OCERA THERAPEUTICS, INC.

FORM 10-K
(Annual Report)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2016

OR

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

FOR THE TRANSITION PERIOD FROM ___ TO ___ .

Commission file number **001-35119**

OCERA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	**63-1192270**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

525 University Avenue, Suite 610

Palo Alto, CA 94301

(Address of principal executive offices including zip code)

650-475-0158

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Common Stock, $0.00001 par value per share	NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 Website, 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐ .

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

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

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

The aggregate market value of the common stock held by non-affiliates computed by reference to the last reported sale price on June 30, 2016 was approximately $35.09 million . As of February 28, 2017 , there were outstanding 23,600,242 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE:

Certain information required by Part III of the Annual Report on Form 10-K is incorporated by reference from the registrant's definitive proxy statement for the registrant's 2017 annual meeting of stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the close of the registrant's fiscal year ended December 31, 2016 .

OCERA THERAPEUTICS, INC.
ANNUAL REPORT ON FORM 10-K
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CORPORATE INFORMATION AND FORWARD-LOOKING STATEMENTS

Corporate Information

On July 15, 2013, Tranzyme, Inc. ("Tranzyme"), completed its merger, or the Merger, with Ocera Therapeutics, Inc., a privately held Delaware corporation, or Private Ocera, in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of April 23, 2013, or the Merger Agreement, by and among Tranzyme, Private Ocera and Terrapin Acquisition, Inc., a wholly-owned subsidiary of Tranzyme, or the Merger Subsidiary. Pursuant to the Merger Agreement, Merger Subsidiary merged with and into Private Ocera, with Private Ocera, renamed as Ocera Subsidiary, Inc., surviving the merger as a wholly-owned subsidiary of the combined company. Immediately following the Merger, the combined company changed its name from “Tranzyme, Inc.” to “Ocera Therapeutics, Inc.”

Unless otherwise stated in this Annual Report on Form 10-K (also referred to as this Annual Report or this Form 10-K) or the context otherwise requires, references to “Ocera,” “we,” “us,” “our,” the “Company” and similar references refer to Ocera Therapeutics, Inc. and its subsidiaries.

Forward-Looking Statement Safe Harbor

This Annual Report on Form 10-K and the information incorporated herein by reference contain forward-looking statements that involve a number of risks, uncertainties and assumptions, including information with respect to our plans and strategy for our strategic process, product candidates, drug discovery platform and business. All statements that express expectations, estimates, forecasts or projections are forward-looking statements. Words such as “expects”, “anticipates”, “intends”, “plans”, “believes”, “seeks”, “estimates”, “projects”, “forecasts”, “may”, “should”, and variations of such words and similar expressions are intended to identify such forward-looking statements. These statements include but are not limited to statements under the captions “Business”, “Risk Factors,” and “Management's Discussion and Analysis of Financial Condition and Results of Operations” as well as other sections in this Annual Report on Form 10-K. You should be aware that the occurrence of any of the events discussed under the heading “Item 1A. Risk Factors” and elsewhere in this report could substantially harm our business, results of operations and financial condition and that if any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock. The cautionary statements made in this report are intended to be applicable to all related forward-looking statements wherever they may appear in this Annual Report on Form 10-K. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. Except as required by law, we assume no obligation to update our forward-looking statements, even if new information becomes available in the future.

Industry and Market Data

This Annual Report on Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by us and third parties. The industry in which we operate is subject to a high degree of uncertainty and risks due to various factors, including those described under the heading “Item 1A. Risk Factors”. These and other factors could cause results to differ materially from those expressed in the estimates made by us and third parties.

Part I.

Item 1. Business

Overview

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

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

In March 2017, we announced data from additional analyses that showed plasma ammonia reduction correlates with clinical improvement. Related to plasma ammonia levels, patients who responded had a greater change in plasma ammonia from baseline than patients who did not respond, (-28.2 and -9.2 µg/mL, respectively), p=0.0006. With regard to clinical improvement, patients on OCR-002 had a higher response rate at 48 hours than placebo, (51 and 37%, respectively), p=0.026. In addition, while not the primary endpoint patient-improvement measure, when patient improvement was measured by the pre-defined endpoint, Physician Overall Treatment Evaluation, a greater proportion of patients on OCR-002 demonstrated improvement over placebo, p=0.026. Rifaximin, although not indicated for hospitalized patients with overt HE, was widely used in the hospital resulting in a significant percentage of study patients having rifaximin concomitantly administered during OCR-002 therapy. Post hoc analysis of the time to improvement in HE symptoms excluding patients who used rifaximin indicates the primary endpoint of the study would have been achieved with high statistical significance, p=0.004. Other study data indicate OCR-002 provided clinical benefit over placebo as observed by improvement in Model for End-Stage Liver Disease, or MELD scores, p=0.051, and improvement in renal function as measured by the change from baseline in Blood Urea Nitrogen, or BUN levels, p=0.04. We currently plan to meet with the United States Food and Drug Administration, or FDA, for an End-of-Phase 2 meeting to discuss next steps regarding future development for the IV formulation of OCR-002. While we prepare for our meeting with the FDA, we continue to evaluate pathways forward for the continued development of OCR-002.

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

phenylacetylglutamine, or PAGN, the end-product responsible for clearing ammonia, was greater in both plasma and urine for all three OCR-002 extended-release dosage forms than RAVICTI at an approximately equivalent molar PAA dose. We plan to initiate a Phase 2a clinical trial with a tablet formulation of OCR-002 in cirrhotic patients in the first half of 2017.

In February 2015, we announced the preliminary topline results of the second part of a Phase 2a investigator-sponsored trial in Spain, which evaluated an IV formulation of OCR-002 in patients with upper gastrointestinal bleeding associated with liver cirrhosis. These patients tend to have elevated ammonia levels because they swallow blood, which produces more ammonia as it is digested. In the first part of this trial, a 10-patient open label safety cohort, OCR-002 was shown to lower ammonia when administered as a continuous intravenous infusion of up to 10 grams per 24 hours. The second part of this trial was a randomized, placebo-controlled cohort of 38 patients receiving either 10 grams per 24 hours of OCR-002 or placebo as a continuous intravenous infusion for five days. The data showed that over the first 12 hours of dosing, OCR-002 lowered ammonia by 19.6% compared to 3.2% in the placebo group, but this difference did not reach statistical significance. The subanalysis by Child-Pugh score showed a statistically significant ammonia decrease in Child-Pugh C treated patients at 36 hours. A statistically significant difference in urinary excretion of ammonia, as measured by PAGN, was observed and OCR-002 demonstrated a favorable safety profile and appeared to be well tolerated. The investigators concluded that 10 grams/day of OCR-002 decreased plasma ammonia after upper gastrointestinal bleeding in cirrhotic patients, especially in Child-Pugh C patients, and that higher doses might be required in Child-Pugh A and B patients to increase ammonia elimination.

In November 2016, results from an investigator-sponsored Phase 2a clinical trial conducted by the National Institutes of Health, or NIH, to evaluate the safety and pK of an IV formulation of OCR-002 in patients with hyperammonemia due to acute liver failure or injury, were presented at the Liver Meeting 2016, the 67 th Annual Meeting of the American Association for the Study of Liver Disease. The Phase 2a study was a multi-center, open-label study, conducted in two cohorts of patients diagnosed with acute liver failure. The study showed that no drug-related serious adverse events were observed and all doses were well tolerated. Therapeutic serum levels of PAA were achieved at infusion rates of OCR-002 20g/24h and resulted in ammonia excretion in urine as PAGN, even in patients with non-oliguric renal failure.

In 2012, we completed Phase 1 pK and safety trials of intravenous OCR-002 in a parallel ascending dose clinical trial of 48 healthy volunteers and 43 stable cirrhotic patients. This study evaluated OCR-002 in doses of up to 60g and infusion rates of up to 40g/4h. No serious adverse events, deaths or discontinuations were reported and infusion rates of ≤10g/4h were associated with fewer adverse effects, including headache, dizziness and nausea, as compared to higher doses and infusion rates. All doses, including the 40g dose, were well tolerated when OCR-002 was given over 24 hours.

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

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

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

OCR-002. We are also obligated to pay tiered royalties in the low to mid-single digits on future net sales of the licensed product candidate.

We are building intellectual property protection of OCR-002. We have exclusively licensed from UCL two patents and one patent application in the United States, and 20 patents and 2 pending patent applications in foreign jurisdictions (including granted patents in Europe, Japan, China and several other countries), related to OCR-002 composition-of-matter or use in the treatment of HE, all of which expire in 2025. We have also exclusively licensed from UCL one pending international PCT application related to the treatment of diseases associated with hepatic stellate cell activation, such as non-alcoholic fatty liver disease. In addition, we exclusively own 4 patents and 1 pending patent application in the United States, and 9 patents and 16 pending patent applications in foreign jurisdictions (including granted patents in China and Japan), related to specific OCR-002 forms or methods of making OCR-002, which expire in 2030-2031. We also co-own with UCL and have exclusively licensed from UCL one pending application in the United States, and 12 patents and 13 pending applications in foreign jurisdictions (including granted patents in Europe, Japan, China and several other countries), related to the use of OCR-002 for the treatment of portal hypertension or other indications, all of which expire in 2030. We also hold exclusive rights to 2 patents in the United States, and 5 patents and 10 pending applications in foreign jurisdictions, for the manufacture of OCR-002, which expire in 2031-2032. We own two pending international PCT applications related to treating and preventing muscle loss and treating and preventing neuron loss. Finally, we exclusively own two pending patent applications in the United States and two pending international PCT applications related to oral formulations of OCR-002.

Hepatic Encephalopathy: A Neurocognitive Disorder Related to Elevated Ammonia Levels

HE is a serious neurological disorder that can occur in patients with advanced cirrhosis or acute liver failure. HE is divided into 2 broad categories based on severity: covert and overt. Covert HE has a significant impact on a patient's quality of life, driving performance, and recently has been associated with increased hospitalizations and death. Likewise, overt HE is associated with increased rates of hospitalizations and mortality, and poor quality of life. HE is believed to occur when the brain is exposed to gut-derived toxins normally removed by the healthy liver. While a variety of these toxins may contribute to HE, it is generally believed that ammonia plays a causal role in the disorder. A third-party study published in *Hepatology* in 2007 showed that higher ammonia levels correlated with greater frequency of HE and elevated intracranial pressure. Additionally, an independent study published in the *American Journal of Medicine* in 2003 showed that ammonia measurements correlated with the severity of HE in patients. Further evidence of ammonia's central role in HE is obtained from a paper published in *Hepatology* in 2013 that showed administration of an ammonia scavenger reduced HE events, as well as ammonia, in patients with known cirrhosis and who had experienced two or more HE events in the six months prior to the study. In addition, we found that there was a statistically significant relationship ($p=0.032$) between the levels of severity of HE and ammonia in cirrhotic patients in our Phase 2b clinical trial, which we completed in January 2017. The diagnosis of HE requires the presence of impaired liver function and the exclusion of an alternative explanation for the symptoms. Blood tests of ammonia levels may assist in the diagnosis.

Currently, lactulose is the only FDA-approved treatment for patients presenting at the hospital with acute HE. Lactulose is a laxative which helps to eliminate ammonia through the gut. In addition to lactulose, the current standard of care for these patients includes hydration, supportive care and potential off-label use of pharmacologic treatment to suppress the production of ammonia by intestinal bacteria, most commonly through administration of non-absorbable antibiotics. There is inconsistent data on the degree of effectiveness of these agents in treating the acute HE patient.

Based on third party analysis of HCUP 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 CMS indicates that approximately 60% of patients suffering from HE are hospitalized for over four days.

Overt HE is believed to be caused by the rapid accumulation of ammonia in the blood in patients with a failing liver. As the ammonia crosses the blood brain barrier, it may lead to brain swelling and serious neurocognitive deficit. These patients are generally very sick, and may be stuporous or comatose, and unable to swallow and effectively absorb oral medications. Therefore, we believe it is preferable to treat them with an intravenous, easily administrable agent that can act rapidly and safely. We believe that OCR-002 may be beneficial in managing these patients.

Potential Additional Applications for Ammonia Reduction

There is evidence from pre-clinical models of liver failure that elevated ammonia may also contribute to conditions beyond HE. It has been observed in such models that in addition to elevated ammonia, the animal can also experience elevated pressure in the blood vessels of the liver (portal hypertension), reduced muscle mass and alterations in protein catabolism, swelling of the brain and loss of brain neurons under conditions of hypotension. When dosing OCR-002 to these various animals, we have observed reductions in portal pressure, attenuated loss of muscle mass, attenuated brain swelling and prevented loss of cortical neurons associated with hypotension. In addition, there is preclinical evidence to suggest that elevated ammonia can activate hepatic stellate cells, thereby leading to fibrosis in the liver. Preclinical work in rat models of NASH is underway to ascertain whether intervention with OCR-002 may impact the condition.

OCR-002 Mechanism of Action

OCR-002, which contains ornithine and phenylacetate, appears to have a dual mechanism of action designed to lower ammonia without involvement of the liver, which is damaged or diseased in HE patients. A preliminary human study conducted by Professor Rajiv Jalan, MD, of UCL, suggested that co-administration of ornithine (delivered as L-ornithine L-aspartate) and phenylacetate (delivered as phenylbutyrate) lowered ammonia levels more than either alone. It is generally believed that ornithine promotes ammonia clearance though the urea cycle. Ornithine is converted to glutamate, which in turn combines with ammonia to create glutamine. Glutamine combines with phenylacetate to form PAGN which is then excreted through the kidneys.

Clinical Development Programs

OCR-002 IV Formulation

Phase 2 Trials

Stop HE Phase 2b Trial

STOP-HE was a placebo-controlled, randomized, double-blind clinical trial designed to evaluate the safety, pharmacokinetics and efficacy of intravenously-administered OCR-002 in resolving neurocognitive symptoms of acute HE in 231 hospitalized patients with liver cirrhosis and elevated serum ammonia (hyperammonemia). Either OCR-002 or placebo was administered to patients intravenously as a continuous infusion for up to five days along with standard of care. The OCR-002 arm was dosed with 10, 15 or 20 grams over 24 hours based on the patient's degree of liver impairment and modeling of OCR-002 metabolism, in addition to safety considerations in this high-risk patient population.

We commenced this trial in the fourth quarter of 2013 and enrolled our first patient in January 2014. To increase the pace of enrollment, we amended our trial protocol in March 2014 to broaden the eligible patient selection criteria. In April 2014, we further amended the protocol to increase patient dosage to up to 20 grams per day based on our review of preliminary pK data from our investigator-sponsored trials discussed below. This increased dosage level remained below the maximum tolerated dose of 40 grams per day observed in our Phase 1 trial. In October 2014, we further amended the protocol to broaden enrollment and clarify certain operational aspects of the trial. The trial was conducted at approximately 100 sites primarily in the United States and Europe. The study included a pre-planned interim analysis and in March 2015, an independent data monitoring committee, or DMC, conducted such interim analysis, reporting that the trial was not futile and that there were no clinically significant safety issues of concern. In addition, the DMC recommended that we continue the trial and increase target enrollment from 140 patients to approximately 230 patients.

In January 2017, we announced the top-line results from the trial. The data showed that OCR-002 was 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 faster clinical improvement and 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.

The following table summarizes other key findings from the trial:

Plasma Ammonia µmol/L	**OCR-002 (Doses)**				**Placebo**	**p-value^**
	-≤10g	**15g**	**20g**	**Total**		
Median Change from Baseline to 3 hours post end-of-infusion	-19.3	-28.4	-38.9	-30.8	-11.8	0.017
Median Change from Baseline in Time Normalized AUC	-15.5	-24.2	-28.8	-22.8	-4.4	<0.001

- Clinical response at 3 hours post end-of-infusion (responder analysis): OCR-002 64%, placebo 55%, p=0.149
- Overall median time to ICU/hospital discharge for ITT population showed no statistically significant difference, (but at higher doses there was a difference)
- Fewer deaths occurred in the OCR-002 arm (11) *versus* placebo (15)

^ Comparison of placebo and total OCR-002 based on Van Elteren test
Time to event analysis based on log-rank test; all tests two-tailed

In March 2017, we announced data from additional analyses that showed plasma ammonia reduction correlates with clinical improvement. Related to plasma ammonia levels, patients who responded had a greater change in plasma ammonia from baseline than patients who did not respond, (-28.2 and -9.2 µg/mL, respectively), p=0.0006. With regard to clinical improvement, patients on OCR-002 had a higher response rate at 48 hours than placebo, (51 and 37%, respectively), p=0.026. In addition, while not the primary endpoint patient-improvement measure, when patient improvement was measured by the pre-defined endpoint, Physician Overall Treatment Evaluation, a greater proportion of patients on OCR-002 demonstrated improvement over placebo, p=0.026. Rifaximin, although not indicated for hospitalized patients with overt HE, was widely used in the hospital resulting in a significant percentage of study patients having rifaximin concomitantly administered during OCR-002 therapy. Post hoc analysis of the time to improvement in HE symptoms excluding patients who used rifaximin indicates the primary endpoint of the study would have been achieved with high statistical significance, p=0.004. Other study data indicate OCR-002 provided clinical benefit over placebo as observed by improvement in Model for End-Stage Liver Disease, or MELD scores, p=0.051, and improvement in renal function as measured by the change from baseline in Blood Urea Nitrogen, or BUN levels, p=0.04. We currently plan to meet with the United States Food and Drug Administration, or FDA, for an End-of-Phase 2 meeting to discuss next steps regarding future development for the IV formulation of OCR-002.

Investigator Sponsored Phase 2a Trials

Phase 2a Trial in Spain

In February 2015, we announced the preliminary topline results of the second part of a Phase 2a investigator-sponsored trial in Spain, which evaluated OCR-002 in patients with upper gastrointestinal bleeding associated with liver cirrhosis. These patients tend to have elevated ammonia levels because they swallow blood, which produces more ammonia as it is digested. In the first part of this trial, a 10-patient open label safety cohort, OCR-002 was shown to lower ammonia when administered as a continuous intravenous infusion of up to 10 grams per 24 hours. The second part of this trial, was a randomized, placebo-controlled cohort of 38 patients receiving either 10 grams per 24 hours of OCR-002 or placebo as a continuous intravenous infusion for five days. The data showed that over the first 12 hours of dosing, OCR-002 lowered ammonia by 19.6% compared to 3.2% in the placebo group, but this difference did not reach statistical significance. The subanalysis by Child-Pugh score showed a statistically significant ammonia decrease in Child-Pugh C treated patients at 36 hours. A statistically significant difference in urinary excretion of ammonia, as measured by PAGN, was observed and OCR-002 demonstrated a favorable safety profile and appeared to be well tolerated. The investigators concluded that 10 grams/day of OCR-002 decreased plasma ammonia after upper gastrointestinal bleeding in cirrhotic patients, especially in Child-Pugh C patients, and that higher doses might be required in Child-Pugh A and B patients to increase ammonia elimination.

Phase 2a NIH Trial

In November 2016, results from an investigator-sponsored Phase 2a clinical trial conducted by NIH to evaluate the safety and pK of OCR-002 in patients with hyperammonemia and HE due to acute liver failure or injury, were presented at the Liver Meeting 2016, the 67 th Annual Meeting of the American Association for the Study of Liver Disease. The Phase 2a study was a multi-center, open-label study, conducted in two cohorts of patients diagnosed with acute liver failure. Patients were treated pursuant to one of four escalating dosing regimens of intravenously-administered OCR-002, which were advanced only after safety and certain pharmacokinetic data were reviewed. Cohort 1 was comprised of affected patients with minimal renal dysfunction (defined as serum creatinine ≤ 1.5 mg/dL and mean arterial pressure of > 65 mm Hg). Cohort 2 included affected patients with compromised renal function (defined as serum creatinine > 1.5 mg/dL and < 10 mg/dL with mean arterial pressure of > 65 mm Hg). Dose levels within the four regimens ranged from approximately 3.33 g/24h to 20 g/24h for up to 5 treatment days. 36 of 47 patients enrolled were considered evaluable having completed at least 72 hours of treatment. The study showed that no drug-related serious adverse events were observed and all doses were well tolerated. Therapeutic serum levels of PAA were achieved at infusion rates of OCR-002 20g/24h and resulted in ammonia excretion in urine as PAGN, even in patients with non-oliguric renal failure. In November 2015, the NIH announced preliminary pK data on the first 24 patients in the study and concluded that OCR-002 was safe and well-tolerated at the levels administered, up to 10 grams per 24 hours. A correlation was observed between the doses administered and the drug levels seen in the blood, but even at the 10 gram dose, the investigators deemed the exposure of the drug to be below the desired range.

Phase 1 Pharmacokinetic Trial - Intravenous Formulation

We completed Phase 1 pK and safety trials of intravenous OCR-002 in a parallel ascending dose clinical trial of 48 healthy volunteers and 43 stable cirrhotic patients. This study evaluated OCR-002 in doses of up to 60g and infusion rates of up to 40g/4h. No serious adverse events, deaths or discontinuations were reported and infusion rates of ≤10g/4h were associated with fewer adverse effects, including headache, dizziness and nausea, as compared to higher doses and infusion rates. All doses, including the 40g dose, were well tolerated when OCR-002 was given over 24 hours.

Pre-clinical Studies

Pre-clinical studies of OCR-002 were performed in two animal models, rat with bile duct ligation as a model for chronic liver disease and pig with hepatic artery ligation as a model for acute liver failure. In the rat model, OCR-002 significantly reduced arterial ammonia and cerebral edema, and in the pig model, OCR-002 significantly attenuated arterial ammonia, extracellular brain ammonia and intracranial pressure.

OCR-002 Oral Formulation

Phase 1 Pharmacokinetic Trial - Oral Prototype Formulations

Phase 1 Trial in Cirrhotic Patients

In January 2017, we completed a Phase 1 clinical trial with orally administered liquid formulation of OCR-002 in patients with cirrhosis. The Phase 1 trial was an open-label, crossover study to determine the pK and the absolute oral bioavailability of OCR-002 in patients with varying degrees of cirrhosis. The study evaluated a single 5g dose of IV OCR-002, and single 5g doses of a liquid oral solution of OCR-002 administered across three treatment arms:

- Fasted while on routine lactulose dosing;
- Fed while on routine lactulose dosing; and
- Fasted with discontinuation of lactulose on the evening before dosing.

OCR-002 was observed to be safe and well-tolerated across all treatment arms with favorable pK, including absolute bioavailability of greater than 95% in the fasted state. Dosing under fed conditions delayed absorption slightly, lowered mean maximum concentration, or Cmax, by 30-40% and reduced the absolute oral bioavailability to 75-80%. These data suggest the drug is potentially suitable to be taken conveniently at mealtime corresponding with when ammonia levels typically begin to rise in patients with HE. Plasma levels of the study drug and PAGN were similar when OCR-002 was dosed before and after the discontinuation of lactulose, indicating the study drug may be unaffected by its concomitant use. PAGN is the molecule formed from the combination of study drug with serum ammonia, and is excreted through the kidneys. Overall mean plasma exposure to study drug (AUC0-inf) was approximately 35-40% higher in Child-Pugh C patients compared to Child-Pugh A patients, as expected given the greater impairment of liver function of Child-Pugh C patients. We believe that the higher plasma exposure is due to lower metabolism of the study drug by the severely impaired livers.

Phase 1 Trial in Healthy Patients

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. The mean Cmax of plasma PAA from the three pilot OCR-002 extended-release formulations ranged from approximately 50 to 90μg/mL occurring at various time points over four to nine hours after dosing. For comparison, RAVICTI produced a mean plasma PAA Cmax of approximately 10μg/mL at four to six hours after dosing. In addition, plasma and urinary PAGN concentrations were greater for all three OCR-002 extended-release dosage forms than with RAVICTI. The mean Cmax of plasma PAGN from the pilot extended-release formulations of OCR-002 ranged from approximately 30 to 45μg/mL occurring at various time points over four to ten hours after dosing. For comparison, RAVICTI produced a mean plasma PAGN Cmax of about 20 to 25μg/mL at approximately five hours.

Based on the strength of these results and the prior clinical proof of concept established with RAVICTI in preventing recurrent HE in patients suffering from liver cirrhosis and a prior history of HE, we plan to continue development of oral OCR-002. We plan to initiate a Phase 2a study with a tablet formulation of OCR-002 in the first half of 2017.

Pre-clinical Studies

Pre-clinical studies of oral formulations of OCR-002 were conducted in both in vitro and in vivo models. As these oral formulations of OCR-002 contain the same active ingredient as our intravenous formulation of OCR-002, we did not base our testing on measures of reducing ammonia. Rather, our focus was to identify an appropriate pharmacokinetic profile that would support a convenient dosing schedule.

Manufacturing

We currently have no manufacturing facilities. We rely on third-party manufacturers to produce bulk drug substance and drug products required for commercial use and for our clinical trials.

We have had clinical supplies of OCR-002 drug substance manufactured for us by Helsinn Chemicals SA in Switzerland and we plan to have further clinical and potentially commercial supply of OCR-002 drug substance manufactured for us by Evonik in France. Finished product manufacturing and filling for OCR-002 IV clinical supplies has been undertaken by AAI Pharma Service Corp in North Carolina. We rely on additional third-parties for manufacturing our research stage oral formulation prototypes. Our third-party manufacturers, their facilities and all lots of drug substance and drug products are required to be in compliance with current Good Manufacturing Practices, or cGMP. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. The manufacturing facilities for our products must meet cGMP requirements and FDA satisfaction before any product is approved for the US market and before we can manufacture commercial products. Our third-party manufacturers are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including warning letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties. These actions could have a material impact on the availability of our products. Contract manufacturers may encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel.

Competition

We face competition from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions, among others, which may in the future develop products to treat HE. Our commercial opportunity may be reduced significantly if our competitors develop and commercialize products that are safer, more effective, more convenient, have fewer side effects or are less expensive than OCR-002. Public announcements regarding the development of competing drugs could adversely affect the commercial potential of OCR-002.

Currently there is no cure for HE other than liver transplantation, which is limited by donor availability and patient eligibility. For treatment of overt HE, the standard of care is treatment with hydration and lactulose. While Ammonul is an ammonia scavenger approved for use in treating hyperammonemia for patients with urea cycle disorders, it has not been adequately tested as treatment for HE and is therefore not approved for patients with HE. In addition, Ammonul contains a significant amount of sodium, and its package label advises that in patients who suffer from severe renal insufficiency or other disorders of sodium retention and edema that the drug should be used with great care, if at all. Acutely ill patients with advanced cirrhosis and HE can have renal insufficiency and fluid overload and we believe may not be suitable candidates for receiving Ammonul. For prevention of recurring HE, lactulose and rifaximin are the only FDA-approved therapies for reducing the risk of episodic HE recurrence. RAVICTI, an orally administered ammonia scavenger approved for urea cycle disorders, was shown to prevent recurrent HE in Phase 2 clinical testing, and while not an immediate competitive threat, could become a threat in the future if this drug resumes testing in HE. To be commercially viable in the treatment of overt HE, we must demonstrate that intravenous OCR-002, an ammonia scavenger that does not contain sodium, shortens the time to meaningful clinical improvement or provides a meaningful economic benefit inside the hospital. To be viable in the chronic treatment of HE, oral OCR-002 must be deliverable in a practical and competitive dosage form as well as offering sufficient efficacy and tolerability. If a curative treatment for HE is developed other than liver transplantation, OCR-002 may become obsolete for that indication.

Intellectual Property

We are seeking patent protection in the United States and internationally for our products and product candidates. Our policy is to pursue, maintain and defend patent rights developed internally and by our licensor UCL to protect the technology, inventions and improvements that are commercially important to the development of our business. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of the existing patents upon which our product candidates rely or any patents granted to us in the future will be commercially useful in protecting our technology. We also rely on trade secrets to protect our product candidates. Our commercial success also depends in part on our non-infringement of the patents or proprietary rights of third parties. For a more comprehensive discussion of the risks related to our intellectual property, please see “Risk Factors - Risks Related to Our Intellectual Property.”

Our success depends in part on our ability to:

- obtain and maintain proprietary and marketing exclusivity rights for OCR-002;
- preserve trade secrets;
- prevent third parties from infringing upon the proprietary rights; and

- operate our business without infringing the patents and proprietary rights of third parties, both in the United States and internationally.

We are building intellectual property protection of OCR-002. We have exclusively licensed from UCL two patents and one patent application in the United States, and 20 patents and 2 pending patent applications in foreign jurisdictions (including granted patents in Europe, Japan, China and several other countries), related to OCR-002 composition-of-matter or use in the treatment of HE, all of which expire in 2025. We have also exclusively licensed from UCL one pending international PCT application related to the treatment of diseases associated with hepatic stellate cell activation, such as non-alcoholic fatty liver disease. In addition, we exclusively own 4 patents and 1 pending patent application in the United States, and 9 patents and 16 pending patent applications in foreign jurisdictions (including granted patents in China and Japan), related to specific OCR-002 forms or methods of making OCR-002, which expire in 2030-2031. We also co-own with UCL and have exclusively licensed from UCL one pending application in the United States, and 12 patents and 13 pending applications in foreign jurisdictions (including granted patents in Europe, Japan, China and several other countries), related to the use of OCR-002 for the treatment of portal hypertension or other indications, all of which expire in 2030. We also hold exclusive rights to 2 patents in the United States, and 5 patents and 10 pending applications in foreign jurisdictions, for the manufacture of OCR-002, which expire in 2031-2032. We own two pending international PCT applications related to treating and preventing muscle loss and treating and preventing neuron loss. Finally, we exclusively own two pending patent applications in the United States and two pending international PCT applications related to oral formulations of OCR-002. However, there is a significant risk that the pending applications will not issue as patents, or that they may issue with substantially narrower claims than those that are currently sought.

We also protect our proprietary technology and processes, in part, by confidentiality and invention assignment agreements with our employees, consultants, scientific advisors and other contractors. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, scientific advisors or other contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

The United States patent system permits the filing of provisional and non-provisional patent applications. A non-provisional patent application is examined by the United States Patent and Trademark Office, or USPTO, and can mature into a patent once the USPTO determines that the claimed invention meets the standards for patentability. A provisional patent application is not examined for patentability, and automatically expires 12 months after its filing date. As a result, a provisional patent application cannot mature into a patent. The requirements for filing a provisional patent application are not as strict as those for filing a non-provisional patent application. Provisional applications are often used, among other things, to establish an earlier filing date for a subsequent non-provisional patent application. The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment or PTA, which compensates a patentee for administrative delays by the USPTO in granting a patent. In view of a recent court decision, the USPTO is under greater scrutiny regarding its calculations where the USPTO erred in calculating the patent term adjustment for the patents in question denying the patentee a portion of the patent term to which it was entitled. Alternatively, a patent's term may be shortened if a patent is terminally disclaimed over another patent.

The effective filing date of a non-provisional patent application is used by the USPTO to determine what information is prior art when it considers the patentability of a claimed invention. If certain requirements are satisfied, a non-provisional patent application can claim the benefit of the filing date of an earlier filed provisional patent application. As a result, the filing date accorded by the provisional patent application may supersede information that otherwise could preclude the patentability of an invention.

The term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, or PTE, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a PTE of up to five years beyond the expiration of the patent. The length of the PTE is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when OCR-002 or any future product candidates we may develop receive FDA or other regulatory approval, we expect to apply for PTEs on patents covering those products. Depending upon the timing, duration and specifics of FDA approval of OCR-002 or any future product candidates we may develop, one or more of our United States patents may be eligible for limited patent term restoration.

Regulatory Matters

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act and related regulations. Drugs are also subject to other federal, state and local statutes and regulations. Failure to comply with the applicable United States regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the imposition by the FDA or an Institutional Review Board, or IRB, of a clinical hold on trials, the FDA's refusal to approve pending applications or supplements, withdrawal of an approval, warning or untitled letters, voluntary product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, distribution, record keeping, approval, advertising and promotion of our products.

The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of OCR-002 or any future product candidates or approval of new disease indications or label changes. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

Marketing Approval

The process required by the FDA before drugs may be marketed in the United States generally involves the following:

- nonclinical laboratory and animal tests;
- submission of an Investigational New Drug, or IND, application which must become effective before clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use or uses;
- pre-approval inspection of manufacturing facilities and clinical trial sites; and
- FDA approval of a New Drug Application, or NDA, which must occur before a drug can be marketed or sold.

The testing and approval process requires substantial time and financial resources, and we cannot be certain that any new approvals for our product candidates will be granted on a timely basis if at all.

Our planned clinical trials for our product candidates may not begin or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in:

- obtaining regulatory approval to commence a trial;
- reaching agreement with third-party clinical trial sites and their subsequent performance in conducting accurate and reliable studies on a timely basis;
- obtaining IRB approval to conduct a trial at a prospective site;
- nonclinical laboratory and animal tests;
- recruiting patients to participate in a trial; and
- supply of the drug.

Prior to commencing the first clinical trial, an initial IND application must be submitted to the FDA. The IND application automatically becomes effective 30 days after receipt by the FDA unless the FDA within the 30-day time period raises concerns or questions about the conduct of the clinical trial. In such case, the IND application sponsor must resolve any outstanding concerns with the FDA before the clinical trial may begin. A separate submission to the existing IND application must be made for each successive clinical trial to be conducted during product development. Further, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that site. Informed consent must also be obtained from each trial subject. Regulatory authorities, an IRB or the sponsor, may suspend or terminate a clinical trial at any time on various grounds, including a finding that the participants are being exposed to an unacceptable health risk.

For purposes of NDA approval, human clinical trials are typically conducted in phases that may overlap:

- Phase 1 - the drug is initially given to healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. These studies may also gain early evidence on effectiveness. During Phase 1 clinical trials, sufficient information about the investigational drug's pharmacokinetics and pharmacologic effects may be obtained to permit the design of well-controlled and scientifically valid Phase 2 clinical trials.

- Phase 2 - studies are conducted in a limited number of patients in the target population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3 - when Phase 2 evaluations demonstrate that a dosage range of the product appears effective and has an acceptable safety profile, and provide sufficient information for the design of Phase 3 studies, Phase 3 trials are undertaken to provide statistically significant evidence of clinical efficacy and to further test for safety in an expanded patient population at multiple clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to further evaluate dosage, effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug, and to provide an adequate basis for product approval by the FDA.

- Phase 4 - post-marketing studies, or Phase 4 clinical trials, may be conducted after initial marketing approval. These studies may be required by the FDA as a condition of approval and are used to gain additional experience from the treatment of patients in the intended therapeutic indication. The FDA also now has express statutory authority to require post-market clinical studies to address safety issues.

All of these trials must be conducted in accordance with good clinical practice requirements in order for the data to be considered reliable for regulatory purposes.

Government regulation may delay or prevent marketing of product candidates or new drugs for a considerable period of time and impose costly procedures upon our activities. We cannot be certain that the FDA or any other regulatory agency will grant approvals for any future product candidates on a timely basis, if at all. Success in early stage clinical trials does not ensure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.

The NDA Approval Process

In order to obtain approval to market a drug in the United States, a marketing application must be submitted to the FDA that provides data establishing to the FDA's satisfaction the safety and effectiveness of the investigational drug for the proposed indication. Each NDA submission requires a substantial user fee payment unless a waiver or exemption applies. The application includes all relevant data available from pertinent nonclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators.

The FDA will initially review the NDA for completeness before it accepts it for filing. The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel drug products or drug products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Based on pivotal Phase 3 trial results submitted in an NDA, upon the request of an applicant, the FDA may grant a priority review designation to a product, which sets the target date for FDA action on the application at six months, rather than the standard ten months. Priority review is given where preliminary estimates indicate that a product, if approved, has the potential to provide a significant improvement compared to marketed products or offers a therapy where no satisfactory alternative therapy exists. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

After the FDA completes its initial review of an NDA, it will communicate to the sponsor that the drug will either be approved, or it will issue a complete response letter to communicate that the NDA will not be approved in its current form and inform the sponsor of changes that must be made or additional clinical, nonclinical or manufacturing data that must be received before the application can be approved, with no implication regarding the ultimate approvability of the application.

Before approving an NDA, the FDA may inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical sites to assure compliance with GCP. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it typically will outline the deficiencies and often will request additional testing or information. This may significantly delay further review of the application. If the FDA finds that a clinical site did not conduct the clinical trial in accordance with GCP, the FDA may determine the data generated by the clinical site should be excluded from the primary efficacy analyses provided in the NDA. Additionally, notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process for a drug requires substantial time, effort and financial resources and this process may take several years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 studies may be made a condition to be satisfied for continuing drug approval. The results of Phase 4 studies can confirm the effectiveness of a product candidate and can provide important safety information. In addition, the FDA has express statutory authority to require sponsors to conduct post-market studies to specifically address safety issues identified by the agency.

Even if a product candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or might contain significant limitations on use in the form of warnings, precautions or contraindications, or in the form of onerous risk management plans, restrictions on distribution, or post-marketing trial requirements. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. In addition, we cannot predict what adverse governmental regulations may arise from future United States or foreign governmental action.

FDA Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including requirements for record-keeping and reporting of adverse experiences with the drug. Drug manufacturers are required to register their facilities with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain quality processes, manufacturing controls and documentation requirements upon us and our third-party manufacturers in order to ensure that the product is safe, has the identity and strength, and meets the quality and purity characteristics that it purports to have. Certain states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP and other FDA regulatory requirements. If our present or future suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, fail to approve any NDA or other application, request that we recall a drug from distribution, shut down manufacturing operations or withdraw approval of the NDA for that drug. Noncompliance with cGMP or other requirements can result in issuance of warning letters, civil and criminal penalties, seizures and injunctive action.

Labeling, Marketing and Promotion

The FDA closely regulates the labeling, marketing and promotion of drugs. While doctors are free to prescribe any drug approved by the FDA for any use, a company can only make claims relating to safety and efficacy of a drug that are consistent with FDA approval, and the company is allowed to actively market a drug only for the particular use and treatment approved by the FDA. In addition, any claims we make for our products in advertising or promotion must be appropriately balanced with important safety information and otherwise be adequately substantiated. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, injunctions and potential civil and criminal penalties. Government regulators recently have increased their scrutiny of the promotion and marketing of drugs.

Orphan Designation and Fast Track Status

OCR-002 received orphan designation for the treatment of hyperammonemia and resultant HE in patients with acute liver failure or acute-on-chronic liver disease. Under the Orphan Drug Act, the FDA may grant orphan designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan designation must be requested before submitting an NDA. After the FDA grants orphan designation, the identity of the applicant, as well as the name of the therapeutic agent and its designated orphan use, are disclosed publicly by the FDA. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Generally, if a drug that receives orphan designation is approved for the orphan indication, it receives orphan drug exclusivity, which for seven years prohibits the FDA from approving another product with the same active chemical entity for the same indication. Orphan exclusivity will not bar approval of another product under certain circumstances, including if the new drug is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or provides a major contribution to patient care, or if the company with the orphan drug exclusivity is not able to meet market demand. More than one product may also be approved by the FDA for the same orphan indication or disease as long as the products contain different active ingredients. As a result, even though OCR-002 has received orphan designation, the FDA can still approve other drugs that have a different active chemical entity for use in treating the same indication or disease covered by OCR-002, which could create a more competitive market for us.

Orphan designation for OCR-002 for HE was granted based on data demonstrating that this disease affects fewer than 200,000 patients in the United States.

OCR-002 has also received Fast Track status from the FDA. Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier.

Anti-Kickback and False Claims Laws

In the United States, in addition to the FDA, the research, manufacturing, distribution, sale and promotion of drug products and medical devices are potentially subject to regulation by various federal, state and local authorities, including the Centers for Medicare & Medicaid Services, other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice, state Attorneys General, and other state and local government agencies. For example, sales, marketing and scientific/educational grant programs must comply with the federal Anti-Kickback Statute, as amended, the False Claims Act, as amended, the privacy regulations promulgated under the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws. Pricing and rebate programs must comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

As noted above, in the United States, we are subject to complex laws and regulations pertaining to healthcare “fraud and abuse,” including, but not limited to, the Anti-Kickback Statute, the federal False Claims Act, and other state and federal laws and regulations. The Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs. In addition, many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to the referral of patients for healthcare services reimbursed by any insurer, not just federal healthcare programs such as Medicare and Medicaid. Due to the breadth of these federal and state anti-kickback laws, the absence of guidance in the form of regulations or court decisions, and the potential for additional legal or regulatory change in this area, it is possible that our future sales and marketing practices and/or our future relationships with physicians might be challenged under anti-kickback laws, which could harm us. Because we intend to commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs, we plan to develop a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which we will or may become subject.

The federal False Claims Act prohibits anyone from knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Although we would not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to “cause” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding

information to customers or promoting a product off-label. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. For example, pharmaceutical companies have been prosecuted under the federal False Claims Act in connection with their off-label promotion of drugs. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between $10,781 and $21,563 for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. If the government were to allege that we were, or convict us of, violating these false claims laws, we could be subject to a substantial fine and may suffer a decline in our stock price. In addition, private individuals have the ability to bring actions under the federal False Claims Act and certain states have enacted laws modeled after the federal False Claims Act.

There are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. In addition, as discussed below, a similar federal requirement has required manufacturers to track and report to the federal government certain payments made to physicians and teaching hospitals made in the previous calendar year. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state and federal authorities.

Patient Protection and Affordable Care Act

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the PPACA, was enacted, which includes measures that have or will significantly change the way health care is financed by both governmental and private insurers. Among the provisions of PPACA of greatest importance to the pharmaceutical industry are the following:

- The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Effective in 2010, PPACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs and biologic products from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended-release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. PPACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by expanding the population potentially eligible for Medicaid drug benefit. In addition, PPACA provides for the public availability of retail survey prices and certain weighted average AMPs under the Medicaid program. The implementation of this requirement by CMS may also provide for the public availability of pharmacy acquisition of cost data, which could negatively impact our sales.

- In order for a pharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to United States government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. The PPACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs when used for the orphan indication. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.

- PPACA imposed a requirement on manufacturers of branded drugs and biologic products to provide a 50% discount off the negotiated price of branded drugs dispensed to Medicare Part D patients in the coverage gap.

- PPACA imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic products, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications.

- PPACA will require pharmaceutical manufacturers to track certain financial arrangements with physicians and teaching hospitals, including any "transfer of value" made or distributed to such entities, as well as any investment interests held by physicians and their immediate family members. Manufacturers of products reimbursable by federal healthcare programs are required to report this information to CMS annually, and CMS posts this information on its website.

- A new Patient-Centered Outcomes Research Institute was established pursuant to PPACA to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products.

- PPACA authorized the creation of the Independent Payment Advisory Board with the authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription drugs.

- PPACA established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation from 2011 to 2019.

Some of the provisions of the PPACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, that while not a law, is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the PPACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the PPACA that are repealed. Thus, the full impact of the PPACA, or any law replacing elements of it, on our business remains unclear.

Privacy

We may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes certain of HIPAA's privacy and security standards directly applicable to business associates, defined as an entity that performs certain functions that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

In addition to HIPAA and HITECH, other federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use and disclosure of personal information. Various foreign countries also have, or are developing, laws governing the collection, use and transmission of personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business.

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

Research and Development

We devote a substantial portion of our resources to developing new product candidates. During the years ended December 31, 2016, 2015 and 2014, we expended approximately $16.1 million , $16.0 million , and $14.9 million , respectively, on research and development activities.

Employees

We had 19 full-time employees as of December 31, 2016. None of our employees are represented by any collective bargaining unit. We believe that we maintain good relations with our employees.

Corporate and Available Information

Our principal corporate offices are located at 525 University Avenue, Suite 610, Palo Alto, CA 94301 and our telephone number is (650) 475-0158. We were incorporated in Delaware in 2004. Our internet address is www.ocerainc.com. We make available on our website, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or the SEC. Our SEC reports can be accessed through the Investors section of our website. Further, a copy of this Annual Report on Form 10-K is located at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D. C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements and other information regarding our filings at http://www.sec.gov. The information found on our website is not incorporated by reference into this Annual Report on Form 10-K or any other report we file with or furnish to the SEC.

All trademarks or trade names referred to in this Form 10-K are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Form 10-K may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report on Form 10-K and in our other public filings in evaluating our business, although the risks described below are not the only risks facing us. If any of the following risks, or any additional risks and uncertainties not currently known to us or that we currently deem to be immaterial, actually occurs, our business, financial condition, results of operations and future prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.

Risks Related to Our Business and the Development, Potential Regulatory Approval and Commercialization of our Product Candidates

We depend substantially on the success of our sole clinical product candidate, OCR-002, and, in light of the failure to demonstrate statistical significance in the clinical endpoints in our recently completed Phase 2b clinical trial of intravenously-administered OCR-002 in hospitalized patients with hepatic encephalopathy, we may never successfully complete the development of OCR-002, obtain regulatory approval or successfully commercialize the product candidate.

Our business is substantially dependent on our ability to complete the development of, obtain regulatory approval for, and successfully commercialize our lone clinical product candidate, OCR-002, in both intravenous, or IV, and oral formulations, for the treatment of acute and chronic hepatic encephalopathy, or 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 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 faster clinical improvement and greater complete response rates compared to the patients on the lowest dose (10 grams) and those on placebo. In addition, consistent with its mechanism of action and the data we observed in pre-clinical studies, OCR-002 exhibited a statistically significant ammonia reduction over placebo for the study's pre-specified exploratory endpoint which was time to achieve normal plasma ammonia levels, p=0.028, hazard ratio 1.69.

In March 2017, we announced data from additional analyses that showed plasma ammonia reduction correlates with clinical improvement. Related to plasma ammonia levels, patients who responded had a greater change in plasma ammonia from baseline than patients who did not respond, (-28.2 and -9.2 µg/mL, respectively), p=0.0006. With regard to clinical improvement, patients on OCR-002 had a higher response rate at 48 hours than placebo, (51 and 37%, respectively),

p=0.026. In addition, while not the primary endpoint patient-improvement measure, when patient improvement was measured by the pre-defined endpoint, Physician Overall Treatment Evaluation, a greater proportion of patients on OCR-002 demonstrated improvement over placebo, p=0.026. Rifaximin, although not indicated for hospitalized patients with overt HE, was widely used in the hospital resulting in a significant percentage of study patients having rifaximin concomitantly administered during OCR-002 therapy. Post hoc analysis of the time to improvement in HE symptoms excluding patients who used rifaximin indicates the primary endpoint of the study would have been achieved with high statistical significance, p=0.004. Other study data indicate OCR-002 provided clinical benefit over placebo as observed by improvement in Model for End-Stage Liver Disease, or MELD scores, p=0.051, and improvement in renal function as measured by the change from baseline in Blood Urea Nitrogen, or BUN levels, p=0.04.

We believe the data from the trial will be integral in determining dose levels and other design elements for future clinical testing and suggest that OCR-002 can become an important intervention in both the treatment and prevention of HE. We currently plan to meet with the FDA to discuss a development path forward for OCR-002. While we believe the results of the trial demonstrate the potential of OCR-002, the FDA may attach less significance to our post-hoc analysis and place greater emphasis on our pre-defined clinical endpoints, which did not achieve statistical significance. As a result, there can be no assurance that we will be able to advance intravenous OCR-002 into Phase 3 development and we may not be able to pursue further development efforts or obtain regulatory approval for OCR-002.

We have not submitted a new drug application, or NDA, for or received regulatory approval to market OCR-002 in any jurisdiction. We have only limited experience in filing the applications necessary to gain regulatory approvals and expect to rely on consultants and third party contract research organizations to assist us in this process. Securing approval by the United States Food and Drug Administration, or FDA, requires the submission of extensive pre-clinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to the FDA for each therapeutic indication to establish a product candidate's safety and efficacy.

OCR-002 and the activities associated with its development and commercialization, including testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. We are not permitted to market OCR-002 or any future product candidates we may develop in the United States until we receive approval of an NDA for the product candidate in a particular indication from the FDA. Failure to obtain regulatory marketing approval for a product candidate will prevent us from commercializing the product candidate, and our ability to generate revenue will be materially impaired.

The process of obtaining necessary regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the product candidates involved. Changes in the regulatory approval policy during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application, may cause delays in the approval or rejection of an application. Regulatory approval obtained in one jurisdiction does not necessarily mean that a product candidate will receive regulatory approval in all jurisdictions in which we may seek approval.

The FDA, European Medicines Agency, or EMA, and other regulators have substantial discretion in the approval process and may form an opinion, after review of our data, that any NDA we may file with the FDA is insufficient to allow approval of OCR-002 for any of the indications we are pursuing. The FDA may require that we conduct additional clinical, nonclinical, manufacturing validation or drug product quality studies and submit data from these studies before it will consider or reconsider any NDA we may file. Depending on the extent of these or any other studies, approval of any applications that we submit may be delayed, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve the use of OCR-002 for the treatment of acute or chronic HE. If any of these outcomes occur, we may not receive regulatory approval for OCR-002. Even if we obtain FDA approval for OCR-002, the approval might contain significant limitations related to use restrictions for certain age groups, warnings, precautions or contraindications, or may be subject to significant post-marketing studies or risk mitigation requirements. If we are unable to successfully commercialize OCR-002, we may not be able to earn sufficient revenues to continue our business.

We plan to meet with the FDA for an End-of-Phase 2 meeting to discuss next steps regarding future development for the IV formulation of OCR-002. At this time, the United States regulatory pathway is highly uncertain and we may never reach a common understanding with the FDA on a path forward to develop OCR-002 in the United States, or obtain regulatory approval of OCR-002. If that were to occur, it would have a material adverse effect on our operations, or ability to obtain financing and our financial condition.

Results from our Phase 2b clinical trial of OCR-002 may not be predictive of the safety and efficacy results in future clinical trials of the product candidate.

Notwithstanding that the clinical endpoints did not reach statistical significance, the patients in our Phase 2b trial of intravenously-administered OCR-002 at the higher doses (15 and 20 grams) had faster clinical improvement and greater complete response rates compared to the patients on the lowest dose (10 grams) and those on placebo. Furthermore, 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 addition, the Phase 2a investigator-sponsored clinical trials of IV OCR-002 have studied, as a primary endpoint, the ability of OCR-002 to reduce plasma ammonia in patients with liver cirrhosis and acute liver failure. In these trials, we believed the dose of OCR-002 administered was insufficient to produce drug levels likely to be sufficiently efficacious at lowering ammonia.

While we believe, based on the results of the Phase 2a and 2b clinical trials, that increased doses of OCR-002 should lead to reductions in plasma ammonia, and that such reduction in plasma ammonia should result in faster time to clinically meaningful improvement in HE symptoms, the results of any future clinical trials of OCR-002 may not bear this out. In addition, although the data from our Phase 2b trial showed that OCR-002 was both safe and well-tolerated at all dose levels evaluated, and we have tested doses of up to 60 grams of OCR-002 in prior clinical trials, there can be no assurance that we will be able to maintain a similar favorable safety profile in future clinical trials, if any, that utilize a higher dosage than our Phase 2b trial. In the event that safety concerns are raised by any future trials of OCR-002, we may no longer be able to pursue further development or commercialization efforts for OCR-002. Further, given that the oral and intravenous formulations of OCR-002 contain the same active pharmaceutical ingredient, safety concerns raised any future trials could also prevent us from further developing or commercializing the oral OCR-002 formulation.

Results from our Phase 1 clinical trials of oral formulations of OCR-002 may not be predictive of the safety and efficacy results in future clinical trials of the product candidate.

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

We cannot assure you that our future clinical trials will achieve similarly positive results due to a number of facts, including:

- Benchmarking against RAVICTI, which works exclusively through phenylacetate while OCR-002 contains phenylacetate and ornithine, might not prove to be effective;
- We may never develop a commercially acceptable oral formulation of OCR-002;
- Results in healthy subjects, as we observed in our first Phase 1 clinical trial of oral OCR-002, may not translate to patients afflicted with liver cirrhosis and other diseases; and
- A multinational, multicenter trial could result in increased variability due to a number of reasons, including varying patient characteristics including demographic factors, health status, underlying reason for disease state and concomitant medications, such as lactulose and rifaximin.

The patient populations suffering from both HE and acute liver failure are small. If we are unable to timely enroll our clinical trials or reach the desired enrollment levels, our development program for OCR-002 will likely be delayed.

We estimate that in the United States, the annual number of hospitalizations that involve HE is approximately 260,000 cases. We now plan to initiate a Phase 2a trial with a tablet formulation of OCR-002 in the first half of 2017 in patients with cirrhosis. If the enrollment in our planned Phase 2a trial in the first half of 2017, or any future studies, is delayed, it will likely result in delays in our OCR-002 development program and the time to commercialization. In addition, if the population of patients afflicted with HE is smaller than we estimate, or is reduced over time due to other treatments for liver diseases, it could have a material adverse impact on the results of our operations.

To obtain regulatory approval to market OCR-002 in additional indications and formulations, additional costly and lengthy clinical studies will be required, and the results are uncertain.

As part of the regulatory approval process, we will conduct, at our own expense, nonclinical and clinical studies for each indication and formulation that we intend to pursue. We expect that the number of nonclinical and clinical studies that the regulatory authorities will require will vary. Generally, the number and size of clinical trials required for approval depends on the nature of the disease and size of the expected patient population that may be treated with a drug. In light of the top-line results from our Phase 2b clinical trial of intravenously-administered OCR-002, our regulatory pathway in the U.S in uncertain. We plan to meet with the FDA for an End-of-Phase 2 meeting to discuss next steps regarding future development for the IV formulation of OCR-002. If we are required to perform additional nonclinical and clinical studies, or studies involving a significantly larger number of patients than our Phase 2b in order to obtain regulatory approval of OCR-002, we may not have the resources or the ability to raise capital to conduct the trial on our own, which could result in a material adverse impact on our business and our ability to return value to our shareholders.

Serious adverse events or other safety risks could require us to abandon development and preclude or limit approval of OCR-002 to treat HE.

We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants or if preliminary data demonstrate that OCR-002 or any future product candidates we may develop are unlikely to receive regulatory approval or unlikely to be successfully commercialized. In addition, regulatory agencies or institutional review boards may at any time order the temporary or permanent discontinuation of our clinical trials or request that we cease using investigators in the clinical trials if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, or that they present an unacceptable safety risk to participants. If we elect or are forced to suspend or terminate a clinical trial of OCR-002, the commercial prospects for OCR-002 will be harmed and our ability to generate product revenues from OCR-002 may be delayed or eliminated.

Even though we have received orphan drug designation, we may not receive orphan drug exclusivity for OCR-002.

As part of our business strategy, we have obtained orphan drug designation in the United States for OCR-002 for the treatment of hyperammonemia and resultant HE in patients with acute liver failure and acute-on-chronic liver disease. We have also obtained orphan drug designation in the European Union for OCR-002 for the treatment of acute liver failure and are considering whether to submit such a request for the HE indication in the near future. In the United States, the company that first obtains FDA approval for a designated orphan drug for the specified rare disease or condition receives orphan drug marketing exclusivity for that drug for a period of seven years. This orphan drug exclusivity prevents the FDA from approving another application, including a full NDA, to market the same drug for the same orphan indication, except in very limited circumstances, including when the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. For purposes of small molecule drugs, the FDA defines "same drug" as a drug that contains the same active chemical entity and is intended for the same use as the drug in question. A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for OCR-002, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition.

Any product for which we obtain marketing approval could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

Even if United States regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly and time consuming post-approval studies, post-market surveillance or clinical trials. Our product candidates will also be subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of safety and other post-market information. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requesting recall or withdrawal of the product from the market or suspension of manufacturing.

If we, or third party manufacturers for OCR-002 or any of our future product candidates, fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements or applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of product, or request us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

The FDA has the authority to require a risk evaluation and mitigation strategy, or REMS, plan as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry.

In addition, if OCR-002 or any future product candidates we may develop are approved, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for OCR-002 or any future product candidates we may develop, physicians may nevertheless prescribe our products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and to commercialize OCR-002 and any future product candidates we may develop and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for OCR-002 and any future product candidates we may develop, restrict or regulate post-approval activities and affect our ability to profitably sell any of our product candidates for which we obtain marketing approval.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted,

or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the United States Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. Drug pricing and other healthcare costs also continue to be subject to intense political and societal pressures, which we anticipate will continue and escalate on a global basis. These pressures may result in harm to our business and reputation, cause our stock price to decline or experience periods of volatility and adversely affect results of operations and our ability to raise funds.

In the United States, the Medicare Modernization Act or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the PPACA, became law in the United States. The PPACA is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms. The PPACA revised the definition of “average manufacturer price” for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the law imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners. Some of the provisions of the PPACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, that while not a law, is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the PPACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the PPACA that are repealed. Thus, the full impact of the PPACA, or any law replacing elements of it, and the political uncertainty relating to its repeal and any replacement on our business remains unclear.

If our competitors are able to develop and market products that are preferred over OCR-002, our commercial opportunity for such product candidate will be reduced.

We face competition from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions, which may in the future develop products to treat HE, acute liver failure and other liver diseases. Even if we complete development, obtain regulatory approval and commercialize OCR-002 to treat HE, we will face competition from Salix Pharmaceuticals, Inc., a subsidiary of Valeant Pharmaceuticals, International, Inc., the manufacturer of rifaximin, as well as generic manufacturers of lactulose and potential generic manufacturers of rifaximin. In addition, researchers are continually learning more about liver disease including HE, and new discoveries may lead to new therapies. Horizon Pharma could also recommence development of RAVICTI for HE. As a result, OCR-002 may be rendered less competitive. Other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity will be reduced if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are more convenient or are less expensive than OCR-002. We expect that our ability to compete effectively will depend upon, among other things, our ability to:

- successfully and rapidly complete clinical trials and obtain all required regulatory approvals in a timely and cost-effective manner;
- raise capital to fund additional clinical develop or seek collaborations or other transactions involving the continued development of OCR-002;
- maintain patent protection for OCR-002 and otherwise prevent the introduction of generics of OCR-002;

- attract and retain key personnel;
- build an adequate sales and marketing infrastructure;
- obtain adequate reimbursement from third-party payors; and
- maintain positive relationships with patient advocacy groups.

The commercial success of OCR-002 will depend upon the degree of market acceptance among physicians, patients, patient advocacy groups, health care payors and the medical community. If we fail to obtain and sustain adequate reimbursement of OCR-002 from commercial third-party and government payors, our revenue will be more limited and it will be more difficult to achieve profitability.

OCR-002, if approved, may not gain sufficient market acceptance among physicians, patients, patient advocacy groups, health care payors and the medical community and our business may suffer. The degree of market acceptance of OCR-002, after approval, if any, will depend on a number of factors, including:

- the effectiveness of OCR-002 as compared to other products indicated for HE or other similar disorders;
- the prevalence and severity of any side effects;
- the market price and patient out-of-pocket costs of OCR-002 relative to other treatment options, including any generics;
- relative convenience and ease of administration with respect to the IV and oral formulations of OCR-002;
- willingness by patients to stop using current treatments and adopt a new treatment;
- restrictions on healthcare provider prescribing of and patient access to our products due to a REMS;
- the strength of our marketing and distribution organizations;
- the quality of our relationship with patient advocacy groups; and
- commercial viability, including sufficient third-party coverage or reimbursement.

If we fail to obtain and sustain an adequate level of reimbursement for OCR-002 by commercial third-party and governmental payors, our sales, revenue and gross margins would be adversely affected, and we may not find it commercially viable. Third-party payors, such as government or private health care insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for, drugs. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors. A current trend in the United States health care industry is toward cost containment. Large public and private payors, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, are questioning the coverage of, and challenging the prices charged for, medical products and services, and many third-party payors limit coverage of or reimbursement for newly approved health care products. In particular, third-party payors may limit the covered indications. Cost-control initiatives could decrease the price we might establish for products, which could result in product revenues being lower than anticipated. If the prices for our products decrease or if governmental and other third-party payors do not provide adequate coverage and reimbursement levels, our revenue and prospects for profitability will suffer.

Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. Reimbursement in the European Union must be negotiated on a country-by-country basis and in many countries the product cannot be commercially launched until reimbursement is approved. The negotiation process in some countries can exceed 12 months.

If we are unable to establish an organization capable of successfully commercializing OCR-002 in the United States, our business may be harmed.

We currently do not have an organization capable of commercializing an approved product candidate. If OCR-002 is approved by the FDA for commercial sale, we may choose to market OCR-002 directly to physicians in the United States through our own sales and marketing force and related internal commercialization infrastructure. We will need to incur significant additional expenses and commit significant additional management resources to establish and train an internal sales and marketing force to market and sell OCR-002. We may not be able to successfully establish these capabilities despite these additional expenditures. We will also have to compete with other pharmaceutical and life sciences companies to recruit, hire, train and retain sales and marketing personnel. In the event we are unable to successfully market and promote OCR-002, our business may be harmed.

If we fail to establish an effective distribution process utilizing specialty pharmacies, our business could suffer materially and our stock price could decline.

We do not currently have the infrastructure necessary for distributing pharmaceutical products to patients. We intend to contract with a third-party logistics company to warehouse these products, if approved, and distribute them to specialty pharmacies. A specialty pharmacy is a pharmacy that specializes in the dispensing of medications for complex or chronic conditions which require a high level of patient education and ongoing management. This distribution network will require significant coordination with our sales and marketing and finance organizations. Failure to secure contracts with a logistics company and specialty pharmacies could negatively impact the distribution of our products, and failure to coordinate financial systems could negatively impact its ability to accurately report product revenue. If we are unable to effectively establish and manage the distribution process, the commercial launch and sales of our products will be delayed or severely compromised and our results of operations may be harmed.

In addition, the use of specialty pharmacies involves certain risks, including, but not limited to, risks that these specialty pharmacies will:

- not provide us with accurate or timely information regarding their inventories, the number of patients who are using our products, or complaints regarding our products;
- not effectively sell or support our products;
- reduce their efforts or discontinue to sell or support our products;
- not devote the resources necessary to sell our products in the volumes and within the time frames that we expect;
- not comply with any requirements imposed on pharmacies through REMS;
- be unable to satisfy financial obligations to us; or
- cease operations.

Any such failure may result in decreased product sales and lower product revenue, which would harm our business.

Even if the FDA approves OCR-002 in the United States, we may never obtain approval for or commercialize OCR-002 outside of the United States, which would limit our ability to realize our full market potential.

In order to market OCR-002 outside of the United States, if approved, we must comply with the regulatory requirements of, and obtain the required regulatory approvals in, other countries. Clinical trials conducted in one country may not be accepted by the regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could require additional nonclinical studies or clinical trials, which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of OCR-002 in those countries. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

Our future growth depends, in part, on our ability to penetrate foreign markets, where we are subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability will depend, in part, on our ability to grow and ultimately maintain our sales in foreign markets. We may rely on third parties to support our foreign operations.

Any foreign operations we establish in the future subject us to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our products in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties who may not put the same priority on our products as we would;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;

- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our products could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions, changes in tariffs and difficulties in staffing and managing foreign operations .

If we obtain approval to commercialize OCR-002 outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If OCR-002 is approved outside the United States, we will likely enter into agreements with third parties to commercialize and distribute OCR-002 outside the United States. We expect that we will be subject to additional risks related to entering into or maintaining these international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- differing United States and foreign drug import and export rules;
- reduced protection for intellectual property rights in foreign countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- different reimbursement systems;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- potential liability resulting from development work conducted by these distributors; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters.

If we fail to attract and retain senior management and key scientific personnel, we may be unable to successfully develop OCR-002, conduct clinical trials and potentially commercialize OCR-002.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management team. The loss of services of any of these individuals or one or more of our other members of senior management could delay or prevent the successful development of product candidates we may develop. In light of the significant stock price decline following the announcement of our Phase 2b topline data, we could experience problems in the future retaining and attracting qualified employees. In addition, competition for qualified personnel in the biotechnology and pharmaceuticals fields is intense. We may not be able to retain and attract quality personnel on acceptable terms who have the expertise we need to sustain and grow our business.

If we are found in violation of federal or state "fraud and abuse" laws, we may be required to pay a penalty and/or be suspended from participation in federal or state health care programs, which may adversely affect our business, financial condition and results of operation.

In the United States, we are subject to various federal and state health care "fraud and abuse" laws, including anti- kickback laws, false claims laws and other laws intended to reduce fraud and abuse in federal and state health care programs. The federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce the referral of business, including the purchase, order or prescription of a particular drug for which payment may be made under a federal health care program, such as Medicare or Medicaid. Under federal government regulations, some arrangements, known as safe harbors, are deemed not to violate the federal Anti-Kickback Statute. Although we seek to structure our business arrangements in compliance with all applicable requirements, these laws are broadly written, and it is often difficult

to determine precisely how the law will be applied in specific circumstances. Accordingly, it is possible that our practices may be challenged under the federal Anti-Kickback Statute. False claims laws prohibit anyone from knowingly and willfully presenting or causing to be presented for payment to third-party payors, including government payors, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services that were not provided as claimed, or claims for medically unnecessary items or services. Cases have been brought under false claims laws alleging that GMP manufacturing violations or off-label promotion of pharmaceutical products or the provision of kickbacks has resulted in the submission of false claims to governmental health care programs. Under the Health Insurance Portability and Accountability Act of 1996, and its relevant amendments, we are prohibited from knowingly and willfully executing a scheme to defraud any health care benefit program, including private payors, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and/or exclusion or suspension from federal and state health care programs such as Medicare and Medicaid and debarment from contracting with the United States government. In addition, private individuals have the ability to bring actions on behalf of the government under the federal False Claims Act as well as under the false claims laws of several states.

Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for health care services reimbursed by any source, not just governmental payors. In addition, California and a few other states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America, Code on Interactions with Healthcare Professionals. In addition, several states impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties.

Neither the government nor the courts have provided definitive guidance on the application of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of its practices may be challenged under these laws. While we believe we have structured our business arrangements to comply with these laws, it is possible that the government could allege violations of, or convict us of violating, these laws. If we are found in violation of one of these laws, we could be required to pay a penalty and could be suspended or excluded from participation in federal or state health care programs, and our business, financial condition and results of operations may be adversely affected.

Risks Related to Our Financial Position and Need for Additional Capital

There is substantial doubt as to our ability to continue as a going concern.

We have a limited operating history and the sales and income potential of its business and market are unproven. We have experienced net losses each year since its inception and, as of December 31, 2016, have an accumulated deficit of $158.3 million . We anticipate that we will continue to incur net losses into the foreseeable future and will need to raise additional capital as we continue the development and commercialization of OCR-002. Our cash, cash equivalents and marketable securities may not be sufficient to fund our operations beyond early 2018. These factors raise substantial doubt about our ability to continue as a going concern within twelve months following the date of the filing of this Form 10-K. As discussed in more detail in Note 1 to our financial statements included in this report, these uncertainties raise substantial doubt regarding our ability to continue as a going concern.

Our ability to continue as a going concern will require 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 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 filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights and our ability to pay off our indebtedness when due. Our ability to finance operations beyond our current resources will depend heavily on value investors see in the data from our previous clinical trials of OCR-002, favorable results from any future clinical trials of OCR-002 we may conduct, and our ability to potentially secure strategic partnership or collaboration related to the continued development and potential commercialization of OCR-002. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. We may seek to raise additional capital through a combination of private and public equity offerings and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, as is the case with our Term Loan Facility, results in increased fixed payment obligations and may involve agreements that include covenants

limiting or restricting our ability to take specific actions such as incurring debt, making capital expenditures or declaring dividends.

If we are unable to raise the capital we need, we may elect to, among other things, attempt to complete a strategic transaction, sell or otherwise dispose of assets. If our board of directors decides to dissolve our company and liquidate our assets, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurance as to the amount or timing of available cash left to distribute to our stockholders after paying our debts and other obligations and setting aside funds for potential future claims.

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

We anticipate that we will continue to incur net losses for the foreseeable future.

We anticipate that a substantial portion of our capital resources and efforts in the foreseeable future will be focused on the continued development of OCR-002. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have an adverse effect on stockholders' deficit and working capital.

We will need additional capital to support the continued development of OCR-002, which may be difficult to obtain and restrict our operations and would result in additional dilution to our stockholders.

We will need to obtain additional financing to fund future operations, including the development and commercialization of OCR-002, if approved. Our future funding requirements will depend on many factors, including, but not limited to:

- the initiation, progress, timing, scope and costs of potential future nonclinical studies and clinical trials, including the ability to timely enroll patients in our potential future clinical trials, if any;
- our ability or inability to locate suitable partners or collaborators;
- the time and cost necessary to obtain regulatory approvals;
- the costs of manufacturing clinical and commercial supplies of OCR-002;
- payments of milestones and royalties to third parties;
- the costs and timing of establishing sales and marketing capabilities in selected markets;
- the terms and timing of establishing collaborations, license agreements and other partnerships on terms favorable to us or at all;
- the time and cost necessary to respond to technological and market developments;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- any changes made to, or new developments in, our restated collaboration agreement with UCL Business PLC, or UCL, or any new collaborative, licensing and other commercial relationships that we may establish; and
- our obligations to repay the outstanding indebtedness under our Term Loan Facility, as defined below.

General market conditions or the market price of our common stock may not support capital-raising transactions, such as an additional public or private offering of our common stock or other securities. In addition, our ability to raise additional capital may be dependent upon our stock being quoted on The NASDAQ Global Market or upon obtaining stockholder approval. There can be no assurance that we will be able to satisfy the criteria for continued listing on The NASDAQ Global Market or that we will be able to obtain stockholder approval if it is necessary. If we are unable to obtain additional funds on a timely basis or on terms favorable to us, we may be required to cease or reduce certain research and development projects, to sell some or all of our technology or assets or to merge all or a portion of our business with another entity. In the event additional financing is needed or advisable, we may seek to fund our operations through the sale of equity securities, additional debt financing and strategic collaboration agreements. We cannot be sure that additional financing from any of these sources will be available when needed or that, if available, the additional financing will be obtained on terms favorable to us or our stockholders. If we raise additional funds by selling shares of our capital stock, the ownership interest of our current stockholders will be diluted. If we attempt to secure additional funds through strategic collaboration agreements, we may not be successful in doing so, or if such an agreement is executed, we may not be successful in securing funds necessary to continue the full development of OCR-002. The terms of any debt facility may involve significant cash

payment obligations as well as covenants and specific financial ratios that may restrict our ability to commercialize OCR-002 or operate our business. Any of these actions could have a material adverse effect on our business, financial condition and results of operations.

Accounting guidance requires management to assess, at each annual and interim reporting period, whether there are conditions or events that raise substantial doubt about our ability to continue as a going concern. Our management has made this assessment in connection with preparing this Annual Report and, as of the date of the filing of this Form 10-K, we believe that there is substantial doubt about our ability to continue as a going concern.

We have a significant amount of debt that may cause risks that could adversely affect our business, operating results and financial condition.

We entered into a Loan and Security Agreement, or the Loan Agreement, with Oxford Finance LLC and Silicon Valley Bank, or collectively, the Lenders on July 30, 2015. We obtained a $10 million term loan under the Loan Agreement, which was funded on July 30, 2015. We refer to this facility as the Term Loan Facility. The Term Loan Facility is secured by substantially all of our assets and the assets of our subsidiary, 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 level and nature of our indebtedness could, among other things:

- make it difficult for us to obtain any necessary financing in the future;
- limit our flexibility in planning for or reacting to changes in our business;
- reduce funds available for use in our operations and corporate development initiatives;
- cause the lenders to declare a material adverse event has occurred, which would accelerate our repayment obligations;
- impair our ability to incur additional debt because of financial and other restrictive covenants or the liens on our assets that secure our current debt;
- hinder our ability to raise equity capital, because in the event of a liquidation of our business, debt holders receive a priority before equity holders;
- make us more vulnerable in the event of a downturn in our business; and
- place us at a possible competitive disadvantage relative to less leveraged competitors and competitors that have better access to capital resources.

Any of these actions could have a material adverse effect on our business, financial condition and results of operations. We may also incur significantly more debt in the future, which will increase each of the risks described above related to our indebtedness.

The Loan Agreement for the Term Loan Facility contains operating covenants that may restrict our business and financing activities.

The Loan Agreement restricts, among other things, 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; or

- 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.

The operating restrictions and covenants in the Loan Agreement, as well as any future financing agreements that we may enter into, may restrict our ability to finance our operations, engage in business activities or expand or fully pursue our business strategies. Our ability to comply with these covenants may be affected by events beyond our control and we may not be able to meet those covenants. A breach of any of the covenants under the Loan Agreement, or the lenders declaring that a material adverse event has occurred, could result in a default under the Loan Agreement, which could cause all of the outstanding indebtedness under the Term Loan Facility to become immediately due and payable.

We may seek to enter into licensing or collaboration agreements with respect to OCR-002. We may not be able to identify suitable collaborators and, even if we do, our dependence on such relationships may adversely affect our business.

Because we have limited resources, we may seek to enter into collaboration agreements with other pharmaceutical or biotechnology companies. Our strategy for commercializing OCR-002 may depend on our ability to enter into agreements with collaborators to obtain assistance and funding for the development and potential commercialization of our product candidates in the territories in which we may seek to partner. Despite our efforts, we may be unable to secure collaborative licensing or other arrangements that are necessary for us to further develop and commercialize OCR-002. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. If we are successful in entering into one or more collaboration agreements, collaborations may involve greater uncertainty for us, as we will have less control over certain aspects of our collaborative programs than we do over our current development and commercialization programs.

Any failure by our partners to perform their obligations or any decision by our partners to terminate these agreements could negatively impact our ability to successfully develop, obtain regulatory approvals for and commercialize OCR-002. In the event we grant exclusive rights to such partners, we could be precluded from potential commercialization of OCR-002 within the territories in which we have a partner. In addition, any termination of our collaboration agreements will terminate any funding we may receive under the relevant collaboration agreement and may impair our ability to fund further development efforts and our progress in our development of OCR-002.

Further, our potential future collaborators may develop alternative products or pursue alternative technologies either on their own or in collaboration with others, including our competitors, and the priorities or focus of our collaborators may shift such that OCR-002 receive less attention or resources than we would like, or they may be terminated altogether. Any such actions by our potential future collaborators may harm our business prospects and ability to earn revenues. In addition, we could have disputes with our potential future collaborators, such as the interpretation of terms in our agreements. Any such disagreements could lead to delays in the development or commercialization of OCR-002 or could result in time-consuming and expensive litigation or arbitration, which may not be resolved in our favor.

Our future financial results could be adversely impacted by asset impairments or other charges.

Applicable accounting standards requires that we test assets determined to have long lives for impairment on an annual, or on an interim basis if certain events occur or circumstances change that would reduce the fair value of an asset below its carrying value. In addition, long-lived assets with finite lives are tested for impairment whenever events or changes in circumstances indicate that its carrying value may not be recoverable. A significant decrease in the fair value of a long-lived asset, an adverse change in the extent or manner in which a long-lived asset is being used or in its physical condition or an expectation that a long-lived asset will be sold or disposed of significantly before the end of its previously estimated life are among several of the factors that could result in an impairment charge. We intend to evaluate the carrying value of our assets to determine if the merger and private placement indicate that the carrying amounts of such assets may not be recoverable. Such a review could result in an impairment charge, which could have a negative impact on our results of operations and financial position, as well as on the market price of our common stock.

Risks Related to Our Reliance on Third Parties

We currently depend on third parties to conduct some of the operations of our clinical trials in connection with the development and application for regulatory approval of OCR-002.

We rely on numerous third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to oversee some of the operations of our clinical trials and to perform data collection and analysis. As a result, we may face additional delays outside of our control if these parties do not perform their obligations in a timely fashion or in accordance with regulatory requirements. If these third parties do not successfully carry out their contractual duties or obligations and meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our financial results and the commercial prospects for OCR-002, if approved, or our other potential product candidates could be harmed, our costs could increase and our ability to obtain regulatory approval and commence product sales could be delayed.

We have no manufacturing capacity and anticipate continued reliance on third-party manufacturers for the development and commercialization of our products.

We do not currently operate manufacturing facilities for clinical or commercial production of any product. We have limited personnel experienced in drug manufacturing and formulation, and we lack the resources and the capabilities to manufacture OCR-002, if approved, on a clinical or commercial scale. We do not intend to develop facilities for the manufacture of drug substance for clinical trials or products for commercial purposes in the foreseeable future. We rely on third-party manufacturers to produce bulk drug substance and drug products required for our clinical trials of OCR-002 and for developing the oral formulation of OCR-002. We plan to continue to rely upon contract manufacturers and, potentially, collaboration partners to manufacture commercial quantities of our products if and when approved for marketing by the applicable regulatory authorities. We have had clinical supplies of OCR-002 drug substance manufactured for us by Helsinn Chemicals SA in Switzerland and our plan is to have further clinical and potentially commercial supply of OCR-002 drug substance manufactured for us by Evonik in France. Finished product manufacturing and filling for OCR-002 IV clinical supplies has been undertaken by AAI Pharma Service Corp in North Carolina. We have not secured commercial supply agreements with any contract manufacturers for OCR-002 and can give no assurance that we will enter commercial supply agreements with any contract manufacturers on favorable terms or at all. Our contract manufacturers' failure to achieve and maintain high manufacturing standards, in accordance with applicable regulatory requirements, or the incidence of manufacturing errors, could result in patient injury or death, product shortages, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business. Contract manufacturers often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel.

Our existing manufacturer and any future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business. In the event of a natural disaster, business failure, strike or other difficulty, we may be unable to replace a third-party manufacturer in a timely manner and the production of our products would be interrupted, resulting in delays and additional costs.

Some of the intellectual property necessary for the commercialization of our products is or will be licensed from third parties, which will require us to pay milestones and royalties.

We have a license agreement on OCR-002 with UCL for worldwide rights to develop and commercialize the product candidate and related technologies for any use. We may be required to make future milestone payments to UCL totaling up to $20.0 million upon the achievement of various milestones related to clinical and regulatory events for OCR-002. We may also be required to pay milestone payments totaling up to $35.0 million upon the achievement of various milestones related to future net sales of OCR-002. Should we seek approval for more than two indications with either formulation of OCR-002 we may be required to pay additional clinical and regulatory milestones. We are also obligated to pay tiered royalties in the low to mid-single digits on future net sales of the licensed product.

We may become obligated to make milestone or royalty payments when we do not have the cash on hand to make these payments or have budgeted cash for our development efforts. This could cause us to delay our development efforts, curtail our operations, scale back our commercialization and marketing efforts or seek additional capital to meet these obligations, which could be on terms unfavorable to us. Additionally, if we fail to make a required payment and do not cure the failure within the required time period, the licensor may be able to terminate our license to use the licensed technology. If our license from UCL is terminated, it may be impossible for us to commercialize OCR-002.

We are increasingly dependent on information technology systems to operate our business and a cyber attack or other breach of our systems, or those of third parties on whom we may rely, could subject us to liability or interrupt the operation of our business.

We are increasingly dependent on information technology systems to operate our business. A breakdown, invasion, corruption, destruction or interruption of critical information technology systems by employees, others with authorized access to our systems or unauthorized persons could negatively impact operations. In the ordinary course of business, we collect, store and transmit confidential information and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such information. Additionally, we outsource certain elements of our information technology systems to third parties. As a result of this outsourcing, our third party vendors may or could have access to our confidential information making such systems vulnerable. Data breaches of our information technology systems, or those of our third party vendors, may pose a risk that sensitive data may be exposed to unauthorized persons or to the public. While we believe that we have taken appropriate security measures to protect our data and information technology systems, and have been informed by our third party vendors that they have as well, there can be no assurance that our efforts will prevent breakdowns or breaches in our systems, or those of our third party vendors, that could adversely affect our business.

Risks Related to Product Liability

If product liability lawsuits are successfully brought against us, we will incur substantial liabilities and may be required to limit the commercialization of OCR-002 or other products.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize our product candidates; and
- a decline in our stock price.

In addition, while we continue to take what we believe are appropriate precautions, we may be unable to avoid significant liability if any product liability lawsuit is brought against us.

If product liability lawsuits are successfully brought against us, our insurance may be inadequate.

We are exposed to the potential product liability risks inherent in the testing, manufacturing and marketing of human pharmaceuticals. We plan to maintain insurance against product liability lawsuits for commercial sale of OCR-002, if approved for sale. We currently maintain insurance for the clinical trials of product candidates. Biopharmaceutical companies must balance the cost of insurance with the level of coverage based on estimates of potential liability. Historically, the potential liability associated with product liability lawsuits for pharmaceutical products has been unpredictable. Although we believe that our current insurance is a reasonable estimate of our potential liability and represents a commercially reasonable balancing of the level of coverage as compared to the cost of the insurance, we may be subject to claims in connection with clinical trials and commercial use of OCR-002 and other product candidates we may develop, for which existing insurance coverage may not be adequate.

The product liability insurance we will need to obtain in connection with the commercial sales of our product and product candidates, if and when they receive regulatory approval, may be unavailable in meaningful amounts or at a reasonable cost. If we are the subject of a successful product liability claim that exceeds the limits of any insurance coverage obtained, we may incur substantial charges that would adversely affect earnings and require the commitment of capital resources that might otherwise be available for the development and commercial launch of product programs.

Risks Related to Our Intellectual Property

We may not be able to protect our proprietary technology in the marketplace.

We place considerable importance on obtaining patent protection for new technologies, products and processes because our commercial success will depend, in part, on obtaining patent protection for new technologies, products and processes, successfully defending these patents against third-party challenges and successfully enforcing our patents against third party competitors. To that end, we file applications for patents covering compositions of matter or uses of our product candidates or our proprietary processes as well as other intellectual property important to our business.

Where appropriate, we seek patent protection for certain aspects of our technology. Patent protection may not be available for some of the product candidates or technologies we are developing. If we must spend significant time and money protecting or enforcing our patents, designing around patents held by others or licensing, potentially for large fees,

patents or other proprietary rights held by others, our business and financial prospects may be harmed. We may not develop additional proprietary products which are patentable.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal, scientific and factual questions. Accordingly, our patent applications may never be approved by United States or foreign patent offices and the patents and patent applications relating to our product candidates and technologies may be challenged, invalidated or circumvented by third parties and might not protect us against competitors with similar products or technologies. Publication of information related to OCR-002 and future product candidates we may develop may prevent us from obtaining or enforcing patents relating to these product candidates, including without limitation composition-of- matter patents, which are generally believed to offer the strongest patent protection.

We own, or have licensed, patents in the United States and in certain foreign jurisdictions related to OCR-002. Patents that we own or license do not ensure the protection of our intellectual property for a number of reasons, including without limitation the following:

- we may be required to disclaim part of the term of one or more patents;
- there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim;
- there may be prior art of which we are aware, which we do not believe affects the validity or enforceability of a patent claim, but which, nonetheless ultimately may be found to affect the validity or enforceability of a patent claim;
- there may be other patents existing in the patent landscape for OCR-002 that will affect our freedom to operate;
- if our patents are challenged, a court or patent office could determine that they are not valid or enforceable;
- a court could determine that a competitor's technology or product does not infringe our patents; and
- our patents could irretrievably lapse due to failure to pay fees or otherwise comply with regulations, or could be subject to compulsory licensing.

If we encounter delays in our development or clinical trials, the period of time during which we could market our products under patent protection would be reduced.

Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours, or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition or invalidity proceedings before United States or foreign patent offices. In addition, under the America Invents Act of 2011, or AIA, the United States patent system, among other things, has transitioned from a first-to-invent to a first-to-file patent system, increases the scope of prior art available for patentability and invalidity determinations for patent applications filed under the first-to-file system, and introduces new procedures, including post-grant review and inter partes review, for challenging United States patents once they have granted. The various provisions of the AIA may impact our ability to secure meaningful patent protection for inventions that we develop in the future.

We also rely on trade secrets to protect technology in cases when we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we require employees, academic collaborators, consultants and other contractors to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary information. Our research collaborators and scientific advisors have rights to publish data and information in which we have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborators and advisors, our ability to receive patent protection or protect our proprietary information may be imperiled.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our in-licensed patents owned patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in

such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing OCR-002 or any future products we may develop.

Our commercial success depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. For example, there could be issued patents of which we are not aware that our products infringe. There also could be patents that we believe we do not infringe, but that we may ultimately be found to infringe. Moreover, patent applications are in some cases maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications we filed. Because patents can take many years to issue, there may be currently pending applications of which we are unaware that may later result in issued patents that our products infringe. For example, pending applications may exist that provide support or can be amended to provide support for a claim that results in an issued patent that our product infringes.

Third parties may assert that we are employing their proprietary technology without authorization. If a court held that any third-party patents are valid, enforceable and cover OCR-002 and any future products we may develop or their use, the holders of any of these patents may be able to block our ability to commercialize OCR-002 or any future products we may develop unless we obtained a license under the applicable patents, or until the patents expire. We may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost or on reasonable terms. Any inability to secure licenses or alternative technology could result in delays in the introduction of OCR-002 or any future products we may develop or lead to prohibition of the manufacture or sale of products by us.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We rely on trade secrets to protect our proprietary know-how and technological advances, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects upon our competitive business position.

Any lawsuits relating to infringement of intellectual property rights necessary to defend us or enforce our rights will be costly and time consuming.

Our ability to defend our intellectual property may require us to initiate litigation to enforce our rights or defend our activities in response to alleged infringement of a third-party. In addition, we may be sued by others who hold intellectual property rights who claim that their issued patents are infringed by OCR-002 or any future products or product candidates. These lawsuits can be very time consuming and costly. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally.

In addition, our patents and patent applications, or those of our licensors, could face other challenges, such as interference proceedings, opposition proceedings, re-examination proceedings, inter-partes review proceedings, post-grant review proceedings, and derivation proceedings. Any of these challenges, if successful, could result in the invalidation of, or in a narrowing of the scope of, any of our patents and patent applications subject to challenge. Any of these challenges, regardless of their success, would likely be time consuming and expensive to defend and resolve and would divert our management's time and attention.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees or consultants have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is commonplace in our industry, we employ individuals who were previously employed at, or performed services for, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject in the future to claims that our employees or prospective employees are subject to a continuing obligation to their former employers (such as non-competition or non-solicitation obligations) or claims that our employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we

are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

If we do not obtain protection under the Hatch-Waxman Amendments and similar foreign legislation by extending the patent terms and obtaining data exclusivity for OCR-002 or any future product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of OCR-002 or any future product candidates we may develop, one or more of our United States patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

Risks Related to Ownership of Our Capital Stock

If we fail to maintain the listing of our common stock with a United States national securities exchange, the liquidity of our common stock could be adversely affected.

If our common stock is delisted by NASDAQ, our common stock may be eligible to trade on the OTC Bulletin Board or another over-the-counter market. Any such alternative would likely result in it being more difficult for us to raise additional capital through the public or private sale of equity securities and for investors to dispose of, or obtain accurate quotations as to the market value of, our common stock. In addition, there can be no assurance that our common stock would be eligible for trading on any such alternative exchange or markets.

Our principal stockholders, executive officers and directors own a significant percentage of our common stock and will be able to exert a significant control over matters submitted to the stockholders for approval.

Our officers and directors, and stockholders who own more than 5% of our common stock beneficially own a significant percentage of our common stock. This significant concentration of share ownership may adversely affect the trading price for our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. These stockholders, if they acted together, could significantly influence all matters requiring approval by the stockholders, including the election of directors. The interests of these stockholders may not always coincide with the interests of other stockholders.

The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses.

Our stock price is likely to be volatile. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price at which it was purchased. The market price for our common stock may be influenced by many factors, including:

- our announcement of additional data from our Phase 2b clinical trial of intravenously-administered OCR-002;
- results of our planned End-of-Phase 2 meeting with the FDA;
- results of any future development efforts involving OCR-002 or any future product candidates we may develop, those of our competitors or those of other companies in our market sector;
- regulatory developments in the United States and foreign countries;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems, especially in light of current reforms to the United States healthcare system;
- announcements by us or our competitors of significant acquisitions, collaborations, licenses, strategic partnerships, joint ventures or capital commitments;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of securities analysts' reports or recommendations;

- sales of our stock by insiders and 5% or greater stockholders;
- general economic, industry and market conditions;
- additions or departures of key personnel;
- intellectual property, product liability or other litigation against us;
- expiration or termination of our relationships with our collaborators; and
- the other factors described in this “Risk Factors” section.

In addition, in the past, stockholders have initiated class action lawsuits against biotechnology and pharmaceutical companies following periods of volatility in the market prices of these companies' stocks. This risk is especially relevant for us because our stock price declined significantly following our announcement of topline data from our Phase 2b clinical trial of intravenously-administered OCR-002. Although we are not currently involved any securities class action litigation, we may be the target of this type of litigation in the future. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expenses related to our development programs;
- addition, modification or termination of our clinical trials;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting OCR-002 or any future product candidates we may develop;
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements; and
- the achievement and timing of milestone payments under our existing strategic partnership agreements.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

Our ability to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments is limited by provisions of the Internal Revenue Code, and may be subject to further limitation as a result of the Merger and prior or future offerings of our stock.

Section 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, contain rules that limit the ability of a company that undergoes an ownership change, which is generally any change in ownership of more than 50% of its stock over a three-year period, to utilize its net operating loss and tax credit carryforwards and certain built-in losses recognized in years after the ownership change. These rules generally operate by focusing on ownership changes involving stockholders owning directly or indirectly 5% or more of the stock of a company and any change in ownership arising from a new issuance of stock by the company. Generally, if an ownership change occurs, the yearly taxable income limitation on the use of net operating loss and tax credit carryforwards and certain built-in losses is equal to the product of the applicable long term tax exempt rate and the value of the company's stock immediately before the ownership change. We may be unable to offset future taxable income, if any, with losses, or our tax liability with credits, before such losses and credits expire and therefore would incur larger federal income tax liability.

It is likely that our reverse merger with Tranzyme, Inc. in July 2013 and other sales of our stock, either on a standalone basis or when combined with future transactions, have caused or will cause us to undergo one or more additional ownership changes. In that event, we generally would not be able to use our pre-change loss or credit carryovers or certain built-in losses prior to such ownership change to offset future taxable income in excess of the annual limitations imposed by Sections 382 and 383 and those attributes already subject to limitations as a result of our prior ownership changes may be subject to more stringent limitations.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may delay or prevent an acquisition of us or a change in our management. These provisions include:

- the prohibition on actions by written consent of our stockholders;
- the limitation on who may call a special meeting of stockholders;
- the establishment of advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings;
- the ability of our board of directors to issue preferred stock without stockholder approval, which would increase the number of outstanding shares and could thwart a takeover attempt; and
- the requirement of at least 75% of the outstanding common stock to amend any of the foregoing provisions.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. Although we believe these provisions collectively provide for an opportunity to obtain greater value for stockholders by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer rejected by our board were considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

We do not intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid any cash dividend on our common stock and do not currently intend to do so for the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

Failure to maintain effective internal controls could have a material adverse effect on our ability to produce accurate financial statements and on our stock price.

As a public company, we are subject to rules and regulations that require us to maintain the effectiveness of both disclosure controls and procedures and internal control over financial reporting. Effective disclosure controls and procedures and internal control over financial reporting are necessary for us to provide reliable financial reports, effectively prevent fraud and operate successfully as a public company. If we cannot provide reliable financial reports or prevent fraud, our reputation and operating results would be harmed. We are subject to the requirement to perform an annual management assessment of the effectiveness of our internal controls over financial reporting.

We may not be able to maintain effective disclosure controls and procedures and internal control over financial reporting in the future. If we are not able to maintain adequate compliance with these requirements in future years, we may be unable to report our financial information on a timely basis, which could result in SEC or other regulatory investigations or proceedings, violations of NASDAQ listing rules and loss of investor confidence in the reliability of our financial statements, and, in turn, materially adversely affect our business, reputation, financial position, results of operations and the market price of our common stock. In addition, we could be required to incur substantial accounting and auditing expense and significant management time in complying with these requirements, remediating any material weaknesses that may be identified in the future, or responding to any regulatory investigations or proceedings.

If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. We have limited research coverage by securities and industry analysts and may not maintain such coverage or obtain research coverage by additional securities and industry analysts. If we do not maintain such existing coverage, and additional securities or industry analysts do not commence coverage of our company, the trading price for our stock would be negatively impacted. If one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or

fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

In October 2013, the Company entered into an agreement to sublease approximately 2,188 square feet of office space located at 525 University Avenue, Palo Alto, California for the period from October 10, 2013 through December 31, 2016 . These premises serve as the Company's corporate headquarters. In December 2016, the Company amended the sublease for this facility by extending term of the lease to June 30, 2017. The Company does not have an option to extend the sublease term beyond June 30, 2017.

Certain of our clinical development operations are located in 8,126 square feet of office space located at 5001 South Miami Boulevard, Durham, North Carolina. In May 2016, we amended the lease for this facility by extending term of the lease through January 31, 2018.

In May 2016, we expanded our clinical operations to 5,000 square feet of office space located at 100 Lakeview Parkway, Vernon Hills, Illinois under a sublease that will expire on May 31, 2019.

We believe that our facilities are suitable and adequate for our current needs and that suitable additional or alternative space will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings

We are not currently subject to any material legal proceedings.

Item 4. Mine Safety Disclosures

Not applicable.

PART II.

Item 5. Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock commenced trading on the NASDAQ Global Market on July 16, 2013 under the symbol "OCRX" following the reverse merger with Tranzyme, Inc. and currently trades on the NASDAQ Global Select Market under the same symbol. The following table sets forth the high and low per share sale prices of our common stock as reported on the NASDAQ Global Select Market during each of the previous eight quarters.

	Price Range	
Fiscal year ending December 31, 2016	**High**	**Low**
1st Quarter	$3.90	$2.00
2nd Quarter	$3.27	$1.76
3rd Quarter	$2.99	$1.84
4th Quarter	$3.15	$1.90
Fiscal year ending December 31, 2015		
1st Quarter	$7.50	$4.18
2nd Quarter	$4.86	$3.30
3rd Quarter	$4.80	$2.88
4th Quarter	$4.57	$2.82

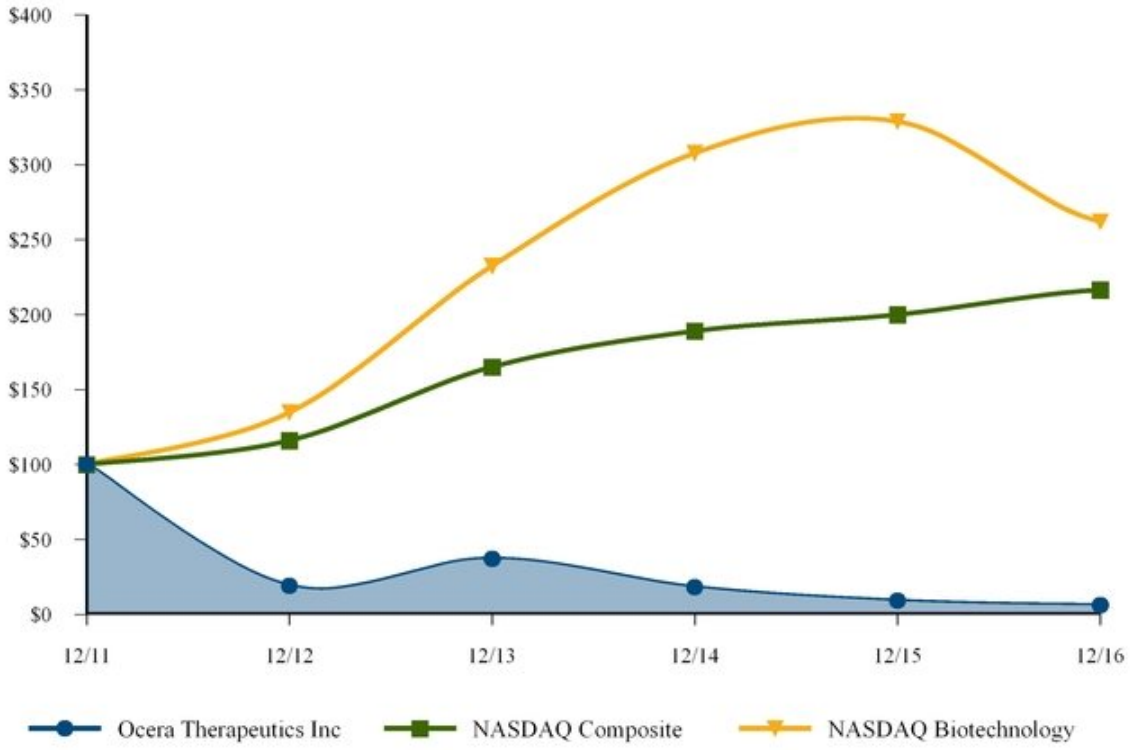
On March 13, 2017, the last trading day prior to March 14, 2017, the closing price for our common stock as reported by the NASDAQ Global Market was $1.47.

Comparative Stock Performance Graph

The graph below matches our cumulative 5 year total shareholder return on common stock with the cumulative total returns of the NASDAQ Composite index and the NASDAQ Biotechnology index. The graph tracks the performance of a $100 investment in our common stock and in each index (with the reinvestment of all dividends) from December 31, 2011 to December 31, 2016. Performance from December 31, 2011 through July 15, 2013 represents Tranzyme, symbol "TZYM" on the NASDAQ Global Market and from July16, 2013 through December 31, 2016 represents Ocera Therapeutics, Inc., symbol "OCRX" on the NASDAQ Global Market. The comparisons in the table and graph are required by the SEC and are not intended to forecast or be indicative of possible future performance of our common stock. The tabular information and graph shall not be deemed "soliciting material" or to be "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act or the Exchange Act.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

Among Ocera Therapeutics Inc., the NASDAQ Composite Index, and the NASDAQ Biotechnology Index



*$100 invested on 12/31/11 in stock or index, including reinvestment of dividends.

Fiscal year ending December 31:

	2011	2012	2013	2014	2015	2016
Ocera Therapeutics, Inc.	$ 100	$ 18.69	$ 37.46	$ 18.37	$ 9	$ 6.06
NASDAQ Composite	100.00	116.41	165.47	188.69	200.32	216.54
NASDAQ Biotechnology	100.00	134.68	232.37	307.67	328.76	262.08

Holders of Record

As of February 28, 2017 , there were approximately 41 holders of record of our common stock, one of which is Cede & Co., a nominee for Depository Trust Company, or DTC. All of the shares of common stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and therefore, are considered to be held of record by Cede & Co. as one stockholder.

Dividends

We have not declared or paid any cash dividends on our common stock since inception and do not plan to declare or pay cash dividends in the foreseeable future. Any future indebtedness that we may incur could preclude us from paying dividends.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Item 6. Selected Financial Data

The following selected consolidated financial data have been derived from our audited consolidated financial statements and should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and notes thereto appearing elsewhere in this Annual Report on Form 10-K. The information set forth below is historical and is not necessarily indicative of our results of future operations (in thousands, except share and per share amounts):

	Years Ended December 31,				
	2016	2015	2014	2013	2012
Consolidated Statements of Operations Data:					
Revenues:					
Royalty and licensing revenues	$ 609	$ 133	$ 341	$ 85	$ —
Operating expenses:					
Research and development	16,125	15,977	14,945	3,549	1,642
General and administrative	10,364	10,321	9,910	8,500	1,739
Amortization of intangibles	—	171	164	295	—
Impairment of intangibles	—	—	—	3,070	—
Total operating expenses	26,489	26,469	25,019	15,414	3,381
Other income (expense), net	(1,015)	(413)	54	(160)	(227)
Net loss from continuing operations	(26,895)	(26,749)	(24,624)	(15,489)	(3,608)
Net income (loss) from discontinued operations	—	227	1,199	(2,025)	—
Net loss	$ (26,895)	$ (26,522)	$ (23,425)	$ (17,514)	$ (3,608)
Net loss per share from continuing operations, basic and diluted	$ (1.22)	$ (1.33)	$ (1.41)	$ (2.52)	$ (5.76)
Net income (loss) per share from discontinued operations, basic and diluted	—	0.01	0.07	(0.33)	—
Net loss per share, basic and diluted	$ (1.22)	$ (1.32)	$ (1.34)	$ (2.85)	$ (5.76)
Shares used to compute net loss per share, basic and diluted	21,957,917	20,067,660	17,525,187	6,145,731	626,593

	As of December 31,				
	2016	2015	2014	2013	2012
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 24,611	$ 35,921	$ 10,127	$ 15,533	$ 2,303
Short and long-term investments	3,749	7,415	41,040	31,680	—
Working capital (deficit), excluding notes payable	24,890	40,188	45,364	42,605	(1,054)
Total assets	29,639	44,737	53,052	51,820	2,410
Notes payable	9,703	9,508	—	—	—
Convertible notes payable	—	—	—	—	2,908
Convertible preferred stock	—	—	—	—	61,743
Accumulated deficit	(158,328)	(131,433)	(104,911)	(81,486)	(63,972)
Total stockholders' equity (deficit)	15,737	31,394	50,145	45,132	(62,806)

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with our audited consolidated financial statements, related notes, and other financial information included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those described in, or implied by, the forward-looking statements. Factors that could cause or contribute to those differences include, but are not limited to, those identified below and those discussed above in the section entitled "Risk Factors."

Overview

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

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

In March 2017, we announced data from additional analyses that showed plasma ammonia reduction correlates with clinical improvement. Related to plasma ammonia levels, patients who responded had a greater change in plasma ammonia from baseline than patients who did not respond, (-28.2 and -9.2 µg/mL, respectively), p=0.0006. With regard to clinical improvement, patients on OCR-002 had a higher response rate at 48 hours than placebo, (51 and 37%, respectively), p=0.026. In addition, while not the primary endpoint patient-improvement measure, when patient improvement was measured by the pre-defined endpoint, Physician Overall Treatment Evaluation, a greater proportion of patients on OCR-002 demonstrated improvement over placebo, p=0.026. Rifaximin, although not indicated for hospitalized patients with overt HE, was widely used in the hospital resulting in a significant percentage of study patients having rifaximin concomitantly administered during OCR-002 therapy. Post hoc analysis of the time to improvement in HE symptoms excluding patients who used rifaximin indicates the primary endpoint of the study would have been achieved with high statistical significance, p=0.004. Other study data indicate OCR-002 provided clinical benefit over placebo as observed by improvement in Model for End-Stage Liver Disease, or MELD scores, p=0.051, and improvement in renal function as measured by the change from baseline in Blood Urea Nitrogen, or BUN levels, p=0.04. We currently plan to meet with the United States Food and Drug Administration, or FDA, for an End-of-Phase 2 meeting to discuss next steps regarding future development for the IV formulation of OCR-002. While we prepare for our meeting with the FDA, we continue to evaluate pathways forward for the continued development of OCR-002.

We are also developing an oral form of OCR-002 with the goal of providing continuity of care for HE patients post discharge in order to prevent subsequent episodes of acute HE. In January 2017, we completed a Phase 1 clinical trial with an orally administered liquid formulation of OCR-002 in patients with cirrhosis. In this open-label crossover study, OCR-002 was observed to be safe and well-tolerated with favorable pharmacokinetics, or pK, including absolute bioavailability of greater than 95%. In the fourth quarter of 2015, we completed a Phase 1 clinical trial with oral formulations of OCR-002 in healthy subjects. This open label, single-dose, five treatment, five-period crossover trial evaluated the pK, safety and tolerability of

three prototype, extended-release oral formulations of OCR-002 compared to an immediate release oral solution of OCR-002 and the FDA-approved ammonia-lowering agent, glycerol phenylbutyrate (RAVICTI). Glycerol phenylbutyrate is a pre-pro-drug of phenylacetate, or PAA, a component of OCR-002. The results of this trial demonstrated a robust, extended-release pattern for all three pilot OCR-002 extended-release formulations, with mean plasma phenylacetate concentrations exceeding those achieved with RAVICTI at all time points for at least 12 hours post-dose. In addition, the concentration of phenylacetylglutamine, or PAGN, the end-product responsible for clearing ammonia, was greater in both plasma and urine for all three OCR-002 extended-release dosage forms than RAVICTI at an approximately equivalent molar PAA dose. We plan to initiate a Phase 2a clinical trial with a tablet formulation of OCR-002 in cirrhotic patients in the first half of 2017.

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

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

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

Merger

On July 15, 2013, Tranzyme, Inc., or Tranzyme, completed its merger (the "Merger") with Ocera Therapeutics, Inc., a privately held Delaware corporation ("Private Ocera") in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of April 23, 2013 (the "Merger Agreement") by and among Tranzyme, Private Ocera and Terrapin Acquisition, Inc., a wholly-owned subsidiary of Tranzyme (the "Merger Subsidiary"). Pursuant to the Merger Agreement, Merger Subsidiary merged with and into Private Ocera, with Private Ocera, renamed as Ocera Subsidiary, Inc., surviving the merger as a wholly-owned subsidiary of the combined company. Immediately following the Merger, the combined company changed its name from “Tranzyme, Inc.” to “Ocera Therapeutics, Inc.”

In connection with the Merger, on July 15, 2013, Tranzyme effected a 12-to-1 reverse stock split of its outstanding common stock. As a result of the Merger and after giving effect to the reverse stock split, each outstanding share of Private Ocera's common stock was converted into the right to receive approximately 0.11969414 shares of our common stock. At the effective time of the Merger, the terms of each of Private Ocera's options and warrants were assumed by us and each outstanding option to purchase Private Ocera's common stock and warrant to purchase Private Ocera's common stock was converted into an option or warrant to purchase our common stock, respectively. No fractional shares of our common stock were issued in connection with the Merger. Instead, Ocera stockholders received cash in lieu of any fractional shares of our common stock such stockholders would otherwise be entitled to receive in accordance with the Merger Agreement.

Discontinued Operations

On September 11, 2013, the Board of Directors approved a restructuring plan related to the operations of Tranzyme Pharma Inc. (“Tranzyme Pharma”) and its Sherbrooke, Quebec facility, whereby we closed the operations of the facility effective November 11, 2013. On December 13, 2013, we entered into a technology transfer and license agreement (the "Technology Transfer and License Agreement") with Genentech, Inc. ("Genentech"), and F. Hoffman-La Roche, Ltd. ("Roche") to sell certain Canadian fixed assets and materials, the MATCH technology and rights to the Genentech and Roche customer agreements and related intellectual property through licensing of patents for $4.0 million. We concluded that the operations of Tranzyme Pharma and related asset groups sold to Genentech and Roche would be accounted for as discontinued operations as the operations and cash flows of the discontinued component or asset group would be eliminated from our ongoing operations and there would not be significant involvement in the component or asset group after the disposal transaction.

Financings

On July 30, 2015, we entered into a loan and security agreement (the "Loan Agreement") with Oxford Finance LLC and Silicon Valley Bank ("SVB") or collectively, the Lenders. The Loan Agreement provides up to $20 million principal in new term loans (the "Term Loan Facility"), $10 million of which was funded on July 30, 2015. The remaining $10 million was not drawn during the year ended December 31, 2016 and it expired at December 31, 2016 due to non-achievement of certain financial and clinical milestones.

On May 15, 2015, we filed a shelf registration statement on Form S-3 (File No. 333-204214) 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 (the "Sales Agreement") with Cowen and Company, LLC ("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 year ended December 31, 2015, we sold an aggregate of 946,497 shares of common stock under the Sales Agreement, at an average price of approximately $3.95 per share, for net proceeds of $3.5 million after deducting commissions and other transactions costs. During the year ended December 31, 2016, we sold an aggregate of 2,865,391 shares of common stock under the Sales Agreement, at an average price of approximately $2.61 per share, for net proceeds of $7.1 million after deducting commissions and other transactions costs. In March 2017, prior to the date of the filing of this Form 10-K, we sold an aggregate of 1,835,425 shares of common stock under the Sales Agreement at an average price of approximately $1.57 per share, for net proceeds of approximately $2.8 million . As of the date of the filing of this Form 10-K, common stock valued at $10.9 million remained available to be sold under the Sales Agreement, subject to the terms and conditions specified therein.

On July 10, 2014, we completed an underwritten public offering of our common stock with Stifel, Nicolaus & Company, Incorporated and Cowen, as representatives of the several underwriters, in which 4,200,000 shares of common stock were sold. The aggregate gross proceeds from the offering were $25.2 million. After deducting underwriters' discounts and commissions and offering expenses, the aggregate net proceeds received totaled approximately $23.4 million. The common stock was offered and sold pursuant to a base prospectus dated May 29, 2012 and a preliminary prospectus supplement filed with the United States Securities and Exchange Commission ("SEC") on July 9, 2014, in connection with a takedown from our prior shelf registration statement on Form S-3 (File No. 333-181215), which expired and was replaced in May 2015. W e have used and expect to continue to use the net proceeds from the offering to continue our clinical development of OCR-002 and for working capital and other general corporate purposes.

On November 8, 2013, we closed on a private placement financing contemplated by the Securities Purchase Agreement (the "Agreement") dated as of November 5, 2013 by and among the entities affiliated with Vivo Capital, Venrock, Deerfield Management, Great Point Partners, QVT Financial, RA Capital Management, InterWest Partners, Three Arch Opportunities Fund and certain other purchasers identified therein (the "Purchasers") pursuant to which we issued an aggregate of 3,940,887 units ("Units") for an aggregate purchase price of $28.0 million. Each Unit consisted of one share of our common stock and a warrant to acquire 0.20 shares of our common stock at an exercise price of $7.66 per share ("Warrants"). The Units consist of an aggregate of 3,940,887 shares of common stock (the "Shares") and Warrants exercisable for an aggregate of 788,177 shares of our Common Stock (the "Warrant Shares"). Concurrently with the execution of the Agreement, we entered into a Registration Rights Agreement that granted customary registration rights to the Purchasers. On December 6, 2013, we filed a registration statement registering the resale of the Shares and Warrant Shares subject to this private placement, which registration statement was declared effective on December 16, 2013.

On April 23, 2013, concurrently with the execution of the Merger Agreement, Tranzyme entered into a Securities Purchase Agreement with certain former Private Ocera stockholders and their affiliates and a Registration Rights Agreement

that granted customary registration rights to the participants of the Financing. Pursuant to the Securities Purchase Agreement, immediately following the consummation of the Merger, in July 2013, we sold 3,317,976 shares of common stock. The aggregate gross proceeds received were $20.0 million at a per share purchase price of $ 6.03 .

Licensing

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

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). The preparation of these 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 financial statements, as well as the reported revenues and expenses during the reporting periods. On a regular basis we evaluate and review the accounting policies, estimates, assumptions and judgments to ensure that our financial statements are presented fairly and in accordance with GAAP. 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 believe that the following accounting estimates are the most critical to aid in fully understanding and evaluating our reported financial results, and they involve a higher degree of judgment and complexity in their application than our other significant accounting policies. Refer to Note 2 to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K for information on significant accounting policies and estimates used in the preparation of the consolidated financial statements.

Clinical Trial Accruals

Clinical trial costs are a component of research and development expenses. We accrue and expense clinical trial activities performed by third parties based upon actual work completed in accordance with agreements established with clinical research organizations and clinical sites. This process involves identifying services that have been performed and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. Our clinical trial accruals are based on estimates of patient enrollment and related costs at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with vendors including, multiple research institutions, and clinical research organizations that conduct and manage clinical trials or provide supporting services on our behalf. We accrue expense related to clinical trials based on contracted amounts applied to the level of patient enrollment and/or estimated level of activity completed. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of clinical trial accruals accordingly on a prospective basis.

The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven timing of payments. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. We have not experienced any material deviations between the accrued clinical trial expenses and actual clinical trial expenses. However, actual services performed, number of patients enrolled and the rate of patient enrollment may vary from our estimates, resulting in adjustments to clinical trial expense in futures periods.

Stock-Based Compensation

Employee stock-based compensation is recognized as an expense in the financial statements based on the grant date fair value of the award. For awards that vest based on service conditions, we record compensation expense, net of estimated forfeitures, on a straight-line basis over the requisite service period which is generally the vesting period for the related award. For performance-based stock options, we evaluate the probability of achieving performance-based goals at each reporting date. We begin to recognize the expense when it is deemed probable that the performance-based goal will be met. We record

equity grants to non-employees as expense at their fair value over the related service period and periodically revalues them at each reporting period over the vesting term.

We estimate the fair value of stock options using a Black-Scholes-Merton option-pricing model which requires the input of highly subjective assumptions that represent our best estimates of volatility, risk-free interest rate, expected life, and dividend yield. We estimate expected volatility based on its own historical volatility supplemented by a review of historical volatilities of industry peers. We have, due to insufficient historical data, used the "simplified method," as described in Staff Accounting Bulletin No. 107, "Share-Based Payment," to determine the expected life of stock options granted with a service condition. The risk-free rate assumption was based on United States Treasury instruments whose terms were consistent with the expected term of the stock options. The expected dividend assumption was based on our history and expectation of dividend payouts.

We account for stock-based compensation arrangements with non-employees using a fair value approach. The fair value of these options is measured using the Black-Scholes-Merton option pricing model reflecting the same assumptions as applied to employee options in each of the reported periods, other than the expected life, which is assumed to be the remaining contractual life of the option. The compensation costs of these arrangements are subject to remeasurement over the vesting terms as earned.

We estimate fair value of stock options with market-based vesting conditions based on Monte Carlo simulation models with assistance from an independent third-party valuation specialist. The Monte Carlo simulation models require the use of highly subjective and complex assumptions which determine the fair value of such awards including price volatility of the underlying stock and derived service periods.

The assumptions used in calculating the fair value of stock options with market-based vesting conditions and expected attainment of performance conditions for performance-based stock options represent our best estimates, but these estimates involve inherent uncertainties and the application of management’s judgment. Future expense amounts for any particular period could be affected by changes in our assumptions.

Income Taxes

We account for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, we determine deferred tax assets and liabilities on the basis of the differences between the financial statement and tax basis of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

We recognize deferred tax assets to the extent that we believe that these assets are more likely than not to be realized. In making such a determination, we consider all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If we determine that we would be able to realize deferred tax assets in the future in excess of their net recorded amount, we would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of tax benefit might change as new information becomes available.

We record uncertain tax positions on the basis of a two-step process in which (1) we determine whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, we recognize the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. Our policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. To date, there have been no interest or penalties charged in relation to the underpayment of income taxes.

Recent Accounting Pronouncements

The information required by this item is included in Note 2 to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K.

Results of Operations

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

	Years Ended December 31,			Change			
	2016	2015	2014	2016 vs. 2015		2015 vs. 2014	
				$	%	$	%
Revenues:							
Royalty and licensing revenues	609	133	341	476	358 %	(208)	(61%)
Operating expenses:							
Research and development	16,125	15,977	14,945	148	1 %	1,032	7%
General and administrative	10,364	10,321	9,910	43	— %	411	4%
Amortization of intangibles	—	171	164	(171)	(100)%	7	4%
Total operating expenses	26,489	26,469	25,019	20	— %	1,450	6%
Total other income (expense), net	(1,015)	(413)	54	(602)	146 %	(467)	(865%)
Net loss from continuing operations	(26,895)	(26,749)	(24,624)	(146)	1 %	(2,125)	9%
Net income from discontinued operations	—	227	1,199	(227)	(100)%	(972)	(81%)
Net loss	$ (26,895)	$ (26,522)	$ (23,425)	$ (373)	1 %	$ (3,097)	13%

Revenues

Licensing revenue for the year ended December 31, 2016 was $0.1 million . This revenue is attributable to the asset license and purchase agreement for the sale and license of *ulimorelin* (the "Lyric Agreement") to Lyric Pharmaceuticals, Inc. ("Lyric") based on a milestone that was achieved by Lyric in 2016. There was no licensing revenue generated for the year ended December 31, 2015. Licensing revenue for the year ended December 31, 2014 was $0.2 million , consisting of an up-front nonrefundable payment for the transfer of intellectual property and materials associated with the Lyric Agreement.

Royalty revenue for the years ended December 31, 2016, 2015 and 2014 was $0.5 million , $0.1 million and $0.1 million , respectively. This revenue is attributable to a licensing agreement acquired in the Merger. In October 2016, we assigned our rights to certain non-core intellectual property related to the licensing agreement to GE Healthcare Dharmacon, Inc. (“GE”), formerly known as Open Biosystems, Inc. In consideration for such assignment, we received a one-time payment of $0.5 million from GE. No further royalty revenue will be recognized pursuant to this agreement as a result of this assignment.

Operating Expenses

Research and Development Expenses

Research and development costs 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 were flat for the year ended December 31, 2016 as compared to 2015. We observed a decrease in expenses incurred with contract research organizations related to the development of the IV formulation of OCR-002 offset by increases in costs associated with the development of the oral formulation of OCR-002 and personnel-related expenses.

Research and development expenses increased by $1.0 million , or 7 %, for the year ended December 31, 2015 as compared 2014. The increase in expenses was primarily due to the increased costs associated with our development program for OCR-002, including the ongoing enrollment and site activation of our Phase 2b trial for OCR-002 and continued development of the oral formulation of OCR-002, including the completion of a Phase 1 clinical trial. These increases were partially offset by a decrease in stock compensation expense due to headcount changes.

General and Administrative Expenses

General and administrative expenses consist of salaries and other personnel-related expenses, including stock-based compensation, consulting and professional services expenses, facility costs, and depreciation and amortization expenses.

General and administrative expenses were flat for the year ended December 31, 2016 as compared to 2015. We observed an increase in expenses related to consulting and professional services offset by a decrease in expenses related to our corporate infrastructure.

General and administrative expenses increased by $0.4 million , or 4 % for the year ended December 31, 2015 as compared to 2014. The increase was primarily driven by an increase in personnel-related costs due to higher headcount partially offset by a decrease in costs associated with professional fees, including legal and accounting expenses.

Amortization of Intangibles

The carrying value of intangible assets acquired in connection with the Merger was fully amortized at December 31, 2015. Accordingly, no amortization expense was recorded related to intangibles during the year ended December 31, 2016.

We recognized $0.2 million for the amortization of the intangible assets during each of the years ended December 31, 2015 and 2014.

Other Income (Expense), Net

Other expense increased by $0.6 million for the year ended December 31, 2016 as compared to the year ended December 31, 2015. This increase was due to twelve months of interest and amortization of debt issuance costs on notes payable related to the Term Loan Facility entered into in July 2015, partially offset by interest income earned on our investment portfolio.

Other expense increased by $0.5 million for the year ended December 31, 2015 as compared to 2014 due to interest and amortization of debt issuance costs on notes payable related to the Term Loan Facility entered into in July 2015, partially offset by interest income earned on our investment portfolio.

Net loss from discontinued operations

For the year ended December 31, 2015, $0.2 million of income was related to certain foreign research credits received by Tranzyme Pharma. On December 14, 2015, Tranzyme Pharma was legally dissolved. Accordingly, no income or loss was recognized in 2016.

Net income from discontinued operations was $0.2 million for the year ended December 31, 2015 as compared to $1.2 million for the year ended December 31, 2014. This decrease of $1.0 million was primarily due to a gain on disposal of assets of $1.1 million related to the sale of our MATCH discovery platform to Genentech and Roche in 2014.

Liquidity and Capital Resources

Cash Flows

The following table summarizes cash flows for the years ended December 31, 2016 , 2015 and 2014 (in thousands):

	Years Ended December 31,		
	2016	2015	2014
Net cash provided by (used in):			
Continuing operating activities	$ (22,096)	$ (20,841)	$ (19,885)
Discontinued operating activities	—	227	(440)
Continuing investing activities	3,616	33,205	(10,028)
Discontinued investing activities	—	—	1,165
Financing activities	7,170	13,203	23,782
Net increase (decrease) in cash and cash equivalents	$ (11,310)	$ 25,794	$ (5,406)

Operating Activities

Cash used in continuing operating activities for the year ended December 31, 2016 was attributable to our net loss from continuing operations of $26.9 million adjusted for non-cash charges of $4.3 million which primarily consisted of stock-based compensation expense and changes in operating assets and liabilities of $0.5 million .

Cash used in continuing operating activities for the year ended December 31, 2015 was attributable to our net loss from continuing operations of $26.7 million and adjusted for changes in operating assets and liabilities of $1.3 million and

non-cash charges of $4.6 million including stock-based compensation expense, accretion of premium on investment in marketable securities, amortization of intangibles and debt discount.

Cash provided by discontinued operating activities for the year ended December 31, 2015 was due primarily to certain foreign research credits received.

Cash used in continuing operating activities for the year ended December 31, 2014 was attributable to our net loss from continuing operations of $24.6 million adjusted for changes in operating assets and liabilities of $0.7 million and non-cash charges of $5.5 million including stock-based compensation expense, accretion of premium on investment in marketable securities, and amortization of intangibles acquired in the Merger.

Cash used in discontinued operating activities for the year ended December 31, 2014 was primarily related to payment of accrued liabilities of discontinued operations.

Investing Activities

Cash provided by continuing investing activities for the year ended December 31, 2016 consisted of proceeds of $11.1 million from investment maturities, partially offset by purchases of investments of $7.5 million .

Cash provided by continuing investing activities for the year ended December 31, 2015 related to $56.6 million of proceeds from investment maturities, partially offset by purchases of investments of $23.3 million .

Cash used by continuing investing activities for the year ended December 31, 2014 related to purchases of investments of $41.4 million partially offset by proceeds from maturities of investments of $31.4 million .

Cash provided by discontinued investing activities for the year ended December 31, 2014 represents cash proceeds related to the Technology Transfer and License Agreement with Genentech and Roche for rights to the MATCH discovery platform and collection of other receivables.

Financing Activities

Cash provided by financing activities for the year ended December 31, 2016 consisted of net proceeds from the issuance of common stock pursuant to the “at the market” equity program of $7.1 million .

Cash provided by financing activities for the year ended December 31, 2015 related to net proceeds from issuance of notes payable related to the Term Loan Facility of $9.7 million and net proceeds from the issuance of common stock pursuant to the “at the market” equity program of $3.5 million .

Cash provided by financing activities for the year ended December 31, 2014 related to net proceeds of $23.4 million generated from our public offering of common stock completed on July 10, 2014, as well as proceeds from the exercise of stock options of $0.4 million .

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 due to non-achievement of certain financial and clinical milestones.

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.

Capital Resources and Funding Requirements

We will require 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 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, and the cost of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights.

On May 15, 2015, we filed a shelf registration statement on Form S-3 (File No. 333-204214) 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 the Sales Agreement, 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 year ended December 31, 2015, we sold an aggregate of 946,497 shares of common stock under the Sales Agreement, at an average price of approximately $3.95 per share, for net proceeds of $3.5 million after deducting commissions and other transactions costs. During the year ended December 31, 2016, we sold an aggregate of 2,865,391 shares of common stock under the Sales Agreement, at an average price of approximately $2.61 per share, for net proceeds of $7.1 million after deducting commissions and other transactions costs. In March 2017, prior to the date of the filing of this Form 10-K, we sold an aggregate of 1,835,425 shares of common stock under the Sales Agreement at an average price of approximately $1.57 per share, for net proceeds of approximately $2.8 million . As of the date of the filing of this Form 10-K, common stock valued at $10.9 million remained available to be sold under the Sales Agreement, subject to the terms and conditions specified therein.

We have a limited operating history and the sales and income potential of our business and market are unproven. We have experienced net losses each year since our inception and, as of December 31, 2016, have an accumulated deficit of $158.3 million . We anticipate that we will continue to incur net losses into the foreseeable future and will need to raise additional capital as we continue the development and commercialization of OCR-002. Our cash, cash equivalents and marketable securities may not be sufficient to fund our operations beyond early 2018. These factors raise substantial doubt about our ability to continue as a going concern within twelve months following the date of the filing of this Form 10-K. Our ability to continue as a going concern and finance operations beyond our current resources will depend heavily on value investors see in the data from our previous clinical trials of OCR-002 and favorable results from any future clinical trials of OCR-002 we may conduct. We plan to raise additional capital through collaboration, licensing or similar arrangements, private and public equity offerings or debt financing, or a combination thereof. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. Collaboration, licensing or similar arrangements may require us to relinquish valuable rights to our potential products or proprietary technologies. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, as is the case with our Term Loan Facility, results in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring debt, making capital expenditures or declaring dividends.

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 our product candidate, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our

current and anticipated clinical trials. Without additional funds, we may be forced to delay, scale back or eliminate some of our research and development activities or operations and potentially delay product development of OCR-002.

Contractual Obligations

The following table summarizes our future commitments arising from our contractual obligations at December 31, 2016 (in thousands):

	Payments due		
	Less than 1 year	1 to 3 years	Total
Notes payable obligations, including interest (1)	$ 3,839	$ 7,703	$ 11,542
Operating lease obligations	361	57	418
Other non-cancelable commitments (2)	921	—	921
Total future contractual obligations (3)	$ 5,121	$ 7,760	$ 12,881

(1) Upon the occurrence of an event of default, as defined in the Loan Agreement, and during the continuance of an event of default, a default interest rate of an additional 5% will be applied to the outstanding notes payable balances, and the Lenders may declare all outstanding obligations immediately due and payable. The principal payments due under the Loan Agreement have been classified as a current liability at December 31, 2016 due to the existence of a material adverse change clause under the Loan Agreement.

(2) Contractual obligation and commitments under clinical contracts that are non-cancelable.

(3) We have no commitments from contractual obligations beyond three years.

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

Off-Balance Sheet Arrangements

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

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Foreign Currency Risk

We have historically contracted with third-party providers to manufacture product and to conduct clinical trials and perform other research and development activities outside of the United States. While the majority of our contractual obligations are denominated in United States dollars, we are indirectly exposed to fluctuations in foreign currency exchange rates in connection with the liabilities incurred by us in these relationships. We do not currently hedge our exposures to foreign currency fluctuations.

Market Risk

Our cash and cash equivalents and investments as of December 31, 2016 consisted primarily of cash, money market funds, commercial paper and United States and foreign corporate debt securities. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of United States interest rates. However, due to the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operations. Additionally, as of December 31, 2016, interest rate for our notes payable was fixed.

If market interest rates were to increase by 100 basis points, or 1%, from December 31, 2016 levels, the impact to the fair value of our investment portfolio would be immaterial. We actively monitor changes in interest rates.

We did not hold any derivative instruments intended to mitigate interest rate risk as of December 31, 2016 and we have never held such instruments in the past.

Item 8. Financial Statements and Supplementary Data

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of
Ocera Therapeutics, Inc.

We have audited the accompanying consolidated balance sheets of Ocera Therapeutics, Inc. as of December 31, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Ocera Therapeutics, Inc. at December 31, 2016 and 2015, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company's recurring losses from operations and negative cash flows from operating activities raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

Redwood City, California
March 14, 2017

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

	December 31,	
	2016	**2015**
Assets		
Current assets:		
Cash and cash equivalents	$ 24,611	$ 35,921
Short-term marketable securities	3,749	7,415
Prepaid expenses and other current assets	584	686
Total current assets	28,944	44,022
Property and equipment, net	64	94
Deposits	36	26
Goodwill	595	595
Total assets	**$ 29,639**	**$ 44,737**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,215	$ 701
Accrued liabilities	2,839	3,133
Notes payable, short-term (Note 8)	9,703	—
Total current liabilities	13,757	3,834
Notes payable, long-term (Note 8)	—	9,508
Other liabilities	145	1
Total liabilities	**13,902**	**13,343**
Commitments and contingencies (Note 13)		
Preferred stock, $0.00001 par value, 5,000,000 shares authorized; no shares issued or outstanding at December 31, 2016 and December 31, 2015.	—	—
Common stock, $0.00001 par value, 100,000,000 shares authorized; 23,600,242 shares issued and outstanding at December 31, 2016 and 20,695,160 shares issued and outstanding at December 31, 2015.	—	—
Additional paid-in capital	174,065	162,832
Accumulated other comprehensive loss	—	(5)
Accumulated deficit	(158,328)	(131,433)
Total stockholders' equity	**15,737**	**31,394**
Total liabilities and stockholders' equity	**$ 29,639**	**$ 44,737**

See accompanying notes.

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

	Years Ended December 31,		
	2016	**2015**	**2014**
Revenues:			
Royalty and licensing revenues	$ 609	$ 133	$ 341
Operating expenses:			
Research and development	16,125	15,977	14,945
General and administrative	10,364	10,321	9,910
Amortization of intangibles	—	171	164
Total operating expenses	26,489	26,469	25,019
Other income (expense):			
Interest and other income	109	89	66
Interest and other expense	(1,124)	(502)	(12)
Total other income (expense), net	(1,015)	(413)	54
Net loss from continuing operations	(26,895)	(26,749)	(24,624)
Net income from discontinued operations	—	227	1,199
Net loss	$ (26,895)	$ (26,522)	$ (23,425)
Net loss per share:			
Net loss per share from continuing operations, basic and diluted	$ (1.22)	$ (1.33)	$ (1.41)
Net income per share from discontinued operations, basic and diluted	—	0.01	0.07
Net loss per share, basic and diluted	$ (1.22)	$ (1.32)	$ (1.34)
Weighted average common shares outstanding used to compute net loss per share of stock, basic and diluted	21,957,917	20,067,660	17,525,187
Comprehensive loss:			
Net loss	$ (26,895)	$ (26,522)	$ (23,425)
Unrealized gain (loss) on investments	5	22	(30)
Comprehensive loss	$ (26,890)	$ (26,500)	$ (23,455)

See accompanying notes.

Ocera Therapeutics, Inc.
Consolidated Statements of Stockholders' Equity
(In Thousands, Except Shares)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2013	15,300,214	$ —	$ 126,615	$ 3	$ (81,486)	$ 45,132
Issuance of common stock, net of issuance cost	4,200,000	—	23,384	—	—	23,384
Issuance of common stock upon exercise of stock options	225,871	—	398	—	—	398
Issuance of common stock upon cashless exercise of stock options	15,673	—	—	—	—	—
Issuance of common stock upon cashless exercise of stock warrants	5,604	—	—	—	—	—
Stock-based compensation expense	—	—	4,686	—	—	4,686
Net loss	—	—	—	—	(23,425)	(23,425)
Other comprehensive loss	—	—	—	(30)	—	(30)
Balance at December 31, 2014	19,747,362	$ —	$ 155,083	$ (27)	$ (104,911)	$ 50,145
Issuance of common stock, net of issuance cost	946,497	—	3,455	—	—	3,455
Issuance of common stock warrants in connection with notes payable	—	—	317	—	—	317
Issuance of common stock upon cashless exercise of stock warrants	1,301	—	—	—	—	—
Stock-based compensation expense	—	—	3,977	—	—	3,977
Net loss	—	—	—	—	(26,522)	(26,522)
Other comprehensive income	—	—	—	22	—	22
Balance at December 31, 2015	20,695,160	$ —	$ 162,832	$ (5)	$ (131,433)	$ 31,394
Issuance of common stock, net of issuance cost	2,865,391	—	7,144	—	—	7,144
Issuance of common stock upon exercise of stock options	23,938	—	26	—	—	26
Issuance of common stock upon cashless exercise of stock warrants	15,753	—	—	—	—	—
Stock-based compensation expense	—	—	4,063	—	—	4,063
Net loss	—	—	—	—	(26,895)	(26,895)
Other comprehensive income	—	—	—	5	—	5
Balance at December 31, 2016	23,600,242	$ —	$ 174,065	$ —	$ (158,328)	$ 15,737

See accompanying notes.

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

	Years Ended December 31,		
	2016	2015	2014
Operating activities			
Net loss	$ (26,895)	$ (26,522)	$ (23,425)
Adjustments to reconcile net loss to net cash used in operating activities:			
Net income from discontinued operations	—	(227)	(1,199)
Depreciation	44	42	36
Amortization of intangibles	—	171	164
Stock-based compensation	4,063	3,977	4,686
Accretion of premium on investment securities	41	367	600
Amortization of debt discount	195	77	—
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	92	346	(469)
Accounts payable	514	(240)	(341)
Accrued liabilities	(150)	1,168	63
Net cash used in continuing operating activities	(22,096)	(20,841)	(19,885)
Net cash provided by (used in) discontinued operating activities	—	227	(440)
Net cash used in operating activities	(22,096)	(20,614)	(20,325)
Investing activities			
Purchases of property and equipment	(14)	(75)	(38)
Purchases of marketable securities	(7,504)	(23,322)	(41,415)
Sale and maturities of marketable securities	11,134	56,602	31,425
Net cash provided by (used in) continuing investing activities	3,616	33,205	(10,028)
Net cash provided by discontinued investing activities	—	—	1,165
Net cash provided by (used in) investing activities	3,616	33,205	(8,863)
Financing activities			
Proceeds from the sale of common stock, net of underwriting discounts, commissions and issuance cost	7,144	3,455	23,384
Proceeds from notes payable, net	—	9,748	—
Proceeds from exercise of common stock options	26	—	398
Net cash provided by financing activities	7,170	13,203	23,782
Net increase (decrease) in cash and cash equivalents	(11,310)	25,794	(5,406)
Cash and cash equivalents, beginning of year	35,921	10,127	15,533
Cash and cash equivalents, end of year	$ 24,611	$ 35,921	$ 10,127
Supplemental disclosures of cash flow information			
Cash paid for interest	$ 828	$ 278	$ —
Supplemental schedule of non-cash investing and financing activities			
Fair value of warrants issued in connection with notes payable	$ —	$ 317	$ —
Unrealized gain (loss) on investments	$ 5	$ 22	$ (30)

See accompanying notes.

Notes to Consolidated Financial Statements

1. Description of Business

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

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

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

The Company has a limited operating history and the sales and income potential of its business and market are unproven. The Company has experienced net losses each year since its inception and, as of December 31, 2016, has an accumulated deficit of $158.3 million . 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, cash equivalents and marketable securities may not be sufficient to fund its operations beyond early 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-K. The Company's ability to continue as a going concern and finance operations beyond its current resources will depend heavily on value investors see in the data from previous clinical trials of OCR-002 and favorable results from any future clinical trials of OCR-002 the Company may conduct.

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

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

2. Summary of Significant Accounting Policies

Basis of Accounting

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and the applicable rules and regulations of the Securities and Exchange Commission ("SEC") and include the accounts of the Company and Ocera Subsidiary, Inc. All significant intercompany balances and transactions have been eliminated in consolidation. All amounts included in these notes to consolidated financial statements are reported in United States dollars, unless otherwise indicated.

Use of Estimates

The preparation of financial statements in conformity with United States 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.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company views and manages its business as one operating segment.

Cash and Cash Equivalents

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

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a significant concentration of credit risk consist primarily of cash and cash equivalents and investments in marketable securities. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. However, management believes the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. Additionally, the Company has established guidelines regarding diversification of its investments in marketable securities and their maturities, which are designed to maintain safety and liquidity.

Investments in Marketable Securities

The Company invests in marketable securities, primarily money market funds, commercial paper, government agency debt securities and United States and foreign corporate debt securities. Investments with original maturities greater than 90 days that mature less than one year from the consolidated balance sheet date are classified as short-term investments. Those investments with a maturity date greater than one year at each balance sheet date are considered to be long-term investments. The Company further classifies investments as short-term or long-term based upon whether such assets are reasonably expected to be realized in cash or sold or consumed during the normal cycle of business. As of December 31, 2016 and 2015 all investments in marketable securities were classified as available-for-sale and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Unrealized gains and losses are excluded from earnings and are reported as a component of accumulated comprehensive income (loss). Realized gains and losses and declines in fair value judged to be other than temporary, if any, on investments in marketable securities are included in interest and other income (expense), net. The cost of securities sold is based on the specific-identification method. Interest earned on investments in marketable securities is included in interest and other income. Debt securities are adjusted for amortization of premiums and accretion of discounts and such amortization and accretion are reported as a component of interest and other income.

Fair Value Measurements

Fair value accounting is applied for all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis.

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Where available, fair value is based on or derived from observable market prices or other observable inputs. Where observable prices or inputs are not available, valuation models are applied. These valuation techniques may involve some level of management estimation and judgment, the degree of which is dependent on the price transparency for the instruments and the instruments' complexity.

The fair value hierarchy prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. All of the Company's cash equivalents and investments are measured using inputs classified at Level 1 or Level 2 within the fair value hierarchy. Level 1 inputs are quoted prices in active markets for identical assets. The Company classifies money market funds as Level 1. Level 2 inputs are based upon quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. The Company's classifies its commercial paper and corporate debt securities as Level 2. Level 3 inputs are unobservable inputs that are supported by little or no market activity and are significant to the fair value of the assets or liabilities. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs obtained from various third-party data providers, including but not limited to, benchmark yields, interest rate curves, reported trades, broker/dealer quotes and market reference data.

Property and Equipment, net

Property and equipment, net, are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets. Useful lives generally range from three to five years .

Goodwill

The Company recorded goodwill upon the Merger. The Company performs an impairment test of goodwill annually and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. To date, an impairment of goodwill has not been recorded.

Revenue Recognition

The Company recognizes revenue from licensing agreements for the development and commercialization of products and royalties from the use of our intellectual property. License fees from license agreements are recognized when the amounts are earned. Royalty revenues are recorded based on sales information provided by the Company's licensors.

Research and Development

Research and development costs are expensed as incurred and consist of salaries and benefits, 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. Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods are received or services are rendered.

Clinical trial costs are a component of research and development expenses. The Company accrues and expenses clinical trial activities performed by third parties based upon actual work completed in accordance with agreements established with clinical research organizations and clinical sites. This process involves identifying services that have been performed and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of actual cost. The Company's clinical trial accruals are based on estimates of patient enrollment and related costs at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with vendors including, multiple research institutions and clinical research organizations that conduct and manage clinical trials or provide supporting services on the Company's behalf. The Company accrues expense related to clinical trials based on contracted amounts applied to the level of patient enrollment and/or estimated level of activity completed. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, the Company modifies the estimates of clinical trial accruals accordingly on a prospective basis.

The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven timing of payments. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones.

Stock-Based Compensation

Employee stock-based compensation is recognized as an expense in the financial statements based on the grant date fair value of the award. For awards that vest based on service conditions, the Company records compensation expense, net of estimated forfeitures, on a straight-line basis over the requisite service period which is generally the vesting period for the related award. For performance-based stock options, the Company evaluates the probability of achieving performance-based goals at each reporting date. The Company begins to recognize the expense when it is deemed probable that the performance-based goal will be met. The Company records equity grants to non-employees as expense at their fair value over the related service period and periodically revalues them at each reporting period over the vesting term.

The Company estimates the fair value of stock options using a Black-Scholes-Merton option-pricing model which requires the input of highly subjective assumptions that represent our best estimates of volatility, risk-free interest rate,

expected life, and dividend yield. The Company estimates expected volatility based on its own historical volatility supplemented by a review of historical volatilities of industry peers. The Company has, due to insufficient historical data, used the "simplified method," as described in Staff Accounting Bulletin No. 107, "Share-Based Payment," to determine the expected life of stock options granted with a service condition. The risk-free rate assumption was based on United States Treasury instruments whose terms were consistent with the expected term of the stock options. The expected dividend assumption was based on our history and expectation of dividend payouts.

The Company accounts for stock-based compensation arrangements with non-employees using a fair value approach. The fair value of these options is measured using the Black-Scholes-Merton option pricing model reflecting the same assumptions as applied to employee options in each of the reported periods, other than the expected life, which is assumed to be the remaining contractual life of the option. The compensation costs of these arrangements are subject to remeasurement over the vesting terms as earned.

The Company estimates fair value of stock options with market-based vesting conditions based on Monte Carlo simulation models with assistance from an independent third-party valuation specialist. The Monte Carlo simulation models require the use of highly subjective and complex assumptions which determine the fair value of such awards including price volatility of the underlying stock and derived service periods.

The assumptions used in calculating the fair value of stock options with market-based vesting conditions and expected attainment of performance conditions for performance-based stock options represent our best estimates, but these estimates involve inherent uncertainties and the application of management’s judgment. Future expense amounts for any particular period could be affected by changes in the Company's assumptions.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, the Company determines deferred tax assets and liabilities on the basis of the differences between the financial statement and tax basis of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that it believes that these assets are more likely than not to be realized. In making such a determination, it considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If it is determined that the Company would be able to realize deferred tax assets in the future in excess of their net recorded amount, it would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of tax benefit might change as new information becomes available.

The Company records uncertain tax positions on the basis of a two-step process in which (1) it determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, the Company recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. To date, there have been no interest or penalties charged in relation to the underpayment of income taxes.

Recent Accounting Pronouncements

Occasionally, new accounting standards are issued or proposed by the Financial Accounting Standards Board (the "FASB"), or other standards-setting bodies that the Company adopts by the effective date specified within the standard. Unless otherwise discussed, standards that do not require adoption until a future date are not expected to have a material impact on the Company's financial statements upon adoption.

In August 2014, the FASB issued Accounting Standards Update ("ASU") 2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40) - Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. The standard requires management to assess, at each annual and interim reporting period, whether there are conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern and provide related disclosures in certain circumstances. The Company adopted the guidance as of December 31, 2016 and has included disclosures on this topic in Note 1.

In August 2016, the FASB issued ASU 2016-15, Classification of Certain Cash Receipts and Cash Payments, which aims to eliminate diversity in practice in how certain cash receipts and cash payments are presented and classified in

the statement of cash flows under Topic 230, Statement of Cash Flows, and other Topics. ASU 2016-15 is effective for annual reporting periods, and interim periods therein, beginning after December 15, 2017. The Company 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 March 2016, the FASB issued ASU 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. ASU 2016-09 is effective for annual reporting periods beginning after December 15, 2016, and interim periods within that reporting period. The Company will adopt this standard in the first quarter of fiscal year 2017 and is currently evaluating the impact of the guidance on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases, to increase transparency and comparability among organizations by requiring recognition of lease assets and lease liabilities on the balance sheet and disclosure of key information about leasing arrangements. The standard will become effective for interim and annual periods beginning after December 15, 2018, with early adoption permitted. The guidance is required to be adopted at the earliest period presented using a modified retrospective approach. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers. The standard’s core principle is that a reporting entity will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard will become effective for the Company beginning in the first quarter of 2018. Early adoption is permitted in 2017. Entities have the option of using either a full retrospective or a modified retrospective approach to adopt this new guidance. In March and April 2016, the FASB issued ASU 2016-08 Revenue From Contracts With Customers: Principal vs. Agent Considerations and ASU 2016-10 Revenue From Contracts with Customers: Identifying Performance Obligations and Licensing to provide supplemental adoption guidance and clarification to ASU 2014-09. The Company 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 completed the full assessment and is not able to estimate the anticipated impact to the consolidated financial statements from the application of the new standard.

The Company reviewed all other recently issued accounting pronouncements and concluded that they were either not applicable or not expected to have a significant impact to the consolidated financial statements. Additionally, the adoption of accounting pronouncements during 2016 did not have an impact on the Company’s consolidated financial position or results of operations.

3. Fair Value Measurements

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

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2016 and 2015 , and indicate the fair value hierarchy of the valuation techniques utilized by the Company to determine such fair value. No transfers between levels have occurred during the periods presented.

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

Assets and liabilities 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
Assets:				
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 .

Assets and liabilities measured at fair value on a recurring basis as of December 31, 2015 are as follows (in thousands):

	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 34,806	$ 34,806	$ —	$ —
Corporate debt securities	7,415	—	7,415	—
Total assets	$ 42,221	$ 34,806	$ 7,415	$ —

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, 2015 .

4. Balance Sheet Component

Cash Equivalents and Marketable Securities

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

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

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

The following table summarizes the Company's cash equivalents and marketable securities as of December 31, 2015 (in thousands):

	Maturity (in Years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Money market funds (1)	n/a	$ 34,806	$ —	$ —	$ 34,806
Corporate debt securities	1 or less	7,420	—	(5)	7,415
Total cash equivalents and marketable securities		$ 42,226	$ —	$ (5)	$ 42,221

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

At each reporting date, the Company reviews its investments for impairment to determine if unrealized losses are other-than-temporary. There have been no other-than-temporary impairments on these securities as of December 31, 2016 and 2015 . 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):

	December 31,	
	2016	2015
Clinical trials	$ 1,519	$ 1,666
Compensation and related expenses	1,124	993
Professional services	102	319
Interest expense and other	94	155
Total accrued liabilities	$ 2,839	$ 3,133

5. Discontinued Operations

On September 11, 2013 , the Board of Directors approved a restructuring plan related to the operations of Tranzyme Pharma Inc. (“Tranzyme Pharma”) and its Sherbrooke, Quebec facility, whereby the Company closed the operations of the facility effective November 11, 2013. On December 13, 2013 , the Company entered into a technology transfer and license agreement (the "Technology Transfer and License Agreement") with Genentech, Inc. ("Genentech"), and F. Hoffman-La Roche, Ltd. ("Roche") to sell certain Canadian fixed assets and materials, the MATCH technology and rights to the Genentech and Roche customer agreements and related intellectual property through licensing of patents for $4.0 million . The Company recorded the disposition of these assets held for sale in the first quarter of 2014. The Company concluded that the operations of Tranzyme Pharma and related asset groups sold to Genentech and Roche would be accounted for as discontinued operations as the operations and cash flows of the discontinued component or asset group would be eliminated from ongoing operations of the Company and there would not be significant involvement in the component or asset group after the disposal transaction.

In 2014, the Company completed its obligations under the Technology Transfer and License Agreement with Genentech and Roche and recognized a gain on disposal of assets of $1.1 million within discontinued operations. There were no assets and liabilities recorded in discontinued operations as of December 31, 2015 . There was $0.2 million in income recorded in discontinued operations for the twelve-month period ended December 31, 2015 that relates to certain foreign research credits received by Tranzyme Pharma in 2015 prior to its dissolution on December 14, 2015 . Upon classification as held for disposal and discontinued operations, the assets and liabilities of Tranzyme Pharma and related asset groups were evaluated for impairment at the lower of carrying amount or fair value less disposal costs, no impairment loss was recorded.

6. License Agreements and Acquired Development and Commercialization Rights

UCL Business PLC

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

Open Biosystems, Inc.

In October 2005, Tranzyme entered into a license and marketing agreement whereby Open Biosystems, Inc. acquired a worldwide royalty-bearing license to certain intellectual property unrelated to Tranzyme's lead product candidates prior to the Merger and its MATCH drug discovery technology, as specified in the agreement. The Company earns royalties on annual net sales at rates that vary by licensed product category as defined in the agreement through 2017 or until the expiration date of the last-to-expire licensed patent or twelve years, whichever occurs last. Royalty revenue recognized from the licensing agreement was $0.5 million , $ 0.1 million , and $0.1 million for the years ended December 31, 2016 , 2015 and 2014 , respectively.

During the year ended December 31, 2016 , the Company assigned its rights to all the intellectual property acquired in the Merger with Tranzyme to GE Healthcare Dharmacon, Inc. (“GE”), formerly known as Open Biosystems, Inc. In connection with the assignment, the Company’s existing license and marketing agreement with GE terminated and all future royalty payments payable from GE to the Company ceased. In consideration for the assignment, the Company received a one-time payment of $0.5 from GE included in the royalty revenue earned for the year ended December 31, 2016 as presented above.

Lyric Pharmaceuticals, Inc.

In September 2014, the Company entered into an asset license and purchase agreement for the sale and license of *ulimorelin* (the "Lyric Agreement"), the former lead compound of Tranzyme to Lyric Pharmaceuticals, Inc. (“Lyric”). Per the terms of the agreement, the Company received an up-front nonrefundable payment of $0.2 million for the transfer of intellectual property and materials associated with the compound and the licensing of associated patents with no further ongoing obligations to be performed by the Company. In addition, Lyric is solely responsible for the pre-clinical and clinical development of all products arising from the further development of the compound. During the year ended December 31,

2016 , Lyric achieved a milestone under the Lyric Agreement, and accordingly, the Company recorded $0.1 million in related milestone revenue in 2016.

If successful, the Company could receive future consideration as a percentage of the proceeds received by Lyric upon its sale or license to a third party, and under certain conditions, clinical and regulatory milestones totaling up to $25.0 million plus royalty payments from potential product sales generated.

7. Net Loss Per Share

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

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

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

	Years Ended December 31,		
	2016	2015	2014
Numerator			
Net loss from continuing operations	$ (26,895)	$ (26,749)	$ (24,624)
Net income from discontinued operations	—	227	1,199
Net loss	$ (26,895)	$ (26,522)	$ (23,425)
Denominator			
Weighted average common shares outstanding used to compute net loss per share, basic and diluted	21,957,917	20,067,660	17,525,187
Net loss per share of common stock, basic and diluted:			
Net loss per share from continuing operations	$ (1.22)	$ (1.33)	$ (1.41)
Net income per share from discontinued operations	—	0.01	0.07
Net loss per share	$ (1.22)	$ (1.32)	$ (1.34)

The following common stock equivalents were excluded from the computation of diluted net loss per share for the periods presented because their effect would be antidilutive.

	Years Ended December 31,		
	2016	2015	2014
Common stock warrants	1,003,984	1,026,249	932,535
Common stock options outstanding	3,928,570	2,429,511	2,086,602
Total potentially dilutive securities	4,932,554	3,455,760	3,019,137

8. Debt

Notes Payable

On July 30, 2015, the Company and Ocera Subsidiary, Inc., 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 $10.0 million funding is 8.275% . Loan payments are interest-only until February 1, 2017, followed by 30 equal monthly payments of principal and interest through the scheduled maturity date of August 1,

2019. 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. These fees and expenses are being accounted for as a debt discount and classified within notes payable on the Company's balance sheet. Related legal and consulting fees of $0.3 million are presented in the balance sheet as a direct deduction from the carrying amount of notes payable, consistent with debt discounts. Debt discounts, issuance costs and the final payment are being amortized or accreted as interest expense over the term of the loan using the effective interest method.

In connection with the Loan Agreement, the Company agreed to issue to the Lenders warrants to purchase shares of common stock equal to 4% of the amount loaned, divided by the exercise price, which was the average closing price of the common stock for the 10 trading days prior to funding. Accordingly, in connection with the initial funding, the Company issued the Lenders warrants to purchase an aggregate of 97,680 shares at an exercise price of $4.10 per share. The Company recorded $0.3 million for the relative value of the warrants as a debt discount within notes payable and an increase to additional paid-in capital on the Company's balance sheet. The debt discount is being amortized as interest expense over the term of the loan using the effective interest method.

The fair value of the warrants issued was approximately $0.3 million and was estimated using a Black-Scholes-Merton valuation model on a non-recurring basis with the following assumptions: fair value of common stock at issuance of $3.84 ; risk-free interest rate of 2.28% based upon observed risk-free interest rates appropriate for the expected term of the warrants; expected volatility of 87% based on the average historical volatilities of a peer group of publicly-traded companies within the Company's industry; expected term of 10 years , which is the contractual life of the warrants; and a dividend yield of 0% . The allocation of proceeds to the warrants in a relative-fair-value allocation with the related notes payable was also $0.3 million .

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, our 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 December 31, 2016 and 2015 . The principal payments due under the Loan Agreement have been classified as a current liability at December 31, 2016 due to the considerations discussed in Note 1 and the assessment that the material adverse change clause 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-K.

The Company recorded interest expense related to the Term Loan Facility of $1.1 million and $0.5 million during the periods ended December 31, 2016 and 2015 . The annual effective interest rate on notes payable, including the amortization of the debt discounts and accretion of the final payments, is 11.72% .

Future payments under the Loan Agreement as of December 31, 2016 are as follows (in thousands):

Years Ending December 31:		
2017	$	3,839
2018		4,442
2019		3,261
Total future minimum payments		11,542
Less amount representing interest		1,542
Notes payable, gross		10,000
Unamortized discount on notes payable		(297)
Notes payable		9,703

Warrants

The Company has issued warrants to purchase shares of its common stock to different entities in connection with legacy debt and equity financings. Additionally, the Company issued warrants in connection with the Term Loan Facility in July 2015 (see Notes Payable above).

In 2016 , 22,265 warrants were exercised at an exercise price of $0.67 per share. In 2015 , 1,586 warrants were exercised at an exercise price of $0.67 per share.

The Company’s outstanding warrants are exercisable for common stock at any time during their respective terms.

The following table summarizes the outstanding common stock warrants and the corresponding exercise price as of December 31, 2016 and 2015 :

	Number of Warrants Outstanding at December 31		Per Share Exercise		
Issuance Date	2016	2015		Price	Expiration
9/30/2010	3,240	3,240	$	160.44	9/30/2017
1/31/2012	13,623	13,623		44.04	1/31/2022
3/30/2012	13,256	24,388		0.67	3/30/2019
6/30/2012	36,583	36,583		0.67	6/30/2019
10/1/2012	51,425	62,558		0.67	10/1/2019
11/8/2013	788,177	788,177		7.66	11/8/2018
7/30/2015	97,680	97,680	$	4.10	7/30/2025
Total outstanding common stock warrants	1,003,984	1,026,249			

9. Stockholders’ Equity

On July 15, 2013, Private Ocera completed the Merger with Tranzyme as discussed in Note 1. Immediately prior to the effective time of the Merger, the principal and interest under Private Ocera's outstanding convertible notes converted into shares of Series C preferred stock of Private Ocera, and, immediately thereafter, all outstanding preferred stock of Private Ocera converted into the common stock of Private Ocera.

At the effective time of the Merger, each outstanding share of Private Ocera's common stock was converted into shares of Tranzyme's common stock at the Exchange Ratio, with cash paid in lieu of any fractional shares.

Pursuant to the Securities Purchase Agreement dated April 23, 2013, immediately following the Merger, the Company sold 3,317,976 shares of common stock at a per share price of $ 6.03 for approximately $20.0 million . Issuance costs of $26,000 were charged to additional paid-in capital.

On November 8, 2013, the Company closed on a private placement pursuant to the Securities Purchase Agreement and sold an aggregate of 3,940,887 shares of common stock and warrants to purchase an additional 788,177 shares of common stock for an aggregate purchase price of $28.0 million . Issuance costs of $1.5 million were charged to additional paid-in capital.

On July 10, 2014, the Company completed an underwritten public offering of its common stock in which 4,200,000 shares of common stock were sold for gross proceeds from the offering of $25.2 million . Issuance costs of $1.8 million were charged to additional paid-in capital.

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 year ended December 31, 2015 , the Company sold an aggregate of 946,497 shares of common stock under the Sales Agreement, at an average price of $3.95 per share, for net proceeds of $3.5 million after deducting commissions and other transaction costs.

During the year ended December 31, 2016 , the Company sold an aggregate of 2,865,391 shares of common stock under the Sales Agreement, at an average price of $2.61 per share, for net proceeds of $7.1 million after deducting commissions and other transactions costs.

10. Stock-Based Compensation

Equity Incentive Plans

In 2005, the Company adopted the Ocera Therapeutics, Inc. 2005 Stock Plan (the "Plan"). At the effective time of the Merger, each outstanding stock option to purchase common stock of Private Ocera under the Plan not exercised immediately prior to the effective time of the Merger, whether or not vested, was assumed by the Company and became exercisable for shares of the Company's common stock in accordance with the terms of the Merger Agreement and the Company assumed the Plan. Upon completion of the Merger, no options remain available for future grant under the 2005 Plan.

On July 15, 2013, in connection with the Merger, the Company assumed the existing Tranzyme 2011 Stock Option and Incentive Plan (the "2011 Plan"). As of December 31, 2016 the Company was authorized to issue 5,002,328 shares of common stock under 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 unit awards, performance stock awards, performance cash awards and other stock awards to employees, officers, directors and consultants.

A summary of the Company's stock option activity under the 2011 Plan and related information are as follows (in thousands):

	Shares Available for Grant	Stock Options Outstanding	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life (in Years)	Aggregate Intrinsic Value
Balance at December 31, 2014	342,210	2,086,602	$ 8.01	8.63	$ 871
Additional shares authorized	1,300,000				
Stock options granted	(707,500)	707,500	3.73		
Stock options exercised	—	—	—		
Stock options canceled	364,591	(364,591)	6.44		
Balance at December 31, 2015	1,299,301	2,429,511	7.00	8.01	287
Additional shares authorized	1,400,000				
Stock options granted	(2,341,350)	2,341,350	2.67		
Stock options exercised	—	(23,938)	1.09		
Stock options canceled	818,353	(818,353)	5.80		
Balance at December 31, 2016	1,176,304	3,928,570	$ 4.71	7.83	119
At December 31, 2016:					
Vested and expected to vest		3,654,294	$ 4.85	7.72	$ 119
Vested and exercisable		1,639,838	$ 6.79	6.01	$ 119

The Company’s stock options generally vest over one to four years and have a ten -year contractual term.

Stock-Based Compensation Expense:

Stock-based compensation expense, net of estimated forfeitures, included in the consolidated statements of operations is as follows (in thousands):

	Years Ended December 31,		
	2016	2015	2014
Research and development	$ 672	$ 648	$ 1,595
General and administrative	3,391	3,329	3,091
Total stock-based compensation expense	$ 4,063	$ 3,977	$ 4,686

The above table includes immaterial amounts of stock compensation expense related to stock option grants to non-employee consultants for all periods presented.

Stock Option Valuation Assumptions:

The Company estimates the fair value of stock options using the Black-Scholes-Merton option-pricing model based on the date of grant. The following summarize the ranges of weighted-average assumptions used to estimate the fair value of stock options granted during each period:

	Years Ended December 31,		
	2016	2015	2014
Expected dividend yield	—%	—%	—%
Risk-free interest rate	0.59% - 2.20%	1.52% - 2.08%	1.74% - 2.01%
Expected term (in years)	0.95 - 8.04	4.99 - 8.06	6.08 - 6.62
Expected volatility	73% - 94%	76% - 92%	95% - 102%

The total estimated grant date fair value of stock options vested during the years ended December 31, 2016 is $3.8 million and for the years ended December 31, 2015 and 2014 is $4.1 million . The aggregate intrinsic value of options exercised during the years ended December 31, 2016 and 2015 , is insignificant and for the years ended December 31, 2014 is $2.7 million .

As of December 31, 2016 , the Company had $5.5 million of unrecognized stock-based compensation expense which is expected to be recognized over a weighted average period of 2.40 years.

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

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

	January 6, 2016
Expected dividend yield	—
Risk-free interest rate	1.82% - 2.05%
Expected term (in years)	6.02 - 8.00
Expected volatility	77% - 89%
Weighted-average fair value per share	1.33 - 1.42

The estimated expense for these awards is being recognized on an accelerated basis over the requisite service period with no adjustments in the future periods based upon the Company's actual common stock price. The Company recorded $0.2 million in stock-based compensation expense during the period ended December 31, 2016 in connection with such awards.

11. Income Taxes

The following table presents consolidated loss before income taxes by income tax jurisdiction for continuing operations (in thousands):

	Years Ended December 31,		
	2016	2015	2014
United States	$ (26,895)	$ (26,749)	$ (24,624)

No provision for federal or state income taxes has been recorded, as the Company has incurred cumulative net operating losses since inception. A reconciliation of the loss from continuing operations at the federal statutory tax rate of 34% to the Company's effective income tax rate is as follows (in thousands):

	Years Ended December 31,		
	2016	2015	2014
Income tax benefit at statutory rate	$ (9,144)	$ (9,094)	$ (8,372)
State income tax, net of federal benefit	54	693	(4,180)
Orphan drug expenses	998	817	1,045
Stock-based compensation	488	54	(45)
Other permanent items	10	35	98
Tax credits	(2,162)	(1,769)	(3,156)
Change in valuation allowance	9,756	9,264	14,610
Provision for income taxes	$ —	$ —	$ —

Components of the Company's deferred tax assets and liabilities for federal and state income tax purposes are as follows (in thousands):

	Years Ended December 31,	
	2016	2015
Deferred tax assets:		
Net operating loss carryforwards	$ 49,635	$ 42,754
Tax credit carryforwards	8,932	7,141
Stock-based compensation	4,164	3,162
Other	127	45
Deferred tax assets before valuation allowance	62,858	53,102
Valuation allowance	(62,858)	(53,102)
Deferred tax assets:	$ —	$ —

The Company has evaluated the evidence bearing upon the realizability of its net deferred tax assets including the Company's history of operating losses and has concluded that it is not more likely than not that the Company will realize the benefit of its deferred tax assets. Accordingly, the Company has recorded a full valuation allowance against its net deferred tax assets at December 31, 2016 and 2015 .

As of December 31, 2016 , the Company has $131.6 million of United States federal net operating loss carryforwards and $10.7 million of orphan drug credit carryforwards, and $2.5 million of United States federal research and development carryforwards available for use, all of which have a full valuation allowance and will begin to expire in 2019 unless utilized.

Not included in the deferred income tax asset balance at December 31, 2016 is approximately $0.3 million which pertains to certain net operating loss carryforwards resulting from the exercise of employee stock options, which to-date have not been recognized.

As of December 31, 2016 , the Company has North Carolina net economic loss carryforwards of approximately $5.4 million , which will begin to expire in 2022 unless utilized, and $0.2 million of research and development credits that will begin to expire in 2028 unless utilized. As of December 31, 2016 , the Company has California state net operating loss carryforwards of approximately $63.1 million , which have begun to expire as of 2016, and $2.5 million of California research and development carryforwards that do not expire.

Pursuant to Internal Revenue Code ("IRC") Sections 382 and 383, annual use of the Company's net operating loss and research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. Additional limitations as to the ability to use net operating loss or tax credit carryforwards may arise if the Company experiences an ownership change in subsequent years. The Company has not performed a Section 382 or 383 analysis.

As of December 31, 2016 , the Company had $6.0 million of unrecognized tax benefits. A reconciliation of the current and prior year changes to the Company's unrecognized tax benefits is as follows (in thousands):

Unrecognized tax benefits as of December 31, 2013	$	1,840
Increases in prior period positions		647
Increases in current period positions		1,286
Unrecognized tax benefits as of December 31, 2014		3,773
Increases in prior period positions		8
Increases in current period positions		980
Unrecognized tax benefits as of December 31, 2015		4,761
Increases in prior period positions		—
Increases in current period positions		1,194
Unrecognized tax benefits as of December 31, 2016	$	5,955

As of December 31, 2016 , no unrecognized tax benefits are included in the balance sheet that would, if recognized, affect the Company's effective tax rate due to the valuation allowance that currently offsets deferred tax assets. The Company does not anticipate the total amount of unrecognized income tax benefits will significantly increase or decrease in the next 12 months. The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. The Company determined that no accrual for interest and penalties was required as of December 31, 2016 .

The statute of limitations for assessment by the Internal Revenue Service ("IRS") and state tax authorities is open for tax years ended December 31, 2011 through 2016 , although carryforward attributes that were generated prior to tax year 2011 may still be adjusted upon examination by the IRS or state tax authorities if they either have been or will be used in a future period. There are currently no federal or state audits in progress.

12. Retirement Savings Plan

The Company provides a qualified 401(k) savings plan for its employees. All employees are eligible to participate, provided they meet the requirements of the plan. Employee contributions are limited to a maximum annual amount as set periodically by the IRC. The Company provides a contribution on the first 3% of an employee's eligible compensation subject to statutory limitations as prescribed by law. For each of the years ended December 31, 2016 , 2015 , and 2014 , the Company recorded $0.1 million of expense associated with the matching of employee contributions.

13. 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 our 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, our insurance carriers may deny coverage or our 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 consolidated results of operations and financial position. Additionally, any such claims, whether or not successful, could damage our 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 our consolidated results of operations or financial position.

Indemnification

As permitted under Delaware law and in accordance with the Company's bylaws and agreements entered into with the Company's officers and directors, the Company indemnifies its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity. The indemnification agreements with the Company's officers and directors terminate upon termination of their employment, but the termination does not affect claims for indemnification relating to events occurring prior to the effective date of termination. The maximum amount of potential future indemnification is not limited; however, the Company's director and

officer insurance policy reduces the Company's exposure and may enable the Company to recover a portion of any future amounts paid.

In addition, the Company customarily agrees in the ordinary course of its business to indemnification provisions in its collaboration and licensing agreements, in agreements relating to the sale of assets, in various agreements involving parties performing services for the Company in the ordinary course of business and in its real estate leases. With respect to lease agreements, the indemnification provisions typically apply to claims asserted against the landlord relating to personal injury or property damage caused by the Company, to violations of law by the Company or to certain breaches of the Company's contractual obligations. The indemnification provisions appearing in the Company's collaboration and licensing agreements and in agreements relating to the sale of assets are similar, but in addition provide some limited indemnification for the collaborator, licensee or purchaser of assets in the event of third party claims alleging infringement of certain intellectual property rights or ownership rights. In each of the cases above, the indemnification obligation generally survives the termination of the agreement for some extended period, although the obligation typically has the most relevance during the contract term and for a short period of time thereafter. The maximum potential amount of future payments that the Company could be required to make under these provisions can be unlimited, but is sometimes limited by the value of payments made under the agreement or by an escrow amount. The Company has purchased insurance policies covering personal injury, property damage and general liability that reduce its exposure for indemnification and would enable it in many cases to recover a portion of any future amounts paid.

The Company has never paid any material amounts to defend lawsuits or settle claims related to these indemnification provisions. The Company accrues for known indemnification issues when a loss is probable and can be reasonably estimated. There were no accruals for expenses related to indemnification issues for each of the years ended December 31, 2016 and 2015 .

Purchase Commitments

In November 2016, the Company entered into an agreement with Evonik, under which Evonik will manufacture clinical supply of OCR-002 drug substance for the Company. Per the terms of the agreement, the Company will purchase clinical supply of OCR-002 totaling $1.3 million . As of December 31, 2016, the Company has paid $0.4 million to Evonik and is subject to a cancellation fee of $0.8 million .

Facilities

The Company leases its corporate, laboratory and other facilities under operating leases which have been subject to several amendments necessary to secure additional space and/or extend the lease term.

In October 2013 , the Company entered into an agreement to sublease office space located at 525 University Avenue, Palo Alto, California for the period from October 10, 2013 to December 31, 2016 . These premises serve as the Company's corporate headquarters. In December 2016 , the Company amended the sublease for this facility by extending term of the lease to June 30, 2017 . The Company does not have an option to extend the sublease term beyond June 30, 2017 .

Upon the Merger, the Company obtained office space located at 5001 South Miami Boulevard, Durham, North Carolina under a lease agreement. In May 2016 , the Company amended the lease for this facility by extending term of the lease through January 31, 2018 .

In May 2016 , the Company entered into an agreement to sublease office space located at 100 Lakeview Parkway, Vernon Hills, Illinois under a lease agreement that will expire on May 31, 2018 . The lease includes an option to extend the lease term to J anuary 2021 .

Provisions of these facilities leases generally provide for abatement of rent during certain periods and escalating rent payments during the original and extended lease terms. Rent expense is being recorded on a straight-line basis over the life of the lease.

Rent expense was $0.4 million , $0.3 million , $0.2 million for the years ended December 31, 2016 , 2015 and 2014 , respectively. The following is a schedule of non-cancelable future minimum lease payments for operating leases at December 31, 2016 (in thousands):

Years Ending December 31,		
2017	$	361
2018		49
2019 and beyond		8
Total future minimum lease payments for operating leases	$	418

14. Subsequent Event

Pursuant to the Company's "at the market" equity program, in March 2017, prior to the date of the filing of this Form 10-K, the Company sold an aggregate of 1,835,425 shares of common stock under the Sales Agreement at an average price of approximately $1.57 per share, for net proceeds of approximately $2.8 million .

15. Summary of Operations by Quarter (Unaudited)

The following tables present certain unaudited quarterly financial information. This information has been prepared on the same basis as the audited consolidated financial statements and includes all normal recurring adjustments necessary to present fairly the unaudited quarterly results of operations set forth herein (in thousands, except per share amounts):

	Quarter (1)			
Year Ended December 31, 2016:	**First**	**Second**	**Third**	**Fourth**
Revenues	$ 33	$ 26	$ 38	$ 512
Operating expenses	7,301	6,879	6,901	5,408
Net loss	(7,514)	(7,103)	(7,125)	(5,153)
Net loss per share, basic and diluted	(0.36)	(0.33)	(0.32)	(0.22)
Weighted average common shares outstanding used to compute net loss per share, basic and diluted	20,943,966	21,552,089	22,096,610	23,223,569

	Quarter (1)			
Year Ended December 31, 2015:	**First**	**Second**	**Third**	**Fourth**
Revenues	$ 31	$ 43	$ 35	$ 24
Operating expenses	6,695	6,290	6,648	6,836
Net loss from continuing operations	(6,651)	(6,221)	(6,793)	(7,084)
Net loss	(6,651)	(6,221)	(6,574)	(7,076)
Net loss per share from continuing operations, basic and diluted	(0.34)	(0.31)	(0.34)	(0.34)
Net loss per share, basic and diluted	(0.34)	(0.31)	(0.33)	(0.34)
Weighted average common shares outstanding used to compute net loss per share, basic and diluted	19,747,362	19,772,345	20,183,939	20,556,822

(1) Quarterly results may not sum precisely to annual totals due to rounding.

Because of the method used in calculating per share data, the quarterly per share data will not necessarily add to the per share data as computed for the year.

Item 9. Changes In and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report.

Inherent Limitations Over Internal Controls

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). The Company’s internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with United States generally accepted accounting principles (“GAAP”). The Company’s internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of its assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of its financial statements in accordance with generally accepted accounting principles, and that its receipts and expenditures are being made only in accordance with authorizations of its management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on its financial statements.

Management, including the Company's Chief Executive Officer and Chief Financial Officer, does not expect that the Company's internal controls will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of internal controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Also, any evaluation of the effectiveness of controls in future periods are subject to the risk that those internal controls may become inadequate because of changes in business conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Exchange Act Rules 13a-15 or 15d-15 that occurred during our fourth fiscal quarter that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

Under the supervision of our Chief Executive Officer and our Chief Financial Officer with the participation of our management, we have conducted an evaluation of the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - 2013 Integrated Framework. Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2016. Such disclosure controls and procedures were effective in ensuring information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934, as amended, is (i) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and (ii) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Our disclosure controls and procedures are designed to provide a reasonable level of assurance that their objectives are achieved.

Item 9B. Other Information

None.

Part III.

Item 10. Directors, Executive Officers and Corporate Governance

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to regulation 14A, which proxy statement is expected to be filed with Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2016 .

We intend to disclose on our website any amendments to, or waivers from, our Code of Business Conduct and Ethics that are required to be disclosed pursuant to the rules of the SEC. Information contained on, or connected to, our website is not incorporated by reference into this Form 10-K and should not be considered part of this report or any other filing that we make with the SEC.

Item 11. Executive Compensation

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to regulation 14A, which proxy statement is expected to be filed with Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2016 .

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to regulation 14A, which proxy statement is expected to be filed with Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2016 .

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to regulation 14A, which proxy statement is expected to be filed with Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2016 .

Item 14. Principal Accounting Fees and Services

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to regulation 14A, which proxy statement is expected to be filed with Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2016 .

Part IV.

Item 15. Exhibits and Financial Statement Schedules

(a) Financial Statements and Schedules:

1. Financial Statements

The following are included in Item 8 of this report:

Report of Independent Registered Public Accounting Firm	54
Consolidated Balance Sheets	55
Consolidated Statements of Operations and Comprehensive Loss	56
Consolidated Statements of Stockholders' Equity	57
Consolidated Statements of Cash Flows	58
Notes to Consolidated Financial Statements	59

2. Financial Statement Schedules

All schedules are omitted because they are not applicable or the required information is shown in the Financial Statements or notes thereto.

3. List of Exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b) Exhibits:

The following exhibits are filed as part of, or incorporated by reference into, this report:

Exhibits

Exhibit Number	Description
2.1	Agreement and Plan of Merger and Reorganization, dated as of April 23, 2013, by and among the Company, Terrapin Acquisition, Inc. and Ocera Therapeutics, Inc. (Incorporated by reference to Exhibit 2.1 of the Company's Current Report on Form 8-K, as filed on April 29, 2013).
2.2	Technology Transfer and License Agreement, dated as of December 13, 2013, by and among the Company, Genentech, Inc. and F. Hoffman-La Roche, Ltd (Incorporated by reference to Exhibit 2.1 of the Company's Current Report on Form 8-K, as filed on February 24, 2014).
3.1	Eighth Amended and Restated Certificate of Incorporation of the Company, as amended (Incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013).
3.2	Form of Amended and Restated Bylaws of the Company (Incorporated by reference to Exhibit 3.3 of the Company's Registration Statement on Form S-1, as amended (File No. 333-170749)).
4.1	Specimen Common Stock Certificate (Incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K, as filed on July 15, 2013).
4.2	Registration Rights Agreement, dated as of April 23, 2013, by and among the Company and certain shareholders of Ocera Therapeutics, Inc. named therein (Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, filed on April 29, 2013).
4.3	Warrant to Purchase Stock dated September 30, 2010 issued by the Company to Compass Horizon Funding Company LLC (Incorporated by reference to Exhibit 4.5 of the Company's Registration Statement on Form S-1, as amended (File No. 333-170749)).
4.4	Warrant to Purchase Stock dated September 30, 2010 issued by the Company to Oxford Finance Corporation (Incorporated by reference to Exhibit 4.6 of the Company's Registration Statement on Form S-1, as amended (File No. 333-170749)).
4.5	Form of Warrant to Purchase Stock issued by the Company on January 31, 2012. (Incorporated by reference to Exhibit 4.1 to the Company's current report on Form 8-K, filed on February 1, 2012).
4.6	Form of Common Stock Purchase Warrants, dated March 30, 2012, issued by Ocera Subsidiary, Inc. (f/k/a Ocera Therapeutics, Inc.) (Incorporated by reference to Exhibit 4.8 of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013).
4.7	Form of Common Stock Purchase Warrants, dated October 1, 2012, issued by Ocera Subsidiary, Inc. (f/k/a Ocera Therapeutics, Inc.) (Incorporated by reference to Exhibit 4.9 of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013).
4.8	Form of Warrant (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 7, 2013).
4.9	Warrant to Purchase Stock dated as of July 30, 2015 issued by the Company to Oxford Finance LLC (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on August 4, 2015).
4.10	Warrant to Purchase Stock dated as of July 30, 2015 issued by the Company to Silicon Valley Bank (Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on August 4, 2015).
10.1#	Second Amended and Restated License Agreement by and between the Company and UCL Business PLC, dated as of July 1, 2015 (Incorporated by reference to Exhibit 10.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015).
10.2†	Ocera Therapeutics, Inc. Third Amended and Restated Non-Employee Director Compensation Policy (Incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016).

10.3†	Form of Indemnification Agreement by and between the Company and directors of Ocera Subsidiary, Inc. (f/k/a Ocera Therapeutics, Inc.) appointed to the Company's Board of Directors and officers of Ocera Subsidiary, Inc. (f/k/a Ocera Therapeutics, Inc.) appointed as officers of the Company in connection with the Merger (Incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on August 14, 2013).
10.4†	2005 Stock Plan of Ocera Therapeutics, Inc. (now known as Ocera Subsidiary, Inc.), as amended (the "2005 Plan") (Incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed on August 14, 2013).
10.5†	Form of Notice of Stock Option Grant (Traditional Vesting) pursuant to the 2005 Plan (Incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013).
10.6†	Form of Notice of Stock Option Grant (Single Trigger) pursuant to the 2005 Plan (Incorporated by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013).
10.7†	Form of Notice of Stock Option Grant (Double Trigger) pursuant to 2005 Plan (Incorporated by reference to Exhibit 10.9 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013).
10.8†	Ocera Therapeutics, Inc. Fourth Amended and Restated 2011 Stock Option and Incentive Plan, together with forms of award agreements (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 15, 2016).
10.9†	Amended and Restated Employment Agreement dated as of April 8, 2016 by and between the Company and Linda Grais (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016).
10.10†	Amended and Restated Employment Agreement dated as of January 6, 2016 by and between the Company and Michael Byrnes (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on January 8, 2016).
10.11†	Employment Agreement dated as of January 5, 2016 by and between the Company and Stan Bukofzer, M.D. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 8, 2016).
10.12	Office Lease, dated as of November 28, 2011, by and between the Company and James Campbell Company LLC (Incorporated by reference to Exhibit 10.1 of the Company's Current Report on 8-K filed on December 1, 2011).
10.13	First Amendment to the Lease Agreement dated August 29, 2014 by and between James Campbell, LLC and the Company (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014).
10.14	Second Amendment to the Lease Agreement dated June 5, 2015 by and between James Campbell, LLC and the Company (Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015).
10.15	Third Amendment to Lease Agreement dated May 16, 2016 by and between James Campbell, LLC and the Company (Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016).
10.16	Sales Agreement, dated May 15, 2015, by and between the Company and Cowen and Company, LLC (Incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015).
10.17	Loan and Security Agreement dated as of July 30, 2015 by and among the Company, Ocera Subsidiary, Inc., Oxford Finance LLC and Silicon Valley Bank (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 4, 2015).
21.1*	Subsidiaries of the Company.
23.1*	Consent of Independent Registered Public Accounting Firm.
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS+	XBRL Instance Document
101.SCH+	XBRL Taxonomy Extension Schema Document
101.CAL+	XBRL Taxonomy Calculation Linkbase Document
101.LAB+	XBRL Taxonomy Label Linkbase Document
101.PRE+	XBRL Taxonomy Presentation Linkbase Document
101.DEF+	XBRL Taxonomy Definitions Linkbase Document

*Filed herewith
**Furnished herewith
† Indicates a management contract or compensation plan, contract or arrangement.
# Portions of these exhibits have been omitted pursuant to a request for confidential treatment submitted to the Securities and Exchange Commission.

Item 16. Form 10-K Summary

None.

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: March 14, 2017

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Linda S. Grais, M.D. Linda S. Grais, M.D.	President, Chief Executive Officer and Director	March 14, 2017
/s/ Michael Byrnes Michael Byrnes	Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 14, 2017
/s/ Eckard Weber, M.D. Eckard Weber, M.D.	Chairman of the Board of Directors	March 14, 2017
/s/ Willard Dere, M.D. Willard Dere, M.D.	Director	March 14, 2017
/s/ Steven P. James Steven P. James	Director	March 14, 2017
/s/ Nina Kjellson Nina Kjellson	Director	March 14, 2017
/s/ Michael Powell, Ph.D. Michael Powell, Ph.D.	Director	March 14, 2017
/s/ Anne M. VanLent Anne M. VanLent	Director	March 14, 2017
/s/ Wendell Wierenga, Ph.D. Wendell Wierenga, Ph.D.	Director	March 14, 2017

Exhibit 21.1

List of Subsidiaries of the Company.

- Ocera Subsidiary, Inc., a Delaware corporation

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

1. Registration Statement (Form S-3 No. 333-204214) of Ocera Therapeutics, Inc.,
2. Registration Statement (Form S-8 No. 333-173535) pertaining to the 2001 Employee Stock Option Plan of Tranzyme, Inc., 2001 Non-Employee Stock Option Plan of Tranzyme, Inc., Amended and Restated 2003 Stock Option Plan of Tranzyme, Inc., Amended and Restated 2004 Stock Option Plan of Tranzyme Pharma, Inc., and the 2011 Stock Option and Incentive Plan of Tranzyme, Inc.,
3. Registration Statement (Form S-8 No. 333-182408) pertaining to the Amended and Restated 2011 Stock Option and Incentive Plan of Tranzyme, Inc.,
4. Registration Statement (Form S-8 No. 333-191644) pertaining to the Ocera Therapeutics, Inc. 2005 Stock Plan,
5. Registration Statement (Form S-8 No. 333-193094) pertaining to the Ocera Therapeutics, Inc. Second Amended and Restated 2011 Stock Option and Incentive Plan,
6. Registration Statement (Form S-8 No. 333-205475) pertaining to the Ocera Therapeutics, Inc. Third Amended and Restated 2011 Stock Option and Incentive Plan, and
7. Registration Statement (Form S-8 No. 333-212053) pertaining to the Ocera Therapeutics, Inc. Fourth Amended and Restated 2011 Stock Option and Incentive Plan,

of our reports dated March 14, 2017 , with respect to the consolidated financial statements of Ocera Therapeutics, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2016.

/s/ Ernst & Young LLP

Redwood City, California
March 14, 2017

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 Annual Report on Form 10-K 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: March 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 Annual Report on Form 10-K 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: March 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 Annual Report of Ocera Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2016 , as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Linda S. Grais, M.D., President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated in the Report.

Date: March 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 Annual Report of Ocera Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2016 , as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael Byrnes, Chief Financial Officer and Treasurer 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: March 14, 2017

By: /s/ Michael Byrnes

Michael Byrnes
Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)