

OMEROS CORP  
Form 10-K  
March 16, 2015

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

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FORM 10-K

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(Mark One)

☒ 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: 001-34475

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OMEROS CORPORATION  
(Exact name of registrant as specified in its charter)

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Washington	91-1663741
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

201 Elliott Avenue West	98119
Seattle, Washington	(Zip Code)
(Address of principal executive offices)	

(206) 676-5000

(Registrant's telephone number, including area code)

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

Common Stock, \$0.01 par value per share	The NASDAQ Stock Market LLC
(Title of each class)	(Name of each exchange on which registered)

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

None

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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, as amended, 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 ☐

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

Indicate by check mark 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.

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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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of the last business day of the registrant’s most recently completed second fiscal quarter was \$550,709,113.

As of March 12, 2015, the number of outstanding shares of the registrant’s common stock, par value \$0.01 per share, was 37,802,462.

**DOCUMENTS INCORPORATED BY REFERENCE**

Specified portions of the registrant’s proxy statement with respect to the 2015 Annual Meeting of Shareholders to be held May 22, 2015, which is to be filed pursuant to Regulation 14A within 120 days after the end of the registrant’s fiscal year ended December 31, 2014, are incorporated by reference into Part III of this Form 10-K.

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Exchange Act, which are subject to the “safe harbor” created by those sections for such statements. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. All statements other than statements of historical fact are “forward-looking statements.” Terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “goal,” “intend,” “may,” “potential,” “predict,” “project,” “should,” “will,” “would,” and similar expressions and variations thereof are intended to identify forward-looking statements, but these terms are not the exclusive means of identifying such statements. Examples of these statements include, but are not limited to, statements regarding:

- our anticipation that we will begin U.S. commercial sales of Omidria™ broadly in early April 2015;
- our ability to receive regulatory approval for our Marketing Authorisation Application, or MAA, for OMS302, or Omidria, in the European Union, or EU;
- our expectation that we will receive an opinion on the MAA from the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, in the first half of 2015;
- our ability to partner in Europe and our anticipation that we will initiate marketing and sales of Omidria in the EU in 2015, assuming approval of our MAA for Omidria;
- our plans for sales, marketing and distribution of Omidria in the U.S. and for partnering, sales, marketing and distribution in the EU and other international territories;
- our expectation that transitional pass-through reimbursement status for Omidria granted by the Centers for Medicare and Medicaid Services, or CMS, will remain in effect until December 31, 2017, our expectation regarding the pass-through reimbursement rate for Omidria, and our expectation that this pass-through reimbursement will be effective as of January 1, 2015;
- our expectations regarding the clinical, therapeutic and competitive benefits of Omidria and our product candidates;
- our anticipated future sales from Omidria and our estimate regarding how long our existing cash, cash equivalents and short-term investments will be sufficient to fund our anticipated operating expenses, capital expenditures and interest and principal payments on our outstanding notes;
- our anticipation that we will rely on contract manufacturers to develop and manufacture our product candidates and to manufacture Omidria for commercial sale;
- whether pediatric studies may afford Omidria an additional six months of exclusivity;
- our expectations about the commercial competition that Omidria and our product candidates may face;
- the extent of protection that our patents provide and that our pending patent applications will provide, if patents issue from such applications, for our technologies, programs, products and product candidates;
- our ability to successfully complete our Phase 2 clinical trials for OMS721 and OMS824;
- whether the applicable European regulatory authority will approve the requested access to OMS721 for compassionate use;
- our expectation regarding the timing for submission of results of the further evaluation of nonclinical data in our OMS824 program to the U.S. Food and Drug Administration, or FDA;
- our ability to recommence active enrollment in our Phase 2 clinical trial of OMS824 in Huntington’s disease or initiate further clinical studies in either our OMS824 Huntington’s or schizophrenia programs;
- our ability to initiate or complete post-marketing studies for Omidria;
- whether our OMS103 Phase 3 clinical program in arthroscopic partial meniscectomy surgery may be redesigned to include reduction of early postoperative pain as the primary endpoint;
- whether there may be an opportunity to have OMS103 and/or OMS201 produced and commercialized by a registered outsourcing facility;
- our ability to raise additional capital through the capital markets or through one or more corporate partnerships, equity offerings, debt financings, collaborations, licensing arrangements or asset sales;
- our ability to enter into acceptable arrangements with potential corporate partners;
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our expected financial position, performance, growth, expenses, magnitude of net losses and availability of resources; and

our estimates regarding our future net losses, revenues, research and development expenses and selling, general and administrative expenses.

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Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks, uncertainties and other factors described in Item IA of Part I of this Annual Report on Form 10-K under the headings “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and in our other filings with the Securities and Exchange Commission, or SEC. Given these risks, uncertainties and other factors, actual results or developments anticipated may not be realized or, even if substantially realized, they may not have the expected consequences to or effects on our company, business or operations. Accordingly, you should not place undue reliance on these forward-looking statements, which represent our estimates and assumptions only as of the date of the filing of this Annual Report on Form 10-K. You should read this Annual Report on Form 10-K completely and with the understanding that our actual results in subsequent periods may materially differ from current expectations. Except as required by applicable law, including the securities laws of the United States and the rules and regulations of the SEC, we assume no obligation to update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

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OMEROS CORPORATION

ANNUAL REPORT ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2014

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## PART I

This Annual Report on Form 10-K contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results may differ materially from those discussed in these forward-looking statements due to a number of factors, including those set forth in the section entitled “Risk Factors” and elsewhere in this Annual Report. Please refer to the special note regarding forward-looking statements at the beginning of this Annual Report on Form 10-K for further information.

### ITEM 1. BUSINESS

#### Overview

We are a biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, coagulopathies and disorders of the central nervous system. Our marketed drug product Omidria™ (phenylephrine and ketorolac injection) 1%/0.3% is approved in the U.S. for use during cataract surgery or intraocular lens, or IOL, replacement surgery, to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain. Omidria is derived from our proprietary PharmacoSurgery® platform, which is designed to improve clinical outcomes of patients undergoing ophthalmological, arthroscopic, urological and other surgical procedures, and is based on low-dose combinations of FDA-approved therapeutic agents delivered directly to the surgical site throughout the duration of the procedure to inhibit preemptively inflammation and other problems caused by surgical trauma and to provide clinical benefits both during and after surgery. We have an additional six clinical-stage development programs in our pipeline, which also includes a diverse group of preclinical programs as well as two additional platforms: one capable of unlocking new G protein-coupled receptor, or GPCR, drug targets and the other used to generate antibodies. For Omidria and each of our product candidates and our programs, we have retained all manufacturing, marketing and distribution rights.

Currently, our primary focus is on the U.S. commercial launch of Omidria. A controlled launch of Omidria to a small number of surgeons in the U.S. began in February 2015. These surgeons were selected in part based on their practice locations, collectively representing all of the Medicare Administrative Contractors, or MACs, across the country. The purpose of the controlled launch is to evaluate Omidria commercialization processes, including those directed to distribution and reimbursement. The broad U.S. launch of the product is expected in early April 2015.

Omidria™ (phenylephrine and ketorolac injection) 1%/0.3%

Overview. Omidria was approved by the FDA in May 2014 for use during cataract surgery or IOL replacement surgery to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain. Omidria is a proprietary drug product containing two active pharmaceutical ingredients, or APIs: ketorolac, an anti-inflammatory agent, and phenylephrine, a mydriatic, or pupil dilating, agent. FDA-approved drugs containing each of these APIs have been used in ophthalmological clinical practice for more than 20 years, and both APIs are contained in generic, FDA-approved drugs. Cataract and other lens replacement surgery involves replacement of the original lens of the eye with an artificial intraocular lens. These procedures are typically performed to replace a lens opacified by a cataract or to correct a refractive error. Omidria is added to standard irrigation solution used during cataract and lens replacement surgery and is delivered intracamerally, or within the anterior chamber of the eye, to the site of the surgical trauma throughout the procedure. Preventing pupil constriction is essential for these procedures and, if miosis occurs, the risk of damaging structures within the eye and other complications increase as does the operating time required to perform the procedure.

In October 2014 we were granted transitional pass-through reimbursement status from CMS for Omidria, effective January 1, 2015. Pass-through status allows for separate payment under Medicare Part B for new drugs and other medical technologies that meet well-established criteria specified by federal regulations governing Medicare spending. We expect pass-through to remain in effect until December 31, 2017, near which time CMS will evaluate utilization of Omidria and will re-assess its reimbursement status. CMS has set the reimbursement rate for Omidria under Medicare Part B at the product’s wholesale acquisition cost, or WAC, of \$465 plus six percent (6%) per single-use vial for the second and third quarters of 2015 after which the rate will be based on average selling price, or ASP, plus six percent (6%). Based on our discussions with CMS, we expect this pass-through reimbursement to be effective as of



January 1, 2015.

In the EU, we submitted an MAA to the EMA in September 2013 seeking the authorization to permit us to market and sell Omidria in the EU for use in patients undergoing cataract and IOL replacement surgery. In October 2013, the MAA for Omidria was validated by the EMA and we expect to receive an opinion on the MAA from the EMA's Committee for Medicinal Products for Human Use, the scientific committee of the EMA, in the first half of 2015. In the EU and other international territories, we plan to enter into one or more partnerships for the marketing and distribution of Omidria.

Assuming approval of our MAA for Omidria and success in partnering for Omidria in Europe, we anticipate the initiation of EU marketing and sales of Omidria in 2015.

Pediatric Studies. We have initiated a pediatric study for Omidria in the U.S. and have discussed with the EMA the design for a pediatric study for Omidria in the EU, each of which may afford Omeros an additional six months of exclusivity in the U.S. and the EU, respectively, if completed in accordance with agreements with the respective regulatory agencies.

#### PharmacoSurgery® Platform

We believe that current standards of care for the management and treatment of surgical trauma are limited in effectiveness. Surgical trauma causes a complex cascade of molecular signaling and biochemical changes, resulting in inflammation, pain, pupil constriction, muscle spasm, loss of function and other problems. As a consequence, multiple pharmacologic actions are required to manage the complexity and inherent redundancy of the cascade. Accordingly, we believe that single-agent treatments acting on single targets do not result in optimal therapeutic benefit. Further, current pre-operative treatments are not optimally effective because the administration of standard irrigation solution during the surgical procedure washes out pre-operatively delivered drugs. In addition, current postoperative therapies are not optimally effective because the cascade and resultant inflammation, pain, pupil constriction, muscle spasm, loss of function and other problems have already begun and are difficult to reverse and manage after surgical trauma has occurred. Also, drugs that currently are delivered systemically to target these problems, such as by oral or intravenous administration, are frequently associated with adverse side effects.

In contrast, we generate from our PharmacoSurgery platform proprietary products, such as Omidria, and product candidates that are combinations of therapeutic agents designed to act simultaneously at multiple discrete targets to block preemptively the molecular-signaling and biochemical cascade caused by surgical trauma and to provide clinical benefits both during and after surgery. These products and product candidates are supplied in pre-dosed, pre-formulated, single-use containers and added to standard surgical irrigation solutions, delivered intraoperatively to the site of tissue trauma throughout the surgical procedure. This is expected to result in the delivery of low concentrations of agents with minimal systemic uptake and reduced risk of adverse side effects and does not require a surgeon to change his or her operating routine. In addition to ease of use and potential for improved patient outcomes, we believe that the clinical benefits of our product candidates could provide surgeons with a competitive marketing advantage and may facilitate third-party payer acceptance, all of which we expect will drive adoption and market penetration.

While our patent position covers both generic and proprietary agents, Omidria, as well as our current PharmacoSurgery product candidates, OMS103 and OMS201, are specifically comprised of APIs contained in generic drugs already approved by the FDA with established profiles of safety and pharmacologic activities. As a result, the path to commercialization of our PharmacoSurgery product candidates may be less costly and time-consuming than programs that involve more extensive nonclinical, clinical and pharmacology efforts required for drug products containing new chemical entities.

#### Our Product Candidates and Development Programs

Our product candidates and pipeline of development programs consist of the following:

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Product Candidate/Program	Targeted Procedure/Disease	Development Status	Next Expected Milestone	Worldwide Rights
Clinical Programs				
MASP (OMS721) - Complement-Mediated Disorders	TMA (aHUS, TTP, transplant-related TMA)	Phase 2	Complete Phase 2 Trial	Omeros (In-licensed)
PDE10 (OMS824) - CNS Disorders	Schizophrenia	Phase 2 <sup>(1)</sup>	Complete Phase 2 Trial	Omeros
PDE10 (OMS824) - CNS Disorders	Huntington's Disease	Phase 2 <sup>(1)</sup>	Complete Phase 2 Trial	Omeros
OMS103 - Arthroscopy	Arthroscopic Meniscectomy	Phase 3	Determine Commercialization Path	Omeros
PPAR (OMS405) - Addiction	Opioid and Nicotine Addiction	Phase 2	Complete Phase 2 Trials	Omeros
OMS201 - Urology	Ureteroscopy	Phase 1/2	Determine Commercialization Path	Omeros
Preclinical Programs				
PDE7 (OMS527)	Addictions and Compulsive Disorders; Movement Disorders	Preclinical	Complete Human Dose-Enabling Toxicology Studies and GMP Manufacturing	Omeros (Compounds In-licensed)
Plasmin (OMS616)	Surgical and Traumatic Bleeding	Preclinical	Complete Human Dose-Enabling Toxicology Studies and GMP Manufacturing	Omeros (In-licensed)
MASP (OMS906)	Paroxysmal nocturnal hemoglobinuria (PNH) and Other Alternative Pathway Disorders	Preclinical	Complete Manufacturing Scale-up of a Clinical Candidate for IND-Enabling Toxicology Studies	Omeros
GPR17 - CNS disorders	Demyelinating Disorders	Preclinical	Compound Optimization	Omeros
GPCR Platform	Multiple Disorders Across Therapeutic Areas	Preclinical	Continue Drug Discovery and Selected Medicinal Chemistry for Class A Orphan and Class B GPCRs	Omeros
Antibody Platform	Multiple Disorders Across Therapeutic Areas	Preclinical	Continue Developing Antibodies Targeting Alternative Pathway of Complement System and Expanding Antibody Library	Omeros (In-licensed)

Our OMS824 programs are currently suspended pending further evaluation of nonclinical data from a study in rats (1) in response to a request from the FDA. For additional information, see "Business-Clinical Programs-PDE10

Programs-OMS824 for Schizophrenia and Huntington's Disease."

#### Clinical Programs

##### MASP Program - OMS721

Overview. Mannan-binding lectin-associated serine protease-2, or MASP-2, is a novel pro-inflammatory protein target involved in activation of the complement system, which is an important component of the immune system. The complement system plays a role in the inflammatory response and becomes activated as a result of tissue damage or trauma or microbial pathogen invasion. MASP-2 appears to be unique to, and required for the function of, one of the principal complement activation pathways, known as the lectin pathway. Importantly, inhibition of MASP-2 does not

appear to interfere with the antibody-dependent classical complement activation pathway, which is a critical component of the acquired immune response to infection, and abnormal function of the classical pathway is associated with a wide range of autoimmune disorders. MASP-2 is generated solely by the liver and is then released into the circulation so, following inhibition of MASP-2, restoration of circulating levels of MASP-2 is dependent on the time required for hepatic regeneration of the enzyme. Published studies demonstrate that adult humans who are genetically deficient in one of the proteins that activate MASP-2 do not appear to be detrimentally affected. We are developing MASP-2 antibodies and we

expect that the intended therapeutic effect can be achieved with subcutaneous and other systemic routes of administration. OMS721 is our lead human monoclonal antibody targeting MASP-2.

OMS721 has received Orphan Drug designation for the prevention (inhibition) of complement-mediated thrombotic microangiopathies, or TMAs.

**Clinical Trial Results.** A Phase 2 clinical program to evaluate the efficacy and safety of OMS721 in patients with disorders associated with lectin pathway activation is currently in progress. The first OMS721 Phase 2 clinical trial, currently underway, is evaluating the effects of the drug on patients with complement-mediated TMAs, including atypical hemolytic uremic syndrome, or aHUS, thrombotic thrombocytopenic purpura, or TTP, stem cell transplant-related TMA and renal transplant-related TMA.

In February 2015, we announced the completion of dosing of the low-dose cohort of patients in this Phase 2 trial. In the clinical trial, the first cohort consisted of three aHUS patients treated with the lowest dose of OMS721. All patients in this study cohort received OMS721 and improvements were observed across TMA disease markers. Platelet count, serum lactate dehydrogenase, or LDH, and serum haptoglobin were measured as markers of disease activity. When compared to baseline levels, platelet counts improved in all patients. Serum LDH levels remained normal in one patient, substantially decreased to close to the normal range in another and remained elevated in the third. Haptoglobin improved in two patients, normalizing in one. Creatinine levels in the one patient with independent renal function also improved. Based on observations in this cohort, a European investigator requested that Omeros provide extended access to OMS721 for compassionate use in his two study patients, both of whom suffer from aHUS. We agreed to provide the requested access to OMS721 for compassionate use, subject to approval from the applicable European regulatory authority. Assuming regulatory approval of this program of extended access, which cannot be guaranteed, the two patients treated by the investigator requesting compassionate use will continue to undergo dosing with OMS721. The third patient, treated at a site other than that of the requesting investigator, appeared clinically to no longer be in the acute phase of the disease after treatment with OMS721. The patient subsequently relapsed following cessation of OMS721 treatment. This patient was discontinued from the trial for precautionary reasons because of a serious adverse event – a localized inflammatory response often related to certain types of infections, one of which the patient previously had for three years while on immunosuppressive therapy. No other significant safety issues were observed in this trial. Consistent with the Phase 2 trial protocol, a pre-planned data review by internal and external physicians resulted in a recommendation to proceed with the planned dose escalation to the mid-dose cohort. We plan to release additional Phase 2 data later this year.

In April 2014, we concluded a Phase 1 trial in Europe evaluating OMS721. This Phase 1 trial was a placebo-controlled, double-blind, single-ascending-dose study to evaluate the safety, tolerability, pharmacodynamics and pharmacokinetics of OMS721 in healthy subjects. Seven cohorts of subjects received OMS721 or placebo by either subcutaneous injection or intravenous infusion at increasing dose levels. In this trial, OMS721 administration was well tolerated in all subjects, there were no drug-related adverse events, and no clinically significant abnormalities on laboratory tests or electrocardiograms have been observed. At the highest dose evaluated, both subcutaneous and intravenous routes of administration resulted in a high degree of lectin-pathway inhibition and successfully achieved the pharmacologic target of sustained inhibition for at least one week.

**Other Studies.** We have completed a series of in vivo studies using either proprietary MASP-2 knock-out mice and/or MASP-2 antibodies in established models of disease that are linked to activation of the complement system. Our findings in those studies suggest that antibody-blockade of MASP-2 may have a preventive or therapeutic effect in the treatment of a wide range of complement-related diseases and disorders, including TMAs (e.g., aHUS, TTP), which is the disorder targeted by our first Phase 2 clinical trial.

In March 2014, we reported results from a study evaluating OMS721 in ex vivo studies of human endothelial activation relevant to the pathophysiology of aHUS in support of the clinical evaluation of OMS721 in patients with aHUS and other TMAs. The experimental model is based on the finding that serum samples from aHUS patients cause complement deposition when incubated with human microvascular endothelial cells. The data showed that OMS721 inhibited complement deposition in the model using serum samples from aHUS patients obtained during the acute phase of disease ( $p < 0.01$ ) and during remission ( $p < 0.001$ ) compared to untreated controls. The laboratories that conducted the study have previously shown in this same model system that treatment with agents that block

complement factor C5 has a similar inhibitory effect on complement deposition. Eculizumab (Soliris®) is an anti-C5 monoclonal antibody that is approved by the FDA and the EMA to treat patients with aHUS.

In November 2014, we announced positive data using OMS721 to inhibit thrombus formation in an ex vivo pathophysiologic system of aHUS. The data resulted from studies in a well-established experimental model of TMA aimed at assessing the potential therapeutic benefits of OMS721 in TMA using serum samples from aHUS patients with

different etiologies obtained during the acute phase of disease as well as during remission. The experimental model is based on the finding that sera from aHUS patients promote the formation of thrombi on human microvascular endothelial cells, the defining pathological feature of TMA. The studies reported showed that OMS721 significantly inhibited thrombus formation when added to serum samples from aHUS patients obtained during the acute phase of disease ( $p < 0.01$ ) as well as during remission ( $p < 0.0001$ ). OMS721 was as effective at inhibiting thrombus formation as the positive control in the studies – soluble complement receptor 1, an agent that completely blocks the complement system.

Also in November 2014, we announced positive data using a derivative of OMS721 in a well-established animal model of stroke. Compared to control antibody-treated mice, mice treated with MASP-2 antibody in this study demonstrated significantly reduced neurological deficits 48 hours after an ischemic stroke. In addition, the infarcted area of the brain was significantly smaller in MASP-2 antibody-treated mice. A similar degree of protection was also observed in gene-targeted MASP-2-deficient mice, which showed significantly lesser neurological deficits and infarct sizes compared to wild-type control mice.

In addition, we have generated positive preclinical data in in vivo models of macular degeneration, myocardial infarction, renal disease, diabetic neuropathy and other diseases and disorders.

**Licensing Arrangements.** We hold worldwide exclusive licenses to rights related to MASP-2, the antibodies targeting MASP-2 and the therapeutic applications for those antibodies from the University of Leicester, from its collaborator, Medical Research Council at Oxford University, or MRC, and from Helion Biotech ApS, or Helion. For a more detailed description of these licenses, see “Business-License and Development Agreements.”

**PDE10 Programs - OMS824 for Schizophrenia and Huntington’s disease**

**Overview.** Phosphodiesterase 10, or PDE10, is an enzyme that is expressed in areas of the brain strongly linked to diseases that affect cognition, including schizophrenia and Huntington’s disease. Cognitive dysfunction occurs early in these diseases and is responsible for substantial disability. PDE10 inhibitors have been shown to be effective in multiple animal models of behavior and cognition, and there remain substantial unmet clinical needs with current treatments. Our proprietary compound OMS824 inhibits PDE10 and is being developed in clinical programs for the treatment of cognitive disorders, including schizophrenia and Huntington’s disease. In schizophrenia, OMS824 may have, in addition to cognitive enhancement, beneficial effects on the positive (e.g., hallucinations) and negative (e.g., flat affect) symptoms of the disease. In Huntington’s disease, OMS824 may improve motor and behavioral abnormalities as well as cognition. OMS824 may address other limitations of current treatments for both schizophrenia and Huntington’s disease, for example, by avoiding the weight gain, hyperlipidemia, and the risk of sudden cardiac death associated with current antipsychotic medications as well as the depression and suicidal ideation seen with tetrabenazine, the only FDA-approved treatment for Huntington’s disease.

OMS824 has received Orphan Drug designation for the treatment of Huntington’s disease and Fast Track designation for the treatment of cognitive impairment in patients with Huntington’s disease. Our OMS824 programs are currently suspended pending further evaluation of nonclinical data from a study in rats in response to a request from the FDA, as further discussed below.

**Clinical Trial Results.** We have been evaluating OMS824 in two Phase 2 programs: one in patients with schizophrenia and the other in Huntington’s disease patients. The OMS824 Phase 2 trial in patients with Huntington’s disease began enrollment in February 2014 and is a sequential-dose cohort study to evaluate safety and efficacy of OMS824 for purposes of determining dose levels, endpoints and trial design for subsequent, including registration, trials. In October 2014, we announced the suspension of our Huntington’s clinical trial for OMS824 resulting from an observation in a nonclinical study in rats being conducted concurrently with our Huntington’s trial. Following preliminary data collection from that nonclinical study, we submitted a report on an observation in several of the rats receiving the maximum dose administered in the study to the FDA’s Division of Neurology Products and its Division of Psychiatry Products, the FDA divisions that cleared our Investigational New Drug, or IND, applications for Huntington’s disease and schizophrenia, respectively. In response to a request from the FDA in follow-up communications, we suspended the ongoing Huntington’s disease trial. The FDA requested that we further evaluate the nonclinical data from the study in rats, as well as from nonclinical studies that we conducted that did not yield the observation, to characterize the observation more fully before we can reinitiate clinical enrollment in our OMS824

clinical program, including our Phase 2 Huntington's clinical trial or other clinical trials in our Huntington's or schizophrenia programs. This evaluation is ongoing and we are working toward the reinitiation of clinical enrollment. We currently estimate enrollment will recommence in the near future.



The Phase 2a schizophrenia trial, which commenced in September 2013, evaluated the product candidate's tolerability, safety, pharmacokinetics, potential interactions with concomitant antipsychotic medications, and potential effects on cognition using a battery of cognitive tests in patients with stable schizophrenia. In this randomized, double-blind, placebo-controlled trial, OMS824 was administered at three dose levels for two weeks to psychiatrically stable patients whose antipsychotic medications were temporarily discontinued or who continued their usual antipsychotic regimen. The trial enrolled 41 patients. In January 2014, we reported positive results from this Phase 2a trial in which the drug was well tolerated and demonstrated comparable systemic pharmacokinetics when administered alone and concomitantly with approved antipsychotic agents, opening the potential for the drug to be delivered as a monotherapy or as an adjunct to commercially available antipsychotics. We concurrently announced that we were considering evaluating an additional higher dose level in this trial. In March 2014, we reported additional positive results at that higher dose level with the drug continuing to be tolerated and demonstrating approximately 50% higher plasma concentrations of OMS824 than previously reached at the next-highest dose in the Phase 2a trial. The drug concentrations in these schizophrenia patients were also approximately 50% higher than levels that corresponded to an average of 66% "occupancy" or enzyme interaction at PDE10 in a Phase 1 positron emission tomography, or PET, study in healthy subjects.

We have been conducting a Phase 1 clinical program evaluating the safety, tolerability and pharmacokinetics of OMS824 in healthy subjects, which is also suspended pending resolution of the nonclinical data finding discussed above. The first Phase 1 clinical trial conducted was randomized, double-blind, and placebo-controlled. In this clinical trial, single doses of OMS824 were well tolerated and demonstrated linear pharmacokinetics, a long half-life consistent with once-daily dosing and good systemic exposure that, at the highest dose administered, resulted in the expected pharmacological effects in healthy subjects. Also in this Phase 1 trial, multiple doses of OMS824 taken for up to 10 days were well tolerated by all subjects, and the only apparent drug-related adverse event was mild somnolence at the highest dose evaluated. These study results showed that the pharmacokinetic parameters increased linearly with the dose and that OMS824 had a long half-life consistent with once daily dosing. This clinical trial included single- and multiple-dose escalation results from 100 healthy male subjects. In this trial, 60 subjects received a single dose of OMS824, 24 subjects received multiple doses for seven to 10 days, and 16 subjects received placebo. At the highest level of multiple-dosing administered, OMS824 was well tolerated and the only apparent drug-related adverse events were mild. Almost all adverse events were self-limiting and resolved during the 10-day dosing period. Also as a part of our Phase 1 clinical program, we conducted a clinical trial to evaluate target "occupancy" or enzyme interaction of OMS824 using PET scans in healthy subjects by measuring the extent to which OMS824 binds to PDE10 in the striatum, a region of the brain that has been linked to a wide range of diseases that affect cognition. In May 2013, we announced positive results for subjects receiving once daily dosing of OMS824 for seven days. Quantitation of PET images showed that approximately 50% occupancy of PDE10 in the striatum was achieved by this dosing regimen, OMS824 was well tolerated and, consistent with earlier studies, mild somnolence was the only apparent adverse effect. In October 2013, we announced additional positive data in healthy male subjects receiving OMS824 once daily for seven days at a dose higher than previously reported. An average of 63% occupancy at PDE10 was seen in the striatum. The drug was well tolerated with mild somnolence as the only apparent side effect. In February 2014, we reported additional positive results in healthy male subjects receiving OMS824 once daily for 10 days. An average of 66% and a high of approximately 70% occupancy at PDE10 were seen in the striatum. The drug was well tolerated in all subjects with mild somnolence as the main side effect.

Funding Agreement with The Stanley Medical Research Institute. Our preclinical development of OMS824 was supported by funds from The Stanley Medical Research Institute, or SMRI, a non-profit corporation that supports research on the causes and treatment of schizophrenia and bipolar disorder. For a more detailed description of our agreement with SMRI, see "Business-License and Development Agreements."

#### OMS103-Arthroscopy

Overview. OMS103 is our PharmacoSurgery product candidate being developed for use during arthroscopic procedures, including partial meniscectomy surgery, and was designed to provide a multimodal approach to block preemptively the inflammatory cascade induced by arthroscopy. OMS103 is a proprietary combination of anti-inflammatory/analgesic APIs, specifically amitriptyline, ketoprofen and oxymetazoline, each with well-known

safety and pharmacologic profiles. Each of the APIs are components of generic, FDA-approved drugs that have been marketed in the U.S. as over-the-counter, or OTC, or prescription drug products for over 20 years and have established and well-characterized safety profiles.

One of the major challenges facing orthopedic surgeons performing arthroscopic procedures is adequately controlling the local inflammatory response to surgical trauma, particularly the inflammatory pain and swelling that are associated with detrimental effects on the long-term health of the joint. Added to standard irrigation solutions, OMS103 is delivered

directly to the joint throughout arthroscopy, and is designed to act simultaneously at multiple distinct targets to block preemptively the inflammatory cascade induced by arthroscopic surgery. Our Phase 3 clinical program in arthroscopic partial meniscectomy surgery may be redesigned to include reduction of early postoperative pain as the primary endpoint. In addition, we are evaluating alternative approaches to make OMS103 commercially available, such as through a registered outsourcing facility, without the need to conduct any additional clinical trials.

**Clinical Trial Results.** In 2012, we completed a multicenter, double-blind, Phase 3 clinical trial comparing OMS103 to vehicle control in 344 patients undergoing arthroscopic partial meniscectomy surgery. The pre-specified primary endpoint was the Symptoms Subscale of the Knee Injury and Osteoarthritis Outcome Score, or KOOS, which consists of five subscale scores: symptoms, pain, activities of daily living, sport and recreation function, and knee-based quality of life. In addition, pain measured in the early postoperative period was a pre-specified secondary endpoint. Although the Symptoms Subscale of the KOOS did not reach statistical significance, OMS103 achieved statistically significant ( $p=0.0003$ ) reduction of postoperative pain. OMS103 also demonstrated improvement across a series of pain-related assessments including postoperative narcotic usage (with more than twice as many OMS103-treated patients taking no postoperative narcotics), incidence of inflammatory adverse events, tourniquet use during surgery, and crutch use as well as time to discontinuation of crutches and return to work, a number of which also achieved statistical significance. In this study, OMS103 was well tolerated. Although the positive results from our Phase 3 clinical trial evaluating OMS103 are encouraging, there can be no assurance that they will be predictive of the results obtained from later trials, should later trials be conducted.

#### PPAR Program - OMS405

**Overview.** In our peroxisome proliferator-activated receptor gamma, or PPAR  $\gamma$ , program, we are developing proprietary compositions that include PPAR  $\gamma$  agonists for the treatment and prevention of addiction to substances of abuse, which may include opioids, nicotine and alcohol. We believe that Omeros is the first to demonstrate a link between PPAR  $\gamma$  and addiction disorders. Data from European pilot clinical studies and animal models of addiction suggest that PPAR  $\gamma$  agonists could be efficacious in the treatment of a wide range of addictions. Our collaborators at The New York State Psychiatric Institute are conducting two Phase 2 clinical trials related to our PPAR  $\gamma$  program. These studies are evaluating a PPAR  $\gamma$  agonist, alone or in combination with other agents, for treatment of addiction to opioids and to nicotine. The National Institute on Drug Abuse is providing substantially all of the funding for these clinical trials and is solely overseeing the conduct of these trials. We have the right or expect to be able to reference the data obtained from these studies for subsequent submissions to the FDA and continue to retain all other rights in connection with the PPAR  $\gamma$  program.

**Patent Assignment Agreement with Roberto Ciccocioppo, Ph.D.** We acquired the patent applications and related intellectual property rights for our PPAR  $\gamma$  program in February 2009 from Roberto Ciccocioppo, Ph.D. of the Università di Camerino, Italy, pursuant to a patent assignment agreement. For a more detailed description of our agreement with Dr. Ciccocioppo, see “Business-License and Development Agreements.”

#### OMS201-Urology

**Overview.** OMS201 is our PharmacoSurgery product candidate being developed for use during urological procedures, including ureterscopy for removal of ureteral or renal stones. OMS201 is a proprietary combination of an anti-inflammatory API and a smooth muscle relaxant API. OMS201 is intended for local delivery to the bladder, ureter, urethra, and other urinary tract structures by inclusion in the standardly used irrigation solution used during endoscopic urological procedures. Both of the APIs in OMS201, specifically ketoprofen and nifedipine, are contained in generic, FDA-approved drugs that have been marketed in the U.S. for more than 20 years and have well-known safety and pharmacologic profiles. Each of the APIs in OMS201 has been individually prescribed to manage the symptoms of ureteral and renal stones.

Uroendoscopic procedures are performed within the urinary tract using a flexible camera device, or endoscope, and cause tissue injury that activates local mediators of pain and inflammation, which results in inflamed tissue, pain, smooth muscle spasm and lower urinary tract symptoms including frequency, urgency and painful urination, and can prolong recovery. Added to standard irrigation solutions in urological surgery, OMS201 is designed for delivery directly to the surgical site during uroendoscopic procedures, such as bladder endoscopy, or cystoscopy, minimally invasive prostate surgery and ureteroscopy, to inhibit surgically induced inflammation, pain and smooth muscle

spasm, or excess contractility.

The next step in our OMS201 program is to design a Phase 2 clinical program, which is on hold given current availability of clinical development resources. We are also evaluating alternative approaches to make OMS201 commercially available, such as through a registered outsourcing facility without the need to conduct any additional clinical trials.

**Clinical Trial Results.** In 2010, we completed a Phase 1/Phase 2 clinical trial in 24 patients designed to evaluate the safety and systemic absorption of two sequentially higher concentrations of OMS201 added to standard irrigation solution and delivered to patients undergoing ureteroscopy for removal of ureteral or renal stones. This multicenter, double-blind, vehicle-controlled clinical trial also explored potential efficacy endpoints but was not powered to assess efficacy. OMS201 was well tolerated in this study. The incidence of adverse events was similar in the two OMS201-concentration arms and the group receiving vehicle. No adverse events were considered treatment-related by investigators.

#### Preclinical Programs

##### PDE7 Program - OMS527

**Overview.** Our phosphodiesterase 7, or PDE7, program is based on our discoveries of previously unknown links between PDE7 and any addiction or compulsive disorder and between PDE7 and any movement disorders, such as Parkinson's disease. PDE7 appears to modulate the dopaminergic system, which plays a significant role in regulating both addiction and movement. We believe that PDE7 inhibitors could be effective therapeutics for the treatment of addiction and compulsive disorders as well as for movement disorders. Data generated in preclinical studies support both of these potential indications. We have selected a clinical candidate and are prepared to initiate toxicology studies under good laboratory practices, or GLP, intended to support the submission of an IND or clinical trial application, or CTA, and subsequent clinical trials.

**Exclusive License Agreement with Daiichi Sankyo Co., Ltd.** We hold an exclusive license to certain PDE7 inhibitors claimed in patents and pending patent applications owned by Daiichi Sankyo Co., Ltd. (successor-in-interest to Asubio Pharma Co., Ltd.), or Daiichi Sankyo, for use in the treatment of movement, addiction and compulsive disorders as well as other specified indications. For a more detailed description of our agreement with Daiichi Sankyo, see "Business-License and Development Agreements."

##### Plasmin Program - OMS616

**Overview.** We are developing antifibrinolytic agents for the control of blood loss during surgery or resulting from trauma or other hyperfibrinolytic conditions. Excessive bleeding during cardiac or trauma surgery is known to increase overall morbidity and mortality. In an attempt to control this bleeding, patients undergoing cardiac and other extensive surgery often receive antifibrinolytic compounds. These drugs inhibit plasmin, an enzyme present in blood that degrades fibrin clots. Because plasmin degrades fibrin clots, an agent that inhibits plasmin may have potential utility for reducing blood loss due to trauma or surgery.

Prior to withdrawal from the U.S. and European markets in 2008 for safety concerns, the antifibrinolytic Trasylo<sup>®</sup> (aprotinin) had been shown in a number of studies to be more effective at reducing blood loss than the other two most commonly used antifibrinolytics on the market today, tranexamic acid and epsilon aminocaproic acid. While Trasylo<sup>®</sup> is a potent inhibitor of plasmin, it is non-selective. In addition to plasmin, it significantly inhibits kallikrein and Factor XIa, two enzymes important in promoting clotting, and their inhibition can increase bleeding. Trasylo<sup>®</sup> was found to be associated with a number of safety issues, including increased mortality. Further, it is a bovine protein associated with anaphylactic reactions. While the specific cause of increased death remains unknown, an often-cited explanation is the lack of specificity of Trasylo<sup>®</sup>.

Our proprietary agents also inhibit plasmin but, unlike Trasylo<sup>®</sup>, they do not significantly inhibit kallikrein or Factor XIa. Additionally, our agents are derived from human protein, which may reduce immunological side effects. The properties of our proprietary agents are described in a peer-reviewed article titled "Engineering Kunitz Domain 1 (KD1) of Human Tissue Factor Pathway Inhibitor-2 to Selectively Inhibit Fibrinolysis: Properties of KD1-L17R Variant" that was published in the February 11, 2011 issue of the Journal of Biological Chemistry. We believe that the potential efficacy, human-protein derivation and improved selectivity of our proprietary agents provide a novel approach to the control of bleeding from surgery and trauma.

We have selected a lead clinical candidate and are in the process of manufacturing preclinical supplies to enable the initiation of GLP toxicology studies intended to support the submission of an IND or CTA and subsequent clinical trials. Ex vivo studies in human plasma comparing the efficacy of our lead clinical candidate to that of Trasylo<sup>®</sup> in inhibiting plasmin demonstrated that, in these studies, our candidate was at least as effective as Trasylo<sup>®</sup>. Given that our molecule is (1) a human-derived protein rather than bovine-derived as is Trasylo<sup>®</sup> and (2) does not have the

off-target activity seen with Trasylol® against kallikrein and Factor XIa, we expect that our molecule will compare favorably to Trasylol® with respect to safety. This expectation will need to be borne out by clinical trials.

Exclusive License Agreement with The Regents of the University of California. We hold a worldwide exclusive license to patent rights related to certain antifibrinolytics from The Regents of the University of California, or The Regents. For a more detailed description of this agreement, see “Business-License and Development Agreements.”

**MASP Program - OMS906**

**Overview.** As part of our MASP program, we have identified what we believe to be the key activators of the alternative pathway of the complement system and believe that we are the first to make this discovery. The complement system is part of the immune system’s innate immune response and the alternative pathway is the first pathway of the complement system to be activated. We have expanded our intellectual property position to protect inventions stemming from these discoveries that are directed to inhibition of both the lectin and/or alternative pathway, and we are developing inhibitors of the alternative pathway as well as inhibitors of both the alternative and lectin pathways. We have identified MASP-3 as the primary activator of the alternative pathway and are developing MASP-3 inhibitors that show the potential to treat subjects suffering from a wide range of diseases and conditions, including paroxysmal nocturnal hemoglobinuria, or PNH, age-related macular degeneration, or AMD, ischemia-reperfusion injury, arthritis, disseminated intravascular coagulation, thrombotic microangiopathy, asthma, dense deposit disease, pauci-immune necrotizing crescentic glomerulonephritis, traumatic brain injury, aspiration pneumonia, endophthalmitis, neuromyelitis optica and Behcet’s disease.

**Licensing Arrangements.** We jointly own and hold worldwide exclusive license rights related to therapeutic applications for inhibiting MASP-3 from the University of Leicester. For a more detailed description of these licenses, see “Business-License and Development Agreements.”

#### **GPR17 Program**

**Overview.** We are optimizing compounds against GPR17, a GPCR that is linked to myelin formation. Myelin is an insulating layer rich in lipids and proteins that forms a sheath around the nerve fibers, which is essential for the proper functioning of the nervous system. Loss of the myelin sheath is the hallmark of several diseases, including multiple sclerosis, acute disseminated encephalomyelitis, neuromyelitis optica, transverse myelitis, chronic inflammatory demyelinating polyneuropathy, Guillain-Barré syndrome, central pontine myelinosis, inherited demyelinating diseases such as leukodystrophy, and Charcot-Marie-Tooth disease. We believe GPR17 inhibitors have the potential to promote remyelination and improve the outcome of these diseases as well as traumatic brain injury and spinal cord injury, conditions that have been associated with GPR17. Discovering GPR17 inhibitors has previously been challenging to the pharmaceutical industry because this receptor is an orphan GPCR, i.e., its natural ligand is not known, as discussed below. However, using our proprietary cellular redistribution assay, which allows compound screening against orphan GPCRs without knowledge of a given receptor’s natural ligand, we have been able to identify over 120 compounds that functionally interact with GPR17.

#### **GPCR Platform**

**Overview.** GPCRs comprise one of the largest families of proteins in the genomes of multicellular organisms. It is estimated that there are over 1,000 GPCRs in the human genome, comprising three percent of all human proteins. GPCRs are cell surface membrane proteins involved in mediating both sensory and nonsensory functions. Sensory GPCRs are involved in the perception of light, odors, taste and sexual attractants. Non-sensory GPCRs are involved in metabolism, behavior, reproduction, development, hormonal homeostasis and regulation of the central nervous system. The vast majority of GPCR drug targets are non-sensory. Although GPCRs form a super-family of receptors, individual GPCRs display a high degree of specificity and affinity for the molecules, or the ligands, that bind to that given receptor. Ligands can either activate the receptor (agonists) or inhibit it (antagonists and inverse agonists). When activated by its ligand, the GPCR interacts with intracellular G proteins, resulting in a cascade of signaling events inside the cell that ultimately leads to the particular function linked to the receptor.

The high degree of specificity and affinity associated with GPCRs has contributed to their becoming the largest family of drug targets for therapeutics against human diseases. It is estimated that 30% to 40% of all drugs sold worldwide target GPCRs. Based on available data, we believe that there are 363 human non-sensory GPCRs, of which approximately 120 have no known ligands, and we refer to those receptors as orphan GPCRs. Without a known ligand, there is no template from which medicinal chemistry efforts can be readily initiated nor a means to identify the GPCR’s signaling pathway and, therefore, drugs cannot easily be developed against orphan GPCRs. “Unlocking” these

orphan GPCRs could lead to the development of drugs that act at these new targets. To our knowledge, despite efforts by others in the biopharmaceutical industry, Omeros' technology is the first commercially viable technology capable of identifying ligands of orphan GPCRs in high throughput.



We have scientific expertise in the field of GPCRs and members of our scientific team were the first to identify and characterize all non-sensory GPCRs common to mice and humans. Our work was published in a peer-reviewed article titled “The G protein-coupled receptor repertoires of human and mouse” that appeared in the April 2003 issue of Proceedings of the National Academy of Sciences (Vol. 100, No. 8: pp. 4903-4908). We also have developed a proprietary rapid mouse gene knock-out platform technology, which is described in a peer-reviewed article titled “Large-scale, saturating insertional mutagenesis of the mouse genome” that appeared in the September 2007 issue of Proceedings of the National Academy of Sciences (Vol. 104, No. 36: pp. 14406-14411). We have used this platform to create 61 different GPCR-specific strains of knock-out mice, and we have established a battery of behavioral tests that allows us to characterize these knock-out mice and identify candidate drug targets. The genes disrupted in these strains of knock-out mice include those linked to orphan GPCRs. In addition, we have developed a platform technology to efficiently produce reversible and inducible mouse gene knockout and rescue, which allows the mouse to fully develop before knocking out the gene rather than creating the knockout in the mouse embryo. As a result, we can evaluate the function of a gene even when its mutation would cause compensation by other genes or death during embryonic or neonatal development. This platform technology is described in a peer-reviewed article titled “An Inducible and Reversible Mouse Genetic Rescue System” that appeared in the May 2008 issue of PLoS Genetics (Vol. 4, Issue. 5).

Together with these assets, we have developed a proprietary cellular redistribution assay, or CRA, which we use in a high-throughput manner to identify synthetic ligands, including antagonists, agonists and inverse agonists, that bind to and affect the function of orphan GPCRs. We believe that we are the first to possess the capability to conduct high-throughput drug discovery for orphan GPCRs and that there is no other existing high-throughput technology able to “unlock” orphan GPCRs. We have been screening Class A orphan GPCRs against our small-molecule chemical libraries using the CRA. As of February 28, 2015, we had identified and confirmed compounds that interact with 54 Class A orphan GPCRs linked to a wide range of indications including cancer as well as metabolic, cardiovascular, inflammatory and central nervous system disorders. We have initiated medicinal chemistry efforts to optimize compounds against several orphan GPCRs including GPR17, tied to re-myelination, GPR151, linked to neuropathic pain, and GPR161, which is strongly associated with triple negative breast cancer.

In addition to Class A orphan GPCRs, we have also begun screening orphan and non-orphan Class B receptors. Class B GPCRs have large extracellular domains and their natural ligands are generally large peptides, making the development of orally active, small-molecule drugs against these receptors, such as glucagon and parathyroid hormone, a persistent challenge. Despite the fact that oral agents are not available, the current sales for the commercialized Class B GPCR-targeting peptide drugs are large. Our CRA technology finds functionally active small molecules for GPCRs, which we believe could lead to the development of oral medications for many of the Class B GPCRs. Our focus to date has remained on Class A orphan GPCRs and, as of February 28, 2015, we had identified and confirmed sets of compounds that interact selectively with, and modulate signaling of, a small subset of Class B GPCRs, namely glucagon-like peptide-1 receptor, or GLP-1R, and parathyroid hormone 1 receptor, or PTH-1R.

GPCR Platform Funding Agreements with Vulcan Inc. and the Life Sciences Discovery Fund. In October 2010, we entered into funding agreements for our GPCR program with Vulcan Inc. and its affiliate, which we refer to collectively as Vulcan, and an agreement with the Life Sciences Discovery Fund Authority, a granting agency of the State of Washington, or LSDF. We received \$20.0 million and \$5.0 million, respectively, under the agreements with Vulcan and LSDF. Under these agreements, we have agreed to pay Vulcan and LSDF tiered percentages of the net proceeds, if any, that we derive from the GPCR program. The percentage rates of net proceeds payable to Vulcan and LSDF decrease as the cumulative net proceeds reach specified thresholds, and the blended percentage rate payable to Vulcan and LSDF in the aggregate is in the mid-teens with respect to the first approximately \$1.5 billion of cumulative net proceeds that we receive from our GPCR program. If we receive cumulative net proceeds in excess of approximately \$1.5 billion, the percentage rate payable to Vulcan and LSDF in the aggregate decreases to one percent. Under our agreement with Vulcan, we granted Vulcan a security interest in our personal property related to the GPCR program, other than intellectual property, which security interest is junior to any existing or future security interests granted in connection with a financing transaction and which will be released automatically after Vulcan receives \$25.0 million under the agreement. We also agreed not to grant any liens on intellectual property related to the GPCR

program. The term of our agreement with Vulcan is 35 years, provided that the term will automatically extend until the cumulative net proceeds that we receive from the GPCR program are approximately \$1.5 billion.

The term of our agreement with LSDF expires on the six-month anniversary following the last date that we deliver a report related to our incurrence of grant-funded expenses described in the agreement, provided that certain obligations will survive the expiration of the term. The term of our payment obligations to LSDF is the same as that under our agreement with Vulcan.

## Antibody Platform

**Overview.** Our proprietary ex vivo platform for the discovery of novel, high-affinity monoclonal antibodies, which was in-licensed from the University of Washington and then further developed by our scientists, utilizes a chicken B-cell lymphoma cell line and has demonstrated potential for the generation of diverse antibodies that can be readily engineered. This platform offers several advantages over other antibody platforms. The ex vivo immunizations of our proprietary cell line are significantly more rapid than whole animal immunizations and conventional hybridoma technology. By avoiding immunization of mice or other animals, we believe the antibodies we generate from this platform are not limited by immunological tolerance. In addition, our platform is capable of producing novel antibodies against difficult targets, such as highly homologous proteins, enzymes, and receptors with short extracellular domains. Chicken antibodies also have unique features that enable binding capabilities distinct from mammalian antibodies. We have generated antibodies to several clinically significant targets, including highly potent antibodies against MASP-3, and our platform continues to add to our pipeline a series of antibodies against additional important targets.

**Asset Purchase Agreement with Xori Corporation.** In February 2012 we entered into an Asset Purchase Agreement, or the Xori APA, with Xori Corporation, or Xori, pursuant to which we acquired all of Xori's rights and obligations in certain license and material transfer agreements, intellectual property, antibodies and other assets related to our antibody platform. We are obligated to make development and research-related milestone payments to Xori.

**Exclusive License Agreement with the University of Washington.** We hold a worldwide exclusive license to patent rights related to our antibody platform from the University of Washington. For a more detailed description of this agreement, see "Business-License and Development Agreements."

## Sales and Marketing

We have retained all worldwide marketing and distribution rights to Omidria, our product candidates and our programs, which provides us the opportunity to market and sell Omidria or any of our product candidates, if approved, independently, to make arrangements with third parties to perform these services for us, or both.

With respect to Omidria, we have developed our own internal marketing and sales management capabilities and in the U.S. are utilizing a contract sales organization with 40 contract sales representatives solely dedicated to Omeros, all of whom are trained, in the field and calling on surgeons, hospitals and ambulatory surgery centers across the U.S. Because surgeons specializing in cataract surgery are a sub-specialty within ophthalmology, we believe that we can efficiently access high-volume surgeons with a small and focused sales organization. Third-party manufacturing agreements for commercial-scale manufacturing of Omidria in the U.S. and arrangements for the distribution of Omidria through a network of specialty pharmaceutical distributors and wholesalers have been established.

In the EU, we plan to out-license Omidria marketing rights to one or more third-parties that have capabilities to promote to ophthalmologic surgeons, to facilitate distribution and reimbursement, and to manage pharmacovigilance and clinical support. Outside of the U.S. and EU, we are exploring potential regional partnerships to make Omidria available to ophthalmologists. We have not yet entered into any agreements with third parties to market Omidria outside of the U.S. If we are unable to enter into one or more such agreements on terms acceptable to us, we would not expect to see sales of Omidria in those territories.

For the sales and marketing of many of our product candidates, we expect to retain marketing and distribution rights. For others, we expect to make arrangements with third parties to perform those services for us.

## Manufacturing

**Omidria.** We use third parties to produce, store and distribute Omidria and currently do not own or operate manufacturing facilities. We have agreements with Patheon Manufacturing Services, LLC (successor-in-interest to DSM Pharmaceuticals, Inc.), or Patheon, and with Hospira Worldwide, Inc., or Hospira, and Hospira S.p.A., for commercial supply of Omidria. These agreements include confidentiality and intellectual property provisions to protect our proprietary rights related to Omidria. We require manufacturers that produce APIs and finished drug products to operate in accordance with Good Manufacturing Practices, or cGMPs, and all other applicable laws and regulations.

Under the agreement with Patheon, or the Patheon Agreement, Patheon has agreed to manufacture and supply, and we have agreed to purchase, a minimum percentage of our commercial requirements for Omidria in the U.S. during a

term ending December 31, 2015. The Patheon Agreement may be terminated prior to the end of its term upon the occurrence of certain specified events, including any mandate from a regulatory authority prohibiting manufacture at Patheon's relevant facility in the absence of an agreement between the parties to transfer to an alternate Patheon facility. Upon termination of

the Patheon Agreement, we will be required to purchase any quantities of Omidria that are the subject of outstanding purchase orders placed prior to termination of the Patheon Agreement, except in certain circumstances, and will have the right to require Patheon to assist with a transfer of the Omidria manufacturing process to a new manufacturer other than Patheon, at our sole discretion and cost. If the Patheon agreement is terminated before we have completed manufacturing method transfer, validation and approval of Hospira as a manufacturing site for Omidria or an alternative Patheon facility as a manufacturing site for Omidria, we could have a shortage of supply of Omidria. Even if Hospira has been established as a manufacturing site for Omidria, if we elect not to transfer manufacturing of Omidria from the current Patheon facility to an alternative Patheon facility, or if Patheon is unable or unwilling to manufacture Omidria at Patheon's planned alternative facility, or if our supply agreement with Patheon is terminated, we will have only Hospira as a source of supply of Omidria, which may be inadequate to meet product demand. We might also elect to enter into an agreement with one or more facilities in addition to, or instead of, Hospira. The cost of transferring the Omidria manufacturing process to Hospira or to any other facility and potentially also to an alternate Patheon manufacturing facility or to a different manufacturer, or any significant delays in the timely completion of these transfers of the Omidria manufacturing process, could materially harm our business and prospects.

Under the agreement with Hospira and Hospira S.p.A., or the Hospira Omidria agreement, Hospira has agreed to manufacture and supply, and we have agreed to purchase, a minimum percentage of our requirements of Omidria for commercial sales and clinical supplies for the development of additional therapeutic indications in the U.S. In addition, upon receipt of marketing approval in the EU, Hospira has agreed to manufacture and supply a portion of our requirements of Omidria in the EU in an amount to be mutually agreed by the parties (not to exceed a maximum percentage of our EU requirements) within four months of marketing approval in Europe, with there being no minimum purchase and supply requirement in the EU if the parties do not reach agreement during such time period and the agreement is not amended thereafter. The Hospira Omidria agreement has an initial term of five years from the date of first commercial sale of Omidria in any country in the U.S. or EU, and thereafter is renewed automatically for up to two additional one-year periods. The Hospira Omidria agreement may be terminated prior to the end of its term upon the occurrence of certain specified events, including without limitation an uncured breach of the agreement or bankruptcy or dissolution of a party. Upon termination of the Hospira Omidria agreement, except in the case of termination for an uncured breach by Hospira, we will be required to purchase all of Hospira's inventory of Omidria and, if applicable, all work in progress inventory and reimburse Hospira for all supplies purchased or ordered based on firm purchase orders or our estimates of its requirements of Omidria. We are in the process currently of completing the manufacturing method transfer, validation and approval of Hospira as a manufacturing site for Omidria. Until this process is complete, Hospira may not manufacture and supply any of our requirements of Omidria.

We have used multiple suppliers for the Omidria APIs. Given the large amount of these APIs manufactured annually by these and other suppliers, and the quantities of these APIs we have on hand, we anticipate that we will be capable of addressing our commercial API supply needs for Omidria. We have not yet signed commercial agreements with suppliers for the supply of all of our anticipated commercial quantities of these APIs for Omidria, although we may elect to do so in the future.

**Product Candidates.** We have laboratories in-house for analytical method development, bioanalytical testing, formulation, stability testing and small-scale compounding of laboratory supplies of product candidates. We utilize contract manufacturers to produce sufficient quantities of product candidates for use in preclinical and clinical studies and to store and distribute our product candidates, and currently do not own or operate manufacturing facilities for our product candidates. We require manufacturers that produce APIs and finished drug products for clinical use to operate in accordance with cGMPs and all other applicable laws and regulations. We anticipate that we will rely on contract manufacturers to develop and manufacture our product candidates for commercial sale. We maintain agreements with potential and existing manufacturers that include confidentiality and intellectual property provisions to protect our proprietary rights related to our product candidates.

We have entered into agreements with Hospira pursuant to which Hospira has manufactured three registration batches of liquid OMS103 at its facility in McPherson, Kansas, and agreed to manufacture and supply our commercial requirements of liquid OMS103, if approved for marketing. Pursuant to the OMS103 commercial supply agreement

with Hospira, Hospira has agreed to provide, and we have agreed to purchase, a minimum quantity of our commercial supply needs of OMS103, following approval for marketing, at a price based on the volume of our purchases. The term of this commercial supply agreement continues until five years after the commercial launch of OMS103 and automatically extends for up to two additional one-year periods unless either party gives notice that it intends to terminate the agreement at least two years prior to the beginning of an extension period.

We have utilized multiple suppliers for the APIs used in our clinical supplies of OMS103. Given the large amount of these APIs manufactured annually by these and other suppliers, and the quantities of these APIs we have on hand, we

anticipate that we will be capable of addressing our commercial API supply needs for OMS103. We have not yet signed commercial agreements with suppliers for the supply of all of our anticipated commercial quantities of these APIs for OMS103, although we may elect to do so in the future.

Other than for OMS103, we have not yet entered into a commercial supply agreement for any of our product candidates, although we intend to do so prior to the applicable product candidate's commercial launch. Given the nature of the manufacturing processes of our product candidates, we anticipate that we will be capable of identifying contract manufacturers capable of producing these product candidates and entering into agreements for the commercial supply of these drugs.

#### License and Development Agreements

**MASP Program.** Under our exclusive license agreements with the University of Leicester and MRC, we have agreed to pay royalties to each of the University of Leicester and MRC that are a percentage of any proceeds we receive from the licensed MASP-2 technology during the terms of the agreements. Our exclusive license agreement with the University of Leicester, but not our agreement with the MRC, also applies to other MASPs. We must pay low single-digit percentage royalties with respect to proceeds that we receive from products incorporating the licensed technology that are used, manufactured, directly sold or directly distributed by us, and we must pay royalties, in the range of a low single-digit percentage to a low double-digit percentage, with respect to proceeds we receive from sublicense royalties or fees that we receive from third parties to which we grant sublicenses to the licensed technology. We did not make any upfront payments for these exclusive licenses nor are there any milestone payments or reversion rights associated with these license agreements. We also agreed to sponsor research of MASP-2 at these institutions at pre-determined rates for maximum terms of approximately three years. We have agreed to expand the scope of research at the University of Leicester to MASP-3 and have continued the sponsorship of research at the University of Leicester on a year-by-year basis. If mutually agreed, we may sponsor additional research related to MASP-2 at MRC, and to MASP-2 and MASP-3 at the University of Leicester. We retain worldwide exclusive licenses from these institutions to develop and commercialize any intellectual property rights developed in the sponsored research. The term of each license agreement ends when there are no longer any pending patent applications, applications in preparation or unexpired issued patents related to any of the intellectual property rights we are licensing under the agreement. Both of these license agreements may be terminated prior to the end of their terms by us for convenience or by one party if the other party (1) breaches any material obligation under the agreement and does not cure such breach after notice and an opportunity to cure or (2) is declared or adjudged to be insolvent, bankrupt or in receivership and materially limited from performing its obligations under the agreement. In April 2010, we entered into an exclusive license agreement with Helion Biotech ApS, or Helion, pursuant to which we received a royalty-bearing, worldwide exclusive license to all of Helion's intellectual property rights related to MASP-2 antibodies, polypeptides and methods in the field of inhibition of mannan-binding lectin-mediated activation of the complement system for the prevention, treatment or diagnosis of any disease or condition. We are obligated to make remaining development and sales milestone payments to Helion of up to \$6.1 million upon the achievement of certain events, such as the filing of an IND with the FDA, initiation of Phase 2 and 3 clinical trials, receipt of marketing approval, and reaching specified sales milestones. We are obligated to pay Helion a low single-digit percentage royalty on net sales of a MASP-2 inhibitor product covered by the patents licensed under the agreement. The term of the agreement continues so long as there is a valid, subsisting and enforceable claim in any patents or patent applications covered by the agreement. The agreement may be terminated sooner by either party following a material breach of the agreement by the other party that has not been cured within 90 days.

**OMS824.** Our preclinical development of OMS824 was supported by funds from SMRI. Under our funding agreement with SMRI, we received \$5.7 million from SMRI, \$3.2 million of which was recorded as equity funding and \$2.5 million of which was recorded as revenue. We have agreed to pay royalties to SMRI based on any net income we receive from sales of a PDE10 product until we have paid a maximum aggregate amount that is a low single-digit multiple of the amount of grant funding that we have received from SMRI. This multiple increases as time elapses from the date we received the grant funding. There are no minimum payment obligations under our agreement with SMRI. Based on the amount of grant funding that we received from SMRI, the maximum amount of royalties payable to SMRI is \$12.8 million and payment is required only from any net income we receive from sales of a

PDE10 product. The funding agreement and our obligation to pay a royalty to SMRI terminate when we have repaid such amount in the form of royalties.

PPAR . We acquired the patent applications and related intellectual property rights for our PPAR program in February 2009 from Roberto Ciccocioppo, Ph.D. of the Università di Camerino, Italy, pursuant to a patent assignment agreement. In February 2011, we amended the agreement to include all intellectual property rights, including patent applications, related to nutraceuticals that increase PPAR activity. Under the amended agreement, we have agreed to pay Dr. Ciccocioppo a low-single digit percentage royalty on net sales of any products that are covered by any patents that



issue from the patent applications that we acquired from him. In addition, if we grant any third parties rights to manufacture, sell or distribute any such products, we must pay to Dr. Ciccocioppo a percentage of any associated fees we receive from such third parties in the range of low single-digits to low double-digits depending on the stage of development at which such rights are granted. We have also agreed to make total milestone payments of up to \$3.8 million to Dr. Ciccocioppo upon the occurrence of certain development events, such as patient enrollment in a Phase 1 clinical trial and receipt of marketing approval of a product candidate covered by any patents that issue from the patent applications that we acquired from him. If we notify Dr. Ciccocioppo that we have abandoned all research and development and commercialization efforts related to the patent applications and intellectual property rights we acquired from him, Dr. Ciccocioppo has the right to repurchase those assets from us at a price equal to a double-digit percentage of our direct and indirect financial investments and expenditures in such assets. If he does not exercise his right to repurchase those assets within a limited period of time by paying the purchase price, we will have no further obligations to sell those assets to Dr. Ciccocioppo. The term of our agreement with Dr. Ciccocioppo ends when there are no longer any valid and enforceable patents related to the intellectual property rights we acquired from him, provided that either party may terminate the agreement earlier in case of an uncured breach by the other party. Under the terms of the agreement, we have agreed to pay a portion of the payments due to Dr. Ciccocioppo to the Università di Camerino without any increase to our payment obligations.

**PDE7.** Under an agreement with Daiichi Sankyo, we hold an exclusive license to PDE7 inhibitors claimed in certain patents and pending patent applications owned by Daiichi Sankyo for use in the treatment of (1) movement disorders and other specified indications, (2) addiction and compulsive disorders and (3) all other diseases except those related to dermatologic conditions. Under the agreement, we agreed to make milestone payments to Daiichi Sankyo of up to an aggregate total of \$33.5 million upon the achievement of certain events in each of these three fields; however, if only one of the three indications is advanced through the milestones, the total milestone payments would be \$23.5 million. The milestone payment events include successful completion of preclinical toxicology studies; dosing of human subjects in Phase 1, 2 and 3 clinical trials; receipt of marketing approval of a PDE7 inhibitor product candidate; and reaching specified sales milestones. In addition, Daiichi Sankyo is entitled to receive from us a low single-digit percentage royalty of any net sales of a PDE7 inhibitor licensed under the agreement by us and/or our sublicensee(s) provided that, if the sales are made by a sublicensee, then the amount payable by us to Daiichi Sankyo is capped at an amount equal to a low double-digit percentage of all royalty and specified milestone payments received by us from the sublicensee.

The term of the agreement with Daiichi Sankyo continues so long as there is a valid, subsisting and enforceable claim in any patents covered by the agreement. The agreement may be terminated sooner by us, with or without cause, upon 90 days advance written notice or by either party following a material breach of the agreement by the other party that has not been cured within 90 days or immediately if the other party is insolvent or bankrupt. Daiichi Sankyo also has the right to terminate the agreement if we and our sublicensee(s) cease to conduct all research, development and/or commercialization activities for a PDE7 inhibitor covered by the agreement for a period of six consecutive months, in which case all rights held by us under Daiichi Sankyo's patents will revert to Daiichi Sankyo.

**OMS616.** On December 14, 2010, we entered into a license agreement with The Regents, pursuant to which we received an exclusive license to a series of antifibrinolytic agents claimed in certain patents owned by The Regents in exchange for our agreement to make royalty and development milestone payments.

**Antibody Platform.** We hold a worldwide exclusive license to patent rights related to our antibody platform from the University of Washington, or UW. Pursuant to the Xori APA, we acquired all of Xori's exclusive rights under a license agreement with the UW to certain patents and patent applications related to our antibody platform owned by the UW in exchange for our agreement to make royalty and development milestone payments to UW.

#### Competition

The pharmaceutical industry is highly competitive and characterized by a number of established, large pharmaceutical companies, as well as smaller companies like ours. We expect to compete with other pharmaceutical and biotechnology companies, and our competitors may:

- develop and market products that are less expensive, more effective or safer than our future products;
- commercialize competing products before we can launch our products;

operate larger research and development programs, possess greater manufacturing capabilities or have substantially greater financial resources than we do;  
initiate or withstand substantial price competition more successfully than we can;

have greater success in recruiting skilled technical and scientific workers from the limited pool of available talent; more effectively negotiate third-party licenses and strategic relationships; and take advantage of acquisition or other opportunities more readily than we can.

We expect to compete for market share against large pharmaceutical and biotechnology companies, smaller companies that are collaborating with larger pharmaceutical companies, new companies, academic institutions, government agencies and other public and private research organizations. In addition, the pharmaceutical and biotechnology industry is characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to remain current with the rapid changes in each technology. Further, our competitors may render our technologies obsolete by advancing their existing technological approaches or developing new or different approaches. If we fail to stay at the forefront of technological change, we may be unable to compete effectively.

We are not aware of any products comprised of two or more APIs that directly compete with Omidria, or our PharmacoSurgery product candidates, that are approved for intraoperative delivery in irrigation solutions during surgical procedures; however, Omidria and our PharmacoSurgery product candidates could compete with single API products that are delivered intraoperatively as well as preoperative and postoperative treatments for mydriasis, pain or inflammation.

While we do not anticipate traditional product competition for Omidria from other biopharmaceutical companies, our primary competition could come from surgeons' current practices, which may include use of products obtained from distributors or compounding pharmacies at a relatively low cost. In addition, we anticipate that there are some surgeons who do not use intraoperative mydriatics and may not agree with the value proposition of maintaining pupil dilation and inhibiting miosis during the procedure or with the use of a nonsteroidal anti-inflammatory drug, or NSAID, intraoperatively to reduce inflammation and postoperative pain. Although we are not aware of any companies developing similar combination approaches for maintenance of intraoperative pupil size and postoperative pain reduction, such strategies may develop now that Omidria is marketed in the U.S.

Our clinical and preclinical product candidates may face competing products. For example, we are developing PDE10 inhibitors for use in the treatment of schizophrenia, Huntington's disease and other diseases that affect cognition. Other pharmaceutical companies, many with significantly greater resources than we have, are also developing PDE10 inhibitors for the treatment of schizophrenia, Huntington's disease and other diseases that affect cognition and these companies may be further along in development. In addition, Soliris® is the only complement inhibitor approved for commercial use, and our lead MASP-2 inhibitor OMS721 will have to compete with Soliris® if it is approved for any indication(s) for which Soliris® is also approved. Additionally, The Nordic Group is currently authorized to market Trasylol® in Europe for patients undergoing coronary artery bypass graft surgery. In September 2011, the marketing authorization for Trasylol® was also reinstated in Canada, with additional safety warnings, for patients undergoing coronary artery bypass graft surgery. Any product candidate that we develop in our Plasmin program for the same indication would directly compete with Trasylol® in any countries in which Trasylol® is authorized to be marketed. Also, we are aware that other companies are attempting to de-orphanize orphan GPCRs. If any of these companies is able to de-orphanize an orphan GPCR before we do, we may be unable to establish an exclusive or commercially valuable intellectual property position around that orphan GPCR.

#### Intellectual Property

As of February 28, 2015, we owned or held worldwide exclusive licenses to a total of 41 issued patents and 66 pending patent applications in the U.S. and 271 issued patents and 300 pending patent applications in foreign markets directed to therapeutic compositions and methods related to our development programs. For each program, our decision to seek patent protection in specific foreign markets, in addition to the U.S., is based on many factors, including one or more of the following: our available resources, the size of the commercial market, the presence of a potential competitor or a contract manufacturer in the market and whether the legal authorities in the market effectively enforce patent rights.

Our patent portfolio for our PharmacoSurgery technology is directed to locally delivered compositions and treatment methods using agents selected from broad therapeutic classes. These patents and patent applications are directed to combinations of agents, generic and/or proprietary to us or to others, delivered locally and intraoperatively to the site

of any medical or surgical procedure. As of February 28, 2015, our patent portfolio included six U.S. and 79 foreign issued or allowed patents, and nine U.S. and 29 foreign pending patent applications, directed to our PharmacoSurgery products and development programs. Our issued PharmacoSurgery patents have terms that will expire as late as July 30, 2023 for Omidria, September 24, 2022 for OMS103, and July 16, 2029 for OMS201, and, if currently pending patent applications are issued, as late as December 1, 2035 for Omidria, August 3, 2032 for OMS103, and March 17, 2026 for OMS201.

Our pending PharmacoSurgery patent applications are directed to combinations of agents, drawn from therapeutic classes such as pain and inflammation inhibitory agents, spasm inhibitory agents, vasoconstrictive agents, mydriatic agents and agents that reduce intraocular pressure, that are used in ophthalmologic procedures including intraocular procedures, arthroscopic procedures, and urologic procedures including ureteroscopy, for Omidria, OMS103 and OMS201, respectively, as well as covering the specific combinations of agents included in each of these products and product candidates.

**Omidria-Ophthalmology.** Omidria is encompassed by our PharmacoSurgery patent portfolio. The relevant patents and patent applications in this portfolio are directed to combinations of agents, generic and/or proprietary to us or others, drawn from therapeutic classes such as pain and inflammation inhibitory agents, mydriatic agents and agents that reduce intraocular pressure, delivered locally and intra-operatively to the site of ophthalmological procedures, including cataract and lens replacement surgery. As of February 28, 2015, we owned two issued U.S. patents and four pending U.S. patent applications and 29 issued patents and 11 pending patent applications in foreign markets (Argentina, Australia, Canada, China, Europe, Hong Kong, Japan and International Patent Cooperation Treaty) that are directed to Omidria.

**OMS103-Arthroscopy.** OMS103 is encompassed by our PharmacoSurgery patent portfolio. The relevant patents and patent applications in this portfolio are directed to combinations of agents, generic and/or proprietary to us or others, drawn from therapeutic classes such as pain and inflammation inhibitory agents and vasoconstrictive agents, delivered locally and intra-operatively to the site of medical or surgical procedures, including arthroscopy. As of February 28, 2015, we owned two issued U.S. patents, three pending U.S. patent applications, and 42 issued patents and 16 pending patent applications in foreign markets that are directed to OMS103.

**OMS201-Urology.** OMS201 is encompassed by our PharmacoSurgery patent portfolio. The relevant patents and patent applications in this portfolio are directed to combinations of agents, generic and/or proprietary to us or others, drawn from therapeutic classes such as pain and inflammation inhibitory agents and spasm inhibitory agents, delivered locally and intra-operatively to the site of medical or surgical procedures, including uroendoscopy. As of February 28, 2015, we owned one issued U.S. patent, two pending U.S. patent applications, and an additional 36 issued patents and three pending patent applications in foreign markets that are directed to OMS201.

**PDE10 Program - OMS824.** As of February 28, 2015, we own five issued patents and six pending patent application in the U.S., and four issued patents and 29 pending patent applications in foreign markets that are directed to proprietary PDE10 inhibitors.

**PPAR Program - OMS405.** As of February 28, 2015, we owned one issued patent and three pending patent applications in the U.S. and 11 issued patents and 29 pending patent applications in foreign markets directed to our recent discoveries linking PPAR and addictive disorders.

**MASP Program - OMS721.** We hold worldwide exclusive licenses to rights in connection with MASP-2, the antibodies targeting MASP-2 and the therapeutic applications for those antibodies from the University of Leicester, MRC and Helion. As of February 28, 2015, we exclusively controlled 11 issued patents and 18 pending patent applications in the U.S., and 21 issued patents and 93 pending patent applications in foreign markets related to our MASP-2 program and related complement targets.

**PDE7 Program - OMS527.** As of February 28, 2015, we owned one issued patent and two pending patent applications in the U.S., and 10 issued patents and 22 pending patent applications in foreign markets directed to our discoveries linking PDE7 to movement disorders, as well as two pending patent applications in the U.S., and one issued patent and 28 pending patent applications in foreign markets directed to the link between PDE7 and addiction and compulsive disorders. Additionally, under a license from Daiichi Sankyo we exclusively control rights to two issued U.S. patents and one pending U.S. patent application, and 56 issued and six pending patent applications in foreign markets that are directed to proprietary PDE7 inhibitors. For a more detailed description of our agreement with Daiichi Sankyo, see "Business-License and Development Agreements."

**Plasmin Program - OMS616.** We hold worldwide exclusive licenses to a series of antifibrinolytic agents from The Regents. As of January 24, 2015, we exclusively controlled two issued patents and two pending patent application in the U.S. and 21 issued and eight pending patent applications in foreign markets that are directed to these proprietary

agents.

MASP Program - OMS906. We hold worldwide exclusive licenses to a series of antifibrinolytic agents from The Regents. As of February 28, 2015, we exclusively controlled two issued patents and three pending patent

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application in the U.S. and 21 issued and eight pending patent applications in foreign markets that are directed to these proprietary agents.

**GPR17.** As of February 28, 2015, we owned three pending patent applications in the U.S. directed to compounds that functionally interact with GPR17 and their therapeutic applications.

**GPCR Platform.** As of February 28, 2015, we owned five issued patents and 16 pending patent applications in the U.S., and 43 issued patents and eight pending patent applications in foreign markets, which are directed to previously unknown links between specific molecular targets in the brain and a series of CNS disorders, our cellular redistribution assay and other research tools that are used in our GPCR program and to orphan GPCRs and other GPCRs for which we have identified functionally interacting compounds using our cellular redistribution assay.

**Antibody Platform.** As of February 28, 2015, we owned and/or held worldwide exclusive license rights from the UW to two issued patents and three pending patent applications in the U.S., and two issued patents and fifteen pending patent applications in foreign markets directed to our antibody platform. Additionally, we owned one issued U.S. patent, two pending U.S. patent applications and eight pending foreign applications directed to antibodies generated using our platform.

All of our employees enter into our standard employee proprietary information and inventions agreement, which includes confidentiality provisions and provides us ownership of all inventions and other intellectual property made by our employees that pertain to our business or that relate to our employees' work for us or that result from the use of our resources. Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of the use, formulation and structure of our products and product candidates and the methods used to manufacture them, as well as on our ability to defend successfully these patents against third-party challenges. Our ability to protect our products and product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the U.S., and tests used for determining the patentability of patent claims in all technologies are in flux. The pharmaceutical, biotechnology and other life sciences patent situation outside the U.S. is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents that we own or have licensed or in third-party patents.

We have retained all worldwide manufacturing, marketing and distribution rights for Omidria and each of our product candidates and programs. Some of our products and product candidates and programs are based on inventions and other intellectual property rights that we acquired through assignments, exclusive licenses or acquisitions.

**PharmacoSurgery Platform.** Our scientific co-founders, Gregory A. Demopoulos, M.D. and Pamela Pierce Palmer, M.D., Ph.D., conceived the initial invention underlying our PharmacoSurgery platform and transferred all of their related intellectual property rights to us in 1994. Other than their rights as shareholders, our co-founders have not retained any rights to our PharmacoSurgery platform, except that if we file for liquidation under Chapter 7 of the U.S. Bankruptcy Act or voluntarily liquidate or dissolve, other than in connection with a merger, reorganization, consolidation or sale of assets, our co-founders have the right to repurchase the initial PharmacoSurgery intellectual property at the then-current fair market value. Subsequent developments of the PharmacoSurgery intellectual property were assigned to us by Dr. Demopoulos, Dr. Palmer and other of our employees and consultants, without restriction.

**PDE10 and PDE7 Programs.** We acquired our PDE10 and PDE7 programs and some of our related patents and other intellectual property rights as a result of our acquisition of nura, inc. We hold an exclusive license to certain PDE7 inhibitors claimed in patents and pending patent applications owned by Daiichi Sankyo for use in the treatment of movement, addiction and compulsive disorders as well as other specified indications. For a more detailed description of our agreement with Daiichi Sankyo, see "Business-License and Development Agreements."

**MASP Program.** We hold worldwide exclusive licenses to rights related to MASP-2, the antibodies targeting MASP-2 and the therapeutic applications for the antibodies from the University of Leicester, MRC and Helion. We jointly own

and hold worldwide exclusive license rights related to therapeutic applications for inhibiting



MASP-3 from the University of Leicester. For more detailed descriptions of these licenses, see “Business-License and Development Agreements.”

**PPAR Program.** We acquired the patent applications and related intellectual property rights for our PPAR program in 2009 from Roberto Ciccocioppo, Ph.D., of the Università di Camerino, Italy, pursuant to a patent assignment agreement. For a more detailed description of this agreement, see “Business-License and Development Agreements.”

**Plasmin Program.** We hold a worldwide exclusive license to patent rights related to certain antifibrinolytics from The Regents. For a more detailed description of this agreement, see “Business-License and Development Agreements.”

**GPCR Platform.** We acquired our GPCR program and some of our related patents and other intellectual property rights as a result of our acquisition of nura, inc. In November of 2010 we acquired intellectual property rights related to an assay technology for our GPCR program from Patobios Limited for approximately \$10.8 million.

**Antibody Platform.** We hold a worldwide exclusive license to patent rights related to our antibody platform from the UW. For a more detailed description of this agreement, see “Business-License and Development Agreements.”

#### Government Regulation

Government authorities in the U.S., the EU and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution, marketing, and export and import of drug and biologic products such as those we are developing. Failure to comply with applicable requirements, both before and after approval, may subject us, our third-party manufacturers, and other partners to administrative and judicial sanctions, such as warning letters, product recalls, product seizures, a delay in approving or refusal to approve pending applications, civil and other monetary penalties, total or partial suspension of production or distribution, injunctions, and/or criminal prosecutions.

In the U.S., our products and product candidates are regulated by the FDA as drugs or biologics under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations and, in the case of biologics, also under the Public Health Service Act. In Europe, our products and product candidates are regulated by the EMA and national medicines regulators under the rules governing medicinal products in the EU as well as national regulations in individual countries. Omidria has received marketing approval from the FDA, but has not received marketing approval from applicable regulatory authorities in the EU. Our product candidates are in various stages of testing and none has received marketing approval from the FDA or the applicable regulatory authorities in the EU.

The steps required before a product may be approved for marketing by the FDA or the applicable regulatory authorities typically include the following:

- formulation development and manufacturing process development;
- preclinical laboratory and animal testing;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin; and in Europe, a CTA is filed according to the country’s local regulations;
- adequate and well-controlled human clinical trials to establish the efficacy and safety of the product for each indication for which approval is sought;
- adequate assessment of drug product stability to determine shelf life/expiry dating;
- in Europe, submission to the EMA or national regulatory authority of an MAA, and in the U.S., submission to the FDA of an NDA, in the case of a drug product, or a biologics license application, or BLA, in the case of a biologic product;
- satisfactory completion of inspections of clinical sites and the manufacturing facility or facilities at which the product is produced to assess compliance with current Good Clinical Practices, or cGCP, and cGMP; and
- FDA review and approval of an NDA or BLA, or review and approval of an MAA by the applicable regulatory authorities in the EU.

**Manufacturing.** Manufacturing of drug products for use in clinical trials must be conducted according to relevant national guidelines, for example, cGMP. Process and formulation development are undertaken to design suitable routes to manufacture the drug substance and the drug product for administration to animals or humans. Analytical development is



undertaken to obtain methods to quantify the potency, purity and stability of the drug substance and drug product as well as to measure the amount of the drug substance and its metabolites in biological fluids, such as the blood.

**Preclinical Tests.** Preclinical tests include laboratory evaluations and animal studies to assess efficacy, toxicity and pharmacokinetics. The results of the preclinical tests, together with manufacturing information, analytical data, clinical development plan, and other available information are submitted as part of an IND application or CTA.

**The IND/CTA Process.** An IND application or CTA must become effective before human clinical trials may begin.

An IND application will automatically become effective 30 days after receipt by the FDA unless, before that time, the FDA raises concerns or questions and imposes a clinical hold. In that event, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before the clinical hold is lifted and clinical trials can proceed.

Similarly, a CTA must be cleared by the local independent ethics committee and competent authority prior to conducting a clinical trial in the European country in which it was submitted. This process can take from two weeks to several months. There can be no assurance that submission of an IND application or CTA will result in authorization to commence clinical trials. Once an IND application or CTA is in effect, there are certain reporting requirements.

**Clinical Trials.** Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified personnel and must be conducted in accordance with local regulations and cGCP. Clinical trials are conducted under protocols detailing, for example, the parameters to be used in monitoring patient safety and the efficacy criteria, or endpoints, to be evaluated. Each trial must be reviewed and approved by an independent Institutional Review Board or Ethics Committee for each clinical site at which the trial will be conducted before it can begin. Clinical trials are typically conducted in three defined phases, but the phases may overlap or be combined:

Phase 1 usually involves the initial administration of the investigational product to human subjects, who may or may not have the disease or condition for which the product is being developed, to evaluate the safety, dosage tolerance, pharmacodynamics and, if possible, to gain an early indication of the effectiveness of the product.

Phase 2 usually involves trials in a limited patient population with the disease or condition for which the product is being developed to evaluate appropriate dosage, to identify possible adverse side effects and safety risks, and to evaluate preliminarily the effectiveness of the product for specific indications.

Phase 3 clinical trials usually further evaluate and confirm effectiveness and test further for safety by administering the product in its final form in an expanded patient population.

We, our product development partners, Institutional Review Boards or Ethics Committees, the FDA or other regulatory authorities may suspend clinical trials at any time on various grounds, including a belief that the subjects are being exposed to an unacceptable health risk.

**The Application Process.** If the necessary clinical trials are successfully completed, the results of the preclinical trials and the clinical trials, together with other detailed information, including information on the manufacture and composition of the product, are submitted to the FDA in the form of an NDA or a BLA, as applicable, and to the EMA or national regulators in the form of an MAA, requesting approval to market the product for a specified indication. In the EU, an MAA may be submitted to the EMA for review and, if the EMA gives a positive opinion, the European Commission may grant a marketing authorization that is valid across the EU (centralized procedure). Alternatively, an MAA may be submitted to one or more national regulators in the EU according to one of several national or decentralized procedures. The type of submission in Europe depends on various factors and must be cleared by the appropriate authority prior to submission. For most of our product candidates, the centralized procedure will be either mandatory or available as an option.

If the regulatory authority determines the application is not acceptable, they may refuse to accept the application for filing and review, outlining the deficiencies in the application and specifying additional information needed to file the application. Notwithstanding the submission of any requested additional testing or information, the regulatory authority ultimately may decide that the application does not satisfy the criteria for approval. Before approving an NDA or BLA, or an MAA, the FDA or the EMA, respectively, may inspect the clinical sites at which the Phase 3 study(ies) were conducted to assure that GCPs were followed and may inspect facility(ies) at which the product is manufactured to assure satisfactory compliance with cGMP. After approval, changes to the approved product such as adding new indications, manufacturing changes, or additional labeling claims will require submission of a supplemental application or, in some instances, a new application, for further review and approval. The testing and

approval process requires substantial time, effort, and financial resources, and we cannot be sure that any future approval will be granted on a timely basis, if at all.

Some of our drug products may be eligible for submission to the FDA of NDAs for approval under the Section 505(b)(2) process. Section 505(b)(2) applications may be submitted for drug products that represent a modification, such as a new indication or new dosage form, of a previously approved drug. Section 505(b)(2) applications may rely on the FDA's

previous findings for the safety and effectiveness of the previously approved drug in addition to information obtained by the 505(b)(2) applicant to support the modification of the previously approved drug. Preparing Section 505(b)(2) applications may be less costly and time-consuming than preparing an NDA based entirely on new data and information.

The FDA regulates certain of our products and product candidates, such as Omidria and OMS103, as fixed-dose combination drugs under its Combination Drug Policy (21 CFR Section 300.50) because they are comprised of two or more active ingredients. In addition to demonstrating that the drug product is safe and effective, the FDA's Combination Drug Policy requires that we demonstrate that each active ingredient in a drug product contributes to the product's effectiveness. The EMA has a similar Guideline for fixed-dose combination products. Satisfaction of the U.S. or EU requirements for fixed-dose combination products may involve substantial time, effort, and financial resources, and we cannot be sure that work conducted to satisfy these requirements will be deemed acceptable by the applicable regulatory authority. For example, the FDA has maintained questions regarding whether available data and information provided to the FDA demonstrate the contribution of each active ingredient in OMS103. If the data from any subsequent trials that we may conduct to show a contribution from each drug in the OMS103 combination are negative or not acceptable to regulatory authorities, we may be unable to seek, or be significantly delayed in seeking, marketing approval of OMS103.

Some of our product candidates, such as those from our MASP-2 and Plasmin programs, are considered biologics because they are derived from natural sources as opposed to being chemically synthesized. The added complexity associated with manufacturing biologics may result in additional monitoring of the manufacturing process and product changes.

In addition, we, our suppliers, and our contract manufacturers are required to comply with extensive FDA and EMA requirements both before and after approval. For example, we must establish a pharmacovigilance system and are required to report adverse reactions and production problems, if any, to the regulatory authorities. We must also comply with certain requirements concerning advertising and promotion for our products. The regulatory authorities may impose specific obligations as a condition of the marketing authorization, such as additional safety monitoring, or the conduct of additional clinical trials or post-marketing safety studies. Also, quality control and manufacturing procedures must continue to conform to cGMPs after approval. Accordingly, manufacturers must continue to expend time, money, and effort in all areas of regulatory compliance, including production and quality control to comply with cGMPs. In addition, discovery of problems such as safety issues may result in changes in labeling or restrictions on a product manufacturer or marketing authorization holder, including removal of the product from the market.

**Programs for Expedited Review.** Section 506(b) of the FDCA provides for the designation of a drug as a fast track product if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. A program with Fast Track status is afforded greater access to the FDA for the purpose of expediting the product's development, review and potential approval. Many products that receive Fast Track designation are also considered appropriate to receive Priority Review, and their respective applications may be accepted by the FDA as a rolling submission in which portions of an NDA are reviewed before the complete application is submitted. Together, these may reduce time of development and FDA review time. In Europe, products that are considered to be of major public health interest are eligible for accelerated assessment, which shortens the review period substantially. The grant of Fast Track status, Priority Review or accelerated assessment does not alter the standard regulatory requirements for obtaining marketing approval, however.

**Orphan Drug Designation.** Under the Orphan Drug Act, or ODA, the FDA may grant orphan drug designation to drugs or biologics intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the U.S. or more than 200,000 individuals in the U.S. for which the cost of developing and making the product available in the U.S. for this type of disease or condition is not likely to be recovered from U.S. sales for that product. The granting of orphan designation does not alter the standard regulatory requirements and process for obtaining marketing approval. If a product that has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the sponsor of the product qualifies for various development incentives specified in the ODA, including tax credits for qualified clinical testing. Furthermore, the product is entitled to an orphan drug

exclusivity period, which means the FDA may not grant approval to any other application to market the same drug for the same indication for a period of seven years except in limited circumstances. The EU has a similar Orphan Drug program to that of the U.S., and it is administered through the EMA's Committee for Orphan Medicinal Products, or COMP.

**Pediatric Testing and Exclusivity.** In the United States, NDAs and BLAs are subject to both mandatory pediatric testing requirements and voluntary pediatric testing incentives in the form of pediatric exclusivity. An additional six months of exclusivity in the U.S. may be granted to a sponsor of an NDA or BLA if the sponsor conducts certain pediatric studies. This process is initiated by the FDA as a written request for pediatric studies to determine if the drug or biologic

could have meaningful pediatric health benefits. If the FDA determines that the sponsor has conducted the requested pediatric studies in accordance with the written request, then an additional six months of pediatric exclusivity may attach in the case of a drug to any other regulatory exclusivity or patent protection applicable to the drug, and in the case of a biologic to any other regulatory exclusivity applicable to the biologic. The EU has a similar requirement and incentive for the conduct of pediatric studies according to the pediatric investigation plan, which must be adopted by the EMA before an MAA may be submitted.

**Labeling, Marketing, and Promotion.** The FDA closely regulates the labeling, marketing and promotion of drugs. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, injunctions and potential civil and criminal penalties.

In addition, in the United States, the research, manufacturing, distribution, sale and promotion of drug products are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including CMS, 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. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws. Violations of these laws are punishable by prison sentences, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs.

There are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information or impose other special requirements for the sale and marketing of drug products. Many of these laws contain ambiguities as to what is required to comply with the laws. In addition, a provision in the Patient Protection and Affordable Care Act of 2010, or ACA, known as the “Sunshine Act” now requires manufacturers to track and report to the federal government certain payments made to physicians and teaching hospitals made in the previous calendar year, and a related provision of the ACA similarly requires us to report drug samples that we distribute. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition, our reporting actions could be subject to the penalty provisions of the pertinent state and federal authorities.

**Compounding Pharmacies and Registered Outsourcing Facilities.** Title I (the Compounding Quality Act) of the DQSA, which was enacted in November 2013, amends the FDCA to establish a distinct category of drug compounders known as “outsourcing facilities.” A compounding pharmacy who elects to register with the FDA as an outsourcing facility is exempt from certain FDCA requirements, including the obligation to obtain FDA approval of an NDA, if the facility satisfies conditions set out in the statute. The DQSA also imposes restrictions on the materials that may be compounded at registered outsourcing facilities. Like “traditional” pharmacy compounders, such as those found in hospitals, outsourcing facilities may not compound drugs that are “essentially a copy of one or more approved drugs” or that present “demonstrable difficulties for compounding.” The statute also imposes conditions on the compounding of bulk substances. The FDA has identified compounding as an enforcement priority in 2015, but it remains to be seen how the agency will interpret key provisions of the DQSA, such as the prohibition on compounding drugs that are “essentially a copy of one or more approved drugs,” and to what extent the DQSA gives the agency sufficient authority to regulate compounding activities in violation of the FDCA.

**Foreign Regulatory Requirements.** Outside of the United States, our ability to conduct clinical trials or market our products will also depend on receiving the requisite authorizations from the appropriate regulatory authorities. The foreign regulatory approval processes include similar requirements and many of the risks associated with the FDA and/or the EMA approval process described above, although the precise requirements may vary from country to country.

#### **Pharmaceutical Pricing and Reimbursement**

**Overview.** In both U.S. and foreign markets, our ability to commercialize our products and product candidates successfully, and to attract commercialization partners for our products and product candidates, depends in significant part on the availability of adequate financial coverage and reimbursement from third-party payers including, in the U.S., managed care organizations, private health insurers and governmental payers such as the Medicare and Medicaid programs. Third-party payers are increasingly challenging the prices charged for medicines and examining their cost effectiveness in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in

order to demonstrate the cost effectiveness of our products or product candidates. Even with the availability of such studies, third-party payers may not provide coverage and reimbursement for our products or product candidates, in whole or in part.

United States. Political, economic and regulatory influences are subjecting the healthcare industry in the U.S. to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals, such as the Patient Protection and Affordable Care Act of 2010, to change the healthcare system in ways that could significantly



affect our business. We anticipate that the U.S. Congress, state legislatures and the private sector will continue to consider and may adopt healthcare policies intended to curb rising healthcare costs. We are unable to predict what additional legislation, regulations or policies, if any, relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation, regulations or policies would have on our business. Any cost-containment measures, including those listed above, or other healthcare system reforms that are adopted could have a material adverse effect on our business prospects.

In October 2014 we were granted transitional pass-through reimbursement status from CMS for Omidria, effective January 1, 2015, which allows for separate payment for Omidria under Medicare Part B as opposed to having Omidria be included as part of the existing packaged payment for cataract surgery paid by CMS. We expect pass-through to remain in effect until December 31, 2017, near which time CMS will evaluate utilization of Omidria and will re-assess its reimbursement status. CMS has set the reimbursement rate for Omidria under Medicare Part B at the product's WAC of \$465 plus six percent (6%) per single-use vial for the second and third quarters of 2015 after which the rate will be based on ASP plus six percent (6%). Based on our discussions with CMS, we expect this pass-through reimbursement to be effective as of January 1, 2015. Since the majority of patients undergoing cataract surgery are covered by Medicare in the U.S., if we do not receive continuation of separate payment once it expires, we would expect Omidria to be classified within the packaged payment for the cataract procedure. At that time, we may need to adjust our pricing accordingly and our revenue could be lower than if separate payment had continued. In addition to CMS, we will need to arrange for reimbursement from private payers that may, or may not, reference our CMS reimbursement status in their coverage and payment decisions. Other third-party payers often follow, but are not required to follow, the reimbursement methodology adopted by CMS.

Europe. Governments in the various member states of the EU influence the price of medicinal products in their countries through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that assess the cost-effectiveness of a product candidate relative to currently available therapies or relative to a specified standard. The downward pressure on healthcare costs in general, particularly prescription medicines, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

#### Research and Development

We have built a research and development organization that includes expertise in discovery research, preclinical development, product formulation, analytical and medicinal chemistry, manufacturing, clinical development and regulatory and quality assurance. We operate cross-functionally and are led by an experienced research and development management team. We use rigorous project management techniques to assist us in making disciplined strategic research and development programmatic decisions and to limit the risk profile of our product pipeline. We also access relevant market information and key opinion leaders in creating target product profiles and, when appropriate, as we advance our programs to commercialization. We engage third parties on a limited basis to conduct portions of our preclinical research; however, we are not substantially dependent on any third parties for our preclinical research nor do any of these third parties conduct a major portion of our preclinical research. In addition, we engage multiple clinical sites to conduct our clinical trials; however, we are not substantially dependent upon any one of these sites for our clinical trials nor do any of them conduct a major portion of our clinical trials. Research and development expenses were \$47.9 million, \$36.3 million and \$31.9 million in 2014, 2013 and 2012, respectively.

#### Employees

As of February 28, 2015, we had 103 full-time employees, 69 of whom are in research and development and 34 of whom are in finance, legal, business development, sales, marketing and administration, including 5 with M.D.s and 21 with Ph.D.s. None of our employees is represented by a labor union, and we consider our employee relations to be good.

#### Executive Officers and Significant Employees

The following table provides information regarding our executive officers and significant employees as of March 16, 2015:



Name	Age	Position(s)
Executive Officers:		
Gregory A. Demopulos, M.D.	56	President, Chief Executive Officer and Chairman of the Board of Directors
Michael A. Jacobsen	56	Vice President, Finance, Chief Accounting Officer and Treasurer
Marcia S. Kelbon, J.D., M.S.	55	Vice President, Patent and General Counsel and Secretary
Significant Employees:		
Timothy M. Duffy	54	Vice President, Business Development
Kenneth M. Ferguson, Ph.D.	59	Vice President, Development and Chief Development Officer
George A. Gaitanaris, M.D., Ph.D.	58	Vice President, Science and Chief Scientific Officer
Patrick W. Gray, Ph.D.	63	Scientific Fellow
William J. Lambert, Ph.D.	56	Vice President, Chemistry, Manufacturing and Controls
Catherine A. Melfi, Ph.D.	56	Vice President, Regulatory Affairs and Quality Systems
Patricia Sandler	46	Vice President, Sales and Marketing
J. Steven Whitaker, M.D., J.D.	59	Vice President, Clinical Development and Chief Medical Officer

Gregory A. Demopulos, M.D. founded our company and has served as our president, chief executive officer and chairman of the board of directors since June 1994. In an interim capacity, he also served as our chief financial officer and treasurer from January 2009 to October 2013 and as our chief medical officer from June 1994 to March 2010. Prior to founding Omeros, Dr. Demopulos completed his residency in orthopedic surgery at Stanford University and his fellowship training in hand and microvascular surgery at Duke University. Dr. Demopulos currently serves on the Board of Trustees of the Smead Funds Trust and on the board of directors of Onconome, Inc., a privately held company developing biomarkers for early cancer detection. His non-profit service includes the Seattle Community Development Round Table and the Northwest NeuroNeighborhood Board. Dr. Demopulos received his M.D. from the Stanford University School of Medicine and his B.S. from Stanford University. Dr. Demopulos is the brother of Peter A. Demopulos, M.D., a member of our board of directors.

Michael A. Jacobsen joined Omeros in September 2013 and has served as our vice president, finance, chief accounting officer and treasurer since October 2013. Prior to joining Omeros, Mr. Jacobsen served as Vice President of Finance of Sarepta Therapeutics, Inc., a publicly traded biotechnology company, from September 2011 to May 2013 and as its Chief Accounting Officer from September 2011 to December 2012. From April 2007 to August 2011, Mr. Jacobsen was Vice President and Chief Accounting Officer at ZymoGenetics, Inc. Prior to his service with ZymoGenetics, Mr. Jacobsen held various roles at ICOS Corporation, including Senior Director of Finance and Corporate Controller. From April 1995 to October 2001, Mr. Jacobsen held Vice President of Finance or Chief Financial Officer roles at three companies in the software, computer hardware and internet retailing industries, two of which were publicly traded. Mr. Jacobsen is a certified public accountant and received his bachelor's degree in accounting from Idaho State University.

Marcia S. Kelbon, J.D., M.S. has served as our vice president, patent and general counsel since October 2001 and as our secretary since September 2007. Prior to joining Omeros, Ms. Kelbon was a partner with the firm of Christensen O'Connor Johnson & Kindness, PLLC, where she specialized in U.S. and international intellectual property procurement, management, licensing and enforcement issues. Ms. Kelbon received her J.D. and her M.S. in chemical engineering from the University of Washington and her B.S. from The Pennsylvania State University.

Timothy M. Duffy has served as our vice president, business development since March 2010. From November 2008 to March 2010, Mr. Duffy served as the managing director of Pacific Crest Ventures, a life science consulting firm

that he founded. From June 2004 through September 2008, Mr. Duffy served at MDRNA, Inc. (formerly Natestch Pharmaceutical Company, Inc.), a biotechnology company. At MDRNA, he held roles of increasing responsibility in marketing and business development, most recently as the chief business officer. Prior to MDRNA, Mr. Duffy served as vice president, business development at Prometheus Laboratories, Inc., a specialty pharmaceutical company, and as a customer marketing manager at The Procter & Gamble Company. Mr. Duffy received his B.S. from Loras College.

Kenneth M. Ferguson, Ph.D. has served as our vice president, development since November 2010 and as our chief development officer since October 2012. From August 2008 to November 2010, Dr. Ferguson served in various positions, including president, chief executive officer and executive director as well as a consultant, for VacTX International Inc., a biotechnology company. From 1990 to 2007, Dr. Ferguson served at ICOS Corporation. Prior to its acquisition in 2007 by Eli Lilly and Company, Dr. Ferguson served at ICOS as vice president, therapeutic development. He also served as chief operating officer, chief scientific officer and a member of the board of managers of Lilly ICOS LLC, the joint venture of Eli Lilly and ICOS that developed and marketed Cialis®. Following the acquisition of ICOS by Eli Lilly, he served as president of ICOS from January 2007 to December 2007, managing its integration into Eli Lilly. Before joining ICOS, Dr. Ferguson worked for Cold Spring Harbor Laboratory. He holds a Ph.D. in pharmacology from the University of Texas Health Science Center and a B.S. in biological sciences from Cornell University.

George A. Gaitanaris, M.D., Ph.D. has served as our vice president, science since August 2006 and as our chief scientific officer since January 2012. From August 2003 to our acquisition of nura, inc. in August 2006, Dr. Gaitanaris served as the chief scientific officer of nura, a company that he co-founded and that developed treatments for central nervous system disorders. From 2000 to 2003, Dr. Gaitanaris served as president and chief scientific officer of Primal, Inc., a biotechnology company that was acquired by nura in 2003. Prior to co-founding Primal, Dr. Gaitanaris served as staff scientist at the National Cancer Institute. Dr. Gaitanaris received his Ph.D. in cellular, molecular and biophysical studies and his M.Ph. and M.A. from Columbia University and his M.D. from the Aristotelian University of Greece.

Patrick W. Gray Ph.D. has served as our scientific fellow since March 2012. From February 2007 to February 2012, Dr. Gray served as the chief scientific officer of Accelerator Corporation, a biotechnology-company investor and incubator. Prior to Accelerator, Dr. Gray was the chief executive officer of nura, inc. Before nura, he held senior scientific and management positions at Genentech, Inc., ICOS Corporation and MacroGenics, Inc. Dr. Gray received his Ph.D. in chemistry from the University of Colorado and his B.S. in biology from the University of Oregon.

William J. Lambert, Ph.D. joined Omeros as our vice president, chemistry, manufacturing and controls in January 2015. From October 2011 to January 2015, Dr. Lambert headed the Innovative Drug Delivery Group of MedImmune, the global biologics research and development arm of AstraZeneca. From January 2006 to September 2011, Dr. Lambert served as senior vice president of pharmaceutical development at Pacira Pharmaceuticals. Prior to Pacira, Dr. Lambert directed drug delivery, product development and cGMP clinical supply groups at Eisai Inc. He has also held various pharmaceutical research positions at Pfizer Inc. and the Upjohn Company. Dr. Lambert received his Ph.D. in Pharmaceutics from the University of Utah and his B.S. in Pharmacy from the University of Rhode Island.

Catherine A. Melfi, Ph.D. has served as our vice president, regulatory affairs and quality systems since October 2012. Dr. Melfi previously served from January 1996 to October 2012 at Eli Lilly and Company, where she held technical and leadership roles of increasing scope and responsibility, including as senior director and scientific director in Global Health Outcomes and Regulatory Affairs, respectively. Prior to joining Eli Lilly, Dr. Melfi held various faculty and staff positions at Indiana University, including appointments in its Economics Department, in the School of Public and Environmental Affairs, and in the Indiana University School of Medicine. Dr. Melfi received her Ph.D. in Economics from the University of North Carolina - Chapel Hill and B.S. in Economics from John Carroll University.

Patricia Sandler joined Omeros in May 2014 as our national sales director and has served as our vice president, sales and marketing since November 2014. From October 2007 through September 2013, Ms. Sandler served in sales and marketing roles at Sunovion Pharmaceuticals, Inc., including leading a national allergy/asthma sales team from December 2010 to September 2013, managing the Lunesta brand as executive director for central nervous system product marketing from June 2009 to December 2010 and serving as director of respiratory marketing from October 2007 to June 2009. From July 1998 to October 2007, Ms. Sandler served in marketing and sales roles at Johnson & Johnson including as product director of gastroenterology marketing. Prior to Johnson & Johnson, she held various sales positions at large pharmaceutical companies including SmithKline Beecham Pharmaceuticals and Pfizer Inc. Ms. Sandler received her B.S. in Business Administration from Bloomsburg University of Pennsylvania.

J. Steven Whitaker, M.D., J.D. has served as our vice president, clinical development and chief medical officer since March 2010. From May 2008 to March 2010, Dr. Whitaker served as the chief medical officer, vice president of

clinical development at Allon Therapeutics, Inc., a biotechnology company focused on developing drugs for neurodegenerative diseases. From August 2007 to May 2008, he served as a medical consultant to Accelerator Corporation, a biotechnology-company investor and incubator. From May 1994 to May 2007, Dr. Whitaker served at ICOS Corporation, which was acquired by Eli Lilly and Company in 2007. At ICOS, he held roles of increasing responsibility in clinical research and medical affairs, most recently as divisional vice president, clinical research as well as medical director of the Cialis® global product team. Dr. Whitaker received his M.D. from the Indiana University School of Medicine, his J.D. from the University of Washington and his B.S. from Butler University.

## Corporate Information

We were incorporated in 1994 as a Washington corporation. Our principal executive offices are located at 201 Elliott Avenue West, Seattle, Washington, 98119, and our telephone number is (206) 676-5000. Our web site address is [www.omeross.com](http://www.omeross.com). We make available, free of charge through our investor relations web site at [investor.omeross.com](http://investor.omeross.com), our annual report on Form 10-K, our quarterly reports on Form 10-Q, our current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, or Exchange Act, including exhibits to those reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Our web sites and the information contained therein or incorporated therein are not intended to be incorporated into this Annual Report on Form 10-K. In addition, the public may read and copy any materials we file or furnish with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 or may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Moreover, the SEC maintains a web site that contains reports, proxy and information statements, and other information regarding reports that we file or furnish electronically with them at [www.sec.gov](http://www.sec.gov).

## ITEM 1A. RISK FACTORS

The risks and uncertainties described below may have a material adverse effect on our business, prospects, financial condition or operating results. In addition, we may be adversely affected by risks that we currently deem immaterial or by other risks that are not currently known to us. You should carefully consider these risks before making an investment decision. The trading price of our common stock could decline due to any of these risks and you may lose all or part of your investment. In assessing the risks described below, you should also refer to the other information contained in this Annual Report on Form 10-K.

### Risks Related to Our Products, Programs and Operations

If we are unable to successfully commercialize Omidria, or any of our product candidates, if approved, our inability to generate significant revenue from the sales of Omidria or approved product candidates would adversely impact our ability to achieve profitability.

Omidria™ (phenylephrine and ketorolac injection) 1%/0.3% is our only product that has been approved by the FDA for commercial sale in the U.S. and we have not yet generated any significant revenue from any product sales to date. We may not be able to successfully commercialize Omidria or any other product candidate, if approved, for a number of reasons, including:

- a lack of acceptance by physicians, patients, third-party payers and other members of the medical community;
- our limited experience in marketing, selling and distributing Omidria or any other product;
- our limited experience managing third-party commercial manufacturing of Omidria or any other product;
- our reliance on a limited number of manufacturers and a limited number of suppliers of the product's active pharmaceutical ingredients, excipients and packaging materials;
- reimbursement and coverage policies of government and private payers such as Medicare, Medicaid, group purchasing organizations, insurance companies, health maintenance organizations and other plan administrators;
- the availability, relative price and efficacy of the product as compared to alternative treatment options or competing products;
- an unknown safety risk of Omidria or any other product;
- the failure to obtain regulatory approval, including for Omidria in the EU or other foreign territories;
- changed or increased regulatory restrictions in the U.S., EU and other foreign territories; and
- a lack of adequate financial or other resources to commercialize the product successfully.

If we are not able to successfully commercialize Omidria or any other product candidate, if approved, for these or other reasons, our ability to generate revenue from product sales and achieve profitability will be adversely affected and the market price of our common stock could decline significantly.

Our operating results are unpredictable and may fluctuate. If our operating results are below the expectations of securities analysts or investors, the trading price of our stock could decline.

Our operating results are difficult to predict and will likely fluctuate from quarter to quarter and year to year. We believe that our quarterly and annual results of operations may be affected by a variety of factors, including:

- the level of demand for Omidria;



- the extent to which coverage and reimbursement for Omidria is available from government and private third-party payers such as Medicare, Medicaid, insurance companies, group purchasing organizations, health maintenance organizations and other plan administrators;
- the duration of transitional pass-through reimbursement status from CMS for Omidria and the continued availability of separate reimbursement once transitional pass-through reimbursement expires;
- the timing, cost and level of investment in our sales and marketing efforts to support Omidria sales;
- the timing, cost and level of investment in our research and development activities involving Omidria and our product candidates; and
- the timing and cost of conducting required post-approval studies for Omidria and expenditures we will or may incur to acquire or develop additional technologies, products and product candidates.

Further, the number of procedures in which Omidria would be used, or the size of the market in which any other of our products would be used, if commercialized, may be significantly less than the total number of such procedures performed or total possible market size. Our revenues may also depend on commercial arrangements, development funding and the achievement of development and clinical milestones under collaboration and license agreements that we may enter into from time to time in the future. These upfront and milestone payments may vary significantly from quarter to quarter and any such variance could cause a significant fluctuation in our operating results from one quarter to the next.

If we do not have adequate reimbursement from governments or other third-party payers for Omidria or any other approved product that we may develop, or if we do not establish and maintain market-acceptable pricing for Omidria or those approved products, they may not be purchased or used and, as a result, our prospects for revenue and profitability could suffer.

Our future revenue and profit will depend heavily on the pricing and availability of adequate reimbursement for the use of our approved products, including Omidria, from governmental and other third-party payers, both in the U.S. and in other countries. Even if we are successful in bringing one or more products to market, these products may not be considered cost-effective, and the amount reimbursed for any product may be insufficient to allow us to sell the product profitably. Reimbursement by a third-party payer may depend on a number of factors, including the third-party payer's determination that use of a product is:

- covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining reimbursement approval for any product from each government or third-party payer can be a time-consuming and costly process that will require the build-out of a sufficient staff or the engagement of third parties and could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our approved products to each payer. We can provide no assurances at this time regarding the cost-effectiveness of Omidria or any of our product candidates. Further, we can provide no assurance that the amounts, if any, reimbursed to surgical facilities for utilization of any of our surgery-related products, including Omidria, or product candidates or to surgeons for the administration and delivery of these products or product candidates will be considered adequate to justify the use of these products or product candidates. Even if one payer adopts a favorable reimbursement methodology for Omidria or any of our product candidates, if commercialized, there is no guarantee that other third-party payers will adopt the same methodology. For example, other third-party payers often follow, but are not required to follow, the reimbursement methodology adopted by CMS.

There may be significant delays in obtaining reimbursement for newly approved products, and we may not be able to provide data sufficient to be granted reimbursement. Even when a payer determines that a product is eligible for reimbursement, coverage may be limited to the uses of a product that are either approved by the FDA or foreign regulatory agencies and/or appear in a recognized drug compendium, and other conditions may apply. Increasingly, third-party payers who reimburse healthcare costs, such as government and private payers, are requiring that companies provide them with predetermined discounts from list prices and challenging the prices charged for medical

products. Moreover, eligibility for coverage does not mean that any product will be reimbursed at a rate that allows us to make a profit in all cases or at a rate that covers our costs, including research, development, manufacturing, sales and distribution. Even if we receive reimbursement for a product, the initial rate or method at which the product will be reimbursed could become unfavorable to us at the time reimbursement is initiated or in the future. In addition, pass-through reimbursement status is usually granted for a limited duration and we expect pass-through reimbursement status for Omidria to last until December 31, 2017. After pass-through reimbursement status expires, we may not be able to maintain or obtain separate reimbursement for Omidria.

In non-U.S. jurisdictions, we must obtain separate reimbursement approvals and comply with related foreign legal and regulatory requirements. In some countries, including those in the EU, our products may be subject to government price controls. Pricing negotiations with governmental authorities can take a considerable amount of time and expenditure of resources after the receipt of marketing approval for a product.

If the reimbursement that we are able to obtain and maintain for any product that we develop, including Omidria, is inadequate in light of our development and other costs or is significantly delayed, our business could be materially harmed.

If we are unable to market and successfully sell Omidria or our product candidates, if approved, we may be unable to generate product revenue.

Omeros has never sold, marketed or distributed any product. Developing a sales force for any product is expensive and time-consuming, and a delay in hiring and training a sales force, or difficulties managing a contract sales force, could impact the timing or effectiveness of any product launch. We have entered into an agreement with inVentiv for a field sales force and related sales operation services for the U.S. commercial launch of Omidria but we have no experience operating or managing a third-party sales force for any product. Factors that may inhibit our efforts to commercialize any approved products, including Omidria, without commercialization partners include:

- our inability to recruit in a timely manner, and retain, adequate numbers of effective sales and marketing personnel, or to partner or contract with a third party to provide sales and marketing services, in the applicable region of the world;
- the inability of sales personnel to sell or promote any approved product(s) to adequate numbers of hospitals, surgery centers, physicians and/or pharmacists;
- our inability to develop and maintain, or access, adequate information systems to monitor sales by distribution channel, report pricing, maintain customer lists and track selling and marketing operations;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating a sales and marketing organization; and
- our ability to establish and maintain agreements with distributors on commercially reasonable terms.

If we are unsuccessful in building and managing a sales and marketing infrastructure internally or through a third-party partner for any approved product, we will have difficulty commercializing the product, which would adversely affect our business and financial condition.

In the EU, we plan to enter into partnerships for Omidria marketing and distribution with one or more third parties.

Outside of the U.S. and EU, we are exploring potential regional partnerships to make Omidria available to ophthalmologists. We have not yet entered into any agreements with third parties to market Omidria outside of the U.S. Even if we obtain approvals from relevant government authorities in one or more non-U.S. territories, we would not expect to see sales of Omidria in those territories if we are unable to enter into such agreements on terms acceptable to us, if at all, which could adversely affect our business and financial condition.

We are subject to extensive government regulation, including the regulations associated with approval for marketing of Omidria and our product candidates.

Both before and after approval of any product, we and our suppliers, contract manufacturers and clinical investigators are subject to extensive regulation by governmental authorities in the U.S. and other countries, covering, among other things, testing, manufacturing, quality control, clinical trials, labeling, advertising, promotion, distribution, and import and export. Failure to comply with applicable requirements could result in, among other things, one or more of the following actions: warning letters; unanticipated expenditures; delays in approval or refusal to approve a product candidate; product recall or seizure; interruption of manufacturing or clinical trials; operating or marketing restrictions; injunctions; criminal prosecution and civil or criminal penalties including fines and other monetary penalties. We, the FDA or an independent Institutional Review Board or Ethics Committee may suspend or terminate human clinical trials at any time on various grounds, including a finding that the patients are or would be exposed to an unacceptable health risk or because of the way in which the investigators on which we rely carry out the trials.

Obtaining FDA approval of our product candidates requires substantial time, effort, and financial resources, and may be subject to both expected and unforeseen delays, and there can be no assurance that any approval will be granted on any of our product candidates on a timely basis, if at all.

The FDA may decide that our data are insufficient for approval of our product candidates and require additional preclinical, clinical or other studies or additional work related to chemistry, manufacturing and controls. For example, we have

had to suspend clinical trials of OMS824 based on a nonclinical finding, and the FDA has required that we review and further evaluate our nonclinical data before the FDA may permit us to resume or initiate further clinical trials in our OMS824 Huntington's and schizophrenia clinical programs. If, based on our review and evaluation of these data, the FDA concludes that there is an unwarranted safety risk to patients, the FDA may require us to run additional nonclinical studies before permitting us to resume or initiate additional clinical trials, may impose limits on such trials or may not permit us to resume or initiate clinical trials at all. As we develop our product candidates, we periodically discuss with the FDA clinical, regulatory and manufacturing matters, and our views may, at times, differ from those of the FDA. If we are unable to resolve questions raised by the FDA, we may be required to provide additional information, which may necessitate additional preclinical studies or clinical trials. If we are required to conduct additional clinical trials or other testing of our product candidates beyond that which we currently contemplate for regulatory approval, if we are unable to complete successfully our clinical trials or other testing, or if the results of these and other trials or tests fail to demonstrate efficacy or raise safety concerns, we may face substantial additional expenses, be delayed in obtaining marketing approval for our product candidates or may never obtain marketing approval.

Even if regulatory approval of a product candidate is obtained such approval may be subject to significant limitations on the indicated uses for which that product may be marketed, conditions of use, and/or significant post approval obligations, including additional post-marketing studies and clinical trials. These regulatory requirements may, among other things, limit the size of the market for the approved product. Even after approval, discovery of previously unknown problems with an approved product, manufacturer, or facility, such as previously undiscovered side effects or adverse effects or a manufacturer's failure to file current cGMPs, may result in restrictions on any product, manufacturer, or facility, including, among other things, a possible withdrawal of approval of the approved product. The realization of any of these risks could harm our business and operating results.

The commercialization of Omidria and our product candidates, if approved, is subject to extensive regulation and oversight under a number of different healthcare compliance laws. Compliance with these requirements requires the expenditure of substantial resources and attention, and the failure to comply with these requirements could result in criminal penalties, substantial fines or other civil penalties.

In the United States, the commercialization of Omidria and our product candidates, if approved, is subject to regulation and enforcement under a number of federal and state healthcare compliance laws. For example, the FDCA and its implementing regulations require that we advertise and promote our approved products only for uses that FDA has approved and for which we provide appropriate information about safety risks to balance information presented about product effectiveness, and that any product claims be adequately substantiated. The federal Anti-Kickback Law prohibits offering or paying anything of value to a person or entity to induce the use of a good or service covered by a federal health care program such as Medicare or Medicaid. The federal False Claims Act prohibits presenting or causing to be presented a false claim for payment by a federal health care program, and this law has been interpreted to include claims caused by improper drug-manufacturer product promotion or the payment of kickbacks. We are subject to a variety of governmental pricing, price reporting, and rebate requirements, including those under Medicaid and the Veterans Health Care Act. Under the so-called Sunshine Act and related provisions of the Affordable Care Act, we must report to the federal government information on financial payments we make to physicians and certain health care institutions and also on drug samples that we distribute. In addition to these federal law requirements, there are related state law requirements, including some laws that restrict our interactions with physicians and other providers. Also, if we receive protected patient health information, we may be subject to federal or state privacy laws. Similar requirements apply to our operations outside the United States. United States laws such as the Foreign Corrupt Practices Act prohibit the offering or payment of bribes or inducements to foreign public officials, including potentially physicians or other medical professionals who are employees of public health care entities. In addition, many countries have their own laws similar to the health-care compliance laws that exist in the United States. In order to comply with these United States and other laws, we must establish and maintain an effective healthcare compliance program. In addition, some states mandate that we have a compliance program in place. Implementing an effective compliance program requires the expenditure of significant time and resources. If we are found to be in violation of any of these laws, there could be considerable civil or criminal penalties. In addition, if government

enforcement authorities initiate an investigation into potential violations of these laws, we would be required to expend considerable resources and face adverse publicity and the potential disruption of our business, even if we are ultimately found not to have committed a violation.

If we are unable to raise additional capital when needed, we may be unable to complete the development and commercialization of Omidria and our product candidates or to continue our other preclinical development programs. Our operations have consumed substantial amounts of cash since we were incorporated in June 1994. We had net losses of approximately \$73.7 million, \$39.8 million and \$38.4 million for the years ended December 31, 2014, 2013 and 2012, respectively. As of December 31, 2014, we had an accumulated deficit of approximately \$328.0 million. We do not anticipate generating significant revenue from the sale of Omidria until the second half of 2015 at the earliest and expect to continue to incur additional losses and cannot be certain that we will achieve profitability for some time, if at all. We expect to continue to spend substantial amounts to:

- continue the commercialization of Omidria;
- continue research and development in all of our programs;
- make principal and interest payments when due under the Oxford/MidCap Loan Agreement;
- initiate and conduct clinical trials for other programs and product candidates; and
- commercialize and launch any product candidates for which we receive regulatory approval.

If we do not raise additional capital when needed through one or more funding avenues, such as corporate partnering or debt or equity financings, we may be unable to complete these tasks successfully, or at all, which could prevent us from generating sales revenue or limit the amount of sales revenue generated. If we are unable to raise sufficient capital, our business and prospects could be harmed and our stock price could decline significantly.

Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing our products internationally.

We intend to have Omidria and our product candidates, if approved, marketed outside the U.S. In order to market our products in the EU and many other non-U.S. jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The regulatory approval procedure varies among countries and can involve additional testing and data review. The requirements governing marketing authorization, the conduct of clinical trials, pricing and reimbursement vary from country to country. The time required to obtain regulatory approval outside the U.S. may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval discussed in these “Risk Factors” and we may not obtain foreign regulatory approvals on a timely basis, or at all. Approval by the FDA or European Commission does not ensure approval by regulatory agencies in other jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory agencies in other foreign countries or by the FDA or European Commission. The failure to obtain regulatory approval in one or more foreign jurisdictions, or any delays in the regulatory process, could harm our business.

We have submitted an MAA to the EMA for Omidria, which is currently under review. The EU regulatory process is subject to substantial agency discretion and risks, including those described elsewhere in these “Risk Factors.” The EMA may decide not to give a positive opinion on our application, or may require us to obtain additional data regarding Omidria and to resubmit our MAA in order to consider Omidria for approval, further delaying our ability to market and generate revenue from the sale of Omidria in the EU. If there are any negative decisions or delays in the regulatory process, the market price of our common stock could decline significantly.

We cannot be certain that OMS103 will receive regulatory approval.

Our Phase 3 clinical program evaluating OMS103 in patients undergoing arthroscopic partial meniscectomy may be redesigned to include postoperative pain reduction as the primary endpoint before further clinical studies are conducted, if we elect to conduct additional OMS103 trials. While OMS103 demonstrated a drug effect in the first Phase 3 clinical trial by reducing early postoperative pain, which was a secondary endpoint, we can provide no assurance that in subsequent trials, OMS103 will meet the primary endpoint of early postoperative pain reduction or that the design of our Phase 3 program will be acceptable to regulatory authorities. Also, we can provide no assurances that we will have sufficient resources to conduct any subsequent clinical trials that we or regulatory authorities may deem necessary, including any trial regulatory authorities require to show a contribution from each drug in the OMS103 combination. If the data from any subsequent trials are negative or if our program design, data analysis, and proposed label claims are not acceptable to regulatory authorities, we may be unable to seek, or be

significantly delayed in seeking, marketing approval of OMS103, which could cause the market price of our common stock to decline significantly.



We have no internal capacity to manufacture clinical or commercial supplies of Omidria or our product candidates and intend to rely solely on third-party manufacturers.

We intend to rely on third party manufactures to produce commercial quantities of Omidria and any of our product candidates should they receive regulatory approval. Additionally, we intend to rely on third parties to produce clinical drug supplies needed for clinical trials. We can provide no assurance that we will be able to enter into these types of arrangements on commercially reasonable terms, if at all. If we or the manufacturer were to terminate one of these arrangements early, we would be required to transfer the manufacture to an approved alternative facility. Even if we are able to establish additional or replacement manufacturers, identifying these sources and entering into definitive supply agreements and obtaining regulatory approvals may require a substantial amount of time and cost and may create a shortage of the product. Such alternate supply arrangements may not be available on commercially reasonable terms, if at all. Additionally, if we are unable to engage multiple suppliers to manufacture our products, we may have inadequate supply to meet the demand of our product. Any significant delays in the manufacture of clinical or commercial supplies could materially harm our business and prospects.

If the contract manufacturers that we rely on experience difficulties manufacturing Omidria or our product candidates or fail FDA or other regulatory inspections, our clinical trials, regulatory submissions and ability to sell Omidria and our product candidates and generate revenue may be significantly delayed.

Contract manufacturers that we select to manufacture Omidria or our product candidates for clinical testing or for commercial supply may encounter difficulties with the small- and large-scale formulation and manufacturing processes required for such manufacture. These difficulties could result in delays in clinical trials, regulatory submissions, or impact the commercialization of our products and product candidates. Once a product is approved and being marketed, these difficulties could also result in the recall or withdrawal of the product from the market or failure to have adequate supplies to meet market demand. In addition, we and our contract manufacturers must comply with cGMPs that are strictly enforced by the FDA and other regulatory authorities through facilities inspection programs. These cGMPs include quality control, quality assurance and the maintenance of records and documentation. We or our contract manufacturers may be unable to comply with cGMPs or with other FDA, state, local and foreign regulatory requirements. Although we have obligations to review their compliance, we have limited control over our current, and expect to have limited control for any future, contract manufacturers' compliance with these regulations and standards, or with their quality control and quality assurance procedures. Large-scale manufacturing processes that have been developed, or which would be developed in the future, for our product candidates, or establishing additional manufacturers for Omidria, will require validation studies, which the FDA or other regulatory authorities must review and approve. Failure to comply with these requirements by our contract manufacturers could result in the initiation of enforcement actions by the FDA and other regulatory authorities, as well as the imposition of sanctions, including fines and civil penalties, suspension of production, suspension or delay in regulatory approval, product seizure or recall or withdrawal of product approval. If the safety of Omidria or any product candidate supplied by contract manufacturers is compromised due to their failure to adhere to applicable laws or for other reasons, we may not be able to obtain or maintain regulatory approval for or successfully commercialize Omidria or one or more of our product candidates, which would harm our business and prospects significantly.

If one or more of our contract manufacturers were to encounter any of these difficulties or otherwise fail to comply with its contractual obligations, our ability to provide Omidria or product candidates to patients in our clinical trials or on a commercial scale would be jeopardized. Any delay or interruption in the supply of clinical trial materials could delay the completion of our clinical trials, increase the costs associated with maintaining our clinical trial programs and, depending on the period of delay, require us to commence new trials at significant additional expense or terminate the trials completely.

Ingredients, excipients and other materials necessary to manufacture Omidria or our product candidates may not be available on commercially reasonable terms, if at all, which may adversely affect the development and commercialization of Omidria or those product candidates.

We and our third-party manufacturers must obtain from third-party suppliers the active pharmaceutical ingredients, excipients and primary and secondary packaging materials necessary for our contract manufacturers to produce Omidria and our PharmacoSurgery product candidates for our clinical trials and, to the extent approved, for

commercial distribution. Although we have or intend to enter into agreements with third-party suppliers that will guarantee the availability and timely delivery of active pharmaceutical ingredients, excipients and materials for Omidria and our PharmacoSurgery product candidates, we have not yet entered into agreements for the supply of all such ingredients, excipients or materials and we may be unable to secure all such supply agreements or guarantees. Even if we were able to secure such agreements or guarantees, our suppliers may be unable or choose not to provide us the ingredients, excipients or materials in a timely manner or in the quantities required. If we or our third-party manufacturers are unable to obtain the quantities of these ingredients, excipients or materials that are necessary for the manufacture of commercial supplies of Omidria, our ability to generate revenue from the sale of Omidria would be materially and adversely affected. Further, if we or our third-party manufacturers are unable to obtain

active pharmaceutical ingredients, excipients and materials as necessary for our clinical trials or for the manufacture of commercial supplies of our product candidates, if approved, potential regulatory approval or commercialization would be delayed, which would materially and adversely affect our ability to generate revenue from the sale of our product candidates.

If our clinical trials are delayed, we may be unable to develop our product candidates on a timely basis, which will increase our development costs and delay the potential commercialization of our product candidates should they receive regulatory approval.

We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials that will cause regulatory agencies, Institutional Review Boards or Ethics Committees, or us to delay our clinical trials or suspend or delay the analysis of the data from those trials. Clinical trials can be delayed for a variety of reasons, including:

- discussions with the FDA, the EMA or other foreign authorities regarding the scope or design of our clinical trials;
- delays or the inability to obtain required approvals from Institutional Review Boards, Ethics Committees or other responsible entities at clinical sites selected for participation in our clinical trials;
- delays in enrolling patients into clinical trials;
- lower than anticipated retention rates of patients in clinical trials;
- the need to repeat or conduct additional clinical trials as a result of problems such as inconclusive or negative results, failure to replicate positive early clinical data in subsequent clinical trials, poorly executed testing, a failure of a clinical site to adhere to the clinical protocol or an unacceptable study design;
- adverse findings in clinical or nonclinical studies related to the safety of our product candidates in humans;
- an insufficient supply of product candidate materials or other materials necessary to conduct our clinical trials;
- the need to qualify new suppliers of product candidate materials for FDA and foreign regulatory approval;
- an unfavorable FDA inspection or review of a clinical trial site or records of any clinical investigation;
- the occurrence of unacceptable drug-related side effects or adverse events experienced by participants in our clinical trials; or
- the placement by a regulatory agency of a trial on a clinical hold.

In addition, a clinical trial or development program may be suspended or terminated by us, the FDA or other regulatory authorities, or Institutional Review Boards or Ethics Committees due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- the failure to remove a clinical hold in a timely manner (which we cannot predict with certainty) or at all;
- unforeseen safety issues or any determination that a trial presents unacceptable health risks; or
- lack of adequate funding to continue the clinical trial or development program, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties.

Changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to Institutional Review Boards or Ethics Committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

If the results of our clinical trials are not available when we expect or if we encounter any delay in the analysis of data from our clinical trials, we may be unable to file for regulatory approval or conduct additional clinical trials on the schedule we currently anticipate. Any delays in completing our clinical trials may increase our development costs, would slow down our product development and regulatory submission process, could delay our receipt of product revenue and could make it difficult to raise additional capital. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. In addition, significant clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to commercialize our future products and may harm our business.



If we experience delays or difficulties in enrolling patients in our clinical trials, those clinical trials could take longer than expected to complete and our receipt of regulatory approvals could be delayed or prevented.

We may be unable to initiate or continue clinical trials for Omidria or our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, the EMA or other regulatory authorities outside the U.S.

Patient enrollment for any of our clinical trials also may be affected by other factors, including:

- the severity of the disease under investigation;
- the design of the trial protocol;
- the size of the patient population;
- the availability of competing therapies and clinical trials;
- the eligibility criteria of the study in question;
- the perceived risks and benefits of the product or product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately before and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials could result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays may result in increased development costs for our products or product candidates, and we may not have or be able to obtain sufficient cash to fund such increased cost when needed, which could result in further delay or termination of the trial.

We rely on third parties to conduct portions of our preclinical research and clinical trials. If these third parties do not perform as contractually required or otherwise expected, or if we fail to adequately supervise or monitor these parties, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We rely on third parties, such as CROs and research institutions, to conduct a portion of our preclinical research. We also rely on third parties, such as medical institutions, clinical investigators and CROs, to assist us in conducting our clinical trials. Nonetheless, we are responsible for confirming that our preclinical research and clinical trials are conducted in accordance with applicable regulations, the relevant trial protocol and within the context of approvals by an Institutional Review Board or Ethics Committee, and we may not always be successful in ensuring such compliance. Our reliance on these third parties does not relieve us of responsibility for ensuring compliance with FDA and other regulations and standards for conducting, monitoring, recording and reporting the results of preclinical research and clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical and clinical development processes may be extended, delayed, suspended or terminated, and we may not be able to commercialize or obtain regulatory approval for our product candidates.

We may need licenses for active ingredients from third parties to develop and commercialize some of our product candidates, which could increase our development costs and delay our ability to commercialize those product candidates.

Should we decide to use active pharmaceutical ingredients in any of our product candidates that are proprietary to one or more third parties, we would need to obtain licenses to those active ingredients from those third parties. If we are unable to access rights to these active ingredients prior to conducting preclinical toxicology studies intended to support clinical trials, we may need to develop alternate product candidates from these programs by either accessing or developing alternate active ingredients, resulting in increased development costs and delays in commercialization of these product candidates. If we are unable to access rights to the desired active ingredients on commercially reasonable terms or develop suitable alternate active ingredients, we may not be able to commercialize product candidates from these programs.



Our ability to pursue the development and commercialization of products from our MASP-2 program depends on the continuation of licenses from third parties.

Our MASP-2 program is based in part on intellectual property rights that we licensed on a worldwide exclusive basis from the University of Leicester, the UK Medical Research Council at Oxford University and Helion. The continued maintenance of these agreements requires us to undertake development activities and, if regulatory approval for marketing is obtained, to pay royalties to each of these organizations upon commercialization of a MASP-2 product, such as OMS721. In addition, we are obligated to make remaining development and sales milestone payments to Helion of up to \$6.1 million upon the achievement of certain events related to a MASP-2 product, such as the filing of an IND for OMS721 with the FDA, initiation of clinical trials, receipt of marketing approval and reaching specified sales milestones. Our ability to continue development and commercialization of products from our MASP-2 program, including OMS721, depends on our maintaining these exclusive licenses, which cannot be assured.

Our ability to pursue the development and commercialization of product candidates from our MASP-2, MASP-3 and Plasmin programs depends on third-party developers and manufacturers of biologic drug products.

Any product candidate from our MASP-2, MASP-3 or Plasmin programs would be a biologic drug product and we do not have the internal capability to hybridize, clone or manufacture biologics for clinical or commercial use. There are only a limited number of manufacturers of biologic drug products and we cannot be certain that we can enter into supply agreements with them on commercially reasonable terms, if at all. If we are unable to obtain clinical supplies of drug product for one of these programs, clinical trials or the development of any such product candidate for that program could be substantially delayed until we can find and qualify a manufacturer, which may increase our development costs, slow down our product development and approval process, delay receipt of product revenue and make it difficult to raise additional capital.

Our preclinical programs may not produce product candidates that are suitable for clinical trials or that can be successfully commercialized or generate revenue through partnerships.

Any product candidates from our preclinical programs must successfully complete preclinical testing, which may include demonstrating efficacy and the lack of toxicity in established animal models, before entering clinical trials. Many pharmaceutical and biological products do not successfully complete preclinical testing and, even if preclinical testing is successfully completed, may fail in clinical trials. In addition, there can be no assurance that positive results from preclinical studies will be predictive of results obtained from subsequent preclinical studies or clinical trials. For example, our studies of PDE7 inhibitors in different animal models of Parkinson's disease, which may or may not be relevant to the mechanism of action of PDE7 inhibitors in humans, have produced varying results. Further, we cannot be certain that any of our preclinical product development programs will generate product candidates that are suitable for clinical testing. For example, we have not yet generated any products or product candidates from our GPCR program. We may discover that there are fewer druggable targets among the orphan GPCRs than we currently estimate and that, for those orphan GPCRs for which we identify functionally active compounds that we elect to develop independently, we are unable to develop related product candidates that successfully complete preclinical or clinical testing. If we are unable to develop product candidates, potential corporate partners may be unwilling to enter into partnership agreements with us. We also cannot be certain that any product candidates that do advance into clinical trials will successfully demonstrate safety and efficacy in clinical trials. Even if we achieve positive results in early clinical trials, they may not be predictive of the results in later trials.

Because we have a number of product candidates and development programs, we may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications for which there is a greater likelihood of obtaining regulatory approval and that may be more profitable, if approved.

Because we have limited resources, we must focus on the product candidates and clinical and preclinical development programs that we believe are the most promising. As a result, we may forego or delay the pursuit of opportunities with other product candidates or other indications that later prove to have greater commercial potential and may not be able to progress development programs as rapidly as otherwise possible. Our resource allocation decisions may cause us to fail to capitalize on viable potential commercial products or profitable market opportunities. Further, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product through collaboration, license or other royalty arrangements in cases in which it would

have been advantageous for us to retain sole development and commercialization rights.



It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for the use, formulation and structure of our products and product candidates, the methods used to manufacture them, the related therapeutic targets and associated methods of treatment as well as on successfully defending these patents against potential third party challenges. Our ability to protect our products and product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Case law and policy regarding the breadth of claims allowed in biotechnology patents has continued to evolve in the U.S., and tests used for determining the patentability of patent claims in all technologies are in flux. The pharmaceutical, biotechnology and other life sciences patent situation outside the U.S. is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. Further, the determination that a patent application or patent claim meets all of the requirements for patentability is a subjective determination based on the application of law and jurisprudence. For example, in the U.S., a determination of patentability by the U.S. Patent and Trademark Office, or USPTO, or validity by a court or other trier of fact requires a determination that the claimed invention has utility and is both novel and non-obvious to those of ordinary skill in the art in view of prior known publications and public information, and that the patent specification supporting the claim adequately describes the claimed invention, discloses the best mode known to the inventors for practicing the invention, and discloses the invention in a manner that enables one of ordinary skill in the art to make and use the invention. These standards may be challenging to meet for patents directed to some of our technologies, including our target-based technologies. The ultimate determination by the USPTO or by a court or other trier of fact in the U.S., or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. Although we have conducted searches for third-party publications, patents and other information that may impact the patentability of claims in our various patent applications and patents, we cannot be certain that all relevant information has been identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or patent applications, our licensed patents or patent applications or in third-party patents.

We cannot assure you that any of our patent applications will be found to be patentable, including over our own prior art patents, or will issue as patents, nor can we make assurances as to the scope of any claims that may issue from these pending and future patent applications or to the outcome of any proceedings by any potential third parties that could challenge the patentability, validity or enforceability of our patents and patent applications in the U.S. or foreign jurisdictions, which could limit patent protection for our products and product candidates and materially harm our business.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we might not have been the first to make the inventions covered by any of our pending U.S. patent applications filed or having priority dates prior to the U.S. having adopted a first-to-file standard on March 16, 2013, or any U.S. patents issued based on such patent applications;
- we might not have been the first to file patent applications on inventions that are the subject of pending foreign patent applications or that are the subject of pending U.S. patent applications filed or having priority dates after March 16, 2013, or any patents issued based on such foreign or U.S. patent applications;
- others may independently develop similar or alternative technologies or products or duplicate any of our technologies or products or product candidates;
- we may not be able to generate sufficient data to support fully patent applications that protect the entire breadth of developments expected to result from our development programs, including the GPCR program;
-

it is possible that none of our pending patent applications will result in issued patents or, if issued, that these patents will be sufficient to protect our technology or provide us with a basis for commercially viable products or provide us with any competitive advantages;

• if our pending applications issue as patents, they may be challenged by third parties as not infringed, invalid or unenforceable under U.S. or foreign laws;

• if issued, the patents under which we hold rights may not be valid or enforceable; or

• we may develop additional proprietary technologies or products or product candidates that are not patentable and which are unlikely to be adequately protected through trade secrets if, for example, a competitor were to develop independently duplicative, similar or alternative technologies or products.

In addition, to the extent we are unable to obtain and maintain patent protection for one of our products or product candidates or in the event such patent protection expires, it may no longer be cost-effective to extend our portfolio by pursuing additional development of a product or product candidate for follow-on indications.

We also may rely on trade secrets to protect our technologies or products, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisers may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

If we choose to go to court to stop someone else from using our inventions, that individual or company has the right to ask the court to rule that the underlying patents are invalid or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe the patents. It may not be feasible to detect and undertake patent enforcement action to stop infringing activity by a number of individual entities, each on a small scale, such as compounding pharmacies.

Further, a third party may claim that we or our contract manufacturers are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in the alleged infringing activity, including making, using or selling our products and product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we, or our contract manufacturers, are infringing the third party's patents and would order us or our partners to stop the activities covered by the patents. In addition, if we or our contract manufacturers are found to have violated a third party's patent, we or our contract manufacturers could be ordered to pay damages to the other party. We have agreed to or may agree to indemnify our contract manufacturers against certain patent infringement claims and thus may be responsible for any of their costs associated with such claims and actions. The pharmaceutical, biotechnology and other life sciences industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our products and product candidates or methods of use either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

Although we have conducted searches of third-party patents with respect to our programs, we have not obtained written freedom to operate opinions for our programs and may not have identified all relevant third-party patents. Consequently, we cannot assure you that third-party patents containing claims covering our products, product candidates, programs, technologies or methods do not exist, have not been filed, or could not be filed or issued. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the capital necessary to continue our operations.

The terms of our debt facility place restrictions on our operating and financial flexibility and, if we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business. We have borrowed \$32.0 million pursuant to the terms of the loan and security agreement with Oxford Finance LLC, or Oxford, and MidCap Financial SBIC, LP, or MidCap, entered into in March 2014. As collateral for this loan, we pledged substantially all of our assets other than intellectual property. The Oxford/MidCap Loan Agreement restricts our ability to incur additional indebtedness, pay dividends, pledge our intellectual property and engage in significant

business transactions such as a change of control of Omeros, so long as we owe any amounts to the lenders under the Oxford/MidCap Loan Agreement. Any of these restrictions could significantly limit our operating and financial flexibility and ability to respond to changes in our business or competitive activities. In addition, if we default under the Oxford/MidCap Loan Agreement, the lenders may have the right to accelerate all of our repayment obligations under the Oxford/MidCap Loan Agreement and to take control of our pledged assets, which include our cash, cash equivalents and short-term investments, potentially requiring us to renegotiate the Oxford/MidCap Loan Agreement on terms less favorable to us. Further, if we are liquidated, the lenders' right to repayment

would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. An event of default under the Oxford/MidCap Loan Agreement includes the occurrence of any material adverse effect upon our business operations, properties, assets, results of operations or financial condition, taken as a whole with respect to our viability, that would reasonably be expected to result in our inability to repay the loan. If either lender declares all obligations under the Oxford/MidCap Loan Agreement immediately due and payable upon the occurrence of any event that the lender interprets as constituting an event of default as defined under the Oxford/MidCap Loan Agreement, including but not limited to the lender concluding that a material adverse change has occurred as defined under the Oxford/MidCap Loan Agreement, we will be required to repay the loan immediately or to attempt to reverse the declaration through negotiation or litigation. Any declaration of an event of default could significantly harm our business and prospects and could cause our stock price to decline. If we raise any additional debt financing, the terms of such debt could further restrict our operating and financial flexibility.

Our agreements with Vulcan and the Life Sciences Discovery Fund Authority, a granting agency of the State of Washington, or LSDF, include terms that may reduce the purchase price that a third party would be willing to pay for the GPCR program or for us in a change of control.

Under our GPCR funding agreement with Vulcan, if we decide to sell or assign all or substantially all of the assets in our GPCR program prior to the time that Vulcan has received \$60.0 million from us under our agreement, Vulcan may require that the purchaser assume all of our rights and obligations pursuant to the agreement, including our obligation to pay tiered percentages of any net proceeds that we receive from the GPCR program. The term of the Vulcan agreement is at least 35 years. If, at our option, we elect to assign the LSDF agreement in connection with the sale of the GPCR program, a potential purchaser would also have to assume similar payment obligations to LSDF. Potential purchasers of our GPCR program may be less inclined to purchase the program because of these obligations. Further, even if they are willing to assume our rights and obligations, they may be unwilling to pay as much for our GPCR program as they would be without such requirement. In addition, if a transaction results in a change of control of Omeros, the acquiring party will be required to assume our rights and obligations under the Vulcan and LSDF agreements. As a result of these provisions, a party that wants to acquire us through a change of control may be less inclined to do so or not be willing to pay as much.

We have granted Vulcan a lien on all of our GPCR assets, excluding intellectual property, which provides Vulcan a right, senior to our shareholders, to receive proceeds generated from a liquidation of our GPCR assets as well as potentially limiting our operating and financial flexibility.

We have granted Vulcan a lien on all of our GPCR assets, excluding intellectual property, to secure our obligations under our agreement with Vulcan. This lien is, and will continue to be, junior to security interests we grant to third parties in connection with indebtedness for borrowed money. The lien will automatically be released once we have paid Vulcan or its affiliate \$25.0 million out of net proceeds received from the GPCR program. If we default under our agreement with Vulcan, in certain circumstances Vulcan may, subject to the rights of any holders of senior security interests, take control of such pledged assets. We have also agreed with Vulcan not to grant any liens on our GPCR-related intellectual property related to our cellular redistribution assay, subject to specified exceptions. If we are liquidated, Vulcan's right to receive any payments then due under our agreement would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation of our GPCR program assets. Further, the junior lien and negative pledge on our intellectual property restrict our operating and financial flexibility, potentially limiting our ability to pursue business opportunities and making it more difficult for us to respond to changes in our business.

We use hazardous materials in our business and must comply with environmental laws and regulations, which can be expensive.

Our research operations produce hazardous waste products, which include chemicals and radioactive and biological materials. We are subject to a variety of federal, state and local regulations relating to the use, handling, storage and disposal of these materials. Although we believe that our safety procedures for handling and disposing of these materials comply with applicable legal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. We generally contract with third parties for the disposal of such substances and store our low-level radioactive waste at our facility until the materials are no longer considered radioactive. We may be required

to incur further costs to comply with current or future environmental and safety regulations. In addition, although we carry insurance, in the event of accidental contamination or injury from these materials, we could be held liable for any damages that result and any such liability could exceed our insurance coverage and other resources.

The loss of members of our management team could substantially disrupt our business operations. Our success depends to a significant degree on the continued individual and collective contributions of our management team. The members of our management team are at-will employees, and we do not maintain any key-person life insurance policies other than on the life of Gregory A. Demopoulos, M.D., our president, chief executive officer and chairman of the board of directors. Losing the services of any key member of our management team, whether from death or disability, retirement, competing offers or other causes, could delay the execution of our business strategy, cause us to lose a strategic partner, or otherwise materially affect our operations.

We rely on highly skilled personnel and, if we are unable to retain or motivate key personnel or hire qualified personnel, we may not be able to maintain our operations or grow effectively.

Our performance is largely dependent on the talents and efforts of highly skilled individuals. Our future success depends on our continuing ability to identify, hire, develop, motivate and retain highly skilled personnel for all areas of our organization. If we are unable to hire and train a sufficient number of qualified employees for any reason, we may not be able to implement our current initiatives or grow effectively. We have in the past maintained a rigorous, highly selective and time-consuming hiring process. We believe that our approach to hiring has significantly contributed to our success to date. If we do not succeed in attracting qualified personnel and retaining and motivating existing personnel, our existing operations may suffer and we may be unable to grow effectively.

We may encounter difficulties managing our growth, which could delay our business plans or adversely affect our results of operations.

To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems and continue to recruit and train additional qualified personnel. Due to our limited financial resources, we may not be able to manage effectively the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. Additionally, our inability to manage growth effectively could cause our operating costs to grow even faster than we currently are anticipating.

We incur significant costs and demands on management as a result of complying with the laws and regulations affecting public companies.

We have incurred, and will continue to incur, significant costs associated with compliance with public company reporting and corporate governance requirements, including under the Sarbanes-Oxley Act of 2002 and the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, as well as rules implemented by the SEC and The NASDAQ Stock Market. The requirements of applicable SEC rules and regulations may increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. We also expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage than was previously available. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as our executive officers.

We are required to make an assessment of the effectiveness of our internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002. Further, our independent registered public accounting firm has been engaged to express an opinion on the effectiveness of our internal control over financial reporting. If we are unable to comply with the requirements of Section 404, management may not be able to assess whether our internal control over financial reporting is effective, which may subject us to adverse regulatory consequences and could result in a negative reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In addition, if we fail to maintain effective controls and procedures, we may be unable to provide the required financial information in a timely and reliable manner or otherwise comply with the standards applicable to us as a public company. Any failure by us to provide the required financial information in a timely manner could materially and adversely impact our financial condition and the market value of our securities. Cyber-attacks or other failures in telecommunications or IT systems could result in information theft, data corruption and significant disruption of our business operations.

We utilize information technology, or IT, systems and networks to process, transmit and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and



sophistication. These threats pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effect. Similarly, there can be no assurance that our collaborators, CROs and other contractors and consultants will be successful in protecting our clinical and other data that is stored on their systems. Any cyber-attack or destruction or loss of data could have a material adverse effect on our business and prospects. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or other data security breaches, and may incur significant additional expense to implement further data protection measures.

#### Risks Related to Our Industry

Our competitors may develop products that are less expensive, safer or more effective, or which may otherwise diminish or eliminate the commercial success of any products that we may commercialize.

We may not achieve commercial success, particularly if our competitors market products that are safer, more effective, less expensive or faster to reach the market than Omidria or any future products that we may develop and commercialize. Our competitors also may market a product that proves to be unsafe or ineffective, which may affect the market for our competing product, or future product, regardless of the safety or efficacy of our product. For example, other pharmaceutical companies, many with significantly greater resources than we have, are developing PDE10 inhibitors similar to our product candidate OMS824, and these companies may be further along in development and have the resources to develop their product candidates at a faster rate than we can. For example, in 2012, Pfizer Inc. announced that its PDE10 inhibitor product candidate failed to demonstrate efficacy in a Phase 2 clinical trial evaluating the compound in acute exacerbation of schizophrenia. This and other potential clinical trial failures of PDE10 inhibitor product candidates may negatively reflect on the ability of OMS824 to demonstrate safety and efficacy. In addition, we believe that other companies are attempting to find compounds that functionally interact with orphan GPCRs. If any of these companies are able to achieve this for a given orphan GPCR before we do, we may be unable to establish a commercially valuable intellectual property position around that orphan GPCR. The failure of Omidria or any other future product that we may market to effectively compete with products marketed by our competitors would impair our ability to generate revenue, which would have a material adverse effect on our future business, financial condition and results of operations.

The pharmaceutical industry is intensely competitive and many of our competitors have significantly more resources and experience, which may limit our commercial opportunities.

The pharmaceutical industry is intensely competitive in the markets in which we expect to compete. We expect to compete for market share against large pharmaceutical and biotechnology companies, smaller companies that are collaborating with larger pharmaceutical companies, new companies, academic institutions, government agencies and other public and private research organizations. Our competitors may:

- operate larger research and development programs, possess commercial-scale manufacturing operations or have substantially greater financial resources than we do;
- initiate or withstand substantial price competition more successfully than we can;
- have greater success in recruiting skilled technical and scientific workers from the limited pool of available talent;
- more effectively negotiate third-party licenses and strategic relationships; and
- take advantage of acquisition or other opportunities more readily than we can.

In addition, the pharmaceutical and biotechnology industry is characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to remain current with rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Our competitors may render our technologies obsolete by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our product discovery process that we believe we derive from our research approach and proprietary technologies and programs.

Our products 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 products if and when any of them are approved.

Omidria and any product candidate for which we obtain regulatory approval in the future, together with the manufacturing processes, post-approval clinical data, and advertising and promotional activities for such product, will be subject to continued regulation by the FDA and other regulatory agencies. Even if regulatory approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or the approval may contain requirements for costly post-marketing testing and surveillance to monitor

the safety or efficacy of the product. Later discovery of previously unknown problems with Omidria or any of our other approved products, or failure to comply with regulatory requirements, may result in:

- restrictions on such products or manufacturing processes;
- withdrawal of the products from the market;
- voluntary or mandatory recalls;
- fines;
- suspension or withdrawal of regulatory approvals;
- product seizures; or
- injunctions or the imposition of civil or criminal penalties.

If we are slow or unable to adapt to changes in existing regulatory requirements or adoption of new regulatory requirements or policies, we may lose marketing approval for Omidria, or for our product candidates when and if any of them are approved.

Product liability claims may damage our reputation and, if insurance proves inadequate, these claims may harm our business.

We may be exposed to the risk of product liability claims that is inherent in the biopharmaceutical industry. A product liability claim may damage our reputation by raising questions about our product's safety and efficacy and could limit our ability to sell one or more products by preventing or interfering with commercialization of our products and product candidates. In addition, product liability insurance for the biopharmaceutical industry is generally expensive to the extent it is available at all. There can be no assurance that we will be able to obtain or maintain such insurance on acceptable terms or that we will be able to secure increased coverage if the commercialization of Omidria or our product candidates progresses, or that future claims against us will be covered by our product liability insurance.

Further, our product liability insurance coverage may not reimburse us or may be insufficient to reimburse us for any or all expenses or losses we may suffer. A successful claim against us with respect to uninsured liabilities or in excess of insurance coverage could have a material adverse effect on our business, financial condition and results of operations.

#### Risks Related to Our Common Stock

Our stock price has been and may continue to be volatile, and the value of an investment in our common stock may decline.

During the year ended December 31, 2014, our stock traded as high as \$25.10 per share and as low as \$9.76 per share. The trading price of our common stock is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors could include:

- failure of Omidria or any of our product candidates, if approved, to achieve commercial success;
- EMA actions related to our MAA submission for Omidria;
- FDA or foreign regulatory actions related to Omidria or any of our product candidates, including the suspension by the FDA of our OMS824 Phase 2 clinical trial in Huntington's disease;
- results from our clinical development programs, including the data from our ongoing clinical development programs evaluating Omidria, OMS103, OMS824, OMS721 and PPAR ;
- announcements regarding the progress of our preclinical programs, including without limitation our GPCR program;
- quarterly variations in our results of operations or those of our competitors;
- our ability to develop and market new and enhanced products on a timely basis;
- announcements by us or our competitors of acquisitions, regulatory approvals, clinical milestones, new products, significant contracts, commercial relationships or capital commitments;
- third-party coverage and reimbursement policies;
- additions or departures of key personnel;
- commencement of, our involvement in and resolution of litigation;
- our ability to meet our repayment and other obligations under the Oxford/MidCap Loan Agreement;
- the inability of our contract manufacturers to provide us with adequate commercial supplies of Omidria and our product candidates;
- changes in governmental regulations or in the status of our regulatory approvals;



- changes in earnings estimates or recommendations by securities analysts;
- any major change in our board or management;
- the extent to which we raise funds by issuing equity or debt securities;
- general economic conditions and slow or negative growth of our markets; and
- political instability, natural disasters, war and/or events of terrorism.

From time to time, we estimate the timing of the accomplishment of various commercial, scientific, clinical, regulatory and other product development goals or milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. Also, from time to time, we expect that we will publicly announce the anticipated timing of some of these milestones. All of these milestones are based on a variety of assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, our stock price may decline and the commercialization of Omidria and our product candidates may be delayed. In addition, the stock market has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of publicly traded companies. Broad market and industry factors may seriously affect the market price of companies' stock, including ours, regardless of actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

We expect that we will continue to need additional capital in the future; however, such capital may not be available to us on reasonable terms, if at all, when or as we require additional funding. If we issue additional shares of our common stock or other securities that may be convertible into, or exercisable or exchangeable for, our common stock, our existing shareholders would experience further dilution.

Although we expect that we will need additional capital in the future, we cannot be certain that it will be available to us on acceptable terms, if at all, when required. Disruptions in the global equity and credit markets may limit our ability to access capital. To the extent that we raise additional funds by issuing equity securities, our shareholders would experience dilution, which may be significant and could cause the market price of our common stock to decline significantly. Any debt financing, if available, may restrict our operations similar to the Oxford/MidCap Loan Agreement, or in other ways. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the commercialization of Omidria or the development or commercialization of one or more of our product candidates or one or more of our other research and development initiatives. We also could be required to seek collaborators for one or more of our current or future products at an earlier stage than otherwise would be desirable or on terms that are less favorable than otherwise might be available or to relinquish or license on unfavorable terms our rights to technologies or products that we otherwise would seek to develop or commercialize ourselves. We also may have insufficient funds or otherwise be unable to advance our preclinical programs, such as potential new drug targets developed from our GPCR program, to a point where they can generate revenue through partnerships, collaborations or other arrangements. Any of these events could significantly harm our business and prospects and could cause our stock price to decline.

Future sales of shares by holders of outstanding warrants and options could cause our stock price to decline.

Approximately 11.4 million shares of common stock that are either subject to outstanding warrants or subject to outstanding options or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements.

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

Provisions in our articles of incorporation and bylaws and under Washington law may delay or prevent an acquisition of us or a change in our management. These provisions include a classified board of directors, a prohibition on shareholder actions by less than unanimous written consent, restrictions on the ability of shareholders to fill board vacancies and the ability of our board of directors to issue preferred stock without shareholder approval. In addition,

because we are incorporated in Washington, we are governed by the provisions of Chapter 23B.19 of the Washington Business Corporation Act, which, among other things, restricts the ability of shareholders owning 10% or more of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if an offer may be considered

beneficial by some shareholders. In addition, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it difficult for shareholders to replace members of our board of directors, which is responsible for appointing the members of our management.

We have never declared or paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future.

Our business requires significant funding, and we have not generated any material revenue. We currently plan to invest all available funds and future earnings, if any, in the development and growth of our business. Additionally, under the Oxford/MidCap Loan Agreement, we have agreed not to pay any dividends so long as we have any outstanding obligations under the agreement. Therefore, we currently do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, a rise in the market price of our common stock, which is uncertain and unpredictable, will be the sole source of potential gain for shareholders in the foreseeable future, and an investment in our common stock for dividend income should not be relied upon.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We lease approximately 83,000 square feet for our principal office and laboratory space in the building located at 201 Elliott Avenue West, Seattle, Washington, or The Omeros Building, which includes approximately 5,850 square feet of laboratory space that we are subleasing to a third party. The lease term for this space is through November 2027. We also have two options to extend the lease term, each by five years. The annual base rent due under the lease for our principal office and laboratory space is \$4.0 million for 2015, \$4.1 million for 2016 and \$4.2 million for 2017 and will increase by approximately 2.3% each year thereafter. In addition, we are responsible for paying our proportionate share of the building's utilities, taxes, insurance and maintenance as well as a property management fee.

Through November 2015, we have the option to lease specified additional space in The Omeros Building. We have a right of first refusal for the remaining premises as well as a right of first offer for specified premises in The Omeros Building. If at any time during the term of the lease our space requirements exceed the available space in The Omeros Building, the landlord will relocate us to a new building under a build-to-suit lease with no termination penalty payable under our existing lease, subject to the negotiation of a mutually acceptable build-to-suit lease. In addition, beginning with the sixth year of the lease term, if we request from the landlord additional space in The Omeros Building with a minimum square footage specified in the lease and the landlord is unable to provide such additional space to us, we may terminate the lease without payment of any termination fees other than the unamortized portion of a \$3.0 million lease incentive paid to us by the landlord when we entered the lease. We have the right to terminate the lease beginning with year nine of the lease term, subject to the payment of a lease termination fee. If we terminate the lease during years 9 or 10, the termination fee is equal to 30% of the unamortized tenant improvements and 100% of the unamortized lease incentive. If we terminate the lease any time after year 10 of the term, the termination fee is equal to 20% of the unamortized tenant improvements and 100% of the unamortized lease incentive. We believe that these facilities we lease currently are sufficient for our anticipated near-term needs.

ITEM 3. LEGAL PROCEEDINGS

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.



## PART II

## ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

## Market Information

Our common stock is traded on The NASDAQ Global Market under the symbol "OMER."

The following table sets forth the range of high and low sales prices of our common stock as quoted on The NASDAQ Global Market for the periods indicated.

Year Ended December 31, 2014	High	Low
4th Quarter	\$25.10	\$11.18
3rd Quarter	\$18.80	\$12.12
2nd Quarter	\$18.01	\$9.76
1st Quarter	\$14.69	\$10.11

Year Ended December 31, 2013	High	Low
4th Quarter	\$13.76	\$6.92
3rd Quarter	\$10.70	\$4.75
2nd Quarter	\$5.70	\$3.65
1st Quarter	\$6.52	\$3.90

## Holders

As of February 28, 2015, there were approximately 146 holders of record of our common stock.

## Dividends

We have never declared or paid any cash dividends on our capital stock, and under the Oxford/MidCap Loan Agreement we have agreed not to pay any dividends so long as we have any outstanding obligations under the agreement. We expect to retain all available funds and future earnings, if any, to fund the development and growth of our business and we do not anticipate paying any cash dividends in the foreseeable future.

## Stock Performance Graph

The following graph compares the cumulative total shareholder return for our common stock (OMER), the NASDAQ Biotechnology Index (NBI) and the NASDAQ U.S. Benchmark TR Index (NQUSBT) for the period beginning December 31, 2009 and ending December 31, 2014. This graph assumes that \$100 was invested on December 31, 2009 in our common stock, the NASDAQ Biotechnology Index and the NASDAQ U.S. Benchmark TR Index. It also assumes that any dividends were reinvested. The data shown in the following graph is not necessarily indicative of future stock price performance.

The foregoing information shall not be deemed to be “soliciting material” or to be “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities under that Section. In addition, the foregoing information shall not be deemed to be incorporated by reference into any of our filings under the Exchange Act or the Securities Act of 1933, except to the extent that we specifically incorporate this information by reference.

#### Unregistered Sales of Equity Securities

We issued 28,653 shares of our common stock upon the exercise of warrants to purchase 57,581 shares of our common stock in 2014. Related to these warrant exercises, we received proceeds of \$68,857 from the exercise of warrants to purchase 5,621 shares of our common stock upon payment of the cash exercise price of \$12.25 per share, and we issued 23,032 shares of our common stock upon the cashless net exercise of warrants to purchase 51,960 shares of our common stock. The warrants were issued on March 29, 2007 in connection with our Series E preferred stock financing in a transaction that was exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder. We deemed the issuance of common stock upon the exercise of these warrants to be exempt from registration under the Securities Act under the same provisions. No underwriters were involved in the issuance of our common stock upon the exercise of warrants and no commissions were paid in connection with such issuances.

## ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the accompanying notes included elsewhere in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of the results to be expected in any future period.

	Year Ended December 31,				
	2014	2013	2012	2011	2010
	(In thousands, except share data)				
Consolidated Statements of Operations and Comprehensive Loss Data:					
Revenue	\$539	\$1,600	\$6,022	\$4,524	\$2,105
Operating expenses:					
Research and development	47,946	36,297	31,922	23,718	23,465
Selling, general and administrative	22,601	15,819	10,985	8,216	8,746
Total operating expenses	70,547	52,116	42,907	31,934	32,211
Loss from operations	(70,008 )	(50,516 )	(36,885 )	(27,410 )	(30,106 )
Litigation settlement	—	12,500	—	—	—
Investment income	12	12	40	51	167
Interest expense	(3,470 )	(2,366 )	(1,729 )	(1,884 )	(1,535 )
Loss on extinguishment of debt	—	—	—	—	(296 )
Other income (expense), net	(207 )	574	130	697	2,519
Net Loss	\$(73,673 )	\$(39,796 )	\$(38,444 )	\$(28,546 )	\$(29,251 )
Basic and diluted net loss per share	\$(2.22 )	\$(1.39 )	\$(1.59 )	\$(1.29 )	\$(1.37 )
Denominator for basic and diluted net loss per share	33,234,294	28,560,360	24,155,690	22,212,351	21,420,883

	As of December 31,				
	2014	2013	2012	2011	2010
	(In thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	\$6,886	\$ 14,101	\$22,350	\$24,570	\$41,993
Working capital	(9,274 )	2,944	16,341	6,963	27,880
Total assets	11,090	16,535	26,575	26,982	45,704
Notes payable, net of discount	32,709	20,498	20,103	19,446	10,255
Accumulated deficit	(328,046 )	(254,373 )	(214,577 )	(176,133 )	(147,587 )
Total shareholders' equity (deficit)	(42,654 )	(18,384 )	(6,531 )	(5,554 )	20,470

In February 2015, we sold 3.4 million shares of our common stock at a public offering price of \$20.03 per share and sold pre-funded warrants to purchase up to 749,250 shares of our common stock at a public offering price of \$20.02 per pre-funded warrant share. After deducting underwriter discounts and offering expenses of \$4.9 million, we received net proceeds from the transaction of approximately \$79.1 million.

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with the audited annual consolidated financial statements and the related notes thereto included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results may differ materially from those discussed in these forward-looking statements due to a number of factors, including those set forth in the section entitled "Risk Factors" and elsewhere in this Annual Report on Form 10-K. For further information regarding forward-looking statements, please refer to the special note regarding forward-looking statements at the beginning of this Annual Report on Form 10-K. Throughout this discussion, unless the context specifies or implies otherwise, the terms "Company," "we," "us" and "our" refer to Omeros Corporation and our wholly owned subsidiaries.

### Overview

We are a biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, coagulopathies and disorders of the central nervous system. Our marketed drug product Omidria<sup>TM</sup> (phenylephrine and ketorolac injection) 1%/0.3% is approved in the U.S. for use during cataract surgery or intraocular lens, or IOL, replacement surgery, to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain. Omidria is derived from our proprietary PharmacoSurgery<sup>®</sup> platform, which is designed to improve clinical outcomes of patients undergoing ophthalmological, arthroscopic, urological and other surgical procedures, and is based on low-dose combinations of FDA-approved therapeutic agents delivered directly to the surgical site throughout the duration of the procedure to inhibit preemptively inflammation and other problems caused by surgical trauma and to provide clinical benefits both during and after surgery. We also have six clinical-stage development programs in our pipeline, which also includes a diverse group of preclinical programs as well as two additional platforms: one capable of unlocking new G protein-coupled receptor, or GPCR, drug targets and the other used to generate antibodies. For Omidria and each of our product candidates and our programs, we have retained all manufacturing, marketing and distribution rights.

### Commercial Product

Omidria was approved by the U.S. Food and Drug Administration, or FDA, in May 2014 for use during cataract surgery or IOL replacement surgery to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain. In October 2014 we were granted transitional pass-through reimbursement status from the Centers for Medicare and Medicaid Services, or CMS, for Omidria, effective January 1, 2015. Pass-through status allows for separate payment under Medicare Part B for new drugs and other medical technologies that meet well-established criteria specified by federal regulations governing Medicare spending. We expect pass-through to remain in effect until December 31, 2017, near which time CMS will evaluate utilization of Omidria and will re-assess its reimbursement status. CMS has set the reimbursement rate for Omidria under Medicare Part B at the product's wholesale acquisition cost, or WAC, of \$465 plus six percent (6%) per single-use vial for the second and third quarters of 2015 after which the rate will be based on average selling price, or ASP, plus six percent (6%). Based on our discussions with CMS, we expect this pass-through reimbursement to be effective as of January 1, 2015. We commenced a controlled launch of Omidria to a small number of surgeons in the U.S. in February 2015, with the broad U.S. launch of the product anticipated in early April 2015. Our U.S. marketing and sales leadership, including our national and regional sales managers, have been hired and we currently have 40 contract field sales representatives, solely dedicated to Omeros, deployed and in the field.

In the EU, we submitted a Marketing Authorisation Application, or MAA, to the European Medicines Agency, or EMA, in September 2013 seeking the authorization to permit us to market and sell Omidria in the EU for use in patients undergoing IOL replacement surgery. In October 2013, the MAA for Omidria was validated by the EMA and we expect to receive an opinion on the MAA from the EMA's Committee for Medicinal Products for Human Use, the scientific committee of the EMA, in the first half of 2015. In the EU and other international territories, we plan to enter into one or more partnerships for the marketing and distribution of Omidria. Assuming approval of our MAA for Omidria and success in partnering for Omidria in Europe, we anticipate the initiation of EU marketing and sales of

Omidria in 2015.

#### Product Candidates and Development Programs

We have a pipeline of development programs targeting immune-related disorders, pain, inflammation, coagulopathies and disorders of the central nervous system. We have the following six clinical-stage programs in our pipeline: (1) our lead MASP-2 antibody OMS721, which is in a Phase 2 clinical program in patients with complement-mediated thrombotic microangiopathies; (2) our Phase 2 program evaluating our lead phosphodiesterase 10, or PDE10, inhibitor OMS824 for the treatment of Huntington's disease, which is currently suspended pending further evaluation of an observation from a nonclinical study in rats; (3) our Phase 2 program evaluating OMS824 for the treatment of schizophrenia, which is also currently suspended pending such further evaluation; (4) our PharmacoSurgery product candidate OMS103 for reducing

inflammatory pain following arthroscopic partial meniscectomy, which has completed one Phase 3 trial in patients undergoing this procedure; (5) our PPAR program in which two Phase 2 clinical trials are being conducted by our collaborators to evaluate a PPAR agonist, alone or in combination with other agents, for treatment of addiction to opioids and to nicotine; and (6) our PharmacoSurgery product candidate OMS201 for use during urological procedures, including uroendoscopic procedures, which has completed a Phase 1/Phase 2 clinical trial in 2010 and is not currently in active clinical trials. OMS721 has received Orphan Drug designation for the prevention (inhibition) of complement-mediated TMAs. OMS824 has received Orphan Drug designation for the treatment of Huntington's disease and Fast Track designation for the treatment of cognitive impairment in patients with Huntington's disease. In addition, we have a diverse group of preclinical programs, which include: (1) our PDE7 program in which we are developing proprietary compounds to treat addiction and compulsive disorders as well as movement disorders; (2) our Plasmin program in which we are advancing novel antifibrinolytic agents for the control of blood loss during surgery or resulting from trauma as well as for other hyperfibrinolytic states (e.g., liver disease); (4) our OMS906 program in which we are developing MASP-3 inhibitors; and (4) our GPR17 program in which we are optimizing compounds against GPR17, an orphan GPCR linked to myelin formation. We also have two additional platforms: one used to generate antibodies and the other capable of unlocking new G protein-coupled receptor, or GPCR, drug targets.

#### Financial Summary

We recognized net losses of \$73.7 million, \$39.8 million, and \$38.4 million for the years ended December 31, 2014, 2013 and 2012, respectively. These losses are principally from expenses incurred in connection with research and development activities which consisted primarily of clinical trials, manufacturing services and preclinical studies associated with our current research and development programs. We expect our net losses to continue in the near term as we continue to prepare for the planned broad commercial launch of Omidria in the U.S. in early April 2015, advance our clinical trials, and expand our other research and development efforts. As of December 31, 2014, our accumulated deficit was \$328.0 million and total shareholders' deficit was \$42.7 million.

In February 2015, we sold 3.4 million shares of our common stock at a public offering price of \$20.03 per share and sold pre-funded warrants to purchase up to 749,250 shares of our common stock at a public offering price of \$20.02 per pre-funded warrant share. After deducting underwriter discounts and offering expenses of \$4.9 million, we received net proceeds from the transaction of approximately \$79.1 million.

#### Results of Operations

##### Revenue

Historically, our revenue has consisted of grant funding and revenue recognized in connection with funding from third parties.

	Years Ended December 31,		
	2014	2013	2012
	(In thousands)		
Small Business Innovative Research Grant (SBIR)	\$539	\$630	\$721
Vulcan Inc.	—	970	4,677
Life Science Development Fund Authority (LSDF)	—	—	624
Total Revenue	\$539	\$1,600	\$6,022

Revenue was \$539,000, \$1.6 million and \$6.0 million for the years ended December 31, 2014, 2013 and 2012, respectively. The decreases in revenue were primarily due to lower revenue recognized from our GPCR program funding agreements with Vulcan and LSDF. We recognized all remaining revenue associated with these agreements during 2013 and 2012, respectively.

We do not expect to receive significant product revenue until we begin broadly selling Omidria in the U.S., which is currently expected in early April 2015, and we do not expect to receive revenue from our product candidates unless we receive regulatory approval and commercialize our product candidates or enter into collaborative agreements for the development and commercialization of our product candidates. We continue to pursue government and private grant funding as well as collaboration funding for our product candidates and research programs.



## Research and Development Expenses

Our research and development expenses can be divided into direct external expenses, which include clinical research and development and preclinical research and development activities; internal, overhead and other expenses; and stock-based compensation expense. The following table illustrates our expenses associated with these activities:

	Years Ended December 31,		
	2014	2013	2012
	(In thousands)		
Direct external expenses:			
Clinical research and development:			
OMS824	\$10,974	\$7,265	\$990
OMS721	8,064	1,996	—
Omidria (OMS302)	5,751	4,477	8,622
OMS103	89	404	2,773
Other clinical programs	55	35	52
Total clinical research and development	24,933	14,177	12,437
Preclinical research and development	2,252	4,149	6,019
Total direct external expenses	27,185	18,326	18,456
Internal, overhead and other expenses	16,007	14,383	11,275
Stock-based compensation expense	4,754	3,588	2,191
Total research and development expenses	\$47,946	\$36,297	\$31,922

The increase in total research and development expenses during the year ended December 31, 2014 compared to 2013 was due primarily to higher direct external expenses related to our Phase 1 and Phase 2 clinical trials evaluating OMS824 and OMS721, which included costs for manufacturing of drug material used in the clinical trials, drug stability testing, toxicology studies and contract research organization, or CRO, costs for monitoring and management of the clinical studies; higher direct external expenses related to our Phase 3 clinical trials evaluating Omidria, including the U.S. pediatric study; and higher internal, overhead and other expenses. Non-cash stock compensation expense increased for the year-ended December 31, 2014 compared to the same period in 2013 due to the granting of stock options during 2014 related to annual employee performance reviews and the granting of stock options for new personnel. These increased expenses were partially offset by lower preclinical activity on our PDE7 program. We expect our research and development expenses to increase for the year ended December 31, 2015 as compared to the year ended December 31, 2014 as we advance our clinical product candidates through development, continue pediatric and other studies for Omidria, advance Omidria through the European regulatory approval process and initiate clinical trials for our Plasmin and PDE7 programs. We also expect non-cash stock-based compensation expense to increase for the year ended December 31, 2015 due to future stock option grants.

The increase in total research and development expenses for 2013 compared to 2012 was primarily due to higher direct external expenses related to our Phase 1 clinical trials evaluating OMS824 and OMS721; higher internal, overhead and other expenses; the preparation and filing of the NDA and MAA for Omidria and non-cash rent expense associated with the lease of our new facilities; and expense related to non-cash stock compensation. Non-cash stock compensation expense increased for the year-ended December 31, 2013 compared to the same period in 2012 due to the granting of stock options during the fourth quarter of 2012 and the third quarter of 2013 related to annual employee performance reviews and the granting of stock options for new personnel. These increased expenses for the year-ended December 31, 2013 were partially offset by lower clinical research and development expenses related to the completion of our Omidria Phase 3 clinical trial in January 2013 and the first OMS103 Phase 3 clinical trial for meniscectomy in December 2012.

Direct external clinical research and development expenses consist primarily of expenses incurred pursuant to agreements with third-party manufacturing organizations, CROs, clinical trial sites, collaborators, licensors and consultants. Direct external preclinical research and development expenses consist primarily of third-party manufacturing organizations and CROs, laboratory supplies and consulting. Costs are reported in preclinical research



and development until the program enters the clinic. Internal, overhead and other expenses consist of personnel costs, overhead costs such as rent, utilities and depreciation and other miscellaneous costs. Our internal resources, employees and infrastructure are generally not directly tied to any individual research project and are deployed across multiple clinical and preclinical projects that we are advancing in parallel.

At this time, due to the inherently unpredictable nature of our preclinical and clinical development activities and given the early stage of many of our preclinical development programs, we are unable to estimate with any certainty the costs we will incur in the continued development of our product candidates. Clinical development timelines, the probability of success and development costs can differ materially as expectations change. While we currently are focused on advancing our product development programs, our future research and development expenses will depend on the preclinical or clinical success of each product candidate as well as ongoing assessments of each program's commercial potential. In addition, we cannot forecast with any degree of certainty which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

The lengthy process of completing clinical trials and seeking regulatory approval for our product candidates requires the expenditure of substantial resources. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenue and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations, financial condition and liquidity. Because of the factors above, we are not able to estimate with any certainty when we would recognize any net cash inflows from our research and development projects.

#### Selling, General and Administrative Expenses

	Years Ended December 31,		
	2014	2013	2012
	(In thousands)		
Selling, general and administrative, excluding stock-based compensation expense	\$18,437	\$13,155	\$8,895
Stock-based compensation expense	4,164	2,664	2,090
Total selling, general and administrative expenses	\$22,601	\$15,819	\$10,985

The increase in selling, general and administrative expenses during the year ended December 31, 2014 compared to the same period of 2013 was primarily due to higher expenses related to the preparation for the U.S. commercial launch of Omidria, which includes the costs for obtaining and training a third party sales force, the design and creation of marketing materials and the costs related to attending trade shows and conferences; and increased costs related to additional employees and non-cash stock-based compensation related to the stock option grants related to annual employee performance reviews in 2014. These increases were partially offset by reduced legal fees and the expenses incurred in 2013 in connection with the matter against our former insurer and the \$1.064 million we paid in 2013 to the National Institute of Health, or NIH, in connection with its administrative review (see Note 8 to our Consolidated Financial Statements in this Annual Report on Form 10-K). We expect our selling, general and administrative expenses to increase for the year ended December 31, 2015 compared to the year ended December 31, 2014 as we increase our sales and marketing costs due to the planned broad U.S. commercial launch of Omidria in early April 2015. We also expect non-cash stock-based compensation expense to increase for the year ended December 31, 2015 due to future stock option grants.

The increase in the year ended 2013 compared to the same period of 2012 was primarily due to legal matters, including expenses incurred in connection with the matter against our former insurer and patent filing fees related to our product and product candidates, the \$1.064 million we paid to the NIH in connection with its administrative review, higher expenses associated with the preparation for the potential commercial launch of Omidria, expenses related to non-cash stock-based compensation, employee costs and non-cash rent expense associated with the lease of our new facilities.

#### Litigation Settlement

Litigation settlement is the \$12.5 million payment we received from our former insurer related to their defense of, and coverage obligations related to, the Klein lawsuit. See Note 8 to our Consolidated Financial Statements in this Annual Report on Form 10-K for further description of the settlement.

#### Interest Expense

Years Ended December 31,

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	2014	2013	2012
	(In thousands)		
Interest Expense	\$3,470	\$2,366	\$1,729

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Interest expense was \$3.5 million and \$2.4 million for the years ended December 31, 2014 and 2013, respectively. The increase in 2014 compared to 2013 was due to a higher average balance on our note payable during the 2014 period due to our entry in March 2014 into the Oxford/MidCap Loan Agreement with Oxford Finance LLC, or Oxford, and MidCap Financial SBIC, LP, or MidCap, under which we increased the aggregate amount of our outstanding indebtedness by \$12.7 million. Interest expense was \$1.7 million for the year ended December 31, 2012, with the increase in 2013 from 2012 being due to a higher average balance and a higher effective interest rate on our then outstanding Oxford note payable.

Other Income (Expense), Net

Years Ended December 31,		
2014	2013	2012
(In thousands)		

Other Income (Expense), Net	\$(207 )	\$574	\$130
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Other income (expense) principally includes sublease rental income and non-cash charges associated with warrant modifications. The decrease during the year ended December 31, 2014 compared to 2013 is due to \$863,000 of warrant modification expense being recognized partially offset by increased sublease rental income. The increase in other income (expense) during the year ended December 31, 2013 is due to a \$470,000 decrease in the amount of warrant modification expense compared to 2012.

#### Financial Condition - Liquidity and Capital Resources

As of December 31, 2014, we had \$6.9 million in cash, cash equivalents and short-term investments. Our cash, cash equivalents and short-term investment balances are held principally in interest-bearing instruments, including money-market accounts. Cash in excess of immediate requirements is invested in accordance with established guidelines to preserve principal and maintain liquidity.

In February 2015, we sold 3.4 million shares of our common stock at a public offering price of \$20.03 per share and sold pre-funded warrants to purchase up to 749,250 shares of our common stock at a public offering price of \$20.02 per pre-funded warrant share. After deducting underwriter discounts and offering expenses of \$4.9 million, we received net proceeds from the transaction of approximately \$79.1 million. In addition, we anticipate beginning a broad-based U.S. launch of Omidria, our first commercial product, in early April 2015. We may also have the opportunity to raise equity capital through public or private securities offerings, the incurrence of additional debt, corporate partnerships, asset sales or through the pursuit of collaborations and licensing arrangements related to certain of our programs, which may not be available on acceptable terms, if at all. Should it be necessary to manage our operating expenses, we would reduce our projected capital requirements by reducing our expenses by delaying clinical trials, reducing selected research and development efforts, or implementing other restructuring activities. We believe that our existing cash, cash equivalents and short-term investments and the proceeds from our securities offering in February 2015, together with anticipated future sales from Omidria and our ability to manage expenses, will be sufficient to fund our anticipated operating expenses, capital expenditures and interest and principal payments on our outstanding notes for at least the next 12 months.

Years ended December 31,		
2014	2013	2012
(In thousands)		

Selected cash flow data:

Cash provided by (used in):

Operating activities	\$(58,044 )	\$(29,695 )	\$(34,551 )
Investing activities	6,157	7,909	(907 )
Financing activities	50,857	21,650	32,973

Operating Activities. Net cash used in operating activities increased for the year ended December 31, 2014 by \$28.3 million as compared to the same period in 2013. This increase was primarily related to the increase in our net loss by \$33.9 million from 2013 in large part due to an \$18.4 million increase in operating expenses, which were partially offset during 2013 by the \$12.5 million we received in the litigation settlement with our former insurer. The increase

in operating expenses was primarily related to an \$11.6 million increase in research and development operating activities and a \$6.8 million increase in selling, general and administrative expenses in support of our planned launch of Omidria in the U.S. and general operations. Other activities impacting the increase in net cash used in operating activities between the comparative periods was a \$902,000

increase in the deferred rent associated with the rent abatement at The Omeros Building, a \$987,000 increase in prepaid expenses and other current and noncurrent assets and a \$568,000 increase in inventory. An increase of \$5.5 million in accounts payable and accrued liabilities in 2014 partially offset the overall increase in cash used for the year ended December 31, 2014.

Net cash used in operating activities decreased \$4.9 million for the year ended December 31, 2013 as compared to the same period in 2012. Our net loss increased \$1.4 million from 2012 primarily due to a \$4.4 million decrease in revenue and a \$9.2 million increase in our operating expenses partially offset by the \$12.5 million we received in the litigation settlement with our former insurer. Other activities impacting the decrease in net cash used in operating activities was a \$3.5 million increase in deferred rent associated with the rent abatement at The Omeros Building, a \$2.0 million increase in non-cash stock compensation, a \$1.6 million increase in grant and other receivables and a \$1.0 million decrease in deferred revenue.

**Investing Activities.** Investing activities, other than the purchases and sales of short-term investments, consists of purchases of property and equipment. Cash flows from investing activities primarily reflect cash used to purchase short-term investments and proceeds from the sale of short-term investments, thus causing a shift between our cash and cash equivalents and short-term investment balances. Because we manage our cash usage with respect to our total cash, cash equivalents and short-term investments, we do not consider these cash flows to be important to the understanding of our liquidity and capital resources.

Net cash provided from investing activities for the year ended December 31, 2014 was \$6.2 million, a decrease of \$1.8 million from 2013. Of the decrease in cash provided by investing activities between 2014 and 2013, \$1.9 million was from the purchase of short-term investments year-over-year exceeding sale of short-term investments. This was offset by our \$176,000 decrease in purchases of property and equipment in 2014 compared to 2013.

Net cash used in investing activities for the year ended December 31, 2013 was \$7.9 million, an increase of \$8.8 million from 2012. Of the incremental cash provided between 2013 and 2012, \$8.4 million was from the sale of short-term investments exceeding the purchase of short-term investments. In addition, our purchases of property and equipment in 2013 were \$438,000 less than in 2012.

**Financing Activities.** Net cash provided from financing activities in the year ended December 31, 2014 was \$50.9 million, a \$29.2 million increase from 2013 primarily due to the additional proceeds from the sale of our common stock and the additional borrowings in 2014. In March 2014, we received \$37.8 million of net proceeds from the sale of 3.5 million shares of common stock in a public offering and \$12.7 million from net additional borrowings under the Oxford/MidCap Loan Agreement. During the 2014 period, we also received \$1.9 million upon the exercise of employee stock options and paid \$1.5 million of principal on the Oxford notes prior to entering into the Oxford/MidCap Loan Agreement.

Net cash provided from financing activities for the year ended December 31, 2013 was \$21.7 million, a decrease of \$11.3 million from 2012 primarily due to the proceeds from common stock offerings in both periods. During the 2013 period, we received \$16.1 million in May when we sold 3.9 million shares of common stock, \$4.9 million in October from the sale of 374,000 shares of our common stock under our At-the-Market, or ATM, agreement and \$662,000 upon the exercise of employee stock options during the year. This compared to the year ended December 31, 2012 in which we received \$32.3 million in net proceeds from the sale of 3.4 million shares of our common stock in July 2012. In December 2012, we also received net proceeds of \$6.5 million under the Oxford Loan Agreement.

#### Funding Requirements

Because of the numerous risks and uncertainties associated with the development and commercialization of Omidria and our product candidates, and to the extent that we may or may not enter into collaborations with third parties to participate in the development and commercialization of Omidria or one or more of our product candidates, we are unable to estimate the amounts of increased capital requirements and operating expenditures required in the future.

Our future operating and capital requirements will depend on many factors, including:

- our ability to launch Omidria in the U.S. and its commercial success thereafter;
- our ability to enter into a partnership for the distribution of Omidria in the EU;
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the commercial success of Omidria in the EU, if and when Omidria is approved for sale and we have entered into a partnership for the marketing and distribution of Omidria in the EU;

- the progress and results of our preclinical and clinical programs;
- the costs of commercialization activities, including product manufacturing, marketing, sales and distribution and related support activities;
- the cost, timing and outcomes of the regulatory processes for our product candidates;

- the extent to which we raise capital by selling our stock or entering into other forms of financing including debt agreements;
- the terms and timing of receipts or payments related to collaborative or licensing agreements we have or may establish;
- the hiring of new employees to support the commercialization of Omidria and the continued advancement of our development programs;
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to these types of transactions; and
- the cost of preparing, filing, prosecuting, defending and enforcing patent claims and other intellectual property rights.

We expect our continued operating losses to result in an increase in the total amount of cash used in operations until at least the time that Omidria becomes cash flow positive, which may be in several years, if at all. To meet our future capital requirements, we may need to fund our future cash needs through corporate partnerships, equity offerings, debt financings, collaborations, licensing arrangements or asset sales. Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If additional capital is required and we do not raise additional capital through equity or debt financings or collaborations and licensing arrangements, we may be required to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts. We currently do not have any commitments for future external equity or debt funding.

#### Loan and Security Agreement

In March 2014, we entered into the Oxford/MidCap Loan Agreement, with Oxford and MidCap, pursuant to which we borrowed \$32.0 million. We used approximately \$19.1 million of the loan proceeds to satisfy all of the amounts owed by us under our then-outstanding loan from Oxford and, after deducting all loan initiation costs, we received \$12.7 million in net proceeds. Part of the costs paid included \$520,000 for the prorated portion of the \$1.4 million loan maturity fee payable under our then outstanding loan agreement with Oxford, with no further obligation for the remaining \$880,000. We have used the loan proceeds for general corporate purposes and working capital.

Interest on the amounts borrowed under the Oxford/MidCap Loan Agreement accrues at an annual fixed rate of 9.25% and payments are interest-only, payable monthly, in arrears, through March 1, 2015. Beginning April 1, 2015, 36 payments of \$1.0 million, which include principal and interest, are payable monthly, in arrears until all unpaid principal and accrued and unpaid interest are due and payable on March 1, 2018.

In consideration for the lenders agreeing to provide us with a one-year period of interest-only payments, we will be required to pay the lenders a final payment fee equal to 7.00% of the original principal amount borrowed under the Oxford/MidCap Loan Agreement (i.e., \$2.2 million), less any portion of the fee previously paid in connection with a prepayment. We may prepay all or a portion of the outstanding principal and accrued and unpaid interest at any time upon prior notice to the lenders and the payment of a fee equal to 1.00% of the prepaid principal amount in addition to the pro rata portion of the final payment fee attributable to the prepaid principal amount. As security for our obligations under the Oxford/MidCap Loan Agreement, we granted Oxford, as collateral agent for the lenders, a security interest in substantially all of our assets, excluding intellectual property.

The Oxford/MidCap Loan Agreement contains covenants that limit or restrict our ability to incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay dividends or make distributions, pledge our intellectual property or repurchase stock. Additionally, the Oxford/MidCap Loan Agreement includes events of default regarding non-payment, inaccuracy of representations and warranties, covenant breach, occurrence of a material adverse effect, or MAE (as defined below), cross default to material indebtedness, bankruptcy or insolvency, material judgment defaults and a change of control. The occurrence of an event of default could result in the acceleration of the Oxford/MidCap Loan Agreement and, under certain circumstances, could increase our interest rate by 5.0% per annum during the period of default.

MAE is defined as a material adverse effect upon (i) our business operations, properties, assets, results of operations or financial condition of Omeros, taken as a whole with respect to our viability, that reasonably would be expected to result in our inability to repay any portion of the loans in accordance with the terms of the Oxford/MidCap Loan Agreement, (ii) the validity, perfection, value or priority of the lenders' security interest in the collateral, (iii) the



enforceability of any material provision of the Oxford/MidCap Loan Agreement or related agreements, or (iv) the ability of the lenders to enforce their rights and remedies under the Oxford/MidCap Loan Agreement or related agreements. We considered the MAE definition and believe that there has been no MAE under the Oxford/MidCap Loan Agreement as of December 31, 2014.

## Contractual Obligations and Commitments

The following table presents a summary of our contractual obligations and commitments as of December 31, 2014.

	Payments Due Within				
	1 Year	2-3 Years	4-5 Years	More than 5 Years	Total
	(In thousands)				
Operating leases	\$3,993	\$8,250	\$8,603	\$37,713	\$58,559
Capital leases (principal and interest)	54	108	49	—	211
Notes payable (principal and interest)	9,932	24,512	3,064	—	37,508
Goods & Services	\$8,024	\$643	\$—	\$—	8,667
Total	\$22,003	\$33,513	\$11,716	\$37,713	\$104,945

## Operating Leases

We currently lease our office and laboratory space in The Omeros Building under a lease agreement with BMR. The initial term of the lease ends in November 2027 and we have two options to extend the lease term, each by five years. As of December 31, 2014, the remaining aggregate non-cancelable rent payable under the initial term of the lease is approximately \$58.6 million.

## Goods &amp; Services

In June 2014, we entered into an agreement with Ventiv Commercial Services, LLC, or inVentiv, for field sales representatives and related sales operation services for the U.S. commercial launch of Omidria. In October 2014, we entered into an amendment to the agreement with inVentiv for additional sales representatives in the U.S. As of December 31, 2014, under the terms of the amendment, our total monthly fee is approximately \$630,000 including the additional sales representatives provided by inVentiv beginning in December 2014. We can terminate the agreement upon 30 days written notice if Omidria is withdrawn from the market for any reason or a regulatory agency acts to prevent or materially restrict the sale of Omidria, or upon 90 days written notice any time subsequent to January 2016. The estimated costs for this agreement through January 2016 are included in the table above.

We have a non-exclusive agreement with Patheon Manufacturing Services LLC, or Patheon, for commercial supply of Omidria through December 31, 2015. We are required to provide a monthly, non-binding production forecast covering the term of the contract. Upon submission of the monthly forecast, a portion of the forecast becomes a firm purchase commitment. In the event we do not purchase the quantities included in the firm purchase commitment, we would owe a cancellation fee. The firm purchase commitment as of December 31, 2014 is included in the table above.

We may also be required, in connection with in-licensing or asset acquisition agreements, to make certain royalty and milestone payments that we cannot, at this time, determine when or if the related milestones will be achieved or whether the events triggering the commencement of payment obligations will occur. See Note 8 to our Consolidated Financial Statements in this Annual Report on Form 10-K for a description of the agreements that include these royalty and milestone payment obligations.

## Critical Accounting Policies and Significant Judgments and Estimates

The 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 generally accepted accounting principles in the U.S. The preparation of our financial statements requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances; however, actual results could differ from those estimates. An accounting policy is considered critical if it is important to a company's financial condition and results of operations and if it requires the exercise of significant judgment and the use of estimates on the part of management in its application. Although we believe that our judgments and estimates are appropriate, actual results may differ materially from our estimates.



We believe the following to be our critical accounting policies because they are both important to the portrayal of our financial condition and results of operations and they require critical judgment by management and estimates about matters that are uncertain:

- revenue recognition;
- research and development expenses, primarily clinical trial expenses; and
- stock-based compensation.

If actual results or events differ materially from those contemplated by us in making these estimates, our reported financial condition and results of operations for future periods could be materially affected.

#### Revenue Recognition

The accounting standard for revenue provides a framework for accounting for revenue arrangements. A variety of factors are considered in determining the appropriate method of revenue recognition under revenue arrangements, such as whether the various elements can be considered separate units of accounting, whether there is objective and reliable evidence of fair value for these elements and whether there is a separate earnings process associated with a particular element of an agreement.

Revenue is recognized when there is persuasive evidence that an arrangement exists, service has been provided, the price is fixed or determinable and collection is reasonably assured. Our revenue relates to grant funding from third parties. We recognize revenue from grants when the related qualifying research and development expenses are incurred up to the limit of the approved funding amounts. Funds received in advance of services being provided are recorded as deferred revenue and recognized as revenue as research is performed.

#### Research and Development Expenses

Research and development costs are comprised primarily of costs for personnel, including salaries, benefits and stock compensation; an allocation of our occupancy costs; clinical study costs; contracted research; manufacturing; consulting arrangements; depreciation; materials and supplies; milestones; and other expenses incurred to sustain our overall research and development programs. Clinical trial expenses for investigational sites require certain estimates. We estimate these costs based on a cost per patient that varies depending on the clinical trial site. As actual costs become known to us, we adjust our estimates; these changes in estimates may result in understated or overstated expenses at a given point in time. Research and development costs are expensed as incurred.

Advanced payments for goods or services that will be used or rendered for future research and development activities are deferred and then recognized as an expense as the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided.

#### Stock-Based Compensation

Stock-based compensation expense is recognized for all share-based payments made to employees, directors and non-employees based on estimated fair values. The fair value of our stock options is calculated using the Black-Scholes option valuation model, which requires judgmental assumptions, including volatility, forfeiture rates and expected option life. If any of the assumptions used in the Black-Scholes model change significantly, stock-based compensation expense for new awards may differ materially from that recorded for existing awards and stock-based compensation for non-employees will vary as the awards are re-measured over the vesting term.

As stock-based compensation expense is based on options ultimately expected to vest, the expense has been reduced for estimated forfeitures. We estimate forfeitures for expense recognition based on our historical experience. Groups of employees that have similar historical forfeiture behavior are considered separately. We use the straight-line method to allocate compensation cost to reporting periods over the optionees' requisite service period for employees and directors, which is generally the vesting period.

Stock options granted to non-employees are accounted for using the fair-value approach using the Black-Scholes option-pricing model and are re-measured over the vesting term as earned. The estimated fair value is charged to expense over the applicable service period.

#### Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board issued Accounting Standards Update, or ASU, No. 2014-15 related to disclosure of an entity's ability to continue as a going concern. This standard requires management to evaluate whether substantial doubt exists regarding the entity's ability to continue as a going concern at each

reporting period for a

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period of one year after the date the financial statements are issued or available to be issued. The standard establishes certain required disclosures if substantial doubt exists. This standard must be applied prospectively and is effective for interim and annual periods beginning after December 15, 2016. We will review the impact of the standard upon our disclosures, if applicable, beginning in 2017.

In May 2014, the Financial Accounting Standards Board issued ASU No. 2014-09 related to the recognition of revenue that supersedes existing guidance. This standard clarifies the principles for recognizing revenue utilizing a five-step process. This standard must be applied retroactively to each prior reporting period presented, or retrospectively with the cumulative effect of applying the standard recognized in the period adopted. This standard is effective for interim and annual periods beginning after December 15, 2016 and cannot be adopted before that effective date. We are currently evaluating the impact this standard may have on our financial statements once it is adopted.

#### Off-Balance Sheet Arrangements

We have not engaged in any off-balance sheet arrangements.

#### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is primarily confined to our investment securities and notes payable. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in high-credit-quality securities. As of December 31, 2014, we had cash, cash equivalents and short-term investments of \$6.9 million. In accordance with our investment policy, we invest funds in highly liquid, investment-grade securities. These securities in our investment portfolio are not leveraged and are classified as available-for-sale. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that an increase in market rates would have a material negative impact on the realized value of our investment portfolio. We actively monitor changes in interest rates and with our current portfolio of short term investments, we are not exposed to potential loss due to changes in interest rates.

#### ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See Item 15 of this Annual Report on Form 10-K.

#### ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

#### ITEM 9A. CONTROLS AND PROCEDURES

##### Disclosure Controls and Procedures

Our management, with the participation of our principal executive and principal financial officers, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of December 31, 2014. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2014, our principal executive and principal financial officers concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

##### Internal Control Over Financial Reporting

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). 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.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting.

However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Our management, with the participation of our principal executive and principal financial officers, conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2014. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013 framework). Based on the results of this assessment and on those criteria, our management concluded that our internal control over financial reporting was effective as of December 31, 2014.

Ernst & Young LLP has independently assessed the effectiveness of our internal control over financial reporting as of December 31, 2014 and its report is included below.

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during our fourth fiscal quarter of 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.



**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Shareholders of Omeros Corporation

We have audited Omeros Corporation'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). Omeros Corporation'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 Annual 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, Omeros Corporation 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 Omeros Corporation as of December 31, 2014 and 2013, and the related consolidated statements of operations and comprehensive loss, shareholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2014 of Omeros Corporation and our report dated March 16, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP  
Seattle, Washington  
March 16, 2015

ITEM 9B. OTHER INFORMATION

None.

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## PART III

## ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item will be contained in our definitive proxy statement issued in connection with the 2015 Annual Meeting of Shareholders and is incorporated herein by reference. Certain information required by this item concerning executive officers is set forth in Part I of this Annual Report on Form 10-K in “Business-Executive Officers and Key Employees.”

ITEM 11. EXECUTIVE  
COMPENSATION

The information required by this item will be contained in our definitive proxy statement issued in connection with the 2015 Annual Meeting of Shareholders and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND  
RELATED SHAREHOLDER MATTERS

Except for the information set forth below, the information required by this item will be contained in our definitive proxy statement issued in connection with the 2015 Annual Meeting of Shareholders and is incorporated herein by reference.

## Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides certain information regarding our equity compensation plans in effect as of December 31, 2014:

	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans
Equity compensation plans approved by security holders:			
2008 Equity Incentive Plan (1)	6,790,055	\$ 8.98	238,836
Amended and Restated 1998 Stock Option Plan	1,574,239	1.25	—
nura inc.	175	\$ 10.63	—
Total	8,364,469	\$ 7.52	238,836

(1) Our 2008 Equity Incentive Plan (the 2008 Plan) provides for the grant of incentive and nonstatutory stock options, restricted stock, stock appreciation rights, performance units and performance shares to employees, directors and consultants and subsidiary corporations’ employees and consultants. The 2008 Plan also allows any shares returned under our Amended and Restated 1998 Stock Option Plan (the 1998 Plan) as a result of cancellation of options or repurchase of shares issued pursuant to the 1998 Plan, to be issued under the 2008 Plan. In addition, our 2008 Plan provides for annual increases in the number of shares available for issuance thereunder on the first day of each year equal to the lower of: (i) five percent of the outstanding shares of our common stock on the last day of the preceding year; (ii) 1,785,714 shares; and (iii) such other amount as our board of directors may determine. On January 1, 2015, an additional 1,709,273 shares became available for future issuance under our 2008 Plan in accordance with the annual increase. These additional shares from the annual increase are not included in the table above.

## ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item will be contained in our definitive proxy statement issued in connection with the 2015 Annual Meeting of Shareholders and is incorporated herein by reference.

## ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item will be contained in our definitive proxy statement issued in connection with the 2015 Annual Meeting of Shareholders and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this Annual Report on Form 10-K:

1. Financial Statements

Reference is made to the Index to the Financial Statements set forth on page F-1 of this Annual Report on Form 10-K.

2. Financial Statement Schedules

All schedules have been omitted as the required information is either not required, not applicable, or otherwise included in the Financial Statements and notes thereto.

3. Exhibits

Reference is made to the Exhibit Index that is set forth after the Financial Statements in this Annual Report on Form 10-K.

## 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.

OMEROS CORPORATION  
 /s/ GREGORY A. DEMOPULOS, M.D.  
 Gregory A. Demopulos, M.D.  
 President, Chief Executive Officer  
 and Chairman of the Board of Directors

Dated: March 16, 2015

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/ GREGORY A. DEMOPULOS, M.D. Gregory A. Demopulos, M.D.	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	March 16, 2015
/s/ MICHAEL A. JACOBSEN Michael A. Jacobsen	Vice President, Finance, Chief Accounting Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)	March 16, 2015
/s/ RAY ASPIRI Ray Aspiri	Director	March 16, 2015
/s/ THOMAS J. CABLE Thomas J. Cable	Director	March 16, 2015
/s/ PETER A. DEMOPULOS, M.D. Peter A. Demopulos, M.D.	Director	March 16, 2015
/s/ ARNOLD C. HANISH Arnold C. Hanish	Director	March 16, 2015
/s/ LEROY E. HOOD, M.D., PH.D. Leroy E. Hood, M.D., Ph.D.	Director	March 16, 2015

OMEROS CORPORATION  
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders

Omeros Corporation

We have audited the accompanying consolidated balance sheets of Omeros Corporation as of December 31, 2014 and 2013, and the related consolidated statements of operations and comprehensive loss, shareholders' equity (deficit) and cash flows for each of the three 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 also 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 Omeros Corporation at December 31, 2014 and 2013, and the consolidated results of its operations and its cash flows for each of the three 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), Omeros Corporation'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 16, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Seattle, Washington

March 16, 2015

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OMEROS CORPORATION  
CONSOLIDATED BALANCE SHEETS  
(In thousands, except share and per share data)

	December 31,	
	2014	2013
Assets		
Current assets:		
Cash and cash equivalents	\$354	\$1,384
Short-term investments	6,532	12,717
Receivables	392	379
Inventory	568	—
Prepaid expense	1,191	251
Other current assets	120	86
Total current assets	9,157	14,817
Property and equipment, net	782	939
Restricted cash	679	679
Other assets	472	100
Total assets	\$11,090	\$16,535
Liabilities and shareholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$4,915	\$2,329
Accrued expenses	7,070	3,944
Current portion of notes payable, net of discount	6,446	5,600
Total current liabilities	18,431	11,873
Notes payable, net of current portion and discount	26,263	14,898
Deferred rent	9,050	8,148
Commitments and contingencies (Note 8)		
Shareholders' equity (deficit):		
Preferred stock, par value \$0.01 per share:		
Authorized shares—20,000,000 at December 31, 2014 and 2013;		
Issued and outstanding shares—none	—	—
Common stock, par value \$0.01 per share:		
Authorized shares—150,000,000 at December 31, 2014 and 2013;		
Issued and outstanding shares—34,185,464 and 30,359,508 at December 31, 2014 and 2013, respectively	342	304
Additional paid-in capital	285,050	235,685
Accumulated deficit	(328,046 )	(254,373 )
Total shareholders' equity (deficit)	(42,654 )	(18,384 )
Total liabilities and shareholders' equity (deficit)	\$11,090	\$16,535
See notes to consolidated financial statements		

## OMEROS CORPORATION

## CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

	Year Ended December 31,		
	2014	2013	2012
Revenue	\$539	\$1,600	\$6,022
Operating expenses:			
Research and development	47,946	36,297	31,922
Selling, general and administrative	22,601	15,819	10,985
Total operating expenses	70,547	52,116	42,907
Loss from operations	(70,008 )	(50,516 )	(36,885 )
Litigation settlement	—	12,500	—
Investment income	12	12	40
Interest expense	(3,470 )	(2,366 )	(1,729 )
Other income (expense), net	(207 )	574	130
Net loss	\$(73,673 )	\$(39,796 )	\$(38,444 )
Comprehensive loss	\$(73,673 )	\$(39,796 )	\$(38,444 )
Basic and diluted net loss per share	\$(2.22 )	\$(1.39 )	\$(1.59 )
Weighted-average shares used to compute basic and diluted net loss per share	33,234,294	28,560,360	24,155,690
See notes to consolidated financial statements			

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## OMEROS CORPORATION

## CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)

(In thousands, except share and per share data)

	Common Stock		Additional	Accumulated	Total
	Shares	Amount	Paid-in Capital	Deficit	Shareholders' Deficit
Balance at December 31, 2011	22,430,234	\$224	\$170,355	\$(176,133 )	\$(5,554 )
Issuance of common stock, net of offering costs	3,365,854	34	32,272	—	32,306
Issuance of common stock upon exercise of stock options for cash	101,395	1	368	—	369
Stock-based compensation	—	—	4,281	—	4,281
Warrant modification	—	—	511	—	511
Net loss	—	—	—	(38,444 )	(38,444 )
Balance at December 31, 2012	25,897,483	259	207,787	(214,577 )	(6,531 )
Issuance of common stock, net of offering costs	3,903,004	39	16,081	—	16,120
Issuance of common stock utilizing At-The-Market Agreement, net of commissions	373,700	4	4,864	—	4,868
Issuance of common stock upon exercise of stock options for cash	185,321	2	660	—	662
Stock-based compensation	—	—	6,252	—	6,252
Warrant modification	—	—	41	—	41
Net loss	—	—	—	(39,796 )	(39,796 )
Balance at December 31, 2013	30,359,508	304	235,685	(254,373 )	(18,384 )
Issuance of common stock, net of offering costs	3,500,000	35	37,719	—	37,754
Issuance of common stock upon exercise of warrants	28,653	—	68	—	68
Issuance of common stock upon exercise of stock options for cash	297,303	3	1,797	—	1,800
Stock-based compensation	—	—	8,918	—	8,918
Warrant modification	—	—	863	—	863
Net loss	—	—	—	(73,673 )	(73,673 )
Balance at December 31, 2014	34,185,464	\$342	\$285,050	\$(328,046 )	\$(42,654 )

See notes to consolidated financial statements

OMEROS CORPORATION  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
(In thousands)

	Year Ended December 31,		
	2014	2013	2012
Operating activities:			
Net loss	\$(73,673 )	\$(39,796 )	\$(38,444 )
Adjustments to reconcile net loss to net cash used in operating activities:			
Gain on sale of assets	(9 )	—	—
Depreciation and amortization	326	302	320
Stock-based compensation expense	8,918	6,252	4,281
Non-cash interest expense	738	502	354
Warrant modification expense	863	41	511
Changes in operating assets and liabilities:			
Receivables	(13 )	1,555	(1,059 )
Inventory	(568 )	—	—
Prepaid expenses and other current and noncurrent assets	(987 )	84	(438 )
Accounts payable and accrued liabilities	5,459	(1,169 )	(2 )
Deferred revenue	—	(970 )	(4,718 )
Deferred rent	902	3,504	4,644
Net cash used in operating activities	(58,044 )	(29,695 )	(34,551 )
Investing activities:			
Purchases and sales of property and equipment, net	(28 )	(204 )	(642 )
Purchases of investments	(58,849 )	(47,182 )	(49,547 )
Proceeds from the sale and maturities of investments	65,034	55,295	49,282
Net cash provided by (used in) investing activities	6,157	7,909	(907 )
Financing activities:			
Proceeds from issuance of common stock, net of offering costs	37,754	20,988	32,306
Net proceeds from borrowings under notes payable	12,699	—	6,492
Payments on notes payable	(1,464 )	—	(6,194 )
Proceeds from issuance of common stock upon exercise of stock options and warrants	1,868	662	369
Net cash provided by financing activities	50,857	21,650	32,973
Net decrease in cash and cash equivalents	(1,030 )	(136 )	(2,485)
Cash and cash equivalents at beginning of period	1,384	1,520	4,005
Cash and cash equivalents at end of period	\$354	\$1,384	\$1,520
Supplemental cash flow information			
Cash paid for interest	\$2,674	\$1,709	\$1,502
Reduction of equipment cost basis due to assets purchased with grant funding	\$80	\$—	\$67
Property acquired under capital lease	\$200	\$—	\$30
See notes to consolidated financial statements			

OMEROS CORPORATION  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1—Organization and Significant Accounting Policies

Organization

We are a biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, coagulopathies and disorders of the central nervous system. Our marketed drug product Omidria<sup>TM</sup> (phenylephrine and ketorolac injection) 1%/0.3% is approved in the U.S. for use during cataract surgery or intraocular lens replacement (IOL replacement surgery) to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain. Omidria is derived from our proprietary PharmacoSurgery<sup>®</sup> platform, which is designed to improve clinical outcomes of patients undergoing ophthalmological, arthroscopic, urological and other surgical procedures, and is based on low-dose combinations of FDA-approved therapeutic agents delivered directly to the surgical site throughout the duration of the procedure to inhibit preemptively inflammation and other problems caused by surgical trauma and to provide clinical benefits both during and after surgery.

Omidria was approved by the U.S. Food and Drug Administration (FDA) in May 2014 for use during cataract surgery or IOL replacement surgery to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain. In October 2014 we were granted transitional pass-through reimbursement status from the Centers for Medicare and Medicaid Services (CMS) for Omidria, effective January 1, 2015. Pass-through status allows for separate payment under Medicare Part B for new drugs and other medical technologies that meet specific criteria. We commenced a controlled launch of Omidria to a small number of surgeons in the U.S. in February 2015, with the broad U.S. launch of the product anticipated in early April 2015.

In September 2013, we submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for Omidria for use in patients undergoing IOL replacement surgery. In the EU and other international territories, we plan to enter into one or more partnerships for the marketing and distribution of Omidria. Assuming approval of our MAA for Omidria and success in partnering for Omidria in Europe, we anticipate the initiation of EU marketing and sales of Omidria in 2015.

We have six clinical-stage development programs in our pipeline, which also includes a diverse group of preclinical programs as well as two additional platforms: one capable of unlocking new G protein-coupled receptor (GPCR) drug targets and the other used to generate antibodies. For Omidria and each of our product candidates and our programs, we have retained all manufacturing, marketing and distribution rights.

Basis of Presentation

Our consolidated financial statements include the financial position and results of operations of Omeros Corporation (Omeros) and our wholly owned subsidiaries. All inter-company transactions have been eliminated. The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for annual financial information and with the instructions to Form 10-K and Rule 10-01 of Regulation S-X.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Significant items subject to such estimates include revenue recognition, fair market value of investments, stock-based compensation expense and accruals for clinical trials and contingencies. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances; however, actual results could differ from these estimates.

Liquidity and Capital Resources

We generated net losses of \$73.7 million, \$39.8 million, and \$38.4 million in 2014, 2013 and 2012, respectively, and had an accumulated deficit of \$328.0 million as of December 31, 2014. As of December 31, 2014, the Company had cash, cash equivalents and marketable securities of \$6.9 million. The Company's operating plans call for cash expenditures to exceed these amounts for the next twelve months due to the continued advancement of our clinical

and preclinical programs as well as United States launch of sales and marketing activities associated with Omidria. To meet these capital requirements, in February 2015, we sold 3.4 million shares of our common stock at a public offering price of \$20.03 per share and sold pre-funded warrants to purchase up to 749,250 shares of our common stock at a public offering price of \$20.02 per pre-funded warrant share. After deducting underwriter discounts and offering expenses of \$4.9 million, we received net proceeds from the transaction of approximately \$79.1 million (see Note 9). In addition, we anticipate beginning broad-based U.S. sales of Omidria, our first commercial product, in early April 2015. We may also have the opportunity to raise equity capital through

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public or private securities offerings, the incurrence of additional debt, corporate partnerships, asset sales or through the pursuit of collaborations and licensing arrangements related to certain of our programs, which may not be available on acceptable terms, if at all. Should it be necessary to manage our operating expenses, we would reduce our projected capital requirements by reducing our expenses by delaying clinical trials, reducing selected research and development efforts, or implementing other restructuring activities.

We believe that our existing cash, cash equivalents and short-term investments, together with the proceeds from our securities offering in February 2015 and anticipated future sales from Omidria, will be sufficient to fund our anticipated operating expenses, capital expenditures and interest and principal payments on our outstanding notes for at least the next 12 months.

#### Financial Instruments and Concentrations of Credit Risk

Cash and cash equivalents, receivables, accounts payable and accrued liabilities, which are recorded at cost, approximate fair value based on the short-term nature of these financial instruments. The fair value of short-term investments is based on quoted market prices. Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash and cash equivalents, short-term investments and receivables. Cash and cash equivalents are held by financial institutions and are federally insured up to certain limits. At times, our cash and cash equivalents balance exceeds the federally insured limits. To limit the credit risk, we invest our excess cash in high quality securities such as money market mutual funds, certificates of deposit and commercial paper.

#### Cash and Cash Equivalents, Short-Term Investments, and Restricted Cash

Cash and cash equivalents include highly liquid investments with a maturity of three months or less on the date of purchase. Short-term investment securities are classified as available-for-sale and are carried at fair value. Unrealized gains and losses are reported as a separate component of shareholders' deficit. Amortization, accretion, interest and dividends, realized gains and losses and declines in value judged to be other-than-temporary are included in investment income. The cost of securities sold is based on the specific-identification method. Investments in securities with maturities of less than one year, or those for which management intends to use the investments to fund current operations, are included in current assets. We evaluate whether an investment is other-than-temporarily impaired based on the specific facts and circumstances. Factors that are considered in determining whether an other-than-temporary decline in value has occurred include: the market value of the security in relation to its cost basis; the financial condition of the investee; and the intent and ability to retain the investment for a sufficient period of time to allow for recovery in the market value of the investment. Restricted cash consists of cash equivalents used to secure a letter of credit for The Omeros Building lease.

#### Inventory

Inventory is stated at the lower of cost or market determined on a specific identification basis in a manner which approximates the first-in, first-out (FIFO) method. Costs include amounts related to third party manufacturing, transportation and internal labor and overhead. Capitalization of costs as inventory begins when the product candidate receives regulatory approval in the U.S. or the EU, which for Omidria began upon U.S. regulatory approval in May 2014. We expense inventory costs related to product candidates as research and development expenses prior to regulatory approval in the respective territory. Inventory is reduced to net realizable value by reserving for excess and obsolete inventories based on forecast demand. As of December 31, 2014, all inventory is finished goods for Omidria.

#### Receivables

Receivables related to grants are stated at the amount owed for work performed that has been invoiced and not yet collected or work performed for which we have not yet invoiced the National Institutes of Health (NIH). Other receivables consist primarily of subleases for space in The Omeros Building and are stated at the contractual amount due to us. Considering the nature and historic collectability of our receivables, we concluded an allowance for doubtful accounts is not necessary.

#### Property and Equipment

Property and equipment are stated at cost and depreciation is calculated using the straight-line method over the estimated useful life of the assets, which is generally three to ten years. Equipment financed under capital leases is recorded as property and equipment and is amortized over the shorter of the useful lives of the related assets or the

lease term. Expenditures for equipment purchased with grant funds are recorded as a reduction to the cost of the applicable equipment. Expenditures for repairs and maintenance are expensed as incurred.

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#### Impairment of Long-Lived Assets

The carrying amount of long-lived assets is reviewed whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability of these assets is measured by comparing the carrying value to future undiscounted cash flows the asset is expected to generate. If the asset is considered to be impaired, the amount of any impairment will be reflected in the results of operations in the period of impairment. We have not recognized any impairment losses to date.

#### Deferred Rent

We recognize rent expense on a straight-line basis over the noncancelable term of The Omeros Building operating lease and, accordingly, record the difference between cash rent payments and the recognition of rent expense as an increase or decrease in deferred rent liability. We also record landlord-funded lease incentives, such as reimbursable leasehold improvements, as an increase in deferred rent liability which is amortized as a reduction of rent expense over the noncancelable terms of The Omeros Building operating lease.

#### Revenue Recognition

Revenue is recognized when there is persuasive evidence that an arrangement exists, service has been provided, the price is fixed or determinable and collection is reasonably assured. Our revenue to date relates to grant funding from third parties. We recognize revenue from grants when the related qualifying research and development expenses are incurred up to the limit of the approved funding amounts. Funds received in advance of services being provided are recorded as deferred revenue and recognized as revenue as research is performed.

#### Research and Development

Research and development costs are comprised primarily of costs for personnel, including salaries, benefits and stock compensation; an allocation of our occupancy costs; clinical study costs; contracted research; manufacturing; consulting arrangements; depreciation; materials and supplies; milestones; and other expenses incurred to sustain our overall research and development programs. Research and development costs are expensed as incurred.

Advance payments for goods or services that will be used or rendered for future research and development activities are deferred and then recognized as an expense as the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided.

#### Patents

We generally apply for patent protection on processes and product candidates we or our licensors conceive or develop. Patent costs are comprised primarily of external legal fees, filing fees incurred to file patent applications, and periodic renewal fees to keep the patent in force and are expensed as incurred as a component of general and administrative expense.

#### Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their tax bases. Deferred tax assets and liabilities are measured using enacted tax rates applied to taxable income in the years in which those temporary differences are expected to be recovered or settled. We recognize the effect of income tax positions only if those positions are more likely than not of being sustained upon an examination. A valuation allowance is established when it is more likely than not that the deferred tax assets will not be realized.

#### Stock-Based Compensation

Stock-based compensation expense is recognized for all share-based payments made to employees, directors and non-employees based on estimated fair values. The fair value of our stock options is calculated using the Black-Scholes option-pricing model which requires judgmental assumptions including volatility, forfeiture rates and expected option life. If any of the assumptions used in the Black-Scholes model change significantly, stock-based compensation expense for new employees' and directors' awards may differ materially from that recorded for existing awards and stock-based compensation for non-employees will vary as the awards are re-measured over the vesting term as earned. We use the straight-line method to allocate compensation cost to reporting periods over the optionees' requisite service period for employees and directors, which is generally the vesting period. Stock options granted to non-employees are accounted for using the fair value approach and are subject to periodic revaluation over their vesting terms as earned.

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**Accumulated Other Comprehensive Loss**

Comprehensive loss is comprised of net loss and certain changes in equity that are excluded from net loss. There was no difference between comprehensive loss and net loss for the years ended December 31, 2014, 2013 or 2012.

**Segments**

We operate in one segment. Management uses cash flow as the primary measure to manage our business and does not segment our business for internal reporting or decision-making.

**Recent Accounting Pronouncements**

In August 2014, the Financial Accounting Standards Board issued Accounting Standards Update, or ASU, No. 2014-15 related to disclosure of an entity's ability to continue as a going concern. This standard requires management to evaluate whether substantial doubt exists regarding the entity's ability to continue as a going concern at each reporting period for a period of one year after the date the financial statements are issued or available to be issued. The standard establishes certain required disclosures if substantial doubt exists. This standard must be applied prospectively and is effective for interim and annual periods beginning after December 15, 2016. We will review the impact of the standard upon our disclosures, if applicable, beginning in 2017.

In May 2014, the Financial Accounting Standards Board issued ASU No. 2014-09 related to the recognition of revenue that supersedes existing guidance. This standard clarifies the principles for recognizing revenue utilizing a five-step process. This standard must be applied retroactively to each prior reporting period presented, or retrospectively with the cumulative effect of applying the standard recognized in the period adopted. This standard is currently scheduled to be effective for interim and annual periods beginning after December 15, 2016 and cannot be adopted before that effective date. We are currently evaluating the impact this standard may have on our financial statements once it is adopted.

**Note 2—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 for the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and dilutive common share equivalents outstanding for the period, determined using the treasury-stock method.

The basic and diluted net loss per share amounts for the years ended December 31, 2014, 2013 and 2012 were computed based on the shares of common stock outstanding during the respective periods. Potentially dilutive securities excluded from the diluted net loss per share calculation are as follows:

	Year Ended December 31,		
	2014	2013	2012
Outstanding options to purchase common stock	8,364,469	6,969,303	5,269,353
Warrants to purchase common stock	551,435	609,016	609,016
Total	8,915,904	7,578,319	5,878,369

**Note 3—Cash, Cash Equivalents and Investments**

As of December 31, 2014 and 2013, all investments are classified as short-term and available-for-sale on the accompanying Consolidated Balance Sheets. We did not own any securities with unrealized loss positions as of December 31, 2014 or 2013. Investment income consists primarily of interest earned.

**Note 4—Fair-Value Measurements**

On a recurring basis, we measure certain financial assets at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, an exit price, in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The accounting standard establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs, where available. The following summarizes the three levels of inputs required:

Level 1—Observable inputs for identical assets or liabilities, such as quoted prices in active markets;

Level 2—Inputs other than quoted prices in active markets that are either directly or indirectly observable; and  
Level 3—Unobservable inputs in which little or no market data exists, therefore developed using estimates and assumptions developed by us, which reflect those that a market participant would use.

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Our fair-value hierarchy for our financial assets and liabilities measured at fair value on a recurring basis are as follows:

	December 31, 2014			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as non-current restricted cash	\$679	\$—	\$—	\$679
Money-market funds classified as short-term investments	6,532	—	—	6,532
Total	\$7,211	\$—	\$—	\$7,211

	December 31, 2013			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as cash equivalents	\$213	\$—	\$—	\$213
Money-market funds classified as non-current restricted cash	679	—	—	679
Money-market funds classified as short-term investments	12,717	—	—	12,717
Total	\$13,609	\$—	\$—	\$13,609

Cash held in demand deposit accounts of \$354,000 and \$1.2 million is excluded from our fair-value hierarchy disclosure as of December 31, 2014 and 2013, respectively. There were no unrealized gains or losses associated with our short-term investments as of December 31, 2014 or 2013. The carrying amounts reported in the accompanying Consolidated Balance Sheets for receivables, accounts payable and other current monetary assets and liabilities approximate fair value because of the immediate or short-term maturity of these financial instruments.

#### Note 5—Certain Balance Sheet Accounts

##### Receivables

Receivables consisted of the following:

	December 31,	
	2014	2013
	(In thousands)	
Grant receivables	\$324	\$308
Other receivables	68	71
Total receivables	\$392	\$379

## Property and Equipment

Property and equipment consisted of the following:

	December 31,	
	2014	2013
	(In thousands)	
Laboratory equipment	\$1,636	\$1,626
Office equipment and furniture	615	615
Computer equipment	403	431
Capital lease equipment	230	231
Computer software	126	127
Total	3,010	3,030
Less accumulated depreciation and amortization	(2,228)	(2,091)
Total property and equipment, net	\$782	\$939

For the years ended December 31, 2014, 2013 and 2012, depreciation and amortization expense was \$326,000, \$302,000 and \$320,000, respectively.

## Accrued Liabilities

Accrued liabilities consisted of the following:

	December 31,	
	2014	2013
	(In thousands)	
Employee costs	\$2,421	\$1,346
Consulting and professional fees	1,952	649
Contract research	1,280	858
Clinical trials	828	596
Other accruals	589	495
Total accrued liabilities	\$7,070	\$3,944

## Note 6—Notes Payable

## Loan and Security Agreement

In October 2010, we entered into a loan and security agreement (the Oxford Loan Agreement) with Oxford Finance LLC (Oxford). In December 2012, the Oxford Loan Agreement was amended (the Amendment) and we borrowed a net additional \$6.5 million. This brought the outstanding principal balance to \$20.0 million as of December 31, 2012. The Amendment provided for interest-only payments at an annual rate of 9.25% through December 31, 2013, and as such, the outstanding principal balance remained \$20.0 million as of December 31, 2013. Beginning on January 1, 2014, monthly principal and interest payments were due through the maturity date of December 1, 2016.

In association with the Oxford Loan Agreement, we recorded discounts of \$900,000 related to loan maturity fees due at the time of the final payment on the Oxford Loan Agreement. The discounts were being amortized to interest expense using the effective-interest method. When we entered into the Amendment in December 2012, we paid \$588,000 for the prorated portion of the \$900,000 loan maturity fee with no further obligation for the remaining \$312,000. In connection with the Amendment, we also agreed to pay Oxford a \$1.4 million loan maturity fee we recorded as a discount on the outstanding debt and \$168,000 of debt issuance costs which we recorded as other assets. Both of these amounts are being amortized to interest expense using the effective-interest method.

In March 2014, we entered into a new Loan and Security Agreement (the Oxford/MidCap Loan Agreement) with Oxford and MidCap Financial SBIC, LP (MidCap) pursuant to which we borrowed \$32.0 million. We used approximately \$19.1 million of the loan proceeds to repay all of the amounts owed by us under our then outstanding loan from Oxford and, after deducting all loan initiation costs, we received \$12.7 million in net proceeds. Part of the costs paid included \$520,000 for the prorated portion of the \$1.4 million loan maturity fee payable under our then outstanding loan agreement with Oxford, with no



further obligation for the remaining \$880,000. The Oxford/MidCap Loan Agreement provides for interest-only payments at an annual rate of 9.25% through March 1, 2015. Beginning April 1, 2015, monthly principal and interest payments of \$1.0 million are due through the maturity date of March 1, 2018. In addition, the Oxford/MidCap Loan Agreement requires a \$2.2 million loan maturity fee upon full repayment of the loan. We may prepay the outstanding principal balance in its entirety at any time if we pay an additional fee equal to 1.0% of the then-outstanding principal balance, which prepayment fee would be waived if we refinance the indebtedness with Oxford and MidCap and pay the loan maturity fee. As security under the Oxford/MidCap Loan Agreement, we granted Oxford, as collateral agent for the lenders, a security interest in substantially all of our assets, excluding intellectual property.

The Oxford/MidCap Loan Agreement contains covenants that limit or restrict our ability to incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay dividends or make distributions, pledge our intellectual property or repurchase stock. Additionally, the Oxford/MidCap Loan Agreement includes events of default regarding non-payment, inaccuracy of representations and warranties, covenant breach, occurrence of a material adverse effect (MAE, as defined below), cross default to material indebtedness, bankruptcy or insolvency, material judgment defaults and a change of control. The occurrence of an event of default could result in the acceleration of the Oxford/MidCap Loan Agreement and, under certain circumstances, could increase our interest rate by 5.0% per annum during the period of default.

MAE is defined as a material adverse effect upon (i) our business operations, properties, assets, results of operations or financial condition of Omeros, taken as a whole with respect to our viability, that reasonably would be expected to result in our inability to repay any portion of the loans in accordance with the terms of the Oxford/MidCap Loan Agreement, (ii) the validity, perfection, value or priority of the lenders' security interest in the collateral, (iii) the enforceability of any material provision of the Oxford/MidCap Loan Agreement or related agreements, or (iv) the ability of the lenders to enforce their rights and remedies under the Oxford/MidCap Loan Agreement or related agreements. As of December 31, 2014, we were not in default under the Oxford/MidCap Loan Agreement described above.

We accounted for the Oxford/MidCap Loan Agreement as a debt modification and, accordingly, the remaining unamortized debt issuance costs of \$103,000 associated with the then outstanding loan with Oxford and the debt issuance costs of \$244,000 associated with the Oxford/MidCap Loan Agreement are being amortized to interest expense using the effective interest method through the March 1, 2018 maturity date. Additionally, the \$2.2 million maturity fee, which is treated as a debt discount, is being amortized to interest expense using the effective-interest method through March 1, 2018.

As of December 31, 2014, the outstanding principal on the Oxford/MidCap Loan Agreement was \$32.0 million and the remaining unamortized discount and debt issuance costs are \$1.7 million and \$256,000, respectively.

#### Equipment Financing

We have capital leases for copier equipment with remaining principal payments totaling \$185,000 and \$99,000 as of December 31, 2014 and 2013, respectively which have lease terms expiring between October 2017 and June 2019. Equipment related to these capital leases of \$230,000 and \$231,000 is included in our property and equipment as of December 31, 2014 and December 31, 2013, respectively. At December 31, 2014 and 2013, accumulated depreciation on this equipment was \$52,000 and \$145,000, respectively.



## Future Principal Payments

Future principal payments as of December 31, 2014 under the Oxford/MidCap Loan Agreement and our equipment financing, based on stated contractual maturities, are as follows:

Year Ending December 31,	Total (In thousands)
2015	\$7,234
2016	10,439
2017	11,447
2018	3,064
2019	1
Total future principal payments	\$32,185

The principal payments reflected in the table above exclude the unamortized balance of the debt discount and include the principal payments on our equipment financings. The short-term portion of our equipment financings of \$43,000 are included in accrued liabilities in the accompanying Consolidated Balance Sheet.

## Note 7—Revenue

Revenues recognized from grants and other sources are as follows:

	Year Ended December 31,		
	2014	2013	2012
	(In thousands)		
Small Business Innovative Research Grant (SBIR)	\$539	\$630	\$721
Vulcan Inc.	—	970	4,677
Life Science Development Fund Authority (LSDF)	—	—	624
Total revenue	\$539	\$1,600	\$6,022

We have periodically received Small Business Innovative Research (SBIR) grants from the NIH which are used to support the research and development of our product candidates. We recorded revenue related to these grants of \$539,000, \$630,000 and \$721,000 for the years ended December 31, 2014, 2013 and 2012, respectively. We recorded cost reductions to property and equipment due to assets being purchased with grant funding of \$80,000, \$0 and \$7,000 for the years ended December 31, 2014, 2013 and 2012, respectively. As of December 31, 2014, \$566,000 of potential revenue remained available under these grants, if qualifying research is performed.

In October 2010, we entered into a platform development funding agreement with Vulcan Inc. and its affiliate (collectively, Vulcan) pursuant to which we received \$20.0 million for our G protein-coupled receptor (GPCR) program. The revenue was recognized as costs were incurred or as a reduction to the costs of assets purchased in direct proportion to the related GPCR expenses. For the years ended December 31, 2013 and 2012, we recognized revenue of \$970,000 and \$4.7 million, respectively. In addition, we recognized \$60,000 as cost reductions to assets for the year ended December 31, 2012. As of December 31, 2013, all of the deferred revenue pertaining to the Vulcan agreement had been recognized. See additional discussion of the Vulcan agreement under Note 8.

In conjunction with the Vulcan agreement, we also entered into an agreement with the Life Sciences Discovery Fund Authority (LSDF), a granting agency of the State of Washington, under which we received a \$5.0 million grant for our GPCR program. For the year ended December 31, 2012, we recognized revenue of \$624,000. As of December 31, 2012, all of the deferred revenue under the LSDF agreement had been recognized. See additional discussion of the LSDF agreement under Note 8.

## Note 8—Commitments and Contingencies

## Real Estate Lease Obligations

In January 2012, we entered into a real estate lease (the Lease) with BMR-201 Elliott Avenue LLC (BMR) for office and laboratory spaces in The Omeros Building. In November 2012, we entered into the First and Second Lease Amendments and in October 2013, the Third Amendment to the Lease (collectively the Lease Amendments). The term of the Lease and associated Lease Amendments is through November 2027 with two options to extend the lease term, each by five years. The Lease and the Lease Amendments did not require us to pay any base rent until November 2013, but did require us to provide security deposits totaling \$679,000. The security deposit is recorded as restricted cash on the accompanying Consolidated Balance Sheet. The Lease and the Lease Amendments include certain rent escalation terms.

As of December 31, 2014, we have received net lease incentives of \$4.8 million which included a \$3.0 million cash lease incentive and a period of free rent, among other incentives. The net lease incentives are recorded as deferred rent on our accompanying Consolidated Balance Sheets and the remaining deferred rent balance relates to rent deferrals since the inception of the Lease. Deferred rent is being amortized to research and development and selling, general and administrative expense over the initial 15 year term of the Lease on a straight-line basis.

Rent expense, including the amortization of lease incentives and rent deferrals, totaled \$4.5 million, \$4.3 million and \$2.9 million for the years ended December 31, 2014, 2013 and 2012, respectively.

We periodically sublease unused office and laboratory space in The Omeros Building to third-party tenants. Rental income received under these subleases was \$568,000, \$550,000 and \$635,000 for the years ended December 31, 2014, 2013 and 2012, respectively. Rental income is recorded as other income in the accompanying Consolidated Statements of Operations and Comprehensive Loss.

We rent equipment under various operating lease agreements. Future minimum payments related to these leases and The Omeros Building Lease and the Lease Amendments, which exclude common area maintenance and related operating expenses, at December 31, 2014, are as follows:

Year Ending December 31,	Lease Payments (In thousands)	Sublease Income	Net Lease Payments
2015	\$3,995	\$631	\$3,364
2016	4,085	600	3,485
2017	4,167	481	3,686
2018	4,253	—	4,253
2019	4,350	—	4,350
Thereafter	37,713	—	37,713
Total	\$58,563	\$1,712	\$56,851

## Contracts

In June 2014, we entered into an agreement with Ventiv Commercial Services, LLC (inVentiv) for field sales representatives and related sales operation services for the U.S. commercial launch of Omidria. We had a monthly fee of approximately \$300,000 which began in August 2014. In October 2014, we entered into an amendment to the agreement for additional sales representatives which increased our monthly fee to approximately \$630,000 beginning in December 2014. We can terminate the agreement upon 30 days written notice if Omidria is withdrawn from the market for any reason or a regulatory agency acts to prevent or materially restrict the sale of Omidria, or upon 90 days written notice any time subsequent to January 2016.

We have a non-exclusive agreement with Patheon Manufacturing Services LLC (Patheon) for commercial supply of Omidria through December 31, 2015. Pursuant to the terms of the contract, we are required to provide a monthly, non-binding production forecast covering the term of the contract. Upon submission of the monthly forecast, a portion of the forecast becomes a firm purchase commitment. In the event we do not purchase the quantities included in the firm purchase commitment, we would owe a cancellation fee. As of December 31, 2014, we had a firm purchase commitment requiring payment of approximately \$320,000.



In October 2014, we entered into a non-exclusive agreement with Hospira S.p.A and Hospira Worldwide, Inc. (together, “Hospira”) for commercial supply of Omidria. We have no firm purchase commitments under this agreement until, in connection with the commencement of commercial manufacturing of Omidria at Hospira, we provide monthly rolling forecasts that will be used to calculate our firm purchase commitment. We have not commenced commercial manufacturing of Omidria at Hospira and, therefore, do not currently have any firm purchase commitments under this agreement.

#### Development Milestones and Product Royalties

**Phosphodiesterase 10 (PDE10) inhibitors** - In connection with a funding agreement with The Stanley Medical Research Institute entered into in December 2006, beginning the first calendar year after commercial sales of any therapeutic product that inhibits or modulates PDE10 (including for schizophrenia or Huntington’s disease), we are obligated to pay royalties based on net income of the product, as defined in the agreement. Based on the amount of grant funding received, the maximum amount of royalties payable by us is \$12.8 million. For the years ended December 31, 2014, 2013 and 2012, we did not owe any royalties.

**Peroxisome proliferators activated receptor gamma (PPAR $\gamma$ )** - In February 2009, we entered into a patent assignment agreement whereby we acquired all intellectual property rights, including patent applications, related to PPAR agonists for the treatment and prevention of addictions to substances of abuse, as well as other compulsive behaviors. In February 2011, we amended the patent assignment agreement to include all intellectual property rights, including patent applications, related to dietary supplements that increase PPAR activity. We will be required to make payments up to \$3.8 million in total, for both PPAR agonists and dietary supplements that increase PPAR activity, upon achievement of certain development events, such as the initiation of clinical trials and receipt of marketing approval. In addition, we are obligated to pay a low single-digit percentage royalty on any net sales of drug products that are covered by the patent assignment agreement. For the years ended December 31, 2014, 2013 and 2012, we did not owe any development milestones or royalties.

**Phosphodiesterase 7 (PDE7) inhibitors** - Under a license agreement with Daiichi Sankyo Co., Ltd. (Daiichi Sankyo) we hold an exclusive license to phosphodiesterase 7 (PDE7) inhibitors owned by Daiichi Sankyo for use in (1) the treatment of movement disorders and other specified indications; (2) addiction and compulsive disorders; and (3) all other indications except those related to dermatologic conditions. We will be required to make milestone payments to Daiichi Sankyo of up to \$33.5 million upon the achievement of certain events, such as successful completion of certain preclinical toxicology studies; dosing of human subjects in Phase 1, 2 and 3 clinical trials; receipt of marketing approval of a PDE7 inhibitor product; and reaching specified sales milestones. However, if only one of the three indications is advanced through each milestone, the total milestone payments would be \$23.5 million. In addition, we are obligated to pay Daiichi Sankyo a low single-digit percentage royalty on any net sales of a PDE7 inhibitor licensed under the agreement provided that if the sales are made by a sublicensee, the amount payable by us to Daiichi Sankyo is capped at a low double-digit percentage of all royalty and specified milestone payments that we receive from the sublicensee. For the year ended December 31, 2013, we paid \$50,000 upon execution of an amendment which was recognized as research and development expense. For the years ended December 31, 2014, 2013 and 2012, we did not owe any development milestones or royalties.

**Mannan-binding lectin-associated serine protease-2 (MASP-2)** - In April 2010, we entered into an exclusive license agreement with Helion Biotech ApS (Helion), pursuant to which we received a royalty bearing, worldwide exclusive license to all of Helion’s intellectual property rights related to MASP-2 antibodies, polypeptides and methods in the field of inhibition of mannan-binding lectin-mediated activation of the complement system for the prevention, treatment or diagnosis of any disease or condition. We will be required to make development and sales milestone payments to Helion of up to \$6.1 million upon the achievement of certain events, such as the filing of an Investigational New Drug Application (IND) with the FDA; initiation of Phase 2 and 3 clinical trials; receipt of marketing approval; and reaching specified sales milestones. We are obligated to pay Helion a low single-digit percentage royalty on net sales of a MASP-2 inhibitor product covered by the patents licensed under the agreement. For the year ended December 31, 2014, we incurred development milestone costs of \$500,000 under this agreement which was recognized as research and development expense. For the years ended December 31, 2013 and 2012, we did not owe any development milestones or royalties.

G protein-coupled receptor (GPCR) - In connection with our funding agreements with Vulcan and LSDF discussed in Note 7, we agreed to pay Vulcan and LSDF tiered percentages of the net proceeds derived from the GPCR program. The percentage rates decrease as the cumulative net proceeds reach specified thresholds, and the blended percentage rate in the aggregate is in the mid-teens with respect to approximately the first \$1.5 billion of cumulative net proceeds. If we receive cumulative net proceeds in excess of approximately \$1.5 billion, the percentage rate decreases to one percent. Pursuant to the agreement with Vulcan, we may pay a portion of Vulcan's share of the one percent of net proceeds to a life sciences initiative (LSI) to be established in accordance with the LSDF agreement. The LSI will be a non-profit, tax-exempt organization with a mission to advance life sciences in the State of Washington.

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Net proceeds are generally defined in the Vulcan and LSDF agreements as (1) all consideration received by us in any form relating directly to the GPCR program less (2) all expenses and expenditures in excess of \$25.0 million incurred by us in connection with the GPCR program. Any consideration that we receive (a) from government entities (subject to specified exceptions), (b) from third parties that have designated such consideration for the purpose of funding research and development expenses and related overhead or (c) in the form of grants, as well as any expenses or expenditures that we incur that are paid for with such consideration, are excluded for purposes of determining net proceeds.

Under our agreement with Vulcan, we granted Vulcan a security interest in our personal property related to the GPCR program, other than intellectual property, which security interest is junior to any existing or future security interests granted in connection with a financing transaction and which will be automatically released after Vulcan receives \$25.0 million under the agreement. We also agreed not to grant any liens on intellectual property related to the GPCR program. The term of our agreement with Vulcan is 35 years, provided that the term will automatically extend until the cumulative net proceeds that we receive from the GPCR program are approximately \$1.5 billion.

Under our agreement with LSDF, after LSDF receives \$25.0 million, any remaining amounts that would be payable to LSDF will be paid to LSI. Our obligations with respect to LSI are limited to creating LSI's charter documents, incorporating LSI, selecting directors and applying for tax exempt status, all in consultation with LSDF. The term of our agreement with LSDF expires on the six-month anniversary following the last date that we deliver a report related to our incurrence of grant-funded expenses described in the agreement. The term of our payment obligations to LSDF is the same as that under our agreement with Vulcan.

As of December 31, 2014, we have not derived any net proceeds as defined in the Vulcan and LSDF agreements from our GPCR program.

#### Litigation

Omeros and its chief executive officer, Gregory A. Demopoulos, M.D., entered into a Settlement Agreement with Richard J. Klein, our former chief financial officer, in October 2012, to resolve a lawsuit filed by Mr. Klein alleging wrongful termination of Mr. Klein's employment and asserting qui tam claims on behalf of the U.S. Government under the Federal False Claims Act related to two NIH grants. We paid \$3.95 million to Mr. Klein, which was reimbursed by our former insurer and all claims were dismissed with prejudice to the parties in November 2012. The dismissal of these claims was without prejudice to the U.S. Government, which previously had declined to intervene in the lawsuit. In connection with an administrative review by NIH of the grants that were the subject of the Klein lawsuit, we reimbursed the NIH \$1.064 million in October 2013. The payment was recorded as selling, general and administrative expense in the accompanying Consolidated Statement of Operations and Comprehensive Loss.

In October 2013, we and our chief executive officer entered into a settlement agreement with our former insurer related to our former insurer's defense of, and coverage obligations related to, the Klein lawsuit. Per the settlement agreement, we received \$12.5 million in October 2013 which we recorded as litigation settlement in the accompanying Consolidated Statements of Operation and Comprehensive Loss. We considered this particular litigation settlement an infrequent item given the nature of the lawsuit and have included the settlement as a separate component of nonoperating income.

#### Note 9—Shareholders' Equity

##### Common Stock

As of December 31, 2014, we had reserved shares of common stock for the following purposes:

Options granted and outstanding	8,364,469
Options available for future grant	238,836
Common stock warrants	551,435
Total shares reserved	9,154,740

Options Available for Future Grant - On January 1, 2015, an additional 1,709,273 shares became available for future issuance under the 2008 Equity Incentive Plan (the 2008 Plan) in accordance with the annual increase provisions of the 2008 Plan. These additional shares from the annual increase are not included in the table above.



Securities Offerings - In February 2015, we sold 3.4 million shares of our common stock at a public offering price of \$20.03 and sold pre-funded warrants to purchase up to 749,250 shares of our common stock at a public offering price of \$20.02 per pre-funded warrant share. The public offering price for the pre-funded warrants was equal to the public offering price of the common stock, less the \$0.01 per share exercise price of each pre-funded warrant. After deducting underwriter discounts and offering expenses of \$4.9 million, we received net proceeds from the transaction of approximately \$79.1 million.

In March 2014, we sold 3.5 million shares of our common stock at a public offering price of \$11.50 per share. After deducting underwriter discounts and offering expenses of \$2.5 million, we received net proceeds from the transaction of \$37.8 million.

In May 2013, we sold 3.9 million shares of our common stock at a price of \$4.14 per share in a registered direct offering. After deducting offering expenses of \$39,000, we received net proceeds from the transaction of \$16.1 million.

In July 2012, we sold 3.4 million shares of our common stock at a public offering price of \$10.25 per share. After deducting underwriting discounts and other offering expenses of \$2.2 million, we received net proceeds of \$32.3 million.

At-the-Market Sales Agreement - In October 2013, we sold 374,000 shares of our common stock with a weighted average price of \$13.29 per share under an At-the-Market Sales Agreement and received \$4.9 million in net proceeds. The agreement expired in April 2014.

#### Warrants

The following table summarizes our outstanding warrants at December 31, 2014, which have a weighted average exercise price of \$25.06:

Outstanding At December 31, 2014	Expiration Date	Exercise Price
139,897	March 29, 2015	\$12.25
133,333	October 21, 2015	20.00
133,333	October 21, 2015	30.00
133,333	October 21, 2015	40.00
11,539	April 26, 2015	9.13
551,435		

In March 2012 and March 2013, we extended the expiration dates of warrants to purchase approximately 197,000 shares of our common stock at an exercise price of \$12.25 per share by one year. In March 2014 and September 2014, we extended the expiration dates of the same warrants by six months. These warrants were issued on March 29, 2007 to brokers who assisted us in connection with our Series E financing. We evaluated the fair value of the warrants before and after the modifications and we recorded the \$863,000, \$41,000 and \$511,000 change in fair value as other expense in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the years ended December 31, 2014, 2013 and 2012, respectively.

For the year ending December 31, 2014, warrants to purchase a total of 57,581 shares of our common stock with an exercise price of \$12.25 per share were exercised by the warrant holders resulting in the issuance of 28,653 shares of our common stock. Of that amount, 5,621 shares were issued upon cash exercise of warrants, pursuant to which we received proceeds of \$68,857, and the remainder were issued pursuant to cashless net exercise provisions in the warrants. Additionally, between January 1, 2015 and February 28, 2015, warrants to purchase a total of 104,741 shares of our common stock with an exercise price of \$12.25 per share were exercised for cash, resulting in proceeds of \$1.3 million to the Company. As of February 28, 2015, 29,462 warrants with an exercise price of \$12.25 per share remained outstanding.

In October 2010, in connection with the Vulcan agreement, we issued three warrants to purchase our common stock, each exercisable for 133,333 shares, with exercise prices of \$20, \$30 and \$40 per share, respectively. The warrants expire on October 21, 2015.



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## Note 10—Stock-Based Compensation

The 2008 Plan provides for the grant of incentive and non-statutory stock options, restricted stock, stock appreciation rights, performance units and performance shares to employees, directors and consultants and subsidiary corporations' employees and consultants. Options are granted with exercise prices equal to the closing fair market value of the common stock on the date of the grant. The terms of options may not exceed 10 years and options generally vest over a four-year period.

The 2008 Plan also allows any shares returned under our Amended and Restated 1998 Stock Option Plan (the 1998 Plan), as a result of cancellation of options or repurchase of shares issued pursuant to the 1998 Plan, to be issued under the 2008 Plan. In addition, the 2008 Plan provides for annual increases in the number of shares available for issuance thereunder on the first day of each year, equal to the lower of:

five percent of the outstanding shares of our common stock on the last day of the preceding year;

4,785,714 shares; or

such other amount as our board of directors may determine.

On January 1, 2015, an additional 1,709,273 shares became available for future issuance under our 2008 Plan in accordance with the annual increase. As of December 31, 2014, a total of 8,603,305 shares were reserved for issuance under our stock plans, of which 238,836 were available for future grants.

Compensation cost for stock options granted to employees and directors is based on the grant-date fair value and is recognized over the vesting period of the applicable option on a straight-line basis. Stock-based compensation expense is based on options ultimately expected to vest, and therefore has been reduced for estimated forfeitures. We estimate forfeitures based on our historical experience; separate groups of employees that have similar historical forfeiture behavior are considered separately for expense recognition.

The fair value of each option grant to employees and directors is estimated on the date of grant using the Black-Scholes option-pricing model. The following assumptions were applied to employee & director stock option grants during the periods ended:

	Year Ended December 31,					
	2014		2013		2012	
Estimated weighted-average fair value	\$7.39		\$6.87		\$7.35	
Weighted-average assumptions:						
Expected volatility	73	%	88	%	86	%
Expected term, in years	5.8		5.8		5.7	
Risk-free interest rate	1.87	%	1.66	%	0.95	%
Expected dividend yield	—	%	—	%	—	%

Expected Volatility. Historically the expected volatility rate used to value stock option grants was based on volatilities of a peer group of similar companies whose share prices were publicly available due to our limited trading history. The peer group was developed based on companies in the pharmaceutical and biotechnology (A) industry in a similar stage of development. As of October 2014, we believe it is appropriate to rely 100% on our own historical realized volatility given our own trading history is roughly equivalent to the average expected term of our options and we do not anticipate future volatility will differ significantly from the past. This change in estimate did not have a material impact on our operating income, net income or earnings per share.

Expected Term. We elected to utilize the “simplified” method for “plain vanilla” options to determine the expected term of our stock option grants. We will continue to use the simplified method until we have sufficient historical (B) data necessary to provide a reasonable estimate of expected life based on the exercise behavior of our option holders. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option.

Risk-free Interest Rate. The risk-free interest rate assumption was based on zero-coupon U.S. Treasury instruments (C) that had terms consistent with the expected term of our stock option grants.

Expected Dividend Yield. We have never declared or paid any cash dividends and do not presently plan to pay (D) cash dividends in the foreseeable future.

Stock options granted to non-employees are accounted for using the fair value approach. The fair value of non-employee option grants are estimated using the Black-Scholes option-pricing model and are re-measured over the vesting term as earned. The estimated fair value is charged to expense over the applicable service period. During the years ended December 31, 2014,

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2013 and 2012, we granted to non-employees options to purchase 86,500, 40,000 and 28,000 shares of common stock, respectively.

Stock-based compensation expense includes amortization of stock options granted to employees and non-employees and has been reported in our Consolidated Statements of Operations and Comprehensive Loss as follows:

	Year Ended December 31,		
	2014	2013	2012
	(In thousands)		
Research and development	\$4,754	\$3,588	\$2,191
Selling, general and administrative	4,164	2,664	2,090
Total stock-based compensation expense	\$8,918	\$6,252	\$4,281

In connection with the non-employee options, we recognized expense of \$289,000, \$71,000 and \$64,000 during the years ended December 31, 2014, 2013 and 2012, respectively.

Stock option activity for all stock plans and related information is as follows:

	Options Outstanding	Weighted-Average Exercise Price per Share	Remaining Contractual Life (in years)	Aggregate Intrinsic Value (In thousands)
Balance at December 31, 2013	6,969,303	\$6.38		
Granted	2,005,850	11.72		
Exercised	(297,303 )	6.06		
Forfeited and expired	(313,381 )	10.30		
Balance at December 31, 2014	8,364,469	\$7.52	6.99	\$ 144,348
Vested and expected to vest at December 31, 2014	8,047,969	\$7.40	6.91	\$ 139,877
Exercisable at December 31, 2014	5,166,081	\$5.63	5.69	\$ 98,949

The total intrinsic value of options exercised during the years ended December 31, 2014, 2013 and 2012 was \$2.9 million, \$1.1 million and \$578,000, respectively.

Information about stock options outstanding and exercisable is as follows:

Range of Exercise Price	December 31, 2014			Options Exercisable	
	Options Outstanding	Weighted-Average Remaining Contractual Life (Years)	Weighted-Average Exercise Price	Options	Weighted-Average Exercise Price
\$0.98 - \$4.09	1,565,934	2.09	\$1.19	1,564,898	\$1.19
\$4.10 - \$8.00	2,063,380	6.37	5.31	1,897,969	5.29
\$8.01 - \$11.42	2,839,321	8.27	9.80	1,425,343	9.78
\$11.43 - \$21.49	1,895,834	9.79	11.76	277,871	11.61
\$0.98 - \$21.49	8,364,469	6.99	\$7.52	5,166,081	\$5.63

At December 31, 2014, there were 3,198,388 unvested options outstanding that will vest over a weighted-average period of 2.5 years. Excluding non-employee stock options, the remaining estimated compensation expense to be recognized in connection with these options is \$18.3 million.



## Note 11—Income Taxes

We have a history of losses and therefore have made no provision for income taxes. Deferred income taxes reflect the tax effect of net operating loss and tax credit carryforwards and the net temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

Significant components of deferred tax assets are as follows:

	December 31,	
	2014	2013
	(In thousands)	
Deferred tax assets:		
Net operating loss carryforwards	\$88,399	\$68,942
Deferred rent	3,077	2,770
Stock-based compensation	5,511	3,537
Tax credit carryforwards	9,569	5,707
Other	2,084	1,866
Total deferred tax assets	108,640	82,822
Less valuation allowance	(108,640)	(82,822)
Net deferred tax assets	\$—	\$—

As of December 31, 2014 and 2013, we had net operating loss carryforwards of approximately \$264.1 million and \$205.9 million, respectively, and research and development tax credit carryforwards of approximately \$9.6 million and \$5.7 million, respectively. Approximately \$4.1 million of our net operating loss carryforwards relate to tax deductible stock-based compensation in excess of amounts recognized for financial statement purposes. To the extent that net operating loss carryforwards, if realized, relate to stock-based compensation, the resulting tax benefits will be recorded to shareholders' equity, rather than to the results of operations.

In certain circumstances, due to ownership changes, our net operating loss and tax credit carryforwards may be subject to limitations under Section 382 of the Internal Revenue Code. To date, we have not completed a Section 382 study. Unless previously utilized, our net operating loss and research and development tax credit carryforwards expire between 2019 and 2034.

We have established a 100% valuation allowance due to the uncertainty of our ability to generate sufficient taxable income to realize the deferred tax assets. Our valuation allowance increased \$25.8 million, \$14.5 million and \$13.6 million in 2014, 2013 and 2012, respectively, primarily due to net operating losses incurred during these periods. Deferred tax assets at December 31, 2012 did not include \$1.1 million of research and development credits generated for the year ended December 31, 2012. The American Taxpayer Relief Act of 2012 was signed into law on January 2, 2013, which retroactively extended the research and development credit back to January 1, 2012. Therefore, the 2012 research and development credits of \$1.1 million are included in 2013.

A reconciliation of the Federal statutory tax rate of 34% to our effective income tax rate follows:

	Year ended December 31,		
	2014	2013	2012
Federal statutory tax rate	(34)%	(34)%	(34)%
Permanent differences	2%	3%	2%
Change in valuation allowance	35%	36%	35%
Tax credits	(4)%	(5)%	—%
Other	1%	—%	(3)%
Effective tax rate	—%	—%	—%

We file income tax returns in the United States, which typically provides for a three-year statute of limitations on assessments. However, because of net operating loss carryforwards, substantially all of our tax years remain open to federal tax examination.

The guidance for accounting for uncertainties in income taxes requires that we recognize the financial statement effects of a tax position when it is more likely than not, based on the technical merits, that the position will be sustained upon examination. As of December 31, 2014, 2013 and 2012, we maintained an uncertain tax position of \$212,000 related to a reduction of our research and development credit deferred tax asset. Further, there were no unrecognized tax benefits that, if recognized, would impact our effective tax rate.

We recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense. To date, there have been no interest or penalties charged to us in relation to the underpayment of income taxes.

#### Note 12—401(k) Retirement Plan

We have adopted a 401(k) plan. To date, we have not matched employee contributions to the plan. All employees are eligible to participate, provided they meet the requirements of the plan.

#### Note 13—Quarterly Information (Unaudited)

The following table summarizes the unaudited statements of operations and comprehensive loss for each quarter of 2014 and 2013 (in thousands, except per share amounts):

2014	For the Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
Revenue	\$100	\$45	\$214	\$180
Total operating expenses	15,784	17,262	17,346	20,155
Loss from operations	(15,684)	(17,217)	(17,132)	(19,975)
Net loss	(16,642)	(17,991)	(18,327)	(20,713)
Basic and diluted net loss per share	\$(0.54)	\$(0.53)	\$(0.54)	\$(0.61)

2013	For the Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
Revenue	\$1,095	\$140	\$196	\$169
Total operating expenses	11,115	13,300	13,630	14,071
Loss from operations	(10,020)	(13,160)	(13,434)	(13,902)
Net loss	(10,489)	(13,592)	(13,870)	(1,845)
Basic and diluted net loss per share	\$(0.40)	\$(0.48)	\$(0.46)	\$(0.05)

In October 2013, Omeros and its chief executive officer entered into a settlement agreement with Omeros' former insurer related to the defense of, and coverage obligations related to, the Klein lawsuit (as discussed in Note 8). Per the settlement agreement, Omeros received \$12.5 million on October 2013 which we recorded as litigation settlement in the accompanying Consolidated Statements of Operation and Comprehensive Loss. The Company considers this particular litigation settlement an infrequent item given the nature of the lawsuit. Infrequent items are required to be displayed as a separate component of nonoperating income.

## EXHIBIT INDEX

Exhibit No.	Exhibit Description	Incorporated by Reference			Filing Date	Filed Herewith
		Form	File No.	Exhibit No.		
3.1	Amended and Restated Articles of Incorporation of Omeros Corporation	10-K	001-34475	3.1	03/31/2010	
3.2	Amended and Restated Bylaws of Omeros Corporation	10-K	001-34475	3.2	03/31/2010	
4.1	Form of Omeros Corporation common stock certificate	S-1/A	333-148572	4.1	10/02/2009	
4.2	Stock Purchase Warrant issued by nura, inc. to Oxford Finance Corporation dated April 26, 2005 (assumed by Omeros Corporation on August 11, 2006)	S-1	333-148572	4.2	01/09/2008	
4.3	Form of Omeros Corporation Stock Purchase Warrant	S-1/A	333-148572	4.4	09/16/2009	
4.4	Form of Omeros Corporation Stock Purchase Warrant	S-1/A	333-148572	4.5	09/16/2009	
4.5	Form of Notice of Waiver of Warrant Termination (applicable to Stock Purchase Warrants filed as Exhibits 4.3 and 4.4)	S-1/A	333-148572	4.6	09/16/2009	
4.6	Notice Regarding the Extension of the Expiration Date of Certain Stock Purchase Warrants to March 29, 2013 (applicable to Stock Purchase Warrants filed as Exhibits 4.3 and 4.4)	8-K	001-34475	4.1	03/29/2012	
4.7	Notice Regarding the Extension of the Expiration Date of Certain Stock Purchase Warrants to March 29, 2014 (applicable to Stock Purchase Warrants filed as Exhibits 4.3 and 4.4)	8-K	001-34475	4.1	03/29/2013	
4.8	Notice Regarding the Extension of the Expiration Date of Certain Stock Purchase Warrants to September 29, 2014 (applicable to Stock Purchase Warrants filed as Exhibits 4.3 and 4.4)	8-K	001-34475	4.1	04/03/2014	
4.9	Notice Regarding the Extension of the Expiration Date of Certain Stock Purchase Warrants to March 29, 2015 (applicable to Stock Purchase Warrants filed as Exhibits 4.3 and 4.4)	8-K	001-34475	4.1	09/29/2014	
4.10	Form of Common Stock Warrant issued by Omeros Corporation to Cougar Investment Holdings LLC, which	8-K	001-34475	10.3	10/25/2010	



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were subsequently assigned to its affiliate Vulcan Capital Venture Capital II LLC (as of December 31, 2014, warrants in this form were issued to purchase up to 399,999 shares of common stock)

4.11	Form of Omeros Corporation Warrant to Purchase Common Stock	8-K	001-34475	4.1	02/02/2015
10.1*	Form of Indemnification Agreement entered into between Omeros Corporation and its directors and officers	S-1	333-148572	10.1	01/09/2008
10.2*	Second Amended and Restated 1998 Stock Option Plan	S-1	333-148572	10.2	01/09/2008
10.3*	Form of Stock Option Agreement under the Second Amended and Restated 1998 Stock Option Plan (that does not permit early exercise)	S-1	333-148572	10.3	01/09/2008
10.4*	nura, inc. 2003 Stock Plan	S-1	333-148572	10.6	01/09/2008

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10.5*	Form of Stock Option Agreement under the nura, inc. 2003 Stock Plan	S-1	333-148572	10.7	01/09/2008
10.6*	2008 Equity Incentive Plan	S-1/A	333-148572	10.8	04/01/2008
10.7*	Form of Stock Option Award Agreement under the 2008 Equity Incentive Plan	10-Q	001-34475	10.2	11/07/2013
10.8*	Second Amended and Restated Employment Agreement between Omeros Corporation and Gregory A. Demopulos, M.D. dated April 7, 2010	8-K	001-34475	10.1	04/12/2010
10.9*	Offer Letter between Omeros Corporation and Marcia S. Kelbon, Esq. dated August 16, 2001	S-1	333-148572	10.12	01/09/2008
10.10*	Technology Transfer Agreement between Omeros Corporation and Gregory A. Demopulos, M.D. dated June 16, 1994	S-1	333-148572	10.14	01/09/2008
10.11	Technology Transfer Agreement between Omeros Corporation and Pamela Pierce, M.D., Ph.D. dated June 16, 1994	S-1	333-148572	10.15	01/09/2008
10.12*	Second Technology Transfer Agreement between Omeros Corporation and Gregory A. Demopulos, M.D. dated December 11, 2001	S-1	333-148572	10.16	01/09/2008
10.13	Second Technology Transfer Agreement between Omeros Corporation and Pamela Pierce, M.D., Ph.D. dated March 22, 2002	S-1	333-148572	10.17	01/09/2008
10.14*	Technology Transfer Agreement between Omeros Corporation and Gregory A. Demopulos, M.D. dated June 16, 1994 (related to tendon splice technology)	S-1	333-148572	10.18	01/09/2008
10.15	Lease dated January 27, 2012 between Omeros Corporation and BMR-201 Elliott Avenue LLC	8-K	001-34475	10.1	02/01/2012
10.16	First Amendment to Lease dated November 5, 2012 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-Q	001-34475	10.2	11/09/2012
10.17	Second Amendment to Lease dated November 16, 2012 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-K	001-34475	10.18	03/18/2013
10.18	Third Amendment to Lease dated October 16, 2013 between Omeros Corporation and BMR-201 Elliott	10-K	001-34475	10.18	03/13/2014

Avenue LLC

10.19	Amended and Restated Settlement Agreement effective as of October 26, 2012 among Omeros Corporation, Gregory A. Demopulos, M.D. and Richard J. Klein	8-K	001-34475	10.1	11/01/2012
10.20	Settlement Agreement and Release effective as of October 2, 2013 among Omeros Corporation, Gregory A. Demopulos, M.D. and Carolina Casualty Insurance Company.	10-K	001-34475	10.20	03/13/2014
10.21†	Commercial Supply Agreement between Omeros Corporation and Hospira Worldwide, Inc. dated October 9, 2007	S-1/A	333-148572	10.28	09/16/2009
10.22†	Exclusive License and Sponsored Research Agreement between Omeros Corporation and the University of Leicester dated June 10, 2004	S-1/A	333-148572	10.29	09/16/2009

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10.23†	Research and Development Agreement First Amendment between Omeros Corporation and the University of Leicester dated October 1, 2005	S-1	333-148572	10.30	01/09/2008	
10.24††	Research and Development Agreement Eighth and Ninth Amendments between Omeros Corporation and the University of Leicester dated March 21, 2012 and September 1, 2013					X
10.25†	Exclusive License and Sponsored Research Agreement between Omeros Corporation and the Medical Research Council dated October 31, 2005	S-1/A	333-148572	10.31	09/16/2009	
10.26†	Amendment dated May 8, 2007 to Exclusive License and Sponsored Research Agreement between Omeros Corporation and the Medical Research Council dated October 31, 2005	S-1	333-148572	10.32	01/09/2008	
10.27†	Funding Agreement between Omeros Corporation and The Stanley Medical Research Institute dated December 18, 2006	S-1/A	333-148572	10.33	05/15/2009	
10.28†	Patent Assignment Agreement between Omeros Corporation and Roberto Ciccocioppo, Ph.D. dated February 23, 2009	S-1/A	333-148572	10.47	09/16/2009	
10.29†	First Amendment to Patent Assignment Agreement between Omeros Corporation and Roberto Ciccocioppo, Ph.D. effective December 31, 2010	10-K	001-34475	10.28	03/18/2013	
10.30*	Omeros Corporation Non-Employee Director Compensation Policy	S-1/A	333-148572	10.50	09/16/2009	
10.31†	License Agreement between Omeros Corporation and Daiichi Sankyo Co., Ltd. (successor-in-interest to Asubio Pharma Co., Ltd.) dated March 3, 2010	10-Q	001-34475	10.1	05/12/2010	
10.32†	Amendment No. 1 to License Agreement with an effective date of January 5, 2011 between Omeros Corporation and Daiichi Sankyo Co., Ltd.	10-Q	001-34475	10.1	05/10/2011	
10.33†	Amendment No. 2 to License Agreement with an effective date of January 25, 2013 between Omeros Corporation and Daiichi Sankyo Co., Ltd.	10-Q	001-34475	10.1	05/09/2013	
10.34†	Exclusive License Agreement between Omeros Corporation and Helion Biotech ApS dated April 20, 2010	10-Q	001-34475	10.2	08/10/2010	

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10.35†	Platform Development Funding Agreement between Omeros Corporation and Vulcan Inc. and its affiliate dated October 21, 2010	10-K	001-34475	10.44	03/15/2011
10.36†	Grant Award Agreement between Omeros Corporation and the Life Sciences Discovery Fund Authority dated October 21, 2010	10-K	001-34475	10.45	03/15/2011
10.37	Loan and Security Agreement among Omeros Corporation, Oxford Finance LLC and MidCap Financial SBIC, LP dated March 5, 2014	8-K	001-34475	10.1	03/07/2014
10.38	Form of Secured Promissory Note issued by the registrant to Oxford Finance LLC dated March 5, 2014	8-K	001-34475	10.2	03/07/2014
10.39	Form of Secured Promissory Note issued by the registrant to MidCap Financial SBIC, LP dated March 5, 2014	8-K	001-34475	10.3	03/07/2014

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10.40	First Amendment to Loan and Security Agreement Loan and Security Agreement among Omeros Corporation, Oxford Finance LLC, Flexpoint MCLS Holdings LLC and MidCap Funding XI, LLC dated December 30, 2014					X
10.41†	Pharmaceutical Manufacturing and Supply Agreement dated March 5, 2014 by and between Patheon Manufacturing Services, LLC (successor-in-interest to DSM Pharmaceuticals, Inc.) and Omeros Corporation	10-Q	001-34475	10.5	05/12/2014	
10.42†	Master Services Agreement between Omeros Corporation and Ventiv Commercial Services, LLC, made as of May 12, 2014	10-Q	001-34475	10.1	08/11/2014	
10.43†	Project Agreement (Detailing and Sales Operation Services) between Omeros Corporation and Ventiv Commercial Services, LLC, made as of May 12, 2014	10-Q	001-34475	10.2	08/11/2014	
10.44	First Amendment to Project Agreement (Detailing and Sales Operation Services) between Omeros Corporation and Ventiv Commercial Services, LLC, dated June 13, 2014	10-Q	001-34475	10.3	08/11/2014	
10.45††	Second Amendment to Project Agreement (Detailing and Sales Operation Services) between Omeros Corporation and Ventiv Commercial Services, LLC, made as of October 17, 2014					X
10.46††	Commercial Supply Agreement among Omeros Corporation, Hospira S.p.A. and Hospira Worldwide, Inc. dated October 3, 2014					X
12.1	Ratio of Earnings to Fixed Charges					X
23.1	Consent of Independent Registered Public Accounting Firm					X
31.1	Certification of Principal Executive Officer Pursuant to Rule 13-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Principal Financial Officer Pursuant to Rule 13-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section					X

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906 of the Sarbanes-Oxley Act of 2002

32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X
99.1	Description of Capital Stock	X
101.INS	XBRL Instance Document	X
101.SCH	XBRL Taxonomy Extension Schema Document	X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document	X

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101.PRE XBRL Taxonomy Extension Presentation Linkbase  
Document

X

\* Indicates management contract or compensatory plan or arrangement.

Portions of this exhibit are redacted in accordance with a grant of confidential treatment.

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