the Offer Acceptance Time and upon the terms and subject to the conditions set forth in the Merger Agreement and in accordance with Section 251(h) of the Delaware General Corporation Law, Purchaser will merge with and into the Company, with the Company surviving as a wholly-owned subsidiary of Parent (the "Merger"), without a meeting or vote of stockholders of the Company. At the effective time of the Merger (the "Effective Time"), the Shares not purchased pursuant to the Offer (other than Shares held by the Company, Parent, its affiliated entities or by stockholders of the Company who have perfected their statutory rights of appraisal under Delaware law) will each be converted into the right to receive the Offer Price.

In addition, at the Effective Time, each option to purchase Shares (a "Company Stock Option") that is then outstanding and unexercised, whether or not vested and with respect to which the applicable exercise price per Share is less than the Closing Amount (each, an "In the Money Company Stock Option"), will be cancelled and converted into the right of the holder of such In the Money Company Stock Option to receive, for each Share underlying such In the Money Company Stock Option, (i) an amount in cash equal to the excess, if any, of the Closing Amount over the applicable exercise price for such Share, and (ii) one CVR.

At the Effective Time, each Company Stock Option other than an In the Money Company Stock Option that is outstanding and unexercised, whether or not vested (each, an "Out of the Money Company Stock Option"), will be cancelled and converted into the right to receive one or more cash payments, if any, from Parent with respect to each Share subject to the Out of the Money Company Stock Option upon each date that a payment would be required to a holder of a CVR under the terms of the CVR Agreement (each such date, a "Milestone Payment Date"), equal to (i) the amount by which the Per Share Value Paid (as defined in the Merger Agreement) exceeds the exercise price payable per Share subject to such Out of the Money Company Stock Option, less (ii) the amount of all payments previously paid with respect to such Out of the Money Company Stock Option. Notwithstanding the foregoing, any Out of the Money Options with an exercise price per Share equal to or greater than $4.10 will be cancelled at the Effective Time without any consideration payable therefor.

At the Effective Time, each restricted stock unit ("RSU"), whether vested or unvested, that is outstanding immediately prior to the Effective Time, shall become fully vested and shall be cancelled and converted at the Effective Time into the right of the holder of such RSU to receive, for each Share underlying such RSU, (i) an amount in cash, equal to the Closing Amount and (ii) one CVR.

In addition, at the Effective Time, each warrant to purchase Shares (a "Company Warrant"), that is outstanding and unexercised immediately prior to the Effective Time shall be cancelled and converted into the right of the holder of such Company Warrant to receive, for each Share underlying such Company Warrant, (i) an amount in cash equal to the excess, if any, of the Closing Amount over the applicable exercise price for such Share, and (ii) one (1) CVR. As of the Effective Time, any Company Warrant with respect to which the applicable exercise price per Share is greater than the Closing Amount shall be cancelled without any consideration payable therefor (the "Cancelled Warrants").

The Merger Agreement includes representations, warranties and covenants of the parties customary for a transaction of this nature. Among other things, until the earlier of the termination of the Merger Agreement or the Effective Time, the Company has agreed to operate its business in the ordinary course consistent with past practice and has agreed to certain other

operating covenants, as set forth more fully in the Merger Agreement. The Merger Agreement also prohibits the Company's ability to solicit, initiate, knowingly facilitate or knowingly encourage any proposals relating to alternative transactions and restricts the Company's ability to furnish information to, or participate in any discussions or negotiations with, any third party with respect to any such transaction, subject to certain limited exceptions.

In the event the Offer Acceptance Time occurs on or before December 31, 2017 and the Company's cash and cash equivalents are insufficient to pay and fully discharge the Indebtedness (as defined in the Merger Agreement) and Transaction Expenses (as defined in the Merger Agreement) on or prior to Closing (the "Closing Shortfall") by more than $250,000, the aggregate amount payable pursuant to the first occurring Milestone Payment (as defined below) shall be reduced by the full amount of the Closing Shortfall. In the event the Offer Acceptance Time occurs after the December 31, 2017 and the Indebtedness and Transaction Expenses due and payable as if the Closing were to occur on December 31, 2017 exceed the Company's aggregate balance of cash and cash equivalents as of December 31, 2017 by more than $250,000 (the "Measurement Date Shortfall"), the first occurring Milestone Payment shall be reduced by the full amount of the Measurement Date Shortfall.

The board of directors of the Company has unanimously adopted resolutions recommending that the Company's stockholders accept the Offer and tender their Shares to Purchaser pursuant to the Offer.

The Merger Agreement may be terminated under certain circumstances, including in specified circumstances in connection with superior proposals, or if the transaction is not consummated by the Outside Date. Upon the termination of the Merger Agreement, under specified circumstances, the Company will be required to pay Parent a termination fee of $1,680,000.

In addition, subject to the terms of the Merger Agreement, either the Company or Parent may terminate the Merger Agreement, at any time prior to the Offer Acceptance Time, if the Merger has not been consummated prior to 5:00 p.m., Eastern Time, on May 1, 2018 (the "Outside Date").

During the three and nine months ended September 30, 2017, the Company incurred transaction expenses related to the merger of $0.4 million, which are included in general and administrative expenses. The Company will owe $0.8 million payable to our financial advisor subject to the consummation of the Merger.

Tender and Support Agreement

Concurrently with the execution and delivery of the Merger Agreement, each director and executive officer of the Company, and certain stockholders affiliated with such directors and executive officers (each a "Tendering Stockholder"), entered into a Tender and Support Agreement (the "Tender Agreement") with Parent and Purchaser, pursuant to which each Tendering Stockholder agreed, among other things, to tender his, her or its Shares and Company Stock Options that are exercised prior to the Offer Acceptance Time, if any (collectively, the "Subject Shares"), pursuant to the Offer and, if necessary, vote his, her or its Subject Shares against any other acquisition proposal, including any superior proposal, and against any other proposed action, agreement or transaction involving the Company that is intended, or would reasonably be likely, to prevent, materially impede, materially delay or otherwise materially and adversely affect or prevent the consummation of the Offer, the Merger or any other transaction contemplated by the Merger Agreement.

Contingent Value Rights Agreement

At or prior to the Offer Acceptance Time, Parent and Mallinckrodt will enter into the CVR Agreement with the Rights Agent governing the terms of the Contingent Consideration. As provided in the Merger Agreement, each share of Company common stock outstanding (other than certain excluded shares) and each share underlying an In the Money Company Stock Option, Company Warrant (other than Cancelled Warrants) and RSU immediately prior to the Effective Time, or the Offer Acceptance Time in the case of a share of Company common stock validly tendered pursuant to the Offer, will be converted automatically into the right to receive, in addition to the Closing Amount, one CVR, which represents the right to receive the Contingent Consideration if the milestones set forth below are achieved on or before December 31, 2029. The amounts of each of the payments under the CVR will be determined by dividing the aggregate milestone payment amounts set forth below, if achieved (as may be reduced by any payments to certain holders of Out of the Money Company Options or in the event of a Closing Shortfall or Measurement Date Shortfall, if any, each such aggregate milestone payment as may be adjusted, a "Milestone Payment"), by the number of CVRs outstanding on the Record Date (as defined in the CVR Agreement).

- *IV Milestone* . Parent will be obligated to pay an aggregate amount equal to $10,000,000 upon the enrollment of the first patient in a Phase 3 clinical trial of an intravenous formulation of the Product (as defined in the CVR Agreement) by Parent, any of its affiliates or their respective licensee or sublicensee with respect to rights to develop or commercialize the Product.
- *Oral Milestone* . Parent will be obligated to pay an aggregate amount equal to $15,000,000 upon the enrollment of the first patient in a Phase 3 clinical trial of an oral formulation of the Product by Parent, any of its affiliates or their respective licensee or sublicensee with respect to rights to develop or commercialize the Product.
- *Product Sales Milestone* . Parent will be obligated to pay an aggregate amount equal to $50,000,000 upon the first occurrence of the achievement of cumulative Product Sales (as defined in the CVR Agreement) in excess of $500,000,000, by Parent, its affiliates and any other Selling Entity (as defined in the CVR Agreement) and any successors, assigns and transferees.

The right to the Contingent Consideration as evidenced by the CVR Agreement is a contractual right only and will not be transferable, except in the limited circumstances specified in the CVR Agreement. The CVRs will not be evidenced by a certificate or other instrument and will not be registered or listed for trading. The CVRs will not have any voting or dividend rights and will not represent any equity or ownership interest in Parent, Purchaser, the Company or any of their affiliates. There can be no assurance that any of the milestones set forth above will be achieved or that any holders of CVRs will receive payments with respect thereto.

Amendment to Bylaws

On November 1, 2017, the board of directors of the Company approved an amendment to the bylaws of the Company (as amended, the "Bylaws") to explicitly provide that the Court of Chancery of the State of Delaware (or, in case such court does not have jurisdiction, the Federal District Court for the District of Delaware or other competent state court of the State of Delaware) will be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Company, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Company to the Company or the Company's stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or the certificate of incorporation or Bylaws, or (iv) any action asserting a claim against the Company governed by the internal affairs doctrine. This amendment was effective upon adoption by the board of directors of the Company.

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.

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 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.

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. In June 2017, we initiated a Phase 2a clinical trial with a tablet formulation of OCR-002 in cirrhotic patients. The Phase 2a trial is an open-label, multiple dose, randomized, 3-period crossover study designed to evaluate the steady state pharmacokinetics and pharmacodynamics of three times daily administration of three daily dose regimens of OCR-002 tablets. Top-line results are expected to be reported by the end 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 $2.0 to $2.6 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 $1.1 billion to $1.4 billion 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, July 2015 and October 2017. As consideration for the license, we paid an up-front fee of $1.0 million. In October 2017, we made a non-refundable payment of $0.5 million, which shall be credited against the future milestone payments related to clinical and regulatory events for OCR-002. We may be required to make future milestone payments to UCL totaling up to $19.5 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.

Recent Developments

Merger Agreement

On November 1, 2017, we entered into an Agreement and Plan of Merger, or the Merger Agreement, with MAK LLC, a Delaware limited liability company, or Parent, MEH Acquisition Co., a Delaware Corporation and a direct wholly-owned subsidiary of Parent, or Purchaser, and for limited purposes, Mallinckrodt plc, an Irish public limited company and the ultimate parent entity of Parent and Purchaser, or Mallinckrodt.

Pursuant to the terms and subject to the conditions of the Merger Agreement, Purchaser commenced a tender offer, or the Offer, on November 9, 2017 to acquire all of the outstanding shares of our common stock, or the Shares, at an offer price of (i) $1.52 per Share in cash (approximately $42 million in the aggregate), or the Closing Amount, plus (ii) one non-transferable

contingent value right per Share, each, a CVR, which represents the contractual right under a Contingent Value Rights Agreement, or the CVR Agreement, to be entered into among Parent, Continental Transfer & Trust Company, as rights agent, or the Rights Agent, and for limited purposes, Mallinckrodt, at or prior to the time that Purchaser accepts for payment all Shares tendered (and not validly withdrawn) pursuant to the Offer, or the Offer Acceptance Time, to receive one or more payments in cash potentially totaling up to $2.58 per CVR (approximately $75 million in the aggregate), or the Contingent Consideration, contingent upon the achievement of certain milestones (one CVR together with the Closing Amount, or any higher amount per Share paid pursuant to the Offer, the Offer Price, in each case without any interest thereon and subject to any required tax withholdings. As a result, the maximum amount payable pursuant to the Merger Agreement is $4.10 per Share.

The obligation of Purchaser to purchase Shares tendered in the Offer is subject to the satisfaction or waiver of a number of conditions set forth in the Merger Agreement, including (i) that there shall have been validly tendered and not validly withdrawn Shares that, considered together with all other Shares, if any, beneficially owned by Parent and affiliated entities, represent one more Share than 50% of the total number of Shares outstanding at the time of the expiration of the Offer (calculated on a fully-diluted basis in accordance with the Merger Agreement), or the Minimum Condition, and (ii) those other conditions set forth in Annex I to the Merger Agreement.

The Offer will initially expire at one minute after 11:59 p.m. Eastern Time on December 8, 2017. Purchaser may, in its discretion and without our consent, extend the Offer on one or more occasions in accordance with the terms set forth in the Merger Agreement and the applicable rules and regulations of the SEC. Purchaser is not required to extend the Offer beyond the earlier to occur of the valid termination of the Merger Agreement and the Outside Date (as defined below), or the Extension Deadline. Purchaser may not terminate the Offer, or permit the Offer to expire, prior to the Extension Deadline without our prior written consent.

As soon as practicable following the Offer Acceptance Time and upon the terms and subject to the conditions set forth in the Merger Agreement and in accordance with Section 251(h) of the Delaware General Corporation Law, Purchaser will merge with and into the Company, with the Company surviving as a wholly-owned subsidiary of Parent, or the Merger, without a meeting or vote of our stockholders. At the effective time of the Merger, or the Effective Time, the Shares not purchased pursuant to the Offer (other than Shares held by the Company, Parent, its affiliated entities or by stockholders of the Company who have perfected their statutory rights of appraisal under Delaware law) will each be converted into the right to receive the Offer Price.

In addition, at the Effective Time, each option to purchase Shares, or Company Stock Option, that is then outstanding and unexercised, whether or not vested and with respect to which the applicable exercise price per Share is less than the Closing Amount, each, an In the Money Company Stock Option, will be cancelled and converted into the right of the holder of such In the Money Company Stock Option to receive, for each Share underlying such In the Money Company Stock Option, (i) an amount in cash equal to the excess, if any, of the Closing Amount over the applicable exercise price for such Share, and (ii) one CVR.

At the Effective Time, each Company Stock Option other than an In the Money Company Stock Option that is outstanding and unexercised, whether or not vested, each, an Out of the Money Company Stock Option, will be cancelled and converted into the right to receive one or more cash payments, if any, from Parent with respect to each Share subject to the Out of the Money Company Stock Option upon each date that a payment would be required to a holder of a CVR under the terms of the CVR Agreement, each such date, a Milestone Payment Date, equal to (i) the amount by which the Per Share Value Paid (as defined in the Merger Agreement) exceeds the exercise price payable per Share subject to such Out of the Money Company Stock Option, less (ii) the amount of all payments previously paid with respect to such Out of the Money Company Stock Option. Notwithstanding the foregoing, any Out of the Money Options with an exercise price per Share equal to or greater than $4.10 will be cancelled at the Effective Time without any consideration payable therefor.

At the Effective Time, each restricted stock unit, or RSU, whether vested or unvested, that is outstanding immediately prior to the Effective Time, shall become fully vested and shall be cancelled and converted at the Effective Time into the right of the holder of such RSU to receive, for each Share underlying such RSU, (i) an amount in cash, equal to the Closing Amount and (ii) one CVR.

In addition, at the Effective Time, each warrant to purchase Shares (a “Company Warrant”), that is outstanding and unexercised immediately prior to the Effective Time shall be cancelled and converted into the right of the holder of such Company Warrant to receive, for each Share underlying such Company Warrant, (i) an amount in cash equal to the excess, if any, of the Closing Amount over the applicable exercise price for such Share, and (ii) one (1) CVR. As of the Effective Time, any Company Warrant with respect to which the applicable exercise price per Share is greater than the Closing Amount shall be cancelled without any consideration payable therefor, or the Cancelled Warrants.

The Merger Agreement includes representations, warranties and covenants of the parties customary for a transaction of this nature. Among other things, until the earlier of the termination of the Merger Agreement or the Effective Time, we have agreed to operate its business in the ordinary course consistent with past practice and has agreed to certain other operating covenants, as set forth more fully in the Merger Agreement. The Merger Agreement also prohibits our ability to solicit, initiate, knowingly facilitate or knowingly encourage any proposals relating to alternative transactions and restricts our ability to furnish information to, or participate in any discussions or negotiations with, any third party with respect to any such transaction, subject to certain limited exceptions.

In the event the Offer Acceptance Time occurs on or before December 31, 2017 and our cash and cash equivalents are insufficient to pay and fully discharge the Indebtedness (as defined in the Merger Agreement) and Transaction Expenses (as defined in the Merger Agreement) on or prior to Closing, or the Closing Shortfall, by more than $250,000, the aggregate amount payable pursuant to the first occurring Milestone Payment (as defined below) shall be reduced by the full amount of the Closing Shortfall. In the event the Offer Acceptance Time occurs after the December 31, 2017 and the Indebtedness and Transaction Expenses due and payable as if the Closing were to occur on December 31, 2017 exceed our aggregate balance of cash and cash equivalents as of December 31, 2017 by more than $250,000, or the Measurement Date Shortfall, the first occurring Milestone Payment shall be reduced by the full amount of the Measurement Date Shortfall.

Our board of directors has unanimously adopted resolutions recommending that our stockholders accept the Offer and tender their Shares to Purchaser pursuant to the Offer.

The Merger Agreement may be terminated under certain circumstances, including in specified circumstances in connection with superior proposals, or if the transaction is not consummated by the Outside Date. Upon the termination of the Merger Agreement, under specified circumstances, we will be required to pay Parent a termination fee of $1,680,000.

In addition, subject to the terms of the Merger Agreement, either us or Parent may terminate the Merger Agreement, at any time prior to the Offer Acceptance Time, if the Merger has not been consummated prior to 5:00 p.m., Eastern Time, on May 1, 2018, or the Outside Date.

Completion of the Offer and the Merger is anticipated to occur in the fourth quarter of 2017, although there can be no assurance the Offer will be completed and the Merger will occur within the expected time frame or at all.

Tender and Support Agreement

Concurrently with the execution and delivery of the Merger Agreement, each of our director s and executive officers, and certain stockholders affiliated with such directors and executive officers, each a Tendering Stockholder, entered into a Tender and Support Agreement, or the Tender Agreement, with Parent and Purchaser, pursuant to which each Tendering Stockholder agreed, among other things, to tender his, her or its Shares and Company Stock Options that are exercised prior to the Offer Acceptance Time, if any, collectively, the Subject Shares, pursuant to the Offer and, if necessary, vote his, her or its Subject Shares against any other acquisition proposal, including any superior proposal, and against any other proposed action, agreement or transaction involving the Company that is intended, or would reasonably be likely, to prevent, materially impede, materially delay or otherwise materially and adversely affect or prevent the consummation of the Offer, the Merger or any other transaction contemplated by the Merger Agreement. As of October 31, 2017, approximately 12.7% of the outstanding Shares are subject to the Tender Agreement.

Contingent Value Rights Agreement

At or prior to the Offer Acceptance Time, Parent and Mallinckrodt will enter into the CVR Agreement with the Rights Agent governing the terms of the Contingent Consideration. As provided in the Merger Agreement, each share of Company common stock outstanding (other than certain excluded shares) and each share underlying an In the Money Company Stock Option, Company Warrant (other than Cancelled Warrants) and RSU immediately prior to the Effective Time, or the Offer Acceptance Time in the case of a share of Company common stock validly tendered pursuant to the Offer, will be converted automatically into the right to receive, in addition to the Closing Amount, one CVR, which represents the right to receive the Contingent Consideration if the milestones set forth below are achieved on or before December 31, 2029. The amounts of each of the payments under the CVR will be determined by dividing the aggregate milestone payment amounts set forth below, if achieved (as may be reduced by any payments to certain holders of Out of the Money Company Options or in the event of a Closing Shortfall or Measurement Date Shortfall, if any, each such aggregate milestone payment as may be adjusted, a “Milestone Payment”), by the number of CVRs outstanding on the Record Date (as defined in the CVR Agreement).

- *IV Milestone* . Parent will be obligated to pay an aggregate amount equal to $10,000,000 upon the enrollment of the first patient in a Phase 3 clinical trial of an intravenous formulation of the Product (as defined in the CVR Agreement) by Parent, any of its affiliates or their respective licensee or sublicensee with respect to rights to develop or commercialize the Product.

- *Oral Milestone* . Parent will be obligated to pay an aggregate amount equal to $15,000,000 upon the enrollment of the first patient in a Phase 3 clinical trial of an oral formulation of the Product by Parent, any of its affiliates or their respective licensee or sublicensee with respect to rights to develop or commercialize the Product.
- *Product Sales Milestone* . Parent will be obligated to pay an aggregate amount equal to $50,000,000 upon the first occurrence of the achievement of cumulative Product Sales (as defined in the CVR Agreement) in excess of $500,000,000, by Parent, its affiliates and any other Selling Entity (as defined in the CVR Agreement) and any successors, assigns and transferees.

The right to the Contingent Consideration as evidenced by the CVR Agreement is a contractual right only and will not be transferable, except in the limited circumstances specified in the CVR Agreement. The CVRs will not be evidenced by a certificate or other instrument and will not be registered or listed for trading. The CVRs will not have any voting or dividend rights and will not represent any equity or ownership interest in Parent, Purchaser, the Company or any of their affiliates. There can be no assurance that any of the milestones set forth above will be achieved or that any holders of CVRs will receive payments with respect thereto.

Amendment to Bylaws

On November 1, 2017, our board of directors approved an amendment to our bylaws, as amended, the Bylaws, to explicitly provide that the Court of Chancery of the State of Delaware (or, in case such court does not have jurisdiction, the Federal District Court for the District of Delaware or other competent state court of the State of Delaware) will be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Company, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to the Company or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or the certificate of incorporation or Bylaws, or (iv) any action asserting a claim against the Company governed by the internal affairs doctrine. This amendment was effective upon adoption by our board of directors.

Cash Update

During the three and nine months ended September 30, 2017, we incurred transaction expenses related to the Merger of $0.4 million, which are included in general and administrative expenses. We expect to incur additional expenses associated with the Merger, including a one-time fairness opinion fee of $0.5 million and an additional $0.8 million payable to our financial advisor subject to the consummation of the Merger.

As of October 31, 2017, our cash equivalents were $12.8 million and the remaining principal balance due on the notes payable was $7.5 million.

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 nine months ended September 30, 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 September 30,		Change		Nine Months Ended September 30,		Change	
	2017	2016	$	%	2017	2016	$	%
Royalty revenue	$ —	$ 38	$ (38)	(100.0)%	$ —	$ 97	$ (97)	(100.0)%
Operating expenses:								
Research and development	3,776	4,283	(507)	(12)%	11,089	12,939	(1,850)	(14)%
General and administrative	2,301	2,618	(317)	(12)%	7,325	8,142	(817)	(10)%
Total operating expenses	6,077	6,901	(824)	(12)%	18,414	21,081	(2,667)	(13)%
Other expense, net	(192)	(262)	70	(27)%	(671)	(758)	87	(11)%
Net loss	$ (6,269)	$ (7,125)	$ 856	(12)%	$(19,085)	$(21,742)	$ 2,657	(12)%

Revenues

No revenues were recorded during the three and nine months ended September 30, 2017. Royalty revenue for the three and nine months ended September 30, 2016 was $38,000 and $97,000, respectively. 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 $0.5 million and $1.9 million for the three and nine months ended September 30, 2017, respectively, compared to the same periods in 2016. The decreases were primarily driven by 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. The decrease was partially offset by costs incurred for the Phase 2a clinical trial of an oral formulation of OCR-002, which we initiated during the second quarter of 2017.

General and Administrative Expenses

General and administrative expenses decreased by $0.3 million and $0.8 million for the three and nine months ended September 30, 2017, respectively, compared to the same periods in 2016. The decrease was driven primarily by decreased personnel-related expenses and professional services fees partially offset by an increase in legal expenses.

Other Expense, Net

Other expense, net, decreased by $0.1 million for the three and nine months ended September 30, 2017, compared to the same periods in 2016. Other expense, net, 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 nine months ended September 30, 2017 and 2016 (in thousands):

	Nine Months Ended September 30,	
	2017	2016
Net cash provided by (used in):		
Operating activities	$(16,159)	$(16,855)
Investing activities	3,751	4,127
Financing activities	2,149	6,022
Net decrease in cash and cash equivalents	$(10,259)	$ (6,706)

Cash used in operating activities for the nine months ended September 30, 2017 was attributable to our net loss from operations of $19.1 million adjusted for a net decrease in operating assets and liabilities of $0.1 million and non-cash charges of $3.1 million which consisted primarily of stock-based compensation expense.

Cash used in operating activities for the nine months ended September 30, 2016 was attributable to our net loss from operations of $21.7 million adjusted for increases in operating assets and liabilities of $1.5 million and non-cash charges of $3.4 million which consisted primarily of stock-based compensation expense.

Cash provided by investing activities for the nine months ended September 30, 2017 consisted of proceeds of $4.1 million from maturities of marketable securities which were offset by purchases of marketable securities of $0.4 million.

Cash provided in investing activities for the nine months ended September 30, 2016 consisted of proceeds of $11.1 million from maturities of marketable securities which were offset by purchases of marketable securities of $7.0 million.

Cash provided by financing activities during the nine months ended September 30, 2017 and 2016 related to proceeds from the issuance of common stock pursuant to the “at the market” equity program of $4.3 million and $6.0 million, respectively. Cash proceeds provided by financing activities were partially offset by a repayment on notes payable of $2.2 million during the nine months ended September 30, 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.

As noted above, on November 2, 2017, we announced that it had entered into a definitive agreement to be acquired by an affiliate of Mallinckrodt. Should the proposed acquisition not be completed, 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 nine months ended September 30, 2017, we sold an aggregate of 2,889,015 shares of common stock under the Sales Agreement, at an average price of approximately $1.55 per share, for net proceeds of $4.3 million after deducting commissions and other transactions costs. As of September 30, 2017, $9.3 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. 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 September 30, 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, except for those set forth below.

Risks Related to our Business and Industry

The Tender Offer and the Merger, the pendency of the Tender Offer and the Merger or our failure to complete the Tender Offer and the Merger could have a material adverse effect on our business, operating results, financial condition and stock price.

Completion of the Tender Offer and the Merger is subject to customary closing conditions, including a majority of the outstanding shares having been tendered in the Tender Offer (as calculated on a fully diluted basis in accordance with the Merger Agreement). There is no assurance that all of the various conditions will be satisfied, or that the Tender Offer and Merger will be completed on the proposed terms, within the expected timeframe, or at all. Furthermore, there are additional inherent risks in the Tender Offer and the Merger, including the risks detailed below.

Risks related to the pendency of the Tender Offer and the Merger

During the period prior to the closing of the Tender Offer and the Merger, our business is exposed to certain inherent risks due to the effect of the announcement or pendency of the Tender Offer and the Merger on our business relationships, operations, results and business generally, including:

- the possibility of disruption to our business and operations, including diversion of management time and resources, increased transaction costs, and the potentially negative impact on our relationships with our suppliers;
- the inability to attract and retain key personnel, and the possibility that our current employees could be distracted, and their productivity decline or they leave the business, due to uncertainty regarding the Tender Offer and the Merger;
- the inability to pursue alternative business opportunities, including additional financing, or make changes to our business pending the completion of the Tender Offer and the Merger, and other restrictions on our ability to conduct our business;
- the fact that under the terms of the Merger Agreement, we are unable to solicit other acquisition proposals during the pendency of the Tender Offer and the Merger;
- the amount of the costs, fees, expenses and charges related to the Merger Agreement, the Tender Offer or the Merger; and
- other developments beyond our control, including, but not limited to, changes in domestic or global economic conditions that may affect the timing or success of the Tender Offer or the Merger.

Risks that the Tender Offer or the Merger may be delayed or may not be completed

The Tender Offer or the Merger may be delayed, and may ultimately not be completed, due to a number of factors, including:

- the failure of a sufficient number of the outstanding shares having been tendered in the Tender Offer to meet the Minimum Condition;
- potential future shareholder litigation and other legal and regulatory proceedings, which could delay or prevent the consummation of the Merger; and
- the failure to satisfy the other conditions to the completion of the Tender Offer and the Merger, including the possibility that a material adverse effect on our business could occur.

Risks to our business if the Tender Offer and the Merger does not close

If the Tender Offer and the Merger does not close, our business and shareholders would be exposed to additional risks, including:

- we will likely find it difficult, if not impossible, to raise the necessary capital to satisfy our indebtedness, pay our expenses and fund our operations, which would not enable us to continue as a going concern;
- to the extent that the current market price of our stock reflects an assumption that the Tender Offer and the Merger will be completed, the price of our common stock could decrease if the Tender Offer and the Merger is not completed;
- investor confidence could decline, shareholder litigation could be brought against us, relationships with existing suppliers and other business partners may be adversely impacted, we may be unable to retain key personnel, and profitability may be adversely impacted due to costs incurred in connection with the pending Tender Offer and Merger; and
- the requirement that we pay a termination fee of $1,680,000 to Mallinckrodt if we terminate the Merger Agreement under certain circumstances.

Risks related to the successful completion of the Tender Offer and the Merger

Even if successfully completed, there are certain risks to our shareholders from the Tender Offer and the Merger, including:

- the first occurring milestone payment pursuant to the CVR Agreement could be reduced by the full amount of the Closing Shortfall or Measurement Date Shortfall;
- there can be no assurance that our shareholders will receive any contingent payments pursuant to the Merger Agreement or CVR Agreement;
- the fact that, if the Tender Offer and the Merger are completed, shareholders will forego the opportunity to realize the potential long-term value of the successful execution of our current strategy as an independent company.

Litigation in connection with the Merger Agreement may be costly, prevent consummation of the Tender Offer and the Merger, divert management's attention and otherwise materially harm our business.

Regardless of the outcome of any future litigation related to the Merger Agreement and the transactions it contemplates, such litigation may be time-consuming and expensive and may distract our management from running the day-to-day operations of our business. The litigation costs and diversion of management's attention and resources to address the claims and counterclaims in any litigation related to the Merger Agreement and the transactions it contemplates may materially adversely affect our business, financial condition and operating results. Furthermore, if the Tender Offer and the Merger are not consummated as a result of litigation, the trading price of our common stock will likely drop because the current market price of our common stock reflects, at least in part, an assumption that the Tender Offer and the Merger will be completed at the announced offer price of $1.52 per share plus one non-transferable contingent value right up to $2.58 per CVR. If the Tender Offer and the Merger are not consummated, for any reason, litigation could be filed in connection with the failure to consummate the Tender Offer and the Merger. Any litigation related to the Tender Offer and the Merger may result in negative publicity or an unfavorable impression of us, which could adversely affect the price of our common stock, impair our ability to recruit or retain employees, damage our relationships with our customers, or otherwise materially harm our operations and financial performance.

The Merger Agreement imposes restrictions on the operation of our business prior to closing, which could adversely affect our business.

Pursuant to the terms of the Merger Agreement, we are subject to certain restrictions on the conduct of our business, including the ability in certain cases to enter into contracts, acquire or dispose of assets, raise equity capital, incur indebtedness or incur capital expenditures, until the Merger becomes effective or the Merger Agreement is terminated. These restrictions may prevent us from taking actions with respect to our business that we may consider advantageous and result in our inability to respond effectively to competitive pressures and industry developments, and may otherwise harm our business and operations.

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, 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: November 14, 2017

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

Date: November 14, 2017

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 14, 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: November 14, 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 September 30, 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: November 14, 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 September 30, 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: November 14, 2017

By: /s/ Michael Byrnes
Michael Byrnes
Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)