# OCERA THERAPEUTICS, INC.

## FORM 10-K
(Annual Report)

Filed 03/13/15 for the Period Ending 12/31/14

| | |
|---|---|
| Address | 525 UNIVERSITY AVENUE<br>SUITE 610<br>PALO ALTO, CA 94301 |
| Telephone | 6504625800 |
| CIK | 0001274644 |
| Symbol | OCRX |
| SIC Code | 2834 - Pharmaceutical Preparations |
| Industry | Biotechnology & Drugs |
| Sector | Healthcare |
| Fiscal Year | 12/31 |

# 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, 2014

**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, 2014 was approximately $77.05 million. As of February 27, 2015 , there were outstanding 19,747,362 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 2014 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, 2014 .

**OCERA THERAPEUTICS, INC.**
**ANNUAL REPORT ON FORM 10-K**
**TABLE OF CONTENTS**

## CORPORATE INFORMATION AND FORWARD-LOOKING STATEMENTS

### Corporate Information

On July 15, 2013, Tranzyme, Inc., or 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.

## Part I.

### Item 1. Business

### Overview

We are a clinical-stage biopharmaceutical company focused on acute and chronic orphan liver diseases. Our initial focus is on the development and commercialization of a clinical candidate, OCR-002, for the treatment of hepatic encephalopathy, or HE. HE is a serious complication of liver cirrhosis, or liver failure, marked by mental changes including confusion, impaired motor skills, disorientation in time and space, and, in its more severe form, stupor, coma and even death. Although the exact cause of HE is not completely understood, there is growing evidence that elevated ammonia is a primary driver of HE, and that lowering ammonia may be beneficial to patients suffering from HE. Common causes of liver malfunction leading to elevated ammonia levels and HE include alcoholism, viral hepatitis and auto-immune diseases, nonalcoholic steatohepatitis, or NASH, as well as obesity, Type II diabetes, and acetaminophen overdose.

OCR-002 is a novel molecule, ornithine phenylacetate, which functions as an ammonia scavenger. In pre-clinical studies, OCR-002 significantly reduced arterial ammonia in an animal model of chronic liver disease and significantly reduced arterial ammonia, brain ammonia and intracranial pressure in a second animal model of acute liver failure. In 2012, we completed a Phase 1 pharmacokinetic and safety clinical trial of the intravenous form of OCR-002. A Phase 2a investigator-sponsored study in Spain tested 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 study, a 10-patient open label safety cohort, OCR-002 was shown to lower ammonia when administered as a continuous intravenous infusion of up to 10 grams per 24 hours. In February 2015, we announced the preliminary topline results of the second part of this study, which was a randomized, placebo-controlled cohort of 38 patients. The data showed

that OCR-002 lowered ammonia by 19.6% over the first 12 hours, compared to 3.2% over the first 12 hours in the placebo group, but this difference did not reach statistical significance. A statistically significant difference in urinary excretion of ammonia, as measured by phenylacetylglutamine, or PAGN, the key ammonia elimination pathway for OCR-002, was observed and OCR-002 demonstrated a favorable safety profile and appeared to be well tolerated.

We are currently conducting a randomized, placebo-controlled double blind Phase 2b clinical trial to evaluate the safety and efficacy of intravenous administration of OCR-002 in reducing the severity of HE symptoms among hospitalized HE patients. We expect to complete trial enrollment at approximately the end of 2015. This expectation is based on recent enrollment rates and assumes that no sample size adjustment will be recommended as a result of an upcoming interim analysis to be performed by an independent Data Safety Monitoring Board. We expect to conduct an interim analysis of this trial at the end of the first quarter of 2015.

In addition, there is an investigator-sponsored Phase 2a clinical trial being conducted by the National Institutes of Health, or NIH, to evaluate the safety of OCR-002 in patients with hyperammonemia and HE due to acute liver failure or injury.

We are also developing an oral form of OCR-002 with the goal to provide continuity of care for HE patients, where the intravenous form would be used for hospital-based acute care and the oral form for chronic maintenance care post discharge. We are conducting in vitro and in vivo formulation studies of several prototypes of an orally deliverable form of OCR-002. We currently plan to initiate a Phase 1 clinical trial in the second half of 2015.

Our strategy is to focus clinical development activities on the intravenous form of OCR-002 to treat acute HE in hospitalized patients and on the oral form of OCR-002, which will be directed to chronic care of HE patients. Based on third party analysis of Healthcare Cost and Utilization Project, or HCUP, and Medicare data, we estimate that there are approximately 120,000 patients with 175,000 hospitalizations for HE in the United States annually, and that this population is growing by about 5% per year. Additional third-party data from Centers for Medicare and Medicaid Services (CMS) indicate that approximately 60% of patients suffering from HE are hospitalized for over five 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 billion in the United States alone. If intravenous OCR-002 is able to reduce the duration of patient stays in hospital intensive care units, we believe it has an annual market potential of up to approximately $600 million and if the oral formulation can reduce the frequency of acute HE episodes, we believe it has an annual market potential of up to approximately $900 million. However, if any of our assumptions or estimates are incorrect, the actual annual market potential could be smaller.

OCR-002 has been granted orphan drug designation and Fast Track status by the U.S. Food and Drug Administration, or 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 the 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 and February 2013. 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 one patent and one patent application in the United States, and fifteen patents and six 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. In addition, we exclusively own three patents and one pending patent application in the United States, and five patents and fourteen pending patent applications in foreign jurisdictions (including a granted patent in China), that include specific drug substance patent claims, all of which expire in 2030. We also co-own with UCL and have exclusively licensed from UCL one pending application in the United States, and five patents and fifteen pending applications in foreign jurisdictions (including granted patents in Europe and China), that include claims related to the use of OCR-002 for the treatment of portal hypertension, all of which expire in

2030. We also hold exclusive rights to one patent and one pending application in the United States, and fifteen pending applications in foreign jurisdictions, for the manufacture of OCR-002, all of which expire in 2031.

We are developing OCR-002 and retain global rights to commercialization for both the intravenous and oral forms of the drug. We may seek partners to help us develop OCR-002, including the potential to partner product commercialization rights.

**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 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, we believe 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. 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 120,000 patients with 175,000 hospitalizations for HE in the United States annually, and that this population is growing by about 5% a year. Additional third-party data from CMS indicates that approximately 60% of patients suffering from HE are hospitalized for over five days.

Acute 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, often 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.

**OCR-002 Mechanism of Action**

OCR-002 appears to have a dual mode of action designed to lower ammonia without involvement of the liver, which is damaged or diseased in HE patients. Once in circulation, OCR-002 breaks down into ornithine and phenylacetate. 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. We believe that ornithine enters the muscle where it 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*

We are currently conducting a randomized, placebo-controlled double blind Phase 2b clinical trial in 140 patients to evaluate the safety and efficacy of intravenously administered OCR-002 in reducing the severity of HE symptoms among hospitalized HE patients. We commenced this trial in the fourth quarter of 2013 and enrolled our first patient in January 2014. We plan to conduct the trial at approximately 100 sites worldwide. 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 pharmacokinetic data from our investigator-sponsored trials discussed below. This increased dosage level remains 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 primary efficacy endpoint of this trial is time to clinically meaningful improvement in HE symptoms. Secondary endpoints include time to complete resolution, proportion of clinical responders,

ammonia reduction, length of hospital stay and time in the intensive care unit, among others. We expect to complete trial enrollment by approximately the end of 2015. This expectation assumes that enrollment outside of the United States progresses at a rate comparable to enrollment in the United States, and that the total sample size of the trial is not increased after our interim analysis. We expect to conduct the interim analysis of this trial at the end of the first quarter of 2015.

*Investigator Sponsored Phase 2a Trials*

In February 2015, we announced the preliminary topline results of the second phase of a Phase 2a investigator-sponsored, double-blind placebo controlled study of OCR-002 conducted in Spain in 38 patients with upper gastrointestinal bleeding associated with liver cirrhosis. This study showed that OCR-002 lowered ammonia by 19.6% over the first 12 hours, compared to 3.2% over the first 12 hours in the placebo group, but this difference did not reach statistical significance. A statistically significant difference in urinary excretion of ammonia, as measured by PAGN, the key ammonia elimination pathway for OCR-002, was observed and OCR-002 demonstrated a favorable safety profile and appeared to be well tolerated. The first phase of this trial was conducted on an open label basis and the investigators observed a rapid decline in ammonia in the 10 patients who received OCR-002 at up to 10 grams per day in addition to the standard of care.

In addition, there is a second investigator-sponsored Phase 2a trial of OCR-002 underway. This trial, sponsored by NIH, is a pilot open label dose ranging study of up to 10 grams per day, assessing safety and pharmacokinetics of OCR-002 in patients with acute liver failure/injury and hyperammonemia. In the NIH trial, there have been 20 evaluable patients enrolled with no drug-related serious adverse events.

***Phase 1 Pharmacokinetic Trial***

We completed Phase 1 pharmacokinetic and safety trials of OCR-002 in a parallel ascending dose clinical trial of 48 healthy volunteers and 43 stable cirrhotic patients. No serious adverse events, deaths or discontinuations were reported. The most common dose-related toxicities included dizziness, headache, nausea and blurred vision. Through this trial, we established the pharmacokinetic profile of OCR-002 and identified safety margins.

***Pre-clinical Studies***

Preclinical 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 in the pig model, OCR-002 significantly reduced arterial ammonia, brain ammonia and intracranial pressure.

OCR-002 Oral Formulation

***Pre-clinical Studies***

We are conducting in vitro and in vivo formulation studies of several prototypes of an orally deliverable form of OCR-002. Our goal is to develop an oral formulation of OCR-002 that would achieve a release profile supporting a convenient dosing schedule.

***Phase 1 Pharmacokinetic Trial***

We plan to initiate a Phase 1 clinical trial evaluating our oral formulation of OCR-002 in the second half of 2015. In this trial, we expect to evaluate the safety and pharmacokinetics of our oral formulation of OCR-002 in healthy volunteers.

**Manufacturing**

We currently have no manufacturing facilities and limited personnel with manufacturing experience. 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 clinical supplies of OCR-002 manufactured for us by Helsinn Chemicals SA in Switzerland. Finished product manufacturing and filling for OCR-002 is being 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 and 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 often 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 acute HE, the standard of care is treatment with hydration and lactulose. For prevention of recurring HE, lactulose and rifaximin are the only FDA-approved therapies for reduction in risk of episodic HE recurrence. In addition to currently marketed treatments for chronic HE, Hyperion Therapeutics, Inc., or Hyperion, completed a Phase 2 study of glycerol phenylbutyrate (Ravicti®), or GPB, for the treatment of HE. Hyperion reported that this study met its primary endpoint with significantly fewer patients treated with GPB experiencing HE events as compared to patients receiving placebo. In addition, Hyperion announced that it intends to begin enrolling patients in a Phase 3 study of GPB for the treatment of patients with HE in the second half of 2015. To be commercially viable in the treatment of acute HE, we must demonstrate that OCR-002 shortens the time to meaningful clinical improvement, and to be viable in the chronic treatment of HE, 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 one patent and one patent application in the United States, and fifteen patents and six 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. In addition, we exclusively own three patents and one pending patent application in the United States, and five patents and fourteen pending patent applications in foreign jurisdictions (including a granted patent in China), that include specific drug substance patent claims, all of which expire in 2030. We also co-own with UCL and have exclusively licensed from UCL one pending application in the United States, and five patents and fifteen pending applications in foreign jurisdictions (including granted patents in Europe and China), that include claims related to the use of OCR-002 for the treatment of portal hypertension, all of which expire in 2030. We also hold exclusive rights to one patent and one pending application in the United States, and fifteen pending applications in foreign jurisdictions, for the manufacture of OCR-002, all of which expire in 2031. However, there is a significant risk that these 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 U.S. patent system permits the filing of provisional and non-provisional patent applications. A non-provisional patent application is examined by the U.S. 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 U.S. 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 letters, 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 study;
- 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 study at a prospective site;
- nonclinical laboratory and animal tests;
- recruiting patients to participate in a study; 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 study 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 study 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 study 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 U.S. 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 cGMPs, 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, require us to 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. 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. 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 for OCR-002 for HE was granted based on data demonstrating that this disease affects fewer than 200,000 patients in the United States.

Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product that has orphan designation is the first such product to receive FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that subsequent to approval the FDA may not approve any other applications to market a drug with the same active moiety for the same disease, except in limited circumstances, for seven years. During orphan exclusivity, the FDA may only permit additional companies to market a drug with the same active chemical entity for the designated condition if such companies can demonstrate substantial improvement, 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 exclusivity, 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.

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 U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. 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 Medicare-Medicaid Anti-Fraud and Abuse Act, as amended, or the Anti-Kickback Statute, 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 $5,500 and $11,000 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, beginning in 2013, 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 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 agents 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 as of 2010 and by expanding the population potentially eligible for Medicaid drug benefit. The Centers for Medicare and Medicaid Services, or CMS, have proposed to expand Medicaid rebate liability to the territories of the United States as well. 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 U.S. 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. Effective in 2010, 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.
- Effective in 2011, PPACA imposed a requirement on manufacturers of branded drugs and biologic agents to provide a 50% discount off the negotiated price of branded drugs dispensed to Medicare Part D patients in the coverage gap.
- Effective in 2011, PPACA imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, 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.
- Effective in 2013, 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 will be required to report this information beginning in 2013.
- As of 2010, 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 created the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription drugs. Under certain circumstances, these recommendations will become law unless Congress enacts legislation that will achieve the same or greater Medicare cost savings.
- 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.

Many of the details regarding the implementation of PPACA are yet to be determined, and at this time, it remains unclear the full effect that PPACA would have on 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, 2014 and 2013, we expended approximately $14.9 million and $3.5 million, respectively, on research and development activities.

**Employees**

We had 16 full-time employees as of December 31, 2014. None of our employees are represented by any collective bargaining unit. We believe that we maintain good relations with our employees.

**Restructuring and Technology Transfer**

On September 11, 2013, our Board of Directors approved a restructuring plan related to the operations of our Sherbrooke, Quebec facility whereby we closed the operations of the Sherbrooke facility effective November 11, 2013. On December 13, 2013, we entered into a Technology Transfer and License Agreement to transfer ownership of certain equipment and tangible materials, and granted a license to our intellectual property rights, related to our Macrocyclic Template Chemistry (MATCH) discovery platform to Genentech, Inc. and F. Hoffman-La Roche, Ltd, which transfer was completed on February 18, 2014.

**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.

**Item 1A. Risk Factors**

*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. If any of the following risks 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, Regulatory Approval and Commercialization of our Product Candidates**

***We depend substantially on the success of our product candidate, OCR-002, and we may not 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 OCR-002 for the treatment of hyperammonemia and associated hepatic encephalopathy, or HE, in patients with liver cirrhosis, acute liver failure and acute liver injury. The process to develop, obtain regulatory approval for and commercialize OCR-002 is long, complex and costly.

We have not submitted a new drug application, or NDA, or received regulatory approval to market for 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

U.S. Food and Drug Administration, or FDA, requires the submission of extensive preclinical 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 any future product candidates we may develop, may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

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 Medicine 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 either HE or acute liver failure. 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 either HE or acute liver failure. 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.

***Any safety or efficacy concerns, including our ability to show a statistically significant reduction in the clinical severity of HE, or delays in enrollment, in our Phase 2b clinical trial, and any future Phase 3 clinical trials we may conduct, could delay or prevent regulatory approval of OCR-002.***

We are currently conducting a randomized, placebo-controlled double blind Phase 2b clinical trial in 140 patients to evaluate the efficacy of intravenously administered OCR-002 in reducing the severity of HE symptoms among hospitalized HE patients. We commenced this trial in the fourth quarter of 2013 and enrolled our first patient in January 2014. The primary efficacy endpoint of this trial is time to clinically meaningful improvement in HE symptoms. Secondary endpoints include severity of HE, ammonia reduction, length of hospital stay and time in the intensive care unit, among others. To date, the clinical trials relating to 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. While we believe that a reduction in patient's plasma ammonia levels is linked to the time to clinically meaningful improvement in HE symptoms, which is the primary efficacy endpoint of our ongoing Phase 2b clinical trial, and likely to be the primary efficacy endpoint of any future Phase 3 clinical trials we may conduct, the trial results may not bear this out. In addition, in the event that safety concerns are raised by this trial, we may no longer be able to pursue further development or commercialization efforts for OCR-002.

In April 2014, we amended the protocol for our Phase 2b clinical to increase patient dosage from up to 10 grams per day to up to 20 grams per day. There can be no assurance that the increased dosage will have a favorable impact on efficacy or that we will be able to meet our clinical endpoints. We intend to release interim analysis for futility and sample size after our observation of a predetermined number of events in our trial. If our interim analysis raises efficacy or safety concerns for OCR-002, or if the remaining sample size needed to achieve statistical significance is not feasible or too costly to undertake, we may need to alter or abandon our current Phase 2b trial, which could prevent us from receiving regulatory approval of intravenously administered OCR-002.

Enrollment in our Phase 2b clinical trial is ongoing. To increase the pace of enrollment, we amended our trial protocol in March 2014 to broaden the eligible patient selection criteria. In October 2014, we further amended the protocol to broaden enrollment and clarify certain operational aspects of the trial. In addition, we expanded the scope of the trial to

include up to 100 sites in the United States and Europe. In spite of these changes, there can be no assurance that enrollment will occur on a timely basis or that the trial will ever achieve full enrollment.

***Any safety or efficacy concerns, or delays in enrollment, relating to the lone remaining externally sponsored Phase 2a studies of OCR-002 may delay or prevent approval of OCR-002.***

The Acute Liver Failure Study Group of the National Institutes of Health is funding a Phase 2a study of OCR-002, for the treatment of patients with acute liver injury, as well as those that have progressed to acute liver failure following acetaminophen overdose. Enrollment in this clinical trial is ongoing. In March 2013, the FDA approved less restrictive enrollment inclusion criteria for the study, which we believe will allow for a somewhat more rapid enrollment of patients. However, there can be no assurance that enrollment will occur on a timely basis or that the study will ever achieve full enrollment. In the event that safety or efficacy concerns are raised by this study, we may no longer be able to pursue an acute liver failure indication for OCR-002.

An additional Phase 2a investigator-sponsored study tested OCR-002 in patients with upper gastrointestinal bleeding associated with liver cirrhosis. In the first part of this study, a 10-patient open label safety cohort, OCR-002 was shown to lower ammonia when administered as a continuous intravenous infusion of up to 10 grams per 24 hours. In February 2015, we announced the preliminary topline results of the second part of this study, which was a randomized, placebo-controlled cohort of 38 patients. The data showed that OCR-002 lowered ammonia by 19.6% over the first 12 hours, compared to 3.2% over the first 12 hours in the placebo group, but this difference did not reach statistical significance. A statistically significant difference in urinary excretion of ammonia, as measured by phenylacetylglutamine, the key ammonia elimination pathway for OCR-002, was observed and OCR-002 demonstrated a favorable safety profile and appeared to be well tolerated. There can be no assurance that we will observe similar efficacy or safety date in our ongoing Phase 2b trial or that our data will be statistically significant. If the results of Phase 2b trial do not show sufficient safety and efficacy, we may be unable to achieve regulatory approval of intravenously administered OCR-002 for reducing the severity of HE symptoms among hospitalized HE patients.

***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 175,000 cases, and the annual number of hospitalizations due to acute liver failure is approximately 2,000-3,000. We currently plan to enroll 140 patients in our Phase 2b clinical trial and, if the Phase 2b clinical trial is successful, any future Phase 3 clinical trials we may conduct might include a number of patients that is greater than what we plan to enroll in our Phase 2b clinical trial. If the enrollment in these studies is delayed, it will result in delays in our OCR-002 development program and the time to commercialization.

***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. For example, we are also developing an oral form of OCR-002 with the goal to provide continuity of care for HE patients, where the intravenous form would be used for hospital-based acute care and the oral form for chronic maintenance care post discharge. We are conducting in vitro and in vivo formulation studies of several prototypes of an orally deliverable form of OCR-002. We currently plan to initiate a Phase 1 clinical trial in the second half of 2015. 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. We may need to perform additional nonclinical and clinical studies, which could result in delays in our ability to market OCR-002 for any additional indications, or in additional formulations.

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

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 demonstrates 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 to treat HE or acute liver failure, 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 both HE and acute liver failure. 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.

***Our product candidates are subject to extensive regulatory requirements.***

Even if a drug is FDA-approved, regulatory requirements still impose significant restrictions on a product's indicated uses and marketing and the FDA may impose ongoing requirements for potentially costly post-marketing studies. Furthermore, any new legislation addressing drug safety issues could result in delays or increased costs to assure compliance.

OCR-002, if approved, will be subject to ongoing regulatory requirements for labeling, packaging, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-market information, including both federal and state requirements in any jurisdiction in which we or a partner commercialize the product. In addition, manufacturers and their facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices, or cGMP. As such, we and our contract manufacturers are subject to continual review and periodic inspections to assess compliance with cGMP. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control. We will also be required to report certain adverse reactions and production problems, if any, to the FDA and applicable foreign regulatory bodies, and to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which we do not have FDA or foreign approval, as applicable.

If 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, or disagrees with the promotion, marketing, or labeling of a product, a regulatory agency may impose restrictions on that product, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- seize or detain products or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenues from OCR-002, if approved. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results

will be adversely affected. Additionally, if we are unable to generate revenues from the sale of OCR-002, if approved, our potential for achieving profitability will be diminished and the capital necessary to fund our operations will be increased.

***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 U.S. 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, OCR-002, any future product candidates we may develop, or the manufacturing facilities for our 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 U.S. 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.

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 Affordability Reconciliation Act, or collectively, the Health Care Reform Law, became law in the United States. The Health Care Reform law 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 new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revised the definition of “average manufacturer price” for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new law imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners. We will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

***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 and acute liver failure. Even if we complete development, obtain regulatory approval and commercialize OCR-002 to treat HE, we will face competition from Salix Pharmaceuticals, Inc., the manufacturer of rifaximin, as well as generic manufacturers of lactulose. Additionally, Hyperion Therapeutics, Inc., or Hyperion, completed a Phase 2 study of glycerol phenylbutyrate (Ravicti®), or GPB, currently approved for the treatment of urea cycle disorder, for the treatment of HE, which we expect to compete with OCR-002. Hyperion reported that this study met its primary endpoint with significantly fewer patients treated with GPB experiencing HE events as compared to patients receiving placebo. In addition, Hyperion announced that it intends to begin enrolling patients in a Phase 3 study of GPB for the treatment of patients with HE in the second half of 2015. In addition, researchers are continually learning more about liver disease including HE, and new discoveries may lead to new therapies. 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;
- 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 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 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;
- 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
- 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 drug 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 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, 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 procedures using 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 U.S. 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 or any future product candidates we may develop, conduct clinical trials and commercialize OCR-002 or any future product candidates we may develop.***

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, as well as other senior scientists and members of our 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 OCR-002 or the commercialization of OCR-002 or any other product candidates we may develop. We need to hire and retain qualified personnel for the development, manufacture and commercialization of drugs. We could experience problems in the future attracting and retaining qualified employees. For example, competition for qualified personnel in the biotechnology and pharmaceuticals fields is intense. We may not be able to attract and retain 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 we are 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, as 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 U.S. 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 has 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**

***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 completing the development and obtaining regulatory approval 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.

***If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully develop and commercialize our most advanced product candidates.***

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

- the initiation, progress, timing, scope and costs of our nonclinical studies and clinical trials, including the ability to timely enroll patients in our current, planned and potential future clinical trials;
- the time and cost necessary to obtain regulatory approvals;
- the costs of manufacture clinical and commercial supplies of OCR-002 and any other product candidates we may develop;
- 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;
- 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; and
- 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.

We have not generated any revenue from the sale of any products and do not know when, or if, we will generate any revenue. Until we can generate a sufficient amount of revenue, we may raise additional funds through collaborations and public or private debt or equity financings. Additional funds may not be available when needed on terms that are acceptable, or at all. 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, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

We believe that our current cash and cash equivalents will be sufficient to fund our anticipated operating requirements through at least the next twelve months. This estimate is based on a number of assumptions that may prove wrong, and changing circumstances beyond our control may cause the consumption of capital more rapidly than currently anticipated. Inability to obtain funding when needed could seriously harm the business.

***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 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 no experience in drug formulation, and we lack the resources and the capabilities to manufacture OCR-002 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 trial 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 clinical supplies of the active pharmaceutical ingredient for OCR-002 manufactured for us by a single drug substance supplier Helsinn Chemicals SA. The OCR-002 finished product manufacturing and filling is undertaken by AAI Pharma Service Corp. on our behalf. We have not secured commercial supply agreements with any contract manufacturers 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. We may also be required to pay incremental milestone payments for an additional dosage form. 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 a 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 will likely be impossible for us to commercialize OCR-002.

**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 technology 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 U.S. 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 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 U.S. or foreign patent offices. In addition, under the America Invents Act of 2011, or AIA, the U.S. 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 U.S. 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 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 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 U.S. 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**

***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:

- results of the 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 U.S. healthcare system;
- announcements by us or our competitors of significant acquisitions, 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' stock. 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 the Merger and other sales of our stock, either on a standalone bases 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.

***Future sales of our common stock may cause our stock price to decline.***

If our existing stockholders sell, or indicate an intent to sell, substantial amounts of our common stock in the public market after legal restrictions lapse, the trading price of our common stock could decline significantly. Moreover, a relatively small number of our stockholders own large blocks of shares. We cannot predict the effect, if any, that public sales of these shares or the availability of these shares for sale will have on the market price of our common stock.

***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. In addition, beginning with this Annual Report, we became subject to the requirement to perform an annual management assessment of the effectiveness of our internal controls over financial reporting and obtain a report from our independent registered public accounting firm addressing 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 or our independent registered public accounting firm may be unable to express an opinion on the effectiveness of our internal control over financial reporting, 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

We lease approximately 761 square feet of office space located at 525 University Avenue, Palo Alto, California under a month to month lease for general office purposes that commenced on October 10, 2013 and will terminate on May 31, 2015.

Following the Merger, our clinical development operations were moved to 8,126 square feet of office space located at 5001 South Miami Boulevard, Durham, North Carolina. In August 2014, we amended the lease for this facility by extending term of the lease through January 2016.

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**

On July 15, 2013 we completed a reverse merger with Tranzyme, Inc., symbol "TZYM" on the NASDAQ Global Market. Following the merger, we changed the name of the combined company to Ocera Therapeutics, Inc. and changed the symbol to "OCRX". The following table details the quarterly high and low sales prices for the common stock as reported by The NASDAQ Global Market for TZYM from January 1, 2013 through July 15, 2013, retroactively adjusted for a 12-for-1 reverse stock split, and for OCRX from July 16, 2013 through December 31, 2014.

| | Price Range | |
|---|---|---|
| **Fiscal year ending December 31, 2014** | **High** | **Low** |
| 1st Quarter | $18.76 | $10.55 |
| 2nd Quarter | $11.12 | $6.80 |
| 3rd Quarter | $7.69 | $4.71 |
| 4th Quarter | $7.94 | $4.96 |
| **Fiscal year ending December 31, 2013** | | |
| 1st Quarter | $0.68 | $0.44 |
| 2nd Quarter | $0.63 | $0.40 |
| 3rd Quarter | $12.09 | $0.45 |
| 4th Quarter | $13.35 | $7.00 |

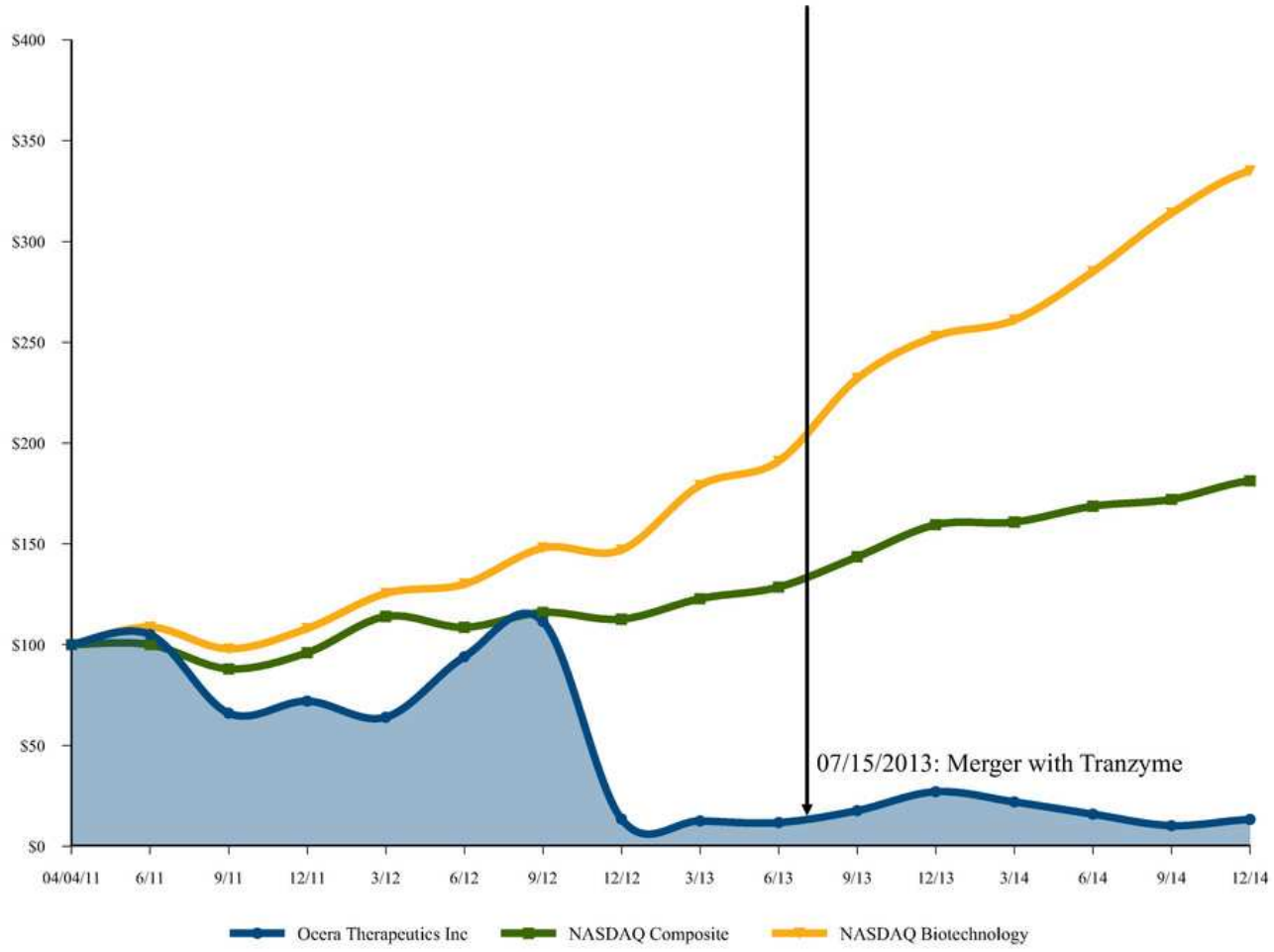
On March 12, 2015, the last trading day prior to March 13, 2015, the closing price for our common stock as reported by the NASDAQ Global Market was $4.56. We paid no cash dividends during the years ended December 31, 2013 and 2014. We currently intend to retain all of our future earnings to finance the growth and development of our business and do not anticipate paying any cash dividends in the foreseeable future.

**Comparative Stock Performance Graph**

The graph below matches our cumulative 44-month 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 April 2, 2011 to December 31, 2014. Performance from April 2, 2011 through July 15, 2013 represents Tranzyme, symbol "TZYM" on the NASDAQ Global Market and from July 15, 2013 through December 31, 2014 represents Ocera Therapeutics, Inc., symbol "OCRX" on the NASDAQ Global Market. The period prior to July 15, 2013 includes information of the predecessor company, Tranzyme and as such historical stockholder return is not necessarily indicative of the performance to be expected for any future periods.

**COMPARISON OF 44 MONTH CUMULATIVE TOTAL RETURN***

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




*$100 invested on 4/4/11 in stock or 3/31/11 in index, including reinvestment of dividends.

**Fiscal year ending December 31:**

| | 4/11 | 6/11 | 9/11 | 12/11 | 3/12 | 6/12 | 9/12 | 12/12 | 3/13 | 6/13 | 9/13 | 12/13 | 3/14 | 6/14 | 9/14 | 12/14 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Ocera Therapeutics Inc** | $100 | $105 | $66 | $72 | $64 | $94 | $112 | $14 | $13 | $12 | $18 | $27 | $22 | $16 | $10 | $13 |
| **NASDAQ Composite** | $100 | $100 | $88 | $96 | $114 | $109 | $116 | $113 | $123 | $129 | $144 | $159 | $161 | $169 | $172 | $181 |
| **NASDAQ Biotechnology** | $100 | $109 | $98 | $108 | $125 | $130 | $148 | $147 | $179 | $191 | $232 | $253 | $261 | $285 | $314 | $335 |

**Holders of Record**

As of February 27, 2015 , there were approximately 70 holders of record of our common stock.

**Dividends**

We have not paid any cash dividends on our common stock since inception and do not anticipate paying cash dividends in the foreseeable future and 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 Consolidated 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.

| | Years Ended December 31, | |
|---|---|---|
| | 2014 | 2013 |
| | (in thousands, except share and per share amounts) | |
| **Consolidated Statements of Operations Data:** | | |
| Revenue: | | |
| Licensing revenue | $ 200 | $ — |
| Royalty revenue | 141 | 85 |
| Total revenue | 341 | 85 |
| Operating expenses: | | |
| Research and development | 14,945 | 3,549 |
| General and administrative | 9,910 | 8,500 |
| Amortization of intangibles | 164 | 295 |
| Impairment of intangibles | — | 3,070 |
| Total operating expenses | 25,019 | 15,414 |
| Other income (expense), net | 54 | (160) |
| Net loss from continuing operations | (24,624) | (15,489) |
| Net income (loss) from discontinued operations | 1,199 | (2,025) |
| Net loss | $ (23,425) | $ (17,514) |
| | | |
| Net loss per share from continuing operations— *basic and diluted* | $ (1.41) | $ (2.52) |
| Net income (loss) per share from discontinued operations— *basic and diluted* | 0.07 | (0.33) |
| Net loss per share— *basic and diluted* | $ (1.34) | $ (2.85) |
| Shares used to compute net loss per share— *basic and diluted* | 17,525,187 | 6,145,731 |

| | As of December 31, | |
|---|---|---|
| | 2014 | 2013 |
| | (in thousands) | |
| **Consolidated Balance Sheet Data:** | | |
| Cash and cash equivalents | $ 10,127 | $ 15,533 |
| Short and long-term investments | 41,040 | 31,680 |
| Working capital | 45,364 | 42,605 |
| Total assets | 53,052 | 51,820 |
| Accumulated deficit | (104,911) | (81,486) |
| Total stockholders' equity | 50,145 | 45,132 |

## 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 "Selected Consolidated Financial Data" and our 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 focused on acute and chronic orphan liver diseases. Our initial focus is on the development and commercialization of a clinical candidate, OCR-002, for the treatment of hepatic encephalopathy, or HE. HE is a serious complication of liver cirrhosis, or liver failure, marked by mental changes including confusion, impaired motor skills, disorientation in time and space, and, in its more severe form, stupor, coma and even death. Although the exact cause of HE is not completely understood, there is growing evidence that elevated ammonia is a primary driver of HE, and that lowering ammonia may be beneficial to patients suffering from HE. Common causes of liver malfunction leading to elevated ammonia levels and HE include alcoholism, viral hepatitis and auto-immune diseases, nonalcoholic steatohepatitis, or NASH, as well as obesity, Type II diabetes, and acetaminophen overdose.

OCR-002 is a novel molecule, ornithine phenylacetate, which functions as an ammonia scavenger. In pre-clinical studies, OCR-002 significantly reduced arterial ammonia in an animal model of chronic liver disease and significantly reduced arterial ammonia, brain ammonia and intracranial pressure in a second animal model of acute liver failure. In 2012, we completed a Phase 1 pharmacokinetic and safety clinical trial of the intravenous form of OCR-002. A Phase 2a investigator-sponsored study in Spain tested 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 study, a 10-patient open label safety cohort, OCR-002 was shown to lower ammonia when administered as a continuous intravenous infusion of up to 10 grams per 24 hours. In February 2015, we announced the preliminary topline results of the second part of this study, which was a randomized, placebo-controlled cohort of 38 patients. The data showed that OCR-002 lowered ammonia by 19.6% over the first 12 hours, compared to 3.2% over the first 12 hours in the placebo group, but this difference did not reach statistical significance. A statistically significant difference in urinary excretion of ammonia, as measured by phenylacetylglutamine, or PAGN, the key ammonia elimination pathway for OCR-002, was observed and OCR-002 demonstrated a favorable safety profile and appeared to be well tolerated.

We are currently conducting a randomized, placebo-controlled double blind Phase 2b clinical trial to evaluate the safety and efficacy of intravenous administration of OCR-002 in reducing the severity of HE symptoms among hospitalized HE patients. We expect to complete trial enrollment at approximately the end of 2015. This expectation is based on recent enrollment rates and assumes that no sample size adjustment will be recommended as a result of an upcoming interim analysis to be performed by an independent Data Safety Monitoring Board. We expect to conduct an interim analysis of this trial at the end of the first quarter of 2015. In addition, there is an investigator-sponsored Phase 2a clinical trial being conducted by the National Institute of Health, or NIH, to evaluate the safety of OCR-002 in patients with hyperammonemia and HE due to acute liver failure or injury.

We are also developing an oral form of OCR-002 with the goal to provide continuity of care for HE patients, where the intravenous form would be used for hospital-based acute care and the oral form for chronic maintenance care post discharge. We are conducting in vitro and in vivo formulation studies of several prototypes of an orally deliverable form of OCR-002. We currently plan to initiate a Phase 1 clinical trial in the second half of 2015.

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

### *Merger*

On July 15, 2013, Tranzyme, Inc., or 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."

In connection with the Merger, on July 15, 2013, Tranzyme, Inc. effected a 12-to-1 reverse stock of its outstanding common stock. As a result of the Merger and after giving effect to a 12-to-1 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.

***Restructuring of Canadian Operations and Sale of Related Assets***

In September 2013, we approved a restructuring plan related to Tranzyme Pharma, Inc., our Canadian subsidiary acquired in the Merger that previously housed the research operations of Tranzyme, or Tranzyme Pharma, including Tranzyme's proprietary chemistry technology platform, MATCH (Macrocyclic Template Chemistry), used to develop its pre-clinical and clinical stage product candidates. The goal of the restructuring plan was to enable us to focus management and financial resources on advancing OCR-002. In November 2013, we terminated most employees at the Canadian location except those needed for final closure of the facility. In December 2013, we entered into a Technology Transfer and License Agreement with Genentech, Inc., or Genentech, and F. Hoffman-La Roche, Ltd, or Roche, including the Research and Early Development arms of both Genentech and Roche, for rights to the MATCH discovery platform. In 2014, we transferred ownership of equipment and materials stipulated under this agreement, and in aggregate have received payments totaling $4.0 million in conjunction with the agreement. In connection with the completion of the transfer we recognized a gain of $1.1 million during the year ended December 31, 2014.

***Financing***

On July 10, 2014, we completed an underwritten public offering of our common stock with Stifel, Nicolaus & Company, Incorporated and Cowen and Company, LLC, 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 U.S. Securities and Exchange Commission, or SEC, on July 9, 2014, in connection with a takedown from our shelf registration statement on Form S-3 (File No. 333-181215) filed on May 7, 2012 and declared effective by the SEC on May 29, 2012. 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, or 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, or the Purchasers, pursuant to which we issued an aggregate of 3,940,887 units, or 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 $7.663 per share, or Warrants. The Units consist of an aggregate of 3,940,887 shares of common stock, or the Shares, and Warrants exercisable for an aggregate of 788,177 shares of our Common Stock, or 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 $ 6.0264 .

***Licensing***

In December 2008, we licensed rights to OCR-002 from UCL Business PLC, an entity affiliated with the 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 and February 2013. 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, or 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 require our most difficult, subjective or complex judgments, resulting from the need to make estimates about the effect of matters that are inherently uncertain.

***Accrued Expenses***

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves communicating with our applicable personnel to identify services that have been performed on our behalf 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. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us. We periodically confirm the accuracy of our estimates with selected service providers and make adjustments, if necessary. To date, we have not adjusted our estimate at any particular balance sheet date by any material amount. Examples of estimated accrued expenses include:

- fees paid to investigative sites in connection with clinical trials;
- fees paid to contract manufacturers in connection with the production of clinical trial materials; and
- professional service fees.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

***Fair Value Measurements***

The carrying amounts of certain of our financial instruments, including cash and cash equivalents, short-term investments and long-term investments, are stated at fair value. We account for the fair value of our financial instruments in accordance with the provisions of the *Fair Value Measurement* topic of the Financial Accounting Standards Board Codification, or the Codification.

Fair value is the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the measurement date. We apply the market approach valuation technique for fair value measurements on a recurring basis and attempt to maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. All of our cash equivalents and short-term 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. 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. 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.

***Stock-Based Compensation***

The provisions of the *Compensation - Stock Compensation* topic of the Codification establish accounting for stock-based awards exchanged for employee services. In accordance with the topic, stock-based compensation cost is measured on the grant date, based on the fair value of the award, and is recognized as expense over the requisite employee service period.

We estimate the fair value of stock options using a Black-Scholes valuation model which require the input of highly subjective assumptions, including the option's expected life and the price volatility of the underlying stock. We have opted to use the simplified method for estimating the expected term as provided by the Securities and Exchange Commission, or SEC. The simplified method calculates the expected term as the average time-to-vesting and the contractual life of the options. We use historical experience to estimate the expected term for non-employee director awards that are exercisable up to one year following termination of services. The expected stock price volatility assumption was determined by examining the historical volatilities of a group of industry peers. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option valuation model, and the resulting charge is expensed using the straight-line attribution method over the vesting period. The Black-Scholes option-pricing model was developed for use in estimating the fair value of short-lived, exchange-traded options that have no vesting restrictions and are fully transferable.

***Research and Development Expenses***

Research and development expenses consisted of costs associated with external research and development expenses incurred under agreements with (i) third-party investigative sites, where a substantial portion of our preclinical studies and all of our clinical trials are conducted, (ii) third-party manufacturing organizations, where a substantial portion of our preclinical supplies and all of our clinical supplies are produced, and (iii) consultants; employee-related expenses, which include salaries and benefits; and facilities, depreciation and amortization and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation of equipment and other supplies.

***Business Combinations***

We accounted for the Merger as a reverse merger under the acquisition method of accounting. The consideration paid to acquire Tranzyme was measured at fair value and included the exchange of our common stock and assumption of vested stock options. The allocation of the purchase price resulted in recognition of intangible assets related to customer relationships, developed technology and goodwill. The allocation of purchase price requires us to make significant estimates and assumptions. The key assumptions in determining the fair value of intangible assets were the discount rate and the probability assigned to the milestone or royalty being achieved.

***Discontinued Operations***

On September 11, 2013, our Board of Directors approved a restructuring plan related to the operations of our Sherbrooke, Quebec facility whereby we closed the operations of the facility effective as of November 11, 2013. On December 13, 2013, we entered into a Technology Transfer and License Agreement to sell our MATCH discovery platform and license the related intellectual property rights. As the Sherbrooke, Quebec operations and MATCH discovery platform comprise a component with distinct operations and cash flows that will be eliminated from ongoing operations and we will not have significant involvement after the disposal, this component will be accounted for as discontinued operations. The results of operations of the components to be disposed of, related restructuring costs and gain on disposal of assets have been classified as net income (loss) from discontinued operations from their acquisition on July 15, 2013 through December 31, 2014. The assets and liabilities of Tranzyme Pharma have been classified as assets and liabilities, respectively, of discontinued operations.

***Intangible Assets and Goodwill***

We recorded intangible assets and goodwill upon the acquisition of Tranzyme on July 15, 2013. Acquired intangible assets are amortized on a straight-line basis over the remaining estimated economic life of 2.5 to 5 years. We review our intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of a long-lived asset may not be recoverable. Recoverability of an asset is measured by comparing its carrying amount to the expected future undiscounted cash flows that the asset group is expected to generate. If it is determined that the carrying amount is not recoverable, an impairment loss is recorded in the amount by which the carrying amount of the asset exceeds its fair value. We recorded an impairment loss of $3.1 million in the year ended December 31, 2013 due to the termination of work on

macrocyclic compounds, licensed to them by Tranzyme prior to the Merger, under collaboration with Bristol-Myers Squibb, or BMS.

We perform an annual qualitative assessment of our goodwill to determine if any events or circumstances exist, such as an adverse change in business climate or adverse developmental or regulatory results of OCR-002, that would indicate that it would more likely than not reduce the fair value of a reporting unit below its carrying amount, including goodwill. If events or circumstances do not indicate that the fair value of a reporting unit is below its carrying amount, then goodwill is not considered to be impaired and no further testing is required. The determination of fair value requires significant judgment and estimates. There has been no impairment of goodwill for any periods presented.

***Revenue Recognition***

We recognized revenues from the delivery of collaborative research services, license agreements for the development and commercialization of products and from royalties. During 2013, collaboration research revenue was disclosed as discontinued operations in our Consolidated Statements of Operation and Comprehensive Loss. For each source of revenue, we apply revenue recognition criteria in the following manner:

Multiple element arrangements such as collaboration agreements which may include an upfront license and ongoing services are analyzed to determine whether the deliverables within the agreement can be separated or whether they must be accounted for as a single unit of accounting. Deliverables under the agreement will be accounted for as separate units of accounting provided that (i) a delivered item has value to the customer on a stand-alone basis; and (ii) if the agreement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in the control of the vendor. The allocation of consideration amongst the deliverables under the agreement is derived using a "best estimate of selling price" if vendor specific objective evidence and third-party evidence of fair value is not available. If the delivered element does not have stand-alone value, the arrangement is then accounted for as a single unit of accounting, and we will recognize the consideration received under the arrangement as revenue on a straight-line basis over the estimated period of performance.

License fees from our license agreements are recognized when the amounts are earned and determinable during the applicable period. We recognize up-front nonrefundable license fees when due under contractual agreements and when we do not have a continuing obligation to provide services related to the agreement. Revenue associated with nonrefundable up-front license fees under arrangements where the license fees and research and development activities cannot be accounted for as separate units of accounting is deferred and recognized as revenue on a straight-line basis over the expected term of our continued involvement in the research and development process.

We recognize royalties as revenue when earned. At the end of each accounting period, estimates of royalty amounts due are made based on estimated sales information from customers.

***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 bases 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 our 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 in accordance with ASC 740, *Income Taxes* 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.

**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 we adopt 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 our financial statements upon adoption.

In July 2013, the FASB issued Accounting Standards Update, or ASU, No. 2013-11, *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists* . ASU 2013-11 provides explicit guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The guidance is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013, with an option for early adoption. We adopted this guidance in the first quarter of fiscal year 2014. The adoption of this standard did not have a material impact on our financial statements.

In April 2014, the FASB issued Accounting Standards Update, or ASU, No. 2014-08, *Presentation of Financial Statements (Topic 205) and Property, Plant and Equipment (topic 360); Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity.* ASU 2014-08 provides additional requirements to classify a disposal of a component of an entity or a group of components of an entity in discontinued operations only if the disposal represents a strategic shift that has (or will have) a major effect on an entity's operations and financial results. The guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2014, with an option for early adoption. We intend to adopt this guidance at the beginning of our first quarter of fiscal year 2015, and do not expect the adoption of this standard will have a material impact on our financial statements.

In May 2014, the FASB issued Accounting Standards Update, or ASU, No. 2014-09, *Revenue from Contracts with Customers.* ASU 2014-09 requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. ASU 2014-09 will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The new standard will become effective for us on January 1, 2017. Early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. We are evaluating the effect that ASU 2014-09 will have on our consolidated financial statements and related disclosures. We have not yet selected a transition method nor have determined the effect of the standard on our ongoing financial reporting.

In June 2014, the FASB issued Accounting Standards Update, or ASU, No. 2014-10, *Development Stage Entities (Topic 915)* . ASU 2014-10 removes the distinction between development stage entities and other reporting entities in U.S. GAAP and eliminates the requirement to label financial statements as those of a development stage entity and eliminates the requirement to present inception to date information in the statements of income, cash flows and shareholder equity. The guidance is applied retroactively and is effective for fiscal years, and interim periods within those years, beginning after December 15, 2014, with an option for early adoption. We early adopted this guidance in 2014, and as a result, have removed the label "A Development Stage Company" from our financial statements and accompanying notes and eliminated the inception to date information from the Consolidated Statements of Operations and Comprehensive Loss and Consolidated Statements of Cash Flows. Other than presentation, the adoption of this standard did not have a material impact on our financial statements.

In August 2014, the FASB issued Accounting Standards Update, or ASU, No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern.* ASU 2014-15 requires management to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. In doing so, companies will have reduced diversity in the timing and content of footnote disclosures than under today's guidance. ASU 2014-15 is effective for us in the first quarter of 2016 with early adoption permitted. We do not believe the impact of adopting this standard will be material on our financial statements.

**Results of Operations**

*Comparison of the Years Ended December 31, 2014 and 2013 (dollars in thousands):*

| | Years Ended December 31, | | | |
|---|---|---|---|---|
| | 2014 | 2013 | $ Change | % Change |
| Revenue: | | | | |
| Licensing revenue | $ 200 | $ — | $ 200 | 100% |
| Royalty revenue | 141 | 85 | 56 | 66% |
| Total revenue | 341 | 85 | 256 | 301% |
| Operating expenses: | | | | |
| Research and development | 14,945 | 3,549 | 11,396 | 321% |
| General and administrative | 9,910 | 8,500 | 1,410 | 17% |
| Amortization of intangibles | 164 | 295 | (131) | (44%) |
| Impairment of intangibles | — | 3,070 | (3,070) | (100%) |
| Total operating expenses | 25,019 | 15,414 | 9,605 | 62% |
| Total other income (expense), net | 54 | (160) | 214 | (134%) |
| Net loss from continuing operations | (24,624) | (15,489) | (9,135) | 59% |
| Net income (loss) from discontinued operations | 1,199 | (2,025) | 3,224 | (159%) |
| Net loss | $ (23,425) | $ (17,514) | $ (5,911) | 34% |

**Revenues**

Licensing revenue for the year ended December 31, 2014 was $200,000, consisting of an up-front nonrefundable payment for the transfer of intellectual property and materials associated with TZP-101 ( *ulimorelin* ) to Lyric Pharmaceuticals, Inc. There was no licensing revenue generated for the year ended December 31, 2013.

Royalty revenue from a licensing agreement for the year ended December 31, 2014 and December 31, 2013 was $141,000 and $85,000 respectively. This revenue is attributable to a license agreement, which was acquired in connection with the Merger in July 2013.

**Costs and Expenses**

*Research and Development Expenses*

Our research and development expenses increased by $ 11.4 million , or 321%, for the year ended December 31, 2014 compared to the year ended December 31, 2013. The increase was due to the continued progress of our development program for OCR-002, including the ongoing enrollment and site activation of our Phase 2b trial for OCR-002, an increase in stock compensation expense related to stock option grants issued after the Merger, increased employee related costs related to additional headcount after the Merger and increased allocable facilities expense.

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

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

need to raise additional money to advance development and commercialization of OCR-002, which may include entering into strategic alliances.

*General and Administrative Expenses*

Our general and administrative expenses increased by $1.4 million , or 17%, for the year ended December 31, 2014 compared to the year ended December 31, 2013. The increase was due primarily to an increase in stock compensation expense, professional fees including legal and accounting expenses and other expenses associated with our corporate governance, including directors and officer insurance and rent. These increases were partially offset by a decrease in costs related to expenses incurred in connection with the Merger, including employee severance costs.

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

*Amortization of intangibles*

On July 15, 2013, we capitalized approximately $5.9 million of intangible assets acquired in the Merger. $2.2 million of these intangible assets acquired were reclassified to discontinued operations and assets held for sale during the fourth quarter of 2013. We recognized $ 164,000 and $295,000 for the amortization of the intangible assets for the years ended December 31, 2014 and 2013, respectively.

*Impairment of intangibles*

Following the Merger, during our periodic reviews of the collaboration agreement with BMS, we determined that BMS would terminate its efforts on the development of all macrocyclic compounds , licensed to them by Tranzyme prior to the Merger, pursuant to the collaboration agreement. As a result, we recognized an impairment loss of $3.1 million for the year ended December 31, 2013 associated with the termination of development by BMS pursuant to the collaboration agreement. No impairment loss was recorded in the year ended December 31, 2014.

*Total Other Income (Expense), Net*

Our total other income (expense), net increased $0.2 million for the year ended December 31, 2014 compared to the year ended December 31, 2013. This increase was attributable to higher average investment balances in 2014, resulting in higher interest income of $48,000 and decrease in interest expense of $181,000 as interest expense and amortization of debt issuance costs on convertible notes payable ceased at such date as a result of the Merger.

*Net loss from discontinued operations*

During the year ended December 31, 2013, we classified our Sherbrooke, Quebec facility and related operations as discontinued operations. During the year ended December 31, 2014, we completed our 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 related to the subsidiary operations of Tranzyme Pharma as detailed below *(in thousands)* :

| | Year Ended December 31, 2014 |
|---|---|
| Proceeds recognized pursuant to Technology Transfer and License Agreement | $ 4,000 |
| Less carrying value of assets sold: | |
| Intangibles assets | (2,053) |
| Property and equipment | (356) |
| Goodwill | (442) |
| Net gain on disposal of assets | $ 1,149 |

Licensing revenue, research and development and general and administrative reflect the operating results of our Sherbrooke, Quebec facility that were discontinued. Restructuring costs represent costs associated with the separation of employment of employees at the Sherbrooke facility and other costs related to the restructuring plan. Amortization of intangible assets relates to the MATCH discovery platform and related intangible assets held for sale at December 31, 2013. The net results of miscellaneous asset sales are recorded in other income (expense), net for each of the years ended December 31, 2014 and 2013.

The following table summarizes the results of discontinued operations for the years ended December 31, 2014 and 2013 *(in thousands)* :

| | Years Ended December 31, | |
|---|---|---|
| | **2014** | **2013** |
| Revenue | $ — | $ 467 |
| Expenses: | | |
| Research and development | — | (1,134) |
| General and administrative | — | (220) |
| Amortization of intangibles | — | (187) |
| Restructuring settlements (charges) | 68 | (859) |
| Gain (loss) on disposal of assets | 1,149 | (86) |
| Other expense, net | (6) | (6) |
| Recognition of accumulated translation adjustments upon deconsolidation of subsidiary | (12) | — |
| Net income (loss) from discontinued operations | **$ 1,199** | **$ (2,025)** |

**Liquidity and Capital Resources**

*Cash Flows*

The following table summarizes our cash flows for the years ended December 31, 2014 and 2013 *(in thousands)* :

| | Years Ended December 31, | |
|---|---|---|
| | **2014** | **2013** |
| Cash flow from: | | |
| Continuing operating activities | $ (19,885) | $ (10,988) |
| Discontinued operating activities | (440) | (1,006) |
| Continuing investing activities | (10,028) | (24,264) |
| Discontinued investing activities | 1,165 | 3,000 |
| Continuing financing activities | 23,782 | 46,488 |
| Net increase (decrease) in cash and cash equivalents | $ (5,406) | $ 13,230 |

The primary use of cash in continuing operating activities for the year ended December 31, 2014 was the result of our net loss from continuing operations of $24.6 million plus changes in working capital of $0.7 million . These changes were partially offset by non-cash charges of $5.5 million including depreciation expense, stock-based compensation expense, accretion of premium on investment securities and amortization of intangible assets acquired in the Merger. Cash used in continuing operating activities for year ended December 31, 2013 was primarily due to our net loss from continuing operations of $15.5 million, partially offset by non-cash charges of $4.0 million including depreciation expense, stock-based compensation expense and the amortization of and impairment of intangibles purchased in the Merger and changes in working capital of $0.5 million.

Cash used in discontinued operating activities for the year ended December 31, 2014 was due primarily to payment of accrued liabilities of discontinued operations. Cash used in discontinued operating activities for year ended December 31, 2013 was primarily related to our net loss from discontinued operations of $2.0 million and offset by changes in working capital of $0.5 million and non-cash charges of $0.5 million including depreciation and amortization expense and the net book value of assets disposed.

Cash used by continuing investing activities for the for the year ended December 31, 2014 related to purchases of commercial paper, corporate debt securities and government agency debt securities totaling $41.4 million , partially offset by maturities of such investments of $31.4 million . Cash used in continuing investing activities for the year ended December 31, 2013 related to purchases of short-term and long-term investments of $34.1 million and offset partially by $7.5 million received from the Merger and maturities of short-term investments of $2.4 million.

Cash provided by discontinued investing activities 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.

Net cash provided by continuing financing activities for the year ended December 31, 2014 related to net proceeds of $23.4 million generated from our public offering completed on July 10, 2014, as well as proceeds from the exercise of stock options of $0.4 million. Net cash provided by continuing financing activities for the year ended December 31, 2013 related to proceeds from issuance of common stock, net of issuance costs, of $46.4 million.

***Capital Resources and Funding Requirements***

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

We expect to fund expenses from our current cash and cash equivalents, possible strategic opportunities and potentially additional financing transactions. We believe that our current cash and cash equivalents will be sufficient to fund our operations for at least the next twelve months.

We have based our estimates of our cash needs on a number of assumptions that may prove to be wrong, and changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, our OCR-002 Phase 2b clinical trial may cost more than we expect, or development of the oral formulation of OCR-002 may involve the license of proprietary technology. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidate, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. If adequate funds are not available to us on a timely basis, or at all, we may be required to terminate or delay clinical trials or other development activities for OCR-002.

Our ability to finance operations beyond our current resources will depend heavily on our ability to obtain favorable results in clinical trials of OCR-002 and to develop and commercialize OCR-002 successfully. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. We may elect to raise additional funds even before we need them if the conditions for raising capital are favorable. We may seek to raise additional capital through a combination of private and public equity offerings and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring debt, making capital expenditures or declaring dividends.

***Contractual Obligations***

The following is a schedule of non-cancellable future minimum lease payments for operating leases at December 31, 2014 ( *in thousands* ):

| **Year Ended December 31,** | | |
|---|---|---|
| 2015 | $ | 200 |
| 2016 | | 18 |
| Total | $ | 218 |

We have license milestone obligation payments that are not included in the table above because the Company cannot determine when or if the payments will occur.

In the normal course of business, we enter into various firm purchase commitments related to active pharmaceutical ingredients, clinical studies and research studies. As of December 31, 2014, we have approximately $6.1 million in contractual obligation and commitments under contracts that are cancellable within 90 days or less.

***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 in Europe. Accordingly, we are 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, 2014 consisted primarily of cash, money market funds, commercial paper, corporate debt securities and government agency 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, because of 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.

We did not hold derivative instruments intended to mitigate interest rate risk as of December 31, 2014, and we have never held such instruments in the past. If market interest rates were to increase by 100 basis points, or 1%, from December 31, 2014 levels, the fair value of our portfolio would decrease by approximately $156,000.

**Item 8. Financial Statements and Supplementary Data**

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Ocera Therapeutics, Inc.

We have audited the accompanying consolidated balance sheets of Ocera Therapeutics, Inc. as of December 31, 2014 and 2013, and the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2014. 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as 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, 2014 and 2013, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Ocera Therapeutics, Inc.’s internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 13, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, CA
March 13, 2015

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

| | December 31, 2014 | December 31, 2013 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 10,127 | $ 15,533 |
| Short-term investments, available-for-sale | 37,112 | 30,167 |
| Accounts receivable | 62 | 93 |
| Prepaid expenses and other current assets | 970 | 470 |
| Assets of discontinued operations | — | 3,029 |
| Total current assets | 48,271 | 49,292 |
| Property and equipment, net | 61 | 59 |
| Long-term investments | 3,928 | 1,513 |
| Deposits | 26 | 26 |
| Intangible assets, net | 171 | 335 |
| Goodwill | 595 | 595 |
| **Total assets** | **$ 53,052** | **$ 51,820** |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 941 | $ 1,282 |
| Accrued liabilities | 1,966 | 1,902 |
| Liabilities of discontinued operations | — | 3,503 |
| Total current liabilities | 2,907 | 6,687 |
| Other liabilities | — | 1 |
| **Total liabilities** | **2,907** | **6,688** |
| Commitments and contingencies (Note 14) | | |
| Preferred stock, $0.00001 par value, 5,000,000 shares authorized; no shares issued or outstanding at December 31, 2014 and December 31, 2013. | — | — |
| Common stock, $0.00001 par value, 100,000,000 shares authorized;19,747,362 shares issued and outstanding at December 31, 2014 and 15,300,214 shares issued and outstanding at December 31, 2013. | — | — |
| Additional paid-in capital | 155,083 | 126,615 |
| Accumulated other comprehensive income (loss) | (27) | 3 |
| Accumulated deficit | (104,911) | (81,486) |
| **Total stockholders' equity** | **50,145** | **45,132** |
| **Total liabilities and stockholders' equity** | **$ 53,052** | **$ 51,820** |

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, | |
|---|---|---|
| | 2014 | 2013 |
| Revenue: | | |
| Licensing revenue | $ 200 | $ — |
| Royalty revenue | 141 | 85 |
| Total revenue | 341 | 85 |
| Operating expenses: | | |
| Research and development | 14,945 | 3,549 |
| General and administrative | 9,910 | 8,500 |
| Amortization of intangibles | 164 | 295 |
| Impairment of intangibles | — | 3,070 |
| Total operating expenses | 25,019 | 15,414 |
| Other income (expense): | | |
| Interest and other income | 66 | 18 |
| Interest and other expense | (12) | (193) |
| Change in fair value of warrant liability | — | 15 |
| Total other income (expense), net | 54 | (160) |
| Net loss from continuing operations | (24,624) | (15,489) |
| Net income (loss) from discontinued operations (including gain on disposal of $1,149 for the year ended December 31, 2014) | 1,199 | (2,025) |
| Net loss | $ (23,425) | $ (17,514) |
| | | |
| Net loss per share: | | |
| Net loss per share from continuing operations, basic and diluted | $ (1.41) | $ (2.52) |
| Net income (loss) per share from discontinued operations, basic and diluted | 0.07 | (0.33) |
| Net loss per share, basic and diluted | $ (1.34) | $ (2.85) |
| Weighted average number of shares used to compute net loss per share of common stock, basic and diluted | 17,525,187 | 6,145,731 |
| Other comprehensive loss: | | |
| Net loss | $ (23,425) | $ (17,514) |
| Unrealized (loss) gain on investments | (30) | 3 |
| Comprehensive loss | $ (23,455) | $ (17,511) |

See accompanying notes.

**Ocera Therapeutics, Inc.**
**Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (deficit)**
**(In Thousands, except shares)**

| | Series A Convertible Preferred Stock | | Series B Convertible Preferred Stock | | Series C Convertible Preferred Stock | | Common Stock | | Additional Paid-In | Accumulated Other Comprehensive | Accumulated | Total Stockholders' |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | Capital | Income (Loss) | Deficit | Equity (deficit) |
| Balance at December 31, 2012 | 1,735,565 | $14,346 | 1,029,369 | $11,983 | 2,075,390 | $35,414 | 626,593 | $ 5 | $ 1,161 | $ — | $ (63,972) | $ (62,806) |
| Restatement of par value of common stock | — | — | — | — | — | — | — | (5) | 5 | — | — | — |
| Conversion of debt to Series C preferred stock | — | — | — | — | 186,218 | 3,187 | — | — | — | — | — | — |
| Conversion of preferred stock to common stock | (1,735,565) | (14,346) | (1,029,369) | (11,983) | (2,261,608) | (38,601) | 5,026,542 | — | 64,930 | — | — | 64,930 |
| Shares issued in merger with Tranzyme | — | — | — | — | — | — | 2,299,751 | — | 13,524 | — | — | 13,524 |
| Issuance of common stock, net of issuance costs | — | — | — | — | — | — | 7,258,863 | — | 46,425 | — | — | 46,425 |
| Issuance of common stock upon exercise of stock options | — | — | — | — | — | — | 88,465 | — | 63 | — | — | 63 |
| Stock-based compensation expense | — | — | — | — | — | — | — | — | 507 | — | — | 507 |
| Net loss | — | — | — | — | — | — | — | — | — | — | (17,514) | (17,514) |
| Other comprehensive income | — | — | — | — | — | — | — | — | — | 3 | — | 3 |
| 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 |

See accompanying notes.

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

| | Years Ended December 31, | |
|---|---|---|
| | **2014** | **2013** |
| **Operating activities** | | |
| Net loss | $ (23,425) | $ (17,514) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Net (income) loss from discontinued operations | (1,199) | 2,025 |
| Depreciation | 36 | 29 |
| Loss on disposal of fixed assets | — | 7 |
| Amortization of intangibles | 164 | 295 |
| Stock-based compensation | 4,686 | 507 |
| Change in valuation of warrant liability | — | (15) |
| Impairment of intangible assets | — | 3,070 |
| Accretion of premium on investment securities | 600 | 39 |
| Debt discount, net and noncash interest expense | — | 92 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 31 | 45 |
| Prepaid expenses and other assets | (500) | (346) |
| Accounts payable | (341) | 14 |
| Accrued liabilities | 63 | 764 |
| Net cash used in continuing operating activities | (19,885) | (10,988) |
| Net cash used in discontinued operating activities | (440) | (1,006) |
| Net cash used in operating activities | (20,325) | (11,994) |
| **Investing activities** | | |
| Purchases of property and equipment | (38) | (12) |
| Purchases of short and long-term investments | (41,415) | (34,116) |
| Sale and maturities of short-term investments | 31,425 | 2,400 |
| Net cash received from merger transaction | — | 7,464 |
| Net cash used in continuing investing activities | (10,028) | (24,264) |
| Net cash provided by discontinued investing activities | 1,165 | 3,000 |
| Net cash used in investing activities | (8,863) | (21,264) |
| **Financing activities** | | |
| Proceeds from the sale of common stock, net of underwriting discounts and commissions and offering expenses | 23,384 | 46,425 |
| Proceeds from exercise of common stock options | 398 | 63 |
| Net cash provided by continuing financing activities | 23,782 | 46,488 |
| Net increase (decrease) in cash and cash equivalents | (5,406) | 13,230 |
| Cash and cash equivalents—beginning of year | 15,533 | 2,303 |
| Cash and cash equivalents—end of year | $ 10,127 | $ 15,533 |
| **Supplemental schedule of noncash investing and financing activities** | | |
| Reclassification of warrant liability to additional paid-in-capital | $ — | $ 1 |
| Conversion of convertible promissory note and interest to common stock | $ — | $ 3,187 |
| Conversion of convertible preferred stock to common stock | $ — | $ 61,743 |
| Common stock issued in connection with merger transaction | $ — | $ 13,524 |

See accompanying notes.

## Notes to Consolidated Financial Statements

### 1. Description of Business and Basis of Presentation

Ocera Therapeutics, Inc. (the "Company") is a clinical stage biopharmaceutical company focused on the development and commercialization of OCR-002 (ornithine phenylacetate). OCR-002 is an ammonia scavenger which has been granted Orphan drug designation and Fast Track status from the FDA to treat hyperammonemia and associated hepatic encephalopathy in patients with liver cirrhosis, acute liver failure and acute liver injury.

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 is considered the acquiring company for accounting purposes as upon completion of the Merger, Private Ocera's former stockholders held a majority of the voting interest of the combined company. In addition, upon the closing of the Merger, six of the nine members of the board of directors of the combined company were former members of the Private Ocera board of directors. Therefore, the former members of the Private Ocera board of directors possessed majority control of the board of directors of the combined company. The Merger was effected pursuant to an Agreement and Plan of Merger and Reorganization (the “Merger Agreement”), dated as of April 23, 2013, by and among Tranzyme, Private Ocera and Merger Sub. 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.

Pursuant to the Merger, Private Ocera’s convertible notes payable plus accrued interest were converted to Series C convertible preferred stock at a rate of $2.04858 per share. Immediately thereafter, all shares of Private Ocera’s Series A, Series B and Series C convertible preferred stock were converted into Private Ocera common stock on a share for share basis. All such Private Ocera common stock was exchanged for Tranzyme common stock at a rate of one Private Ocera share for 0.11969414 Tranzyme shares (the "Exchange Ratio"). All share and per share amounts for all periods presented in these consolidated financial statements have been adjusted retroactively to reflect the exchange for Tranzyme shares. In addition, convertible preferred stock warrants of Private Ocera were converted into common stock warrants of Ocera Therapeutics, Inc., pursuant to the Merger, based upon the Exchange Ratio.

On December 13, 2013, the Company entered into a Technology Transfer and License Agreement with Genentech, Inc. (“Genentech”) and F. Hoffman-La Roche, Ltd (“Roche”) to sell certain Canadian fixed assets and materials, the MATCH technology and rights to the Genentech and Roche customer agreements and related intellectual property through licensing of patents for $4.0 million . On February 18, 2014, the Company received the "Notice of Completion" regarding obligations pursuant to this Agreement. The “Notice of Completion” was considered a substantive performance obligation in the agreement. The Company recorded the disposition of these assets held for sale in the first quarter of 2014.

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

The Company has evaluated subsequent events and transactions for potential recognition or disclosure in the financial statements through the day the financial statements are issued.

The Company has a limited operating history and the sales and income potential of the Company's business and market are unproven. The Company has experienced net losses each year since its inception and, as of December 31, 2014 , had a deficit accumulated of $104.9 million . The Company anticipates that it will continue to incur net losses into the foreseeable future as it continues the development and commercialization of OCR-002 and as it expands its corporate infrastructure. Based on the Company's current operating plan, the Company believes its working capital is sufficient to fund its operations through at least the next twelve months.

### 2. Summary of Significant Accounting Policies

#### Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles in the 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.

**Principles of Consolidation**

The consolidated financial statements include the accounts of Ocera Therapeutics, Inc., and its subsidiary, Ocera Subsidiary, Inc. All significant intercompany balances and transactions have been eliminated. All amounts included in these notes to consolidated financial statements are reported in U.S. dollars, unless otherwise indicated.

**Business Combinations**

The Company accounted for the Merger as a reverse merger under the acquisition method of accounting. The consideration paid to acquire Tranzyme was measured at fair value and included the exchange of the Company's common stock and assumption of vested stock options. This allocation of the purchase price resulted in recognition of intangible assets related to customer relationships, developed technology and goodwill. The allocation of purchase price requires the Company to make significant estimates and assumptions. The key assumptions in determining the fair value of intangible assets were the discount rate and the probability assigned to the milestone or royalty being achieved in the future.

**Discontinued Operations**

On September 11, 2013, the Board of Directors approved a restructuring plan related to the operations of Tranzyme Pharma Inc. and its Sherbrooke, Quebec facility ("Tranzyme Pharma"), whereby the Company closed the operations of the facility effective as of November 11, 2013. On December 13, 2013, the Company entered into a Technology Transfer and License Agreement to sell the Company’s MATCH discovery platform and license the related intellectual property rights. The Company concluded that since Tranzyme Pharma's operations and the MATCH discovery platform comprised a component with distinct operations and cash flows that would be eliminated from ongoing operations, and the Company would not have significant involvement after the disposal, these components would be accounted for as discontinued operations. The results of operations of the components to be disposed of, related restructuring costs and gain on disposal of assets have been classified as net income (loss) from discontinued operations from their date of acquisition on July 15, 2013 through December 31, 2014 . The assets and liabilities of Tranzyme Pharma have been classified as assets and liabilities, respectively, of discontinued operations. Unless noted otherwise, discussion in these notes to the financial statements pertain to the Company's continuing operations.

**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 making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment.

**Cash and Cash Equivalents**

Cash and cash equivalents are stated at cost, which approximates fair value. 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 securities available-for-sale. 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 and their maturities, which are designed to maintain safety and liquidity.

**Investments**

The Company invests in marketable securities, primarily money market funds, commercial paper, government agency debt securities and U.S. and foreign corporate debt securities. The Company considers all investments with a maturity date greater than three months and less than one year at each balance sheet date to be 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. As of December 31, 2014 and 2013 all investments in marketable securities were classified as available-for-sale. These securities are carried at estimated fair value with unrealized gains and losses included in stockholders' equity. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income.

**Fair Value of Financial Instruments**

Fair value is the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the measurement date. The Company uses the market approach valuation technique for fair value measurements on a recurring basis and attempts to maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. All of our 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. 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. 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. The carrying amounts of the Company's financial instruments, including cash equivalents, accounts payable and accrued liabilities, approximate fair value due to their short maturities.

**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 .

**Intangible Assets and Goodwill**

The Company recorded intangible assets and goodwill upon the Merger. Acquired intangible assets are amortized on a straight-line basis over the remaining estimated economic life of 2.5 to 5 years. The Company reviews its intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of a long-lived asset may not be recoverable. Recoverability of an asset is measured by comparing its carrying amount to the expected future undiscounted cash flows that the asset group is expected to generate. If it is determined that the carrying amount is not recoverable, an impairment loss is recorded in the amount by which the carrying amount of the asset exceeds its fair value. The Company recorded an impairment loss of $3.1 million in the year ended December 31, 2013 due to the termination of work by Bristol-Myers Squibb on macrocyclic compounds under the collaboration agreement. No impairment was recorded in the year ended December 31, 2014 .

The Company performs an annual qualitative assessment of its goodwill to determine if any events or circumstances exist, such as an adverse change in business climate or adverse developmental or regulatory results of OCR-002, that would indicate that it would more likely than not reduce the fair value of a reporting unit below its carrying amount, including goodwill. If events or circumstances do not indicate that the fair value of a reporting unit is below its carrying amount, then goodwill is not considered to be impaired and no further testing is required. The determination of fair value requires significant judgment and estimates. For the purpose of impairment testing, the Company has determined that it had two reporting units, continuing operations and discontinued operations. There has been no impairment of goodwill for any periods presented.

**Foreign Currency Translation**

The Company's consolidated financial statements are presented in U.S. dollars. The financial statements of Tranzyme Pharma (a discontinued entity) are re-measured from the local currency to U.S. dollars, as follows: monetary assets and liabilities are translated at the exchange rate in effect at the balance sheet date and non-monetary items at exchange rates in effect when the assets were acquired or non-monetary liabilities incurred. Revenue and expenses are translated at the average exchange rates prevailing during the period of the transaction. The gains and losses resulting from the translation of foreign currency financial statements of discontinued entity into U.S. dollars are reported in loss from discontinued operations. The translation adjustment of cash balances held in Canadian dollars are reported in interest and other expense.

**Revenue Recognition**

The Company recognizes revenue from the delivery of collaborative research services, license agreements for the development and commercialization of products and from royalties. During 2013, collaboration research revenue is disclosed as discontinued operations in the Company’s Consolidated Statements of Operation and Comprehensive Loss. For each source of revenue, the Company applies revenue recognition criteria in the following manner:

Multiple element arrangements such as collaboration agreements which may include an upfront license and ongoing services are analyzed to determine whether the deliverables within the agreement can be separated or whether they must be accounted for as a single unit of accounting. Deliverables under the agreement will be accounted for as separate units of accounting provided that (i) a delivered item has value to the customer on a stand-alone basis; and (ii) if the agreement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in the control of the vendor. The allocation of consideration amongst the deliverables under the agreement is derived using a "best estimate of selling price" if vendor specific objective evidence and third-party evidence of fair value is not available. If the delivered element does not have stand-alone value, the arrangement is then accounted for as a single unit of accounting, and the Company will recognize the consideration received under the arrangement as revenue on a straight-line basis over the estimated period of performance.

License fees from license agreements are recognized when the amounts are earned and determinable during the applicable period. The Company recognizes up-front nonrefundable license fees when due under contractual agreements and when the Company does not have a continuing obligation to provide services related to the agreement. Revenue associated with nonrefundable up-front license fees under arrangements where the license fees and research and development activities cannot be accounted for as separate units of accounting is deferred and recognized as revenue on a straight-line basis over the expected term of our continued involvement in the research and development process.

The Company recognizes royalty payments as revenue when earned. At the end of each accounting period, estimates of royalty amounts due are made based on estimated sales information from the Company's customers.

**Research and Development Expenses**

Research and development costs are expensed as incurred and primarily consist of costs associated with external research and development expenses incurred under agreements with (i) third-party investigative sites, where a substantial portion of our preclinical studies and all of our clinical trials are conducted, (ii) third-party manufacturing organizations, where a substantial portion of our preclinical supplies and all of our clinical supplies are produced, and (iii) consultants, employee-related expenses, which include salaries and benefits, and facilities, depreciation and amortization and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation of leasehold improvements and equipment and laboratory and other supplies.

**Clinical Trial Accruals**

As part of the process of preparing financial statements, the Company estimates its accrued expenses. 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 multiple research institutions and clinical research organizations that conduct and manage clinical trials on the Company's behalf. The Company accrues expenses related to clinical trials based on contracted amounts applied to the level of patient enrollment and activity according to the protocol. 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 accrued expenses accordingly. To date, the Company has had no significant adjustments to accrued clinical trial expenses. Examples of estimated accrued expenses include:

- fees paid to investigative sites in connection with clinical trials;
- fees paid to contract manufacturers in connection with the production of clinical trial materials; and
- professional service fees.

The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period.

**Stock-Based Compensation**

Stock-based compensation is recognized as an expense in the financial statements based on the grant date fair value. For awards that vest based on service conditions, the Company uses the straight-line method to allocate compensation expense to reporting periods. For performance-based stock options, the Company begins to recognize the expense when it is deemed probable that the performance-based goal will be met. The Company evaluates the probability of achieving performance-based goals at each reporting date. Stock-based compensation expense is based on awards ultimately expected to vest, and therefore the recorded expense includes an estimate of future forfeitures. Forfeitures are to be estimated at the

time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company estimates the fair value of stock options and stock purchase rights using a Black-Scholes option pricing model which requires the input of highly subjective assumptions, including the option's expected life and the price volatility of the underlying stock. The Company generally uses the simplified method for estimating the expected term as provided by the Securities and Exchange Commission. The simplified method calculates the expected term as the average of time-to-vesting and the contractual life of the options. The Company uses historical experience to estimate the expected term for non-employee director awards that are exercisable up to one year following termination of services. The expected stock price volatility assumption was determined by examining the historical volatilities of a group of industry peers. Forfeitures are estimated using the Company's historical experience of stock options forfeited.

**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 determine deferred tax assets and liabilities on the basis of the differences between the financial statement and tax bases 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 they believe 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 in accordance with ASC 740, Income *Taxes* on the basis of a two-step process in which 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 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% likely to be realized upon ultimate settlement with the related tax authority.

**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 July 2013, the FASB issued Accounting Standards Update, or ASU, No. 2013-11, *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists* . ASU 2013-11 provides explicit guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The guidance is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013, with an option for early adoption. The Company adopted this guidance in the first quarter of fiscal year 2014. The adoption of this standard did not have a material impact on its financial statements.

In April 2014, the FASB issued Accounting Standards Update, or ASU, No. 2014-08, *Presentation of Financial Statements (Topic 205) and Property, Plant and Equipment (topic 360); Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity.* ASU 2014-08 provides additional requirements to classify a disposal of a component of an entity or a group of components of an entity in discontinued operations only if the disposal represents a strategic shift that has (or will have) a major effect on an entity's operations and financial results. The guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2014, with an option for early adoption. The Company intends to adopt this guidance at the beginning of our first quarter of fiscal year 2015, and does not expect the adoption of this standard will have a material impact on the Company's financial statements.

In May 2014, the FASB issued Accounting Standards Update, or ASU, No. 2014-09, *Revenue from Contracts with Customers.* ASU 2014-09 requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. ASU 2014-09 will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The new standard will become effective for the Company on January 1, 2017.

Early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the effect that ASU 2014-09 will have on its consolidated financial statements and related disclosures. The Company has not yet selected a transition method nor has it determined the effect of the standard on its ongoing financial reporting.

In June 2014, the FASB issued Accounting Standards Update, or ASU, No. 2014-10, *Development Stage Entities (Topic 915)* . ASU 2014-10 removes the distinction between development stage entities and other reporting entities in U.S. GAAP and eliminates the requirement to label financial statements as those of a development stage entity and eliminates the requirement to present inception to date information in the statements of income, cash flows and shareholder equity. The guidance is applied retroactively and is effective for fiscal years, and interim periods within those years, beginning after December 15, 2014, with an option for early adoption. The Company early adopted this guidance in 2014, and as a result, has removed the label “A Development Stage Company” from its financial statements and accompanying notes and eliminated the inception to date information from the Consolidated Statements of Operations and Comprehensive Loss and Consolidated Statements of Cash Flows. Other than presentation, the adoption of this standard did not have a material impact on the Company’s financial statements.

In August 2014, the FASB issued Accounting Standards Update, or ASU, No. 2014-15, *Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern.* ASU 2014-15 requires management to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and to provide related footnote disclosures. In doing so, companies will have reduced diversity in the timing and content of footnote disclosures than under today’s guidance. ASU 2014-15 is effective for the Company in the first quarter of 2016 with early adoption permitted. The Company does not believe the impact of adopting this standard will be material on the Company's financial statements.

**3. Fair Value Measurements**

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, 2014 and 2013 and indicate the fair value hierarchy of the valuation techniques utilized by the Company to determine such fair value. As a basis for categorizing inputs, the Company uses a three-tier fair value hierarchy, which prioritizes the inputs used to measure fair value from market based assumptions to entity specific assumptions:

**Level 1:** Quoted prices in active markets for identical assets or liabilities;

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

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

The Company’s Level 3 financial liabilities consist of warrant liabilities related to warrants to purchase preferred stock.

Assets and liabilities measured at fair value on a recurring basis as of December 31, 2014 are as follows *(in thousands)* :

| | Balance as of December 31, 2014 | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
|---|---|---|---|---|
| Assets: | | | | |
| Money market funds | $ 9,171 | $ 9,171 | $ — | $ — |
| Commercial paper | 3,750 | — | 3,750 | — |
| Corporate debt securities | 36,790 | — | 36,790 | — |
| Government agency debt securities | 500 | — | 500 | — |
| Total assets | $ 50,211 | $ 9,171 | $ 41,040 | $ — |

Assets and liabilities measured at fair value on a recurring basis as of December 31, 2013 are as follows *(in thousands)* :

| | Balance as of December 31, 2013 | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
|---|---|---|---|---|
| Assets: | | | | |
| Money market funds | $ 5,774 | $ 5,774 | $ — | $ — |
| Commercial paper | 15,246 | — | 15,246 | — |
| Corporate debt securities | 20,884 | — | 20,884 | — |
| Total assets | $ 41,904 | $ 5,774 | $ 36,130 | $ — |

The following table provides the change in the fair value of Level 3 liabilities for the year ended December 31, 2013 *(in thousands):*

| | Convertible Preferred Stock Warrant Liability |
|---|---|
| Balance at December 31, 2012 | $ 16 |
| Change in fair value of warrant liability | (15) |
| Conversion of preferred stock warrants into common stock warrants | (1) |
| Balance at December 31, 2013 | $ — |

On July 15, 2013, warrants to purchase convertible preferred stock were converted to warrants to purchase common stock eliminating the terms that caused the preferred stock warrants to be accounted for as a liability.

**4. Balance Sheet Components**

**Investments**

The following table summarizes the Company's available for sale investments as of December 31, 2014 *(in thousands):*

| | Maturity (in Years) | Amortized Cost | Unrealized Gains | Unrealized Losses | Estimated Fair Value |
|---|---|---|---|---|---|
| Short-term investments: | | | | | |
| Commercial paper | 1 or less | $ 3,748 | $ 2 | $ — | $ 3,750 |
| Corporate debt securities | 1 or less | 33,379 | — | (17) | 33,362 |
| Total | | 37,127 | 2 | (17) | 37,112 |
| Long-term investments: | | | | | |
| Corporate debt securities | 1 to 2 | 3,439 | — | (11) | 3,428 |
| Government agency debt securities | 1 to 2 | 501 | — | (1) | 500 |
| Total | | 3,940 | — | (12) | 3,928 |
| Total investments | | $ 41,067 | $ 2 | $ (29) | $ 41,040 |

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

The following table summarizes the Company's available for sale investments as of December 31, 2013 *(in thousands):*

| | Maturity (in Years) | Amortized Cost | Unrealized Gains | Unrealized Losses | Estimated Fair Value |
|---|---|---|---|---|---|
| Short-term investments: | | | | | |
| Commercial paper | 1 or less | $ 15,232 | $ 14 | $ — | $ 15,246 |
| Corporate debt securities | 1 or less | 14,930 | — | (9) | 14,921 |
| Total | | 30,162 | 14 | (9) | 30,167 |
| Long-term investments: | | | | | |
| Corporate debt securities | 1 to 2 | 1,514 | — | (1) | 1,513 |
| Total | | 1,514 | — | (1) | 1,513 |
| Total investments | | $ 31,676 | $ 14 | $ (10) | $ 31,680 |

**Property and Equipment, net**

Property and equipment consisted of the following *(in thousands)* :

| | Useful Life | December 31, | |
|---|---|---|---|
| | (in years) | 2014 | 2013 |
| Computer equipment and software | 1.5 to 3 years | $ 53 | $ 40 |
| Office furniture and equipment | 5 years | 68 | 43 |
| Total property and equipment, gross | | 121 | 83 |
| Less: accumulated depreciation | | (60) | (24) |
| Total property and equipment, net | | $ 61 | $ 59 |

Depreciation expense was $36,000 and $29,000 for the years ended December 31, 2014 and 2013 , respectively.

**Acquired intangible assets**

The net book value of acquired intangible assets as of December 31, 2014 and 2013 were as follows *(in thousands)* :

| | December 31, | |
|---|---|---|
| **Customer Agreements:** | 2014 | 2013 |
| Carrying value | $ 410 | $ 410 |
| Accumulated amortization | (239) | (75) |
| Intangible assets, net | $ 171 | $ 335 |
| Weighted average remaining life (in years) | 1.0 | 2.0 |

On July 15, 2013, the Company capitalized approximately $5.9 million of intangible assets acquired in the Merger.
In 2013, the Company recorded an impairment charge of intangible assets of $3.1 million and $2.2 million of intangible assets were reclassified to discontinued operations and assets held for sale. The Company recognized $164,000 and $295,000 as amortization expense on the intangible assets for the years ended December 31, 2014 and 2013 , respectively. No impairment charges were recorded in 2014.

As of December 31, 2014 expected amortization expense related to our purchased intangible assets is approximately $171,000 during 2015.

**Goodwill**

Goodwill of $1.1 million was recorded pursuant to the Merger. Goodwill of $0.5 million was allocated to discontinued operations upon restructuring and disposal of Tranzyme Pharma, see Note 6. Discontinued Operations. There were no impairments to goodwill during the periods presented.

**Accrued Liabilities**

Accrued liabilities were as follows *(in thousands)* :

| | December 31, | |
|---|---|---|
| | 2014 | 2013 |
| Payroll and related expenses | $ 678 | $ 1,093 |
| Clinical trials | 897 | 417 |
| Professional services | 343 | 315 |
| Other | 48 | 77 |
| | $ 1,966 | $ 1,902 |

**5. Merger with Tranzyme**

On July 15, 2013, Merger Sub, a wholly owned subsidiary of Tranzyme, completed its Merger with Private Ocera. The Merger was accounted for as a reverse merger under the acquisition method of accounting. Under the acquisition method of accounting, Private Ocera was treated as the accounting acquirer and Tranzyme was treated as the "acquired" company for financial reporting purposes as, immediately upon completion of the Merger, Private Ocera stockholders held a majority of the voting interest of the combined company. In addition, six of the nine members of the board of directors of the combined company were former members of Private Ocera board of directors. Therefore, the former members of Private Ocera board of directors possessed majority control of the board of directors of the combined company.

The purchase price for Tranzyme is as follows *(in thousands)* :

| | | |
|---|---|---|
| Fair value of Tranzyme shares outstanding | $ | 13,249 |
| Fair value of vested Tranzyme stock options | | 275 |
| Purchase Price | $ | 13,524 |

In accordance with the acquisition method of accounting, the purchase price has been allocated to the tangible and identifiable intangible assets acquired and liabilities assumed on the basis of their estimated fair values on the date of acquisition, based on valuations performed by a third party. The Company engaged a third party valuation firm to assist management in its analysis of the fair value of assets and liabilities acquired in the Merger with Tranzyme. All estimates, key assumptions, and forecasts were either provided by or reviewed by management. While the Company chose to utilize a third party valuation firm, the fair value analysis and related valuations represent the conclusions of management and not the conclusions or statements of any third party.

In accordance with the acquisition method of accounting, the purchase price has been allocated to the tangible and identifiable intangible assets acquired and liabilities assumed on the basis of their estimated fair values on the date of acquisition.

The following table summarizes the preliminary determination of the purchase price to the assets acquired and liabilities assumed *(in thousands)* :

| | | **Purchase Price** |
|---|---|---|
| Cash and cash equivalents | $ | 7,464 |
| Accounts and investment tax credits receivable, net | | 636 |
| Prepaid expenses and other assets | | 159 |
| Fixed assets | | 744 |
| Intangible assets | | 5,940 |
| Goodwill | | 1,054 |
| Accounts payable | | (1,029) |
| Accrued and long-term liabilities | | (1,307) |
| Deferred revenue | | (137) |
| Total purchase price | $ | 13,524 |

The following table includes the intangible assets identified as of the acquisition date and the estimated lives prior to impairment and reclassification to discontinued operations *(in thousands, except for useful life):*

| | **Continuing operations** | **Discontinued operations** | **Total** | **Useful life** |
|---|---|---|---|---|
| Customer relationships | $ 3,700 | $ 480 | $ 4,180 | 2.5 to 5 years |
| Developed technology | — | 1,760 | 1,760 | 5 years |
| Total | $ 3,700 | $ 2,240 | $ 5,940 | |

The Company believes that the historical values of Tranzyme's current assets and current liabilities approximate their fair value based on the short-term nature of such items. Tranzyme's property and equipment consists of assets whose historical cost less depreciation approximated its fair value. The identifiable intangible assets are Tranzyme's technology,

which consists primarily of its intellectual property related to Tranzyme’s MATCH technology, and the estimated net present value of future cash flows from collaborative agreements to be generated from the MATCH technology used in the development activities.

The collaboration agreements were valued using a risk adjusted multi-period excess earnings analysis, a form of the income approach, which incorporates the estimated future cash flows to be generated from these relationship assets. Excess earnings are the earnings remaining after deducting the market rates of return on the estimated values of contributory assets, including debt-free net working capital, tangible and intangible assets. The excess earnings are thereby calculated for each year of a multi-year projection period, factored for industry-wide probabilities of success and discounted to a present value. Accordingly, the primary components of this method consist of the determination of excess earnings and an appropriate rate of return.

The valuation of the Tranzyme's proprietary MATCH technology is based on replacement method of the cost approach that considers the cost to replace the acquired technology. The cost approach is based on the premise that a prudent investor would pay no more for an asset than its replacement or reproduction cost. The cost to replace the asset would include the cost of constructing a similar asset of equivalent utility at prices applicable at the time of the valuation analysis. The estimated fair value attributed to the developed technology is amortized over a weighted average useful life of approximately 5 years.

Goodwill is calculated as the difference between the fair value of the consideration expected to be transferred and the values assigned to the identifiable tangible and intangible assets acquired and liabilities assumed, is primarily attributable to the acquisition of an established workforce of clinical development professionals and is not deductible for tax purposes.

**6. Discontinued Operations**

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

The Company recorded the disposition of assets sold to Genentech and Roche subject to the Technology Transfer and License Agreement in the first quarter of 2014, upon receipt of a “Notice of Completion” which was considered a substantive performance obligation in the agreement. Agreement consideration of $3.0 million was received in 2013 and was recorded as an accrued liability at December 31, 2013.

During the Year Ended December 31, 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 as detailed below *(in thousands)* :

| | Year Ended December 31, 2014 |
|---|---|
| Proceeds recognized pursuant to Technology Transfer and License Agreement | $ 4,000 |
| Less carrying value of assets sold: | |
| Intangibles assets | (2,053) |
| Property and equipment | (356) |
| Goodwill | (442) |
| Net gain on disposal of assets | $ 1,149 |

The results of Tranzyme Pharma and related asset groups are disclosed as discontinued operations in the Company's Consolidated Statements of Operations and Comprehensive Loss for all periods presented *(in thousands)* :

| | Years Ended December 31, | |
|---|---|---|
| | 2014 | 2013 |
| Revenue | $ — | $ 467 |
| Expenses: | | |
| Research and development | — | (1,134) |
| General and administrative | — | (220) |
| Amortization of intangibles | — | (187) |
| Restructuring settlements (charges) | 68 | (859) |
| Gain (loss) on disposal of assets | 1,149 | (86) |
| Other expense, net | (6) | (6) |
| Recognition of accumulated translation adjustments upon deconsolidation of subsidiary | (12) | — |
| Net income (loss) from discontinued operations | **$ 1,199** | **$ (2,025)** |

The assets and liabilities of Tranzyme Pharma and related asset groups are presented as held for disposal in the Consolidated Balance Sheet as of December 31, 2013. There were no assets and liabilities recorded in discontinued operations as of December 31, 2014. The carrying amount of assets and liabilities are as follows *(in thousands)* :

| | December 31, 2013 |
|---|---|
| Prepaid expenses and other current assets | $ 178 |
| Property and equipment, net | 356 |
| Intangible assets, net | 2,053 |
| Goodwill | 442 |
| Assets of discontinued operations | $ 3,029 |
| | |
| Deposit on sale of assets | $ 3,000 |
| Accounts payable | 106 |
| Accrued liabilities | 397 |
| Liabilities of discontinued operations | $ 3,503 |

Upon classification as held for disposal and discontinued operations, the assets and liabilities of Tranzyme Pharma Inc. 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.

**Restructuring of Tranzyme Pharma (Sherbrooke, Quebec)**

In September 2013, the Company approved a restructuring plan related to the operations of its wholly owned subsidiary, Tranzyme Pharma Inc. at its Sherbrooke, Quebec facility (the "Sherbrooke Facility") in order to focus its management and resources on the clinical development of OCR-002. In connection with the restructuring, the Company terminated all employees at the Canadian location, exited the Sherbrooke Facility and terminated certain contractual obligations. Restructuring charges of $0.9 million were recorded as a component of net loss from discontinued operations during the year ended December 31, 2013. During the year ended December 31, 2014, the Company paid and settled all of the remaining liabilities and recorded an adjustment related to discounts of $68,000 on certain shipping charges related to the restructuring of Tranzyme Pharma.

The following table summarizes the Company's restructuring activities during the years ended December 31, 2014 and December 31, 2013 *(in thousands)* :

| | Post- Employment Benefits | Moving and Shipping Costs | Operating Activities | Total |
|---|---|---|---|---|
| Restructuring charges | $ 700 | $ 114 | $ 45 | $ 859 |
| Cash payments and other settlements | (308) | (15) | (34) | (357) |
| Accrued restructuring at December 31, 2013 | $ 392 | $ 99 | $ 11 | $ 502 |
| Cash payments and other settlements | (392) | (31) | (11) | (434) |
| Settlement of certain restructuring charges | — | (68) | — | (68) |
| Accrued restructuring at December 31, 2014 | $ — | $ — | $ — | $ — |

**7. License Agreements and Acquired Development and Commercialization Rights**

***Kureha Corporation***

In July 2004, the Company in-licensed from Kureha Corporation ("Kureha") the technology and exclusive development and commercialization rights to its AST-120 product candidate for the treatment of liver and gastrointestinal disease for the territories of North America and Europe. The Company paid a $1.5 million up-front fee to Kureha. In March 2008, the Company amended the license agreement, in exchange for a payment of $0.5 million . In January 2014, the Company notified to Kureha that it had discontinued its work on AST-120, terminated the license and returned all rights to AST-120 to Kureha.

***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 and February 2013. 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 $141,000 and $85,000 for the years ended December 31, 2014 and 2013 respectively.

***Bristol-Myers Squibb Company***

In December 2009, Tranzyme entered into a two -year collaboration agreement with Bristol-Myers Squibb Company (“BMS”) to discover, develop and commercialize novel macrocyclic compounds, other than Tranzyme's product candidates and internal programs, directed against a limited number of targets of interest to BMS.

In fiscal year 2013, during the periodic reviews of the BMS collaboration agreement, the Company determined that BMS would terminate its efforts on the development of all macrocyclic compounds under development pursuant to collaboration agreement. The Company recorded an impairment charge of $3.1 million as a result. The Company does not expect to receive any future revenue associated with this collaboration agreement.

***Lyric Pharmaceuticals, Inc.***

During the year ended December 31, 2014 the Company entered into an Asset License and Purchase Agreement for the Sale and License of *ulimorelin* ("TZP-101"), 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 $200,000 for the transfer of intellectual property and materials associated with TZP-101 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 preclinical and clinical development of all products arising from the further development of TZP-101.

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 by TZP-101.

**8. Net Loss Per Share**

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and common share equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. The Company’s potentially dilutive securities which include convertible preferred stock, warrants, convertible notes payable and outstanding stock options under the stock option plan, have been excluded from the computation of diluted net loss per share as their inclusion would be anti-dilutive. For all periods presented, there is no difference in the number of shares used to compute basic and diluted shares outstanding. All shares and per share amounts for all periods presented in the following table have been adjusted retroactively to reflect the exchange for Tranzyme shares.

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

| | Years Ended December 31, | |
|---|---|---|
| | 2014 | 2013 |
| **Numerator** | | |
| Net loss from continuing operations | $ (24,624) | $ (15,489) |
| Net income (loss) from discontinued operations | 1,199 | (2,025) |
| Net loss | $ (23,425) | $ (17,514) |
| **Denominator** | | |
| Weighted average common shares outstanding used to compute net loss per share, basic and diluted | 17,525,187 | 6,145,731 |
| **Net loss per share of common stock, basic and diluted:** | | |
| Net loss per share from continuing operations | $ (1.41) | $ (2.52) |
| Net income (loss) per share from discontinued operations | 0.07 | $ (0.33) |
| Net loss per share | $ (1.34) | $ (2.85) |

Potentially dilutive securities not included in the calculation of dilutive net loss per share are as follows *(in common equivalent shares on a weighted-average basis):*

| | Years Ended December 31, | |
|---|---|---|
| | 2014 | 2013 |
| Convertible preferred stock | — | 2,604,305 |
| Convertible preferred stock warrants | — | 11,243 |
| Common stock warrants | 938,743 | 259,908 |
| Common stock options | 1,887,130 | 624,511 |
| Total | 2,825,873 | 3,499,967 |

In addition to the potentially dilutive securities noted above, the Company had outstanding convertible notes payable and accrued interest that were converted into 186,217 shares of common stock upon completion of the Merger. The Company has excluded these convertible notes payable from the table above.

**9. Convertible Notes Payable**

In March 2012, the Company entered into a convertible note and warrant purchase agreement with existing investors. The Company issued an aggregate principal amount of $1.5 million of convertible notes in an initial closing in March 2012 (the "March 2012 Notes"). The March 2012 Notes had an interest rate of 6% per annum and had a maturity date of the earlier of (i) March 30, 2013, (ii) a change of control, or (iii) an event of default. In connection with the March 2012 Notes, the lenders received warrants to purchase 65,731 shares of the Company's common stock (the "March Warrants") at an exercise price of $0.67 per share. The March Warrants of 26,292 shares have a seven year term expiring on March 30, 2019 and the June Warrants of 39,439 shares have a seven year term expiring on June 30, 2019.

In October 2012, the Company issued an aggregate amount of $1.5 million of convertible notes in a second closing with existing investors (the "October 2012 Notes"). The October 2012 Notes had an interest rate of 6% per annum and had a maturity date of the earlier of (i) October 1, 2013, (ii) a change of control, or (iii) an event of default. In connection with the October 2012 Notes, the lenders received warrants to purchase 65,731 shares of the Company's common stock (the "October Warrants"). at an exercise price of $0.67 per share. The October Warrants have a seven -year term set to expire on October 1, 2019.

The common warrants issued in connection with the March 2012 Notes and October 2012 Notes became immediately exercisable at $ 0.67 per share.

In March 2013, the Company amended the March 2012 Notes to extend the maturity date to October 1, 2013. In April 2013, the March and October 2012 Notes were amended to change the note conversion date to automatically convert the unpaid principal and interest at the time of the Merger into shares of the Series C Preferred Stock of Private Ocera at the Series C Conversion Price of $2.04858 per share. There was no consideration paid, given or committed to the note holders by the Company in exchange for the modifications. The debt modification was evaluated under ASC *470-60, Troubled Debt Restructuring* and under *ASC 470-55, Debt Modification and Extinguishments.* The Company determined that it was appropriate to account for the term extension and change to the conversion date on a prospective basis and the carrying amount of the debt remained unchanged. All costs incurred with third parties directly related to the maturity extension were expensed as incurred. There were no costs associated with the change to the note conversion date.

On July 15, 2013, the March and October 2012 Notes plus accrued interest of $ 0.2 million were converted into 186,217 shares of common stock in connection with the Merger.

The Company recorded an aggregate of $0.2 million of non-cash interest expense and amortization of debt discount related to the convertible notes payable for the years ended December 31, 2013.

**Warrants**

*Common Stock Warrants*

The fair value of the March Warrants was determined to be $32,000 upon issuance, which was recorded as a debt discount and amortized to interest expense using the effective interest method over the term of the March 2012 Notes.

The fair value of the October Warrants was determined to be $111,000 , upon issuance, which was recorded as a debt discount and amortized to interest expense using the effective interest method over the term of the October 2012 Notes.

On July 15, 2013, warrants to purchase 19,243 shares of common stock of Tranzyme became warrants to purchase common stock of the Company in connection with the Merger.

On November 8, 2013, the Company closed on a private placement pursuant to the Securities Purchase Agreement and sold 3,940,887 shares of common stock and warrants exercisable for an aggregate of 788,177 shares of common stock for an aggregate purchase price of $28.0 million . The warrants have a five year life at an exercise price of $7.663 per share.

The following table summarizes the outstanding common stock warrants and the corresponding exercise price as of December 31, 2014 and 2013:

| | Number of Warrants Outstanding at December 31 | | Per-Share Exercise | |
|---|---|---|---|---|
| Issuance Date | 2014 | 2013 | Price | Expiration |
| 12/3/2008 | 2,380 | 2,380 | 84.00 | 12/3/2015 |
| 9/30/2010 | 3,240 | 3,240 | 160.44 | 4/6/2016 |
| 1/31/2012 | 13,623 | 13,623 | 44.04 | 1/31/2022 |
| 3/30/2012 | 25,022 | 26,292 | 0.67 | 3/30/2019 |
| 6/30/2012 | 37,535 | 39,439 | 0.67 | 6/30/2019 |
| 10/1/2012 | 62,558 | 65,731 | 0.67 | 10/1/2019 |
| 11/8/2013 | 788,177 | 788,177 | 7.66 | 11/8/2018 |
| Total | 932,535 | 938,882 | | |

In December 2014, 6,347 warrants were exercised at an exercise price of $0.67 price per share in a cashless exercise with 5,604 shares of common stock being issued.

**10. Stockholders' Equity**

**Convertible Preferred Stock**

Pursuant to the Merger, Private Ocera's convertible notes payable plus accrued interest were converted to Series C convertible preferred stock at a rate of $2.04858 per share. Immediately thereafter, all shares of Private Ocera's Series A, Series B and Series C convertible preferred stock was converted into shares of Private Ocera's common stock on a share for share basis. All resultant Private Ocera common stock was exchanged for 5,026,542 shares of Tranzyme common stock at a rate of one Private Ocera share for 0.11969414 Tranzyme shares.

**Common Stock**

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 consummation of the Merger, the combined company sold 3,317,976 shares of common stock for approximately $20.0 million of its common stock to the parties at a per share purchase price of $ 6.0264 (the "Financing"). 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 . The warrants may be exercised at any time at an exercise price of $7.663 per share and have a five year life. 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.

***Shares Reserved for Future Issuance***

The Company has reserved shares of its common stock for future issuance as of December 31, 2014 as follows:

| | December 31, 2014 |
|---|---|
| Stock options outstanding | 2,086,602 |
| Shares available for grant under stock option plans | 342,210 |
| Outstanding warrants | 932,535 |
| *Total shares reserved for future issuance* | 3,361,347 |

**11. Stock Options**

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 registrant's common stock in accordance with the terms of the Merger Agreement and the Company assumed the 2005 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"), which authorized the issuance of 302,328 shares of common stock under the 2011 Plan.

On August 13, 2013, the Company's board of directors approved an amendment to the 2011 Plan to increase the maximum number of shares that may be issued under the 2011 Plan from 302,328 to 2,302,328 shares. In connection with this amendment, the Company's board of directors authorized the grant of 1,454,200 common stock options to its employees. On August 30, 2013, the Company's board of directors authorized the grant of 140,000 common stock options to non-employee members of the board of directors. The amendment to the 2011 Plan and the common stock option grants were subject to stockholder approval within twelve months from August 13, 2013. The amendment to the 2011 Plan was approved by stockholders on December 19, 2013. Given that the issuance of stock options granted on August 13, 2013 and August 30, 2013 options were subject to shareholder approval of the increase in the number of shares issuable to the 2011 Plan, the Company concluded the grant date for accounting purposes to be December 19, 2013, the date of shareholder approval.

A summary of the Company's stock option activity and related information are as follows:

| | Shares Available for Grant | Stock Options Outstanding | Weighted-avg Exercise Price Per Share | Weighted-avg Remaining Contractual Life (in Years) | Aggregate Intrinsic Value |
|---|---|---|---|---|---|
| | | | | | (in thousands) |
| **Balance at December 31, 2012** | 39,226 | 692,709 | $ 1.42 | 6.13 | $ 368 |
| Adjustments to authorized shares upon assumption of the 2011 Plan | 33,185 | — | | | |
| Stock options assumed in Merger | (217,115) | 217,115 | $ 44.52 | | |
| Additional shares authorized | 2,000,000 | — | | | |
| Stock options granted | (1,414,650) | 1,414,650 | $ 7.75 | | |
| Stock options exercised | — | (88,465) | $ 0.92 | | 650 |
| Stock options cancelled | 322,221 | (326,240) | $ 14.68 | | |
| **Balance at December 31, 2013** | 762,867 | 1,909,769 | $ 8.77 | 8.58 | $ 11,818 |
| Stock options granted | (1,007,500) | 1,007,500 | $ 7.44 | | |
| Stock options exercised | — | (243,824) | $ 1.72 | | 2,719 |
| Stock options cancelled | 586,843 | (586,843) | $ 12.13 | | |
| **Balance at December 31, 2014** | 342,210 | 2,086,602 | $ 8.01 | 8.63 | $ 871 |
| | | | | | |
| **At December 31, 2014:** | | | | | |
| Vested and expected to vest | | 2,010,354 | $ 8.03 | 8.60 | $ 864 |
| Exercisable | | 578,712 | $ 9.04 | 6.81 | $ 762 |

The Company’s stock options generally vest over one to four years and have a ten-year term. Stock options issued under the Plan are exercisable in advance of becoming vested. Stock options assumed in the Merger were fully vested on the date of Merger. As of December 31, 2014 no shares were subject to repurchase. At December 31, 2014 , the intrinsic values of outstanding, vested and expected to vest and exercisable options were determined by multiplying the number of shares by the difference between the exercise price of the options and the fair value of the common stock. The total estimated grant date fair value of stock options vested during the year ended December 31, 2014 is $4.1 million .

In June 2012, the Company issued 61,653 shares of common stock options to an executive. One-half of the stock options vest monthly over a one year period from the vesting commencement date. The remainder of the stock options are performance based and would vest upon the closing of certain strategic or financing transactions. On July 15, 2013 as a result of the Merger, the performance based portion of the stock option vested and $0.2 million of stock compensation expense was recorded for the year ended December 31, 2013.

**Stock-Based Compensation**

The Company's results of operations for the years ended December 31, 2014 and 2013 included stock-based compensation expense of $4.7 million and $0.5 million , respectively.

The Company recognized stock-based compensation expense as follows *(in thousands)* :

| | Years Ended December 31, | |
|---|---|---|
| | 2014 | 2013 |
| Research and development | $ 1,595 | $ 68 |
| General and administrative | 3,091 | 439 |
| Total | $ 4,686 | $ 507 |

**Stock Option Valuation Assumptions**

The following table summarizes the average estimates the Company used in the Black-Scholes option-pricing model for the years ended December 31, 2014 and 2013 to determine the fair value of stock options granted during each period.

| | Years Ended December 31, | |
|---|---|---|
| | 2014 | 2013 |
| Expected dividend yield | —% | —% |
| Risk-free interest rates | 1.74% - 2.01% | 0.06% - 2.02% |
| Expected term (in years) | 6.08 - 6.62 | 0.25 - 6.08 |
| Expected volatility | 95% - 102% | 52% - 100% |

The fair value of each grant of stock options was determined by the Company using the methods and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment to determine.

**Expected Dividend** - The expected dividend assumption is based on the Company's history and expectation of dividend payouts.

**Risk-Free Interest Rate** - The risk-free rate assumption is based on the U.S. Treasury instruments the terms of which were consistent with the expected term of the Company's stock options.

**Expected Term** - The expected term of stock options represents the weighted-average period the stock options are expected to be outstanding. The Company has opted to use the simplified method for estimating the expected term as provided by the Securities and Exchange Commission. The simplified method calculates the expected term as the average time-to-vesting and the contractual life of the options. The Company's expected term for employee stock options is generally estimated to be 6.08 years. In 2014, the Company amended the non-employee director compensation policy to amend the exercise period of new awards from three months to one year following termination of services. The Company uses historical experience to estimate the expected term of awards granted with the extended exercise period. The Company's expected term for non-employee director options with the extended term is estimated to be 6.62 years .

**Expected Volatility** - The expected stock price volatility assumption was determined by examining the historical volatilities of a group of industry peers. The Company will continue to analyze the historical stock price volatility and expected term assumptions as more historical data for the Company's common stock becomes available.

**Forfeiture Rate** - ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience.

The Company may elect to use different assumptions under the Black-Scholes option-pricing model in the future. Future expense amounts for any particular period could be affected by changes in the Company's assumptions. Authoritative literature provides that it is reasonable for a company to continue to use the simplified method of determining the expected option term when a company has insufficient historical exercise data to provide a reasonable basis to estimate the expected option term. The Company expects to continue to use the simplified method for determining its expected employee option term because there is a limited amount of historical exercise data from which to form a reasonable basis to estimate the expected term of the Company's stock options. During the years ended December 31, 2014 and 2013 , the fair value of stock options granted were $5.7 million and $15.8 million , respectively. As of December 31, 2014 , the Company had $11.3 million of unrecognized stock-based compensation costs which is expected to be recognized over a weighted average period of 2.97 years.

In September 2014, the Company modified the terms of an existing stock option to an executive to extend the period of time to exercise the vested stock options from three month to one year following the termination of employment. $51,000 of stock compensation expense was recorded pursuant to this modification.

In June and September 2014, the Company issued performance based stock options to two executives and modified an outstanding stock option agreement to accelerate vesting for a third executive based on the achievement of certain performance conditions. The performance conditions were not achieved by December 31, 2014 and the performance based awards and modified award were canceled. There was no stock compensation expense recorded for these performance based awards.

In June 2012, the Company issued 61,653 shares of common stock options to an executive. One-half of the stock options vest monthly over a one year period from the vesting commencement date. The remainder of the stock options are performance based and would vest upon the closing of certain strategic or financing transactions. In April 2013, the terms of the stock option agreement were modified to further define the meaning of strategic or financing transactions such as the Merger Agreement. On July 15, 2013 as a result of the Merger, the performance based portion of the stock option vested and $0.2 million of stock compensation expense was recorded for the year ended December 31, 2013.

**12. Income Taxes**

The following is a geographical breakdown of consolidated loss before income taxes by income tax jurisdiction for continuing operations *(in thousands)* :

| | Years Ended December 31, | |
|---|---|---|
| | 2014 | 2013 |
| United States | $ (24,624) | $ (15,489) |
| Foreign | — | — |
| Total | $ (24,624) | $ (15,489) |

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, | |
|---|---|---|
| | 2014 | 2013 |
| Income tax (benefit) at statutory rate | $ (8,372) | $ (5,267) |
| State income tax, net of federal benefit | (4,411) | (225) |
| Permanent items | 1,098 | 516 |
| Credits | (2,810) | (198) |
| Refinement of §382 limitation | — | (23,816) |
| Unrecognized tax benefits | — | 1,840 |
| Change in valuation allowance | 14,610 | 26,549 |
| Other | (115) | 601 |
| Provision for income taxes | $ — | $ — |

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

| | Years Ended December 31, | |
|---|---|---|
| | 2014 | 2013 |
| **Deferred tax assets:** | | |
| Net operating loss carryforwards | $ 36,066 | $ 25,967 |
| Credits | 5,659 | 2,760 |
| Equity compensation | 2,121 | 531 |
| Accrued expenses and other reserves | 6 | 37 |
| **Gross deferred tax assets** | 43,852 | 29,295 |
| Valuation allowance | (43,838) | (29,228) |
| **Net deferred tax assets** | 14 | 67 |
| **Deferred tax liabilities:** | | |
| Fixed assets | (7) | (17) |
| Intangible assets | (7) | (50) |
| **Net deferred tax liabilities** | (14) | (67) |
| **Net deferred tax assets (liabilities):** | $ — | $ — |

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, 2014 and 2013.

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. As of December 31, 2014, the Company has $91.8 million of U.S. federal net operating loss (NOL) carryforwards and $5.4 million of Orphan Drug Credit carryforwards, and $2.5 million of U.S. 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, 2014 is approximately $0.4 million which pertains to certain net operating loss carryforwards resulting from the exercise of employee stock options. When recognized, the tax benefit of these losses will be accounted for as a credit to additional paid-in capital rather than a reduction of the income tax provision.

As of December 31, 2014, the Company has North Carolina net economic loss carryforwards of approximately $5.4 million , which will begin to expire in 2022 unless utilized. As of December 31, 2014, the Company has California state net operating loss carryforwards of approximately $68.6 million , which have begun to expire as of 2014, and $2.4 million of California research and development carryforwards that do not expire.

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 adopted accounting guidance related to accounting for uncertainty in income taxes on January 1, 2007, which prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. As of December 31, 2014, the Company had $3.8 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, 2012** | $ | — |
| Increases in prior period positions | | 1,761 |
| Increases in current period positions | | 79 |
| **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 |

As of December 31, 2014 , 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, 2014 .

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 2014, 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.

**13. 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 Internal Revenue Code. Following the Merger, the Company provides a contribution on the first 3% of an employee's eligible compensation subject to statutory limitations as proscribed by law. For the years ended December 31, 2014 , and December 31, 2013 the Company recorded $107,000 and $58,000 of expense, respectively, for 401(k) contributions.

**14. 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.

**Leases**

In October 2013, the Company entered into an agreement to lease office space located at 525 University Avenue, Palo Alto, California for the period October 10, 2013 through May 31, 2015. These premises serve as the Company's corporate headquarters.

Upon the Merger, the Company obtained office space located at 5001 South Miami Boulevard, Durham, North Carolina under a lease that will terminate on January 31, 2015. In August 2014, the Company amended the term of the lease for its North Carolina facility by extending term of the lease through January 2016.

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 $0.2 million , $0.3 million for the years ended December 31, 2014 and 2013 . The following is a schedule of non-cancellable future minimum lease payments for operating leases at December 31, 2014 ( *in thousands* ):

| **Year Ended December 31,** | | |
|---|---|---|
| 2015 | $ | 200 |
| 2016 | | 18 |
| Total | $ | 218 |

**15. Summary of Operations by Quarter (Unaudited)**
**(In Thousands, Except Share and Per Share Amounts)**

| Year Ended December 31, 2014: | Quarter | | | |
|---|---|---|---|---|
| | First | Second | Third | Fourth |
| Revenue | $ 45 | $ 33 | $ 233 | $ 30 |
| Operating expenses | $ 5,240 | $ 7,288 | $ 6,912 | $ 5,579 |
| Net loss from continuing operations | $ (5,182) | $ (7,243) | $ (6,661) | $ (5,538) |
| Net loss | $ (4,065) | $ (7,223) | $ (6,603) | $ (5,534) |
| Net loss per share from continuing operations— *basic and diluted* | $ (0.34) | $ (0.46) | $ (0.34) | $ (0.28) |
| Net loss per share— *basic and diluted* | $ (0.27) | $ (0.46) | $ (0.34) | $ (0.28) |
| Shares used to compute net loss per share— *basic and diluted* | 15,421,234 | 15,539,053 | 19,330,888 | 19,742,245 |

| Year Ended December 31, 2013: | Quarter | | | |
|---|---|---|---|---|
| | First | Second | Third | Fourth |
| Revenue | $ — | $ — | $ 33 | $ 52 |
| Operating expenses | $ 640 | $ 2,017 | $ 6,089 | $ 6,668 |
| Net loss from continuing operations | $ (731) | $ (2,087) | $ (6,065) | $ (6,606) |
| Net loss | $ (731) | $ (2,087) | $ (7,402) | $ (7,294) |
| Net loss per share from continuing operations— *basic and diluted* | $ (1.15) | $ (3.24) | $ (0.63) | $ (0.48) |
| Net loss per share— *basic and diluted* | $ (1.15) | $ (3.24) | $ (0.77) | $ (0.54) |
| Shares used to compute net loss per share— *basic and diluted* | 637,221 | 643,674 | 9,669,825 | 13,632,204 |

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 U.S. 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, the company has 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, 2014. Such disclosure controls and procedures were effective in ensuring information required to be disclosed by Ocera in reports that it files or submits 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 principal executive officer and principal 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.

The effectiveness of our internal control over financial reporting as of December 31, 2014, has been audited by Ernst &Young LLP, our independent registered public accounting firm, as stated in their report which is included as follows.

**Item 9B. Other Information**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

We have audited Ocera Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). Ocera Therapeutics, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) 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 the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Ocera Therapeutics, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Ocera Therapeutics, Inc. as of December 31, 2014 and 2013, and the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2014 of Ocera Therapeutics, Inc. and our report dated March 13, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
March 13, 2015

**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, 2014 .

**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, 2014 .

**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, 2014 .

**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, 2014 .

**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, 2014 .

**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:



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**

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

| 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 | Registration Rights Agreement, dated as of November 5, 2013, by and among Ocera Therapeutics, Inc. and the Purchasers identified therein (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on November 7, 2013). |
| 4.4 | Warrant to Purchase Stock dated December 3, 2008 issued by the Company to Oxford Finance Corporation (Incorporated by reference to Exhibit 4.3 of the Company's Registration Statement on Form S-1, as amended (File No. 333-170749)). |
| 4.5 | Warrant to Purchase Stock dated December 3, 2008 issued by the Company to Silicon Valley Bank (Incorporated by reference to Exhibit 4.4 of the Company's Registration Statement on Form S-1, as amended (File No. 333-170749)). |
| 4.6 | 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)). |
| 4.7 | 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). |
| 4.8 | 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). |
| 4.9 | 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). |
| 4.10 | 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). |

| | |
|---|---|
| 4.11 | 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). |
| 10.1# | Deed by and between Ocera Subsidiary, Inc. (f/k/a Ocera Therapeutics, Inc.) and UCL Business PLC, dated as of February 20, 2013, relating to and amending certain provisions of the Amended and Restated License Agreement by and between Ocera Subsidiary, Inc. and UCL Business PLC, dated as of July 26, 2011, a copy of which is attached to the Deed (Incorporated by reference to Exhibit 10.5 the Company's Current Report on Form 8-K/A filed on September 27, 2013). |

| | |
|---|---|
| 10.2 | Ocera Therapeutics, Inc. Amended and restated Non-Employee Director Compensation Policy (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on September 22, 2014.). |
| 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. Second Amended and Restated 2011 Stock Option and Incentive Plan, together with forms of award agreements (Incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on December 24, 2013). |
| 10.9† | Agreement of Employment dated as of December 19, 2013 by and between the Company and Linda Grais (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 24, 2013). |
| 10.10† | Agreement of Employment dated as of December 19, 2013 by and between the Company and Jeryl Hilleman (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on December 24, 2013). |
| 10.11† | Agreement of Employment dated as of December 19, 2013 by and between the Company and Franck S. Rousseau (Incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on December 24, 2013). |
| 10.12† | Agreement of Employment dated as of April 30, 2014 by and between the Company and Gaurav Aggarwal (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 2, 2014). |
| 10.13† | Employment Agreement dated August 5, 2014 by and between the Company and Rajiv Patni (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 11, 2014). |
| 10.14† | Employment Agreement dated June 17, 2014 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 September 22, 2014). |
| 10.15† | Consulting Agreement dated as of June 2, 2014 by and between the Company and Danforth Advisors (Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2014). |
| 10.16 | 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). |
| 10.17 | 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). |
| 10.18 | Securities Purchase 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 10.1 of the Company's Current Report on Form 8-K, as filed on April 29, 2013). |

| | |
|---|---|
| 10.19 | Securities Purchase Agreement, dated as of November 5, 2013, by and among Ocera Therapeutics, Inc. and the Purchasers identified therein (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 7, 2013). |
| 23.1* | Consent of Independent Registered Public Accounting Firm |
| 31.1* | Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2* | Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1** | Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2** | Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS+ | XBRL Instance Document |
| 101.SCH+ | XBRL Taxonomy Extension Schema Document |
| 101.CAL+ | XBRL Taxonomy Calculation Linkbase Document |
| 101.LAB+ | XBRL Taxonomy Label Linkbase Document |
| 101.PRE+ | XBRL Taxonomy Presentation Linkbase Document |
| 101.DEF+ | XBRL Taxonomy Definitions Linkbase Document |

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

+ Attached as Exhibits 101 to this report are the following financial statements from our Annual Report on Form 10-K for the year ended December 31, 2014, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations and Comprehensive Loss, (iii) the Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (deficit) , (iv) the Consolidated Statements of Cash Flows and (v) related Notes to these Consolidated Financial Statements tagged as blocks of text.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

OCERA THERAPEUTICS, INC.
(Registrant)

Date: March 13, 2015

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.<br>Linda S. Grais, M.D. | President and Chief Executive Officer | March 13, 2015 |
| /s/Michael Byrnes<br>Michael Byrnes | Chief Financial Officer and Treasurer<br>(Principal Financial and Accounting Officer) | March 13, 2015 |
| /s/Eckard Weber, M.D.<br>Eckard Weber, M.D. | Chairman of the Board of Directors | March 13, 2015 |
| /s/Jean-Paul Castaigne, M.D.<br>Jean-Paul Castaigne, M.D. | Director | March 13, 2015 |
| /s/Lars G. Ekman, M.D., Ph.D.<br>Lars G. Ekman, M.D., Ph.D. | Director | March 13, 2015 |
| /s/Steven P. James<br>Steven P. James | Director | March 13, 2015 |
| /s/Nina Kjellson<br>Nina Kjellson | Director | March 13, 2015 |
| /s/Michael Powell, Ph.D.<br>Michael Powell, Ph.D. | Director | March 13, 2015 |
| /s/Anne M. VanLent<br>Anne M. VanLent | Director | March 13, 2015 |
| /s/Wendell Wierenga, Ph.D.<br>Wendell Wierenga, Ph.D. | Director | March 13, 2015 |

**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. 333-192698) of Ocera Therapeutics, Inc.,
2. Registration Statement (Form S-3 No. 333-181215) of Tranzyme, Inc.,
3. 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.,
4. Registration Statement (Form S-8 No. 333-182408) pertaining to the Amended and Restated 2011 Stock Option and Incentive Plan of Tranzyme, Inc.,
5. Registration Statement (Form S-8 No. 333-191644) pertaining to the Ocera Therapeutics, Inc. 2005 Stock Plan, and
6. Registration Statement (Form S-8 No. 333-193094) pertaining to the Ocera Therapeutics, Inc. Second Amended and Restated 2011 Stock Option and Incentive Plan;

of our reports dated March 13, 2015 , with respect to the consolidated financial statements of Ocera Therapeutics, Inc. and the effectiveness of internal control over financial reporting of Ocera Therapeutics, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2014.

/s/ Ernst & Young LLP

San Diego, California
March 13, 2015

**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 13, 2015

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 13, 2015

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, 2014 , as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Linda S. Grais, M.D., President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

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

Date: March 13, 2015

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, 2014 , as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael Byrnes, M.B.A., 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.

Date: March 13, 2015

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