



FOCUS

DEPTH

PEOPLE



OMEROS

ANNUAL REPORT

2013

# NEXT GENERATION THERAPEUTICS TRANSFORMING PATIENT CARE TODAY

WITH WORLD-CLASS ASSETS, SCIENCE AND DRUG DEVELOPMENT, Omeros is well-positioned for commercial success.

DEAR SHAREHOLDERS, in 2013, Omeros achieved a series of significant milestones spanning all of our active programs. Of primary importance, some of those successes have positioned Omeros to complete its transition to a commercial biopharmaceutical company. Omidria™, for use during intraocular lens replacement surgery, looks to be well on its way to becoming our first marketed product. Last fall, we submitted marketing applications for Omidria in both the U.S. and Europe. The regulatory processes have progressed smoothly, and we expect U.S. approval this quarter followed next quarter by U.S. market launch and approval in Europe. Last year, in anticipation of those events, we began assembling the commercial team to lead and implement the planned product launch while remaining focused on securing reimbursement for the drug, and we are confident in our likelihood of success. There is no direct competitor to Omidria, and market research together with discussions with thought leaders in ophthalmic surgery demonstrate that there is a clear need for the product – and the recently passed compounding legislation, the Drug Quality and Security Act (DQSA), should only increase this need. Additional studies are in progress and slated to support further our long-term pricing and reimbursement strategy. We currently plan to commercialize Omidria independently in the U.S., leveraging contract organizations as appropriate, and to partner in Europe, Asia and other international territories.

We made significant strides across our other pipeline programs as well. OMS824, our lead phosphodiesterase (PDE) 10 inhibitor, continued to advance through clinical trials. PDE10 is an enzyme expressed in areas of the brain strongly linked to disorders that affect cognition, including Huntington's disease and schizophrenia. In Huntington's disease, OMS824 not only holds the promise of symptomatic treatment for the motor, behavioral and cognitive deficits but could also play a fundamental role in disease modification. Similarly, in schizophrenia, OMS824 might well treat not only the positive symptoms (e.g., auditory and visual hallucinations) targeted by currently marketed typical and atypical antipsychotics but also the negative (e.g., flat affect) and cognitive symptoms, which current antipsychotics do not address. In 2013, we generated positive data in a Phase 1 program, demonstrating that OMS824 had favorable pharmacokinetic properties, was well tolerated, and could achieve substantially higher target interaction than has been reported for other PDE10 inhibitors in development without triggering extrapyramidal side effects (e.g., involuntary muscle contractions). We also initiated enrollment in a positive Phase 2a schizophrenia trial, earlier this year showing that OMS824 could be administered in conjunction with currently used antipsychotics without exacerbating any of their side effects. These data open the opportunity for OMS824 to be delivered as monotherapy or as an adjunct to commercially available antipsychotics. For OMS824 in Huntington's disease, we received Orphan Drug designation from the FDA and then, in February of this year, also were granted FDA's Fast Track designation. The Phase 2 Huntington's clinical trial is underway and will read out preliminary data later this year.

Our OMS721 program also advanced through multiple value-driving milestones. OMS721 is our lead human monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 (MASP-2), the key regulator of the lectin pathway of the immune system. The lectin pathway is one of the principal complement activation pathways and plays a central role in the innate immune response. We control the worldwide rights to MASP-2 inhibitors and all other therapeutics targeting MASP-2. In 2013, we commenced and reported positive data from a European Phase 1 clinical trial of OMS721, demonstrating that the drug was well tolerated and achieved effectively complete inhibition of the lectin pathway by either intravenous or subcutaneous administration. This is in direct contradiction to the only marketed complement inhibitor, which requires 30-minute to two-hour intravenous infusion. Omeros also reported preclinical findings indicating that blockade of MASP-2 by OMS721 could provide a new treatment for neovascular age-related macular degeneration, a leading cause of vision loss in individuals over 60 years of age, as well as positive data using OMS721 in a well-established model of thrombotic microangiopathies (TMAs). TMAs are a family of rare, debilitating and life-threatening disorders characterized by multiple thrombi (clots) in the microcirculation of the body's organs, most commonly the kidney and brain. Based on the TMA data, the company

received Orphan Drug designation from the FDA for prevention of complement-mediated TMAs. Collectively, these accomplishments laid the foundation for FDA's clearance of our Investigational New Drug Application earlier this month, clearing the way for us to begin enrolling both U.S. and European patients with TMAs (atypical hemolytic uremic syndrome, thrombotic thrombocytopenic purpura and stem-cell transplant-related TMA) later this quarter in an open-label Phase 2 clinical trial evaluating the efficacy and safety of OMS721.

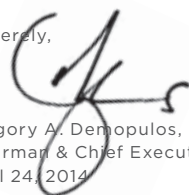
We continued to make progress in our other clinical or near-clinical programs. Discussions began with the FDA on a Phase 3 program for OMS103, our proprietary PharmacoSurgery® product for arthroscopy, to evaluate the drug's effects on postoperative inflammatory pain following arthroscopic partial meniscectomy. In parallel, we began exploring alternative avenues opened by the newly passed DQSA to market and sell OMS103 and OMS201, our patented PharmacoSurgery urologic product, without the need for additional clinical studies. Our addiction franchise similarly made strides with continued enrollment in Phase 2 clinical trials evaluating the PPARγ agonist OMS405 in opioid and nicotine addiction, with both trials run and fully funded by the National Institute on Drug Abuse, as well as with the selection of OMS527 as our lead clinical candidate in our PDE7 inhibitor program. We also selected OMS616, a fully human recombinant plasmin inhibitor, as our lead clinical candidate for the control of blood loss resulting from surgery, trauma or other hyperfibrinolytic conditions, and we began scale-up of the molecule under good manufacturing practices. Both OMS527 and OMS616 are slated for entry into the clinic next year.

We also enjoyed continued success in our GPCR program with the identification of compounds that functionally interact with each of eight additional orphan Class A GPCRs, bringing the number of Class A orphan GPCRs "unlocked" by Omeros to 54 – nearly 70 percent of the 81 Class A orphans and greater than the total number of GPCRs currently targeted by almost 40 percent of all marketed drugs. These unlocked receptors are linked to a wide range of indications including cancer and metabolic and central nervous system disorders as well as cardiovascular and inflammatory diseases. In addition, we identified and advanced the development of small molecules that interact with two non-orphan Class B GPCRs, the glucagon-like peptide 1 receptor and the parathyroid hormone 1 receptor. Throughout the year, we continued our ongoing strategy of filing patent applications directed to the orphan GPCRs that we unlock and expect that we will create strong intellectual property positions around each. We also selected several widely sought-after unlocked receptors for further medicinal chemistry efforts, and compound optimization for each is steadily advancing.

Our many achievements in 2013 together with those anticipated in 2014 are the result of the commitment and dedication of our valued employees and research collaborators, the efforts of our investigators and participants in our clinical trials, and the continued support of you, our shareholders – on behalf of our board of directors, thanks to all for your contributions to the successes of our company. Those successes validate and underscore the strength and relevance of Omeros' core strategy today and in the future: drive profits through commercialization of our PharmacoSurgery products to grow the company and to advance our pipeline; lever key value inflection points to access additional capital through partnerships for a limited number of our clinical or near-clinical pipeline programs; and, from our orphan GPCR platform, select valuable development programs to feed the pipeline, further fueling it with partnering revenue from the large remainder of our GPCR targets.

Omeros' transition to a commercial biopharmaceutical company is nearly complete and on schedule for the second half of 2014.

Sincerely,



Gregory A. Demopoulos, M.D.  
Chairman & Chief Executive Officer  
April 24, 2014



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

---

**FORM 10-K**

---

(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, 2013  
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

---

**OMEROS CORPORATION**

(Exact name of registrant as specified in its charter)

---

**Washington**  
(State or other jurisdiction of  
incorporation or organization)

**91-1663741**  
(I.R.S. Employer  
Identification Number)

**201 Elliott Avenue West**  
**Seattle, Washington**  
(Address of principal executive offices)

**98119**  
(Zip Code)

**(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  
(Title of each class)

The NASDAQ Stock Market LLC  
(Name of each exchange on which registered)

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

**None**

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934, 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

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.

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 \$138,767,404.

As of March 11, 2014, the number of outstanding shares of the registrant's common stock, par value \$0.01 per share, was 30,397,366.

#### **DOCUMENTS INCORPORATED BY REFERENCE**

Specified portions of the registrant's proxy statement with respect to the 2014 Annual Meeting of Shareholders to be held May 23, 2014, which is to be filed pursuant to Regulation 14A within 120 days after the end of the registrant's fiscal year ended December 31, 2013, are incorporated by reference into Part III of this Form 10-K.

## 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. 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," "plan," "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 ability to receive regulatory approval for our New Drug Application, or NDA, and our Marketing Authorisation Application, or MAA, for the commercialization of OMS302, or Omidria™, in the United States and in the European Union, or EU, respectively, in 2014;
- our anticipation that we will begin marketing Omidria, if approved, in the U.S. in the second half of 2014, and that we will initiate marketing Omidria, if approved, in the EU in late 2014 or the first half of 2015;
- our ability to successfully complete our Phase 2 clinical trials for OMS824 and our Phase 1 clinical trial for OMS721;
- our ability to initiate post-marketing studies for Omidria and additional clinical trials for OMS103;
- our ability to initiate a Phase 2 clinical trial for OMS721;
- our expectations regarding the clinical, therapeutic and competitive benefits of our potential products, which we refer to as products;
- whether there may be an opportunity to have our PharmacoSurgery® products produced and commercialized by a registered outsourcing facility, and whether any additional trials may need to be conducted;
- 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 note payments;
- our ability to raise additional capital through the capital markets or one or more corporate partnerships, equity offerings, debt financings, collaboration and licensing arrangements or asset sales;
- our expectation that the second half of 2014 is the earliest period in which any of our products will be commercially available or generate revenue;
- our anticipation that we will rely on contract manufacturers to develop and manufacture our products for commercial sale and will out-license Omidria marketing rights to one or more third-parties in the EU;
- our ability to enter into acceptable arrangements with potential corporate partners;
- our expectation that the clinical benefits of our PharmacoSurgery products could provide surgeons a competitive marketing advantage and facilitate third-party payor acceptance;
- whether pediatric studies may afford Omidria an additional six months of exclusivity;
- our expectation that the intended therapeutic effect of MASP-2 antibodies we develop can be achieved with subcutaneous and other system routes of administration;
- whether the variant KD1 proteins we are developing in our Plasmin program could provide more effective bleeding control with fewer side effects than Trasylo®l, and our expectation that our Plasmin program molecule will compare favorably to Trasylo®l with respect to safety;
- our ability to obtain commercial supplies of our PharmacoSurgery APIs and products and, if approved, our ability to successfully commercialize our PharmacoSurgery products with a limited marketing and sales force;
- our sales and marketing plans for our products and programs, including Omidria;
- our expectations regarding reimbursement and pricing for Omidria, including our expectation that Omidria will meet the criteria for transitional separate payment;
- our expectations about the commercial competition that our products may face;
- our expected financial position, performance, growth, expenses, the magnitude of our net losses and the availability of resources;
- the extent of protection that our patents provide and our pending patent applications may provide, if patents issue from such applications, to our technologies and programs;
- our involvement in potential claims, legal proceedings and administrative actions, the expected course and costs of potential claims, legal proceedings and administrative actions, and the potential outcomes and effects of potential claims, legal proceedings and administrative actions on our business, prospects, financial condition and results of operations; and

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

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 heading "Risk Factors" 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. These forward-looking statements 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 law, we assume no obligation to update these forward-looking statements, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

**OMEROS CORPORATION**  
**ANNUAL REPORT ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2013**

**INDEX**

	<u>Page</u>
<b>Part I — Financial Information</b>	5
Item 1. Business	6
Item 1A. Risk Factors	28
Item 1B. Unresolved Staff Comments	46
Item 2. Properties	46
Item 3. Legal Proceedings	46
Item 4. Mine Safety Disclosures	47
<b>Part II</b>	48
Item 5. Market for Registrant Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities	48
Item 6. Selected Consolidated Financial Data	49
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	50
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	60
Item 8. Financial Statements and Supplementary Data	60
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures	60
Item 9A. Controls and Procedures	60
Item 9B. Other Informations	63
<b>Part III</b>	64
Item 10. Directors, Executive Officers, and Corporate Governance	64
Item 11. Executive Compensation	64
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters	64
Item 13. Certain Relationships and Related Transaction, and Directors' Independence	64
Item 14. Principal Accounting Fees and Services	64
<b>Part IV -- Financial Information</b>	65
Item 15. Exhibits, Financial Statement Schedules	65
Signatures	66
Index to Financial Statements	F-1
Report of Independent Registered Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2013 and 2012	F-3
Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2013, 2012 and 2011	F-4
Consolidated Statement of Shareholder's Equity (Deficit)	F-5
Consolidated Statements of Cash Flows for the Years Ended December 31, 2013, 2012 and 2011	F-6
Notes to Consolidated Financial Statements	F-7
Item 16. Exhibits	F-22



## 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 clinical-stage biopharmaceutical company committed to discovering, developing and commercializing products targeting inflammation, coagulopathies and disorders of the central nervous system. Our most clinically advanced product, Omidria™ for lens replacement surgery, is derived from our proprietary PharmacoSurgery® platform designed to improve clinical outcomes of patients undergoing ophthalmological, arthroscopic, urological and other surgical and medical procedures. Our PharmacoSurgery platform is based on low-dose combinations of 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. In addition to Omidria, we have six other clinical-stage development programs in our pipeline. We also have a deep and diverse pipeline of preclinical programs as well as two additional platforms: one capable of unlocking new G protein-coupled receptor drug targets and the other used to generate antibodies. For each of our products and programs, we have retained all manufacturing, marketing and distribution rights.

## Our Products and Development Programs

Our clinical potential products, which we refer to as products, and pipeline of development programs consist of the following:

Program	Targeted Procedure/Disease	Development Status	Next Expected Milestone	Worldwide Rights
<b><i>Clinical Programs</i></b>				
Omidria (OMS302) - Ophthalmology	Intraocular Lens Replacement Surgery	NDA/MAA filed	Potential Approval of NDA and MAA	Omeros
OMS103 - Arthroscopy	Arthroscopic Meniscectomy	Phase 3	Redesign Phase 3 Program and Determine Commercialization Path	Omeros
PDE10 (OMS824) - CNS Disorders	Schizophrenia	Phase 2	Complete Phase 2 Trial	Omeros
PDE10 (OMS824) - CNS Disorders	Huntington's Disease	Phase 2	Complete Phase 2 Trial	Omeros
MASP (OMS721) - Complement-Mediated Disorders	TMA (aHUS, TTP, transplant-related TMA)	Phase 2	Initiate Enrollment in Phase 2 Trial	Omeros (In-licensed)
PPAR $\gamma$ (OMS405) - Addiction	Opioid and Nicotine Addiction	Phase 2	Complete Phase 2 Trials	Omeros
OMS201 - Urology	Ureteroscopy	Phase 1/2	Design Phase 2 Trial and Determine Commercialization Path	Omeros
<b><i>Preclinical Programs</i></b>				
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)
GPCR Platform	Multiple Disorders Across Therapeutic Areas	Preclinical	Continue Drug Discovery and Selected Medicinal Chemistry for Class A Orphan and Class B GPCRs	Omeros
GPR17 - CNS disorders	Demyelinating Disorders	Preclinical	Compound Optimization	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)

## Clinical Programs

### *PharmacoSurgery<sup>®</sup> Platform*

We believe 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 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 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 procedure. In addition to ease of use and potential for improved patient outcomes, we believe that the clinical benefits of our products could provide surgeons with a competitive marketing advantage and may facilitate third-party payor acceptance, all of which we expect will drive adoption and market penetration. Our current PharmacoSurgery products are specifically comprised of active pharmaceutical ingredients, or APIs, contained in generic drugs already approved by the U.S. Food and Drug Administration, or FDA, with established profiles of safety and pharmacologic activities, so the path to commercialization 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.

In addition to expecting decisions by the FDA and European Medicines Agency, or EMA, on marketing authorizations for Omidria and to preparing for U.S. market launch and European partnering in 2014, we are evaluating alternative approaches to make other patented PharmacoSurgery products commercially available, including OMS103 and OMS201. For example, we are following closely the developing implementation of the recently passed Drug Quality and Security Act, or DQSA, which was signed into law in November 2013, to determine whether there may be an opportunity to have such products produced and commercialized by a registered outsourcing facility without the need to conduct any additional clinical trials.

#### *Omidria (OMS302)-Ophthalmology*

*Overview.* Omidria is being developed for use during intraocular lens replacement, or ILR, including cataract and other lens replacement surgery. Omidria is a proprietary combination of ketorolac, an anti-inflammatory API, and phenylephrine, a mydriatic, or pupil dilating, API. 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. In November 2013, the FDA conditionally accepted Omidria as the proposed brand name for OMS302 in the U.S. and in December 2013, the EMA accepted Omidria as the proposed brand name for OMS302 in the EU. These acceptances are subject to final determination prior to approval of the respective marketing applications.

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 of the lens. Omidria is added to standard irrigation solution used during ILR and delivered intracamerally to maintain intraoperative mydriasis (pupil dilation), to prevent surgically induced miosis (pupil constriction), and to reduce postoperative pain. Mydriasis is essential for these procedures and, if not maintained throughout the surgical procedure or 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.

*Clinical Trial Results.* The safety and efficacy of Omidria have been evaluated through Phase 3 clinical trials in patients undergoing cataract extraction and lens replacement procedures and refractive lens exchange.

A Phase 2b multicenter, randomized, double-blind, vehicle-controlled clinical trial was conducted that included 221 patients. To achieve the trial's full-factorial design, patients were randomized into one of four parallel treatment groups. The first arm (n=55) received Omidria, the second arm (n=55) received only phenylephrine, the third arm (n=54) received only ketorolac and the fourth arm (n=57) received vehicle, which was standard irrigation solution without any study drug. The co-primary endpoints of the trial included maintenance of mydriasis and reduction of postoperative ocular pain. The Omidria group demonstrated statistically significant maintenance of mydriasis over both ketorolac- ( $p < 0.0001$ ) and vehicle-treated ( $p < 0.0001$ ) groups. Omidria was also statistically significantly superior in preventing clinically meaningful miosis when compared to each of the other three treatment arms ( $p = 0.0005$  vs. ketorolac,  $p = 0.0404$  vs. phenylephrine and  $p < 0.0001$  vs. vehicle). Similarly, the Omidria-treated group demonstrated a statistically significant reduction in pain compared with both phenylephrine- ( $p = 0.0089$ ) and vehicle-treated ( $p = 0.0418$ ) groups. All of these results are based on intent-to-treat analyses. These results demonstrate that each component of Omidria contributed to the efficacy of the product, with both phenylephrine and ketorolac additively providing maintenance of pupil dilation and ketorolac alone responsible for postoperative pain reduction.

We have completed two pivotal Phase 3 clinical trials that evaluated Omidria. Each of these trials was a multicenter, double-blind, placebo-controlled clinical trial that included over 400 patients randomized 1:1 to receive either Omidria or

placebo. In the first Phase 3 clinical trial, which we completed in 2012, the primary endpoint was maintenance of intraoperative mydriasis and the principal secondary endpoint was reduction of postoperative ocular pain. These two endpoints were pre-specified as the co-primary endpoints in the second Phase 3 clinical trial that we completed in 2013. In both pivotal trials, Omidria demonstrated statistically significant ( $p < 0.00001$  in each trial) maintenance of intraoperative mydriasis and statistical superiority ( $p < 0.00001$  in the first trial and  $p = 0.0002$  in the second trial) over placebo in reduction of ocular pain in the early postoperative period. In addition to statistical superiority over placebo in maintenance of mydriasis and reduced postoperative pain, Omidria achieved  $p$  values of less than 0.05 in a series of other clinically relevant measures. The most common adverse events were those related to surgery, specifically eye pain, eye inflammation, headache and increased intraocular pressure. The incidence of each of these adverse events was similar between Omidria- and placebo-treated patients.

Omidria was well-tolerated in all clinical trials.

*Development Plan.* We have discussed with the FDA and the EMA the design for pediatric studies for Omidria, which may afford Omeros an additional six months of exclusivity in the U.S. and the EU, respectively, if completed successfully. We expect to initiate these studies in mid-2014. In addition, we are evaluating the potential role of Omidria in the management of intraoperative floppy iris syndrome, or IFIS.

*Commercialization Plan.* We submitted an NDA to the FDA in July 2013 and an MAA to the EMA in September 2013 to allow us to market and sell Omidria in the U.S. and the EU, respectively, for use in patients undergoing ILR surgery. In October 2013, we announced that the FDA accepted the NDA for Omidria for filing and that the MAA for Omidria was validated by the EMA. Assuming approval of Omidria by the FDA within approximately one year of our initial submission of the NDA, we expect to begin marketing Omidria in the U.S. in the second half of 2014. In the EU, we plan to out-license Omidria marketing rights to one or more third-parties that have capabilities to promote Omidria to ophthalmologic surgeons, facilitate distribution and reimbursement, and manage pharmacovigilance and clinical support. Assuming approval of Omidria by the EMA and the out-licensing of Omidria marketing rights to one or more third parties, we anticipate the initiation of EU marketing and sales of Omidria in late 2014 or the first half of 2015. Although the positive results from the Omidria clinical trials are encouraging, there can be no assurance that it will receive marketing approval from the FDA or EMA or that we will be able to market Omidria in 2014 or ever.

### *OMS103-Arthroscopy*

*Overview.* OMS103 is our PharmacoSurgery product 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.

Arthroscopy is a surgical procedure in which a miniature camera lens is inserted into an anatomic joint, such as the knee, through a small incision in the skin. Through similar incisions, surgical instruments are also introduced and manipulated within the joint. During any arthroscopic procedure, an irrigation solution, such as lactated Ringer's solution or saline solution, is flushed through the joint throughout the procedure to distend the joint capsule, allowing better visualization with the arthroscope, and to remove debris resulting from the operation. 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.

*Clinical Trial Results.* In 2010, we completed a multicenter, randomized, double-blind, vehicle-controlled Phase 2 clinical trial of OMS103 in patients undergoing arthroscopic partial meniscectomy surgery. Of the 161 patients who were enrolled and treated, 143 patients met the predetermined surgical criteria and were included in the data analysis (71 OMS103- and 72 vehicle-treated patients). There were no important differences in demographic characteristics between the two treatment groups. During the trial the protocol was amended to collect patient self-reports using 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. The KOOS subset consisted of 67 patients (33 OMS103- and 34 vehicle-treated patients).

In this study, OMS103 provided greater efficacy than vehicle as measured by patient-reported functional scores using the KOOS, passive knee flexion and visual analog scale (VAS) pain scores. The patient-reported outcomes showed a sustained benefit through postoperative Day 90. OMS103 was well tolerated, and adverse events were more frequent in the vehicle dose group. An article describing the results of this Phase 2 clinical study, titled "Novel Drug, OMS103, Reduces Pain and Improves

Joint Motion and Function over 90 Days following Arthroscopic Meniscectomy," was published in the August 2011 edition of *Arthroscopy: The Journal of Arthroscopic and Related Surgery*.

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 KOOS. 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. The pain reduction data were similar in magnitude to those in the Phase 2 clinical trial. 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 2 and Phase 3 clinical trials 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.

*Development Plan.* We are redesigning our Phase 3 clinical program in arthroscopic partial meniscectomy surgery 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.

#### *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.

*Clinical Trial Results.* We are conducting an ongoing Phase 1 clinical program evaluating the safety, tolerability and pharmacokinetics of OMS824 in healthy subjects. The Phase 1 clinical trial is randomized, double-blind, and placebo-controlled, and includes a single-ascending-dose, or SAD, study and a multiple-ascending-dose, or MAD, study. In the SAD study, which concluded in December 2012, OMS824 was 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. With these encouraging data, we advanced OMS824 to the MAD portion of the Phase 1 clinical trial in December 2012 and, in March 2013, we announced the results. OMS824 was 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. In September 2013, we reported additional positive data from this Phase 1 clinical program, which at that point 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.

As part of our Phase 1 clinical program, we are also conducting a clinical trial to evaluate target occupancy of OMS824 using positron emission tomography, or 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. We are planning to evaluate a higher dose of OMS824 in this ongoing trial in an effort to achieve an even greater level of PDE10 occupancy.

We are currently evaluating OMS824 in two Phase 2 programs: one in patients with stable schizophrenia and the other in Huntington's disease patients. The Phase 2a schizophrenia trial, which commenced in September 2013, is evaluating the product'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 at PDE10 in a Phase 1 PET study in healthy subjects.

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.

The FDA has designated OMS824 as an orphan drug for Huntington's disease. OMS824 has also received Fast Track designation from the FDA for the treatment of cognitive impairment in patients with Huntington's disease, and we are seeking Fast Track designation for the evaluation of OMS824 in schizophrenia.

*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. 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 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.

#### *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.

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 thrombotic microangiopathies, or TMAs (*e.g.*, atypical hemolytic uremic syndrome, or aHUS, thrombotic thrombocytopenic purpura, or TTP, etc.), which is the disorder targeted by our first Phase 2 clinical trial (see below).

In April 2013, we announced positive data using OMS721, our lead MASP-2 inhibitor, in a well-established animal model of TMAs, disorders that occur in the microcirculation (e.g., venules and capillaries) of the body's organs, most commonly the kidney and brain. The study evaluated the ability of OMS721 to delay the time both to onset of thrombus formation and to complete occlusion of the blood vessel. In this study, 100% of isotype-antibody control animals versus 71% of OMS721-treated animals showed thrombus formation, with the initiation of thrombus formation delayed approximately three-fold in the OMS721-treated group relative to control (a median of 19.0 vs. 6.8 minutes;  $p=0.0097$ ). Eighty percent of control-treated animals showed complete occlusion within the observation period while only 43% of those treated with OMS721 occluded completely. Median time to complete occlusion was 18.0 minutes for control and 38.0 minutes for the OMS721-treated animals ( $p=0.0036$ ). We also conducted a study using OMS721 in a well-established animal model of neovascular age-related macular degeneration, or AMD. In the fourth quarter of 2013, we received positive data from this study, which showed that systemically administered OMS721 resulted in approximately half of the blood vessel development compared to control treatment. The study included an antibody to vascular endothelial growth factor, or VEGF, that also reduced blood vessel growth, and OMS721 outperformed the anti-VEGF treatment. Anti-VEGF treatment is the current mainstay of commercially available therapies for neovascular AMD.

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 and thrombus formation 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. Experiments evaluating the effects of OMS721 on thrombus formation are planned. The laboratories that conducted the study have previously shown in this same model system that treatment with agents that block the complement factor C5 has a similar inhibitory effect on complement deposition. Eculizumab (Soliris<sup>®</sup>) is an anti-C5 monoclonal antibody that is approved by the FDA and the EMA to treat patients with aHUS.

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

*Clinical Trial Results.* In June 2013, we obtained regulatory clearance to start a Phase 1 trial in Europe evaluating OMS721, which is scheduled to be concluded in April 2014. This Phase 1 trial is 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.

We have initiated a Phase 2 program for OMS721. We submitted an Investigational New Drug, or IND, application to the FDA in March 2014 to begin a Phase 2 clinical trial to evaluate OMS721 for the treatment of TMAs. If the IND application is cleared by the FDA, we intend to initiate this Phase 2 clinical trial in the second quarter of 2014. In December 2013, we announced that OMS721 had received Orphan Drug Designation from the FDA for prevention of complement-mediated TMAs.

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.

*Exclusive License Agreements with the University of Leicester and the Medical Research Council at Oxford University.* 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 technology during the terms of the agreements. 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. If mutually agreed, we may sponsor additional research of MASP-2 at these institutions. 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.

*Exclusive License Agreement with Helion Biotech ApS.* 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 are obligated to make development and sales milestone payments to Helion of up to \$6.9 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.

*MASP Program - Alternative and/or Lectin Pathway.* As part of our MASP program, we have also identified the key activators of the alternative pathway and believe that we are the first to make this discovery. We have expanded our intellectual property position to incorporate these discoveries and to address 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.

#### *PPAR $\gamma$ 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 three 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. 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. In February 2011, we amended the agreement to include all intellectual property rights, including patent applications, related to nutraceuticals that increase PPAR $\gamma$  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 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.

#### *OMS201-Urology*

*Overview.* OMS201 is our PharmacoSurgery product being developed for use during urological procedures, including ureteroscopy for removal of ureteral or renal stones. OMS201 is a proprietary combination of an anti-inflammatory API and a



smooth muscle relaxant API, and 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.

*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.

*Development Plan.* 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 evaluating alternative approaches to make OMS201 commercially available, such as through a registered outsourcing facility without the need to conduct any additional clinical trials.

## **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 good laboratory practices, or GLP, toxicology studies 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.* Under an agreement with Daiichi Sankyo Co., Ltd. (successor-in-interest to Asubio Pharma Co., Ltd.), or 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; 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.

*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 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 Trasyolol® (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 Trasyolol® 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. Trasyolol® 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 Trasyolol®.

Our proprietary agents also inhibit plasmin but, unlike Trasyolol®, 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 preparing to manufacture 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 Trasyolol® in inhibiting plasmin demonstrated that, in these studies, our candidate was at least as effective as Trasyolol®. Given that our molecule is (1) a human-derived protein rather than bovine-derived as is Trasyolol® and (2) does not have the off-target activity seen with Trasyolol® against kallikrein and Factor XIa, we expect that our molecule will compare favorably to Trasyolol® 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.* On December 14, 2010, we entered into a license agreement with The Regents of the University of California, or 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.

### *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 that bind to them, or their respective ligands. 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, which we refer to 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 GPCRs common to mice and humans, with the exception of sensory GPCRs. 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)*. In addition, our proprietary cellular redistribution assay, or CRA, can be used 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 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)*.

Using our expertise and these assets, 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 begun screening Class A orphan GPCRs against our small-molecule chemical libraries using the CRA. As of February 28, 2014, we had identified and confirmed sets of compounds that interact selectively with, and modulate signaling of, 52 Class A orphan GPCRs linked to a wide range of indications including cancer, metabolic and central nervous system disorders as well as cardiovascular and inflammatory diseases.

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. As of February 28, 2014, we had identified and confirmed sets of compounds that interact selectively with, and modulate signaling of, two Class B GPCRs (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.

#### *GPR17 Program*

*Overview.* We are optimizing compounds against GPR17, a G protein-coupled receptor, or GPCR, which 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., in that its natural ligand is not known. However, using our proprietary cellular redistribution assay, which allows compound screening against orphan GPCRs without knowledge of each receptor's natural ligand, we have been able to identify over 100 compounds that functionally interact with GPR17. We are now in the process of developing lead molecules targeting GPR17, which we intend to evaluate in remyelination assays in cell culture systems as well as in animal models.

### *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. As a result, 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, and our platform continues to add antibodies against additional important targets to our pipeline.

*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.* Pursuant to the Xori APA, we acquired all of Xori's exclusive rights under a license agreement with the University of Washington, or 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.

### **Sales and Marketing**

We have retained all marketing and distribution rights to our products and programs, which provides us the opportunity to market and sell any of our products independently, make arrangements with third parties to perform these services for us, or both. For the potential commercial launch of Omidria, if approved, we intend to develop our own internal marketing, managed markets and sales management capabilities, but plan to utilize a contract sales organization to call on surgeons, hospitals and ambulatory surgical centers in 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. We are currently in the process of building our internal capabilities and recruiting experienced managers to design and implement our launch strategies. We have not yet entered into a contract with a third party sales personnel organization. If we are unable to enter into such an agreement on terms acceptable to us or in a timely manner, or if we are unable to enter into such an agreement at all, our sales capabilities with respect to Omidria would be adversely affected, which would harm our business and financial condition.

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, facilitate distribution and reimbursement, and 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 such agreements on terms acceptable to us, or if we are unable to enter into such agreements at all, we would not expect to see sales of Omidria in those territories.

For the sales and marketing of our products in earlier stages of development, we generally expect to retain marketing and distribution rights where we believe it is possible to cost-effectively market them with our own internal commercial infrastructure. If we are unable to determine that we can cost-effectively market and sell any future product with our internal commercial infrastructure, we expect to make arrangements with third parties to perform those services with us.

## **Manufacturing**

We have laboratories in-house for analytical method development, bioanalytical testing, formulation, stability testing and small-scale compounding of laboratory supplies of products, which need not be manufactured in compliance with current Good Manufacturing Practices, or cGMPs. We utilize contract manufacturers to produce sufficient quantities of products for use in preclinical and clinical studies.

We rely on third-party manufacturers to produce, store and distribute our products and currently do not own or operate manufacturing facilities. 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 products 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 products.

In March 2014, we entered into an agreement, or the DSM Agreement, with DSM Pharmaceuticals, Inc., or DSM, pursuant to which DSM has agreed to manufacture and supply commercial quantities of Omidria, if approved. Pursuant to the DSM Agreement, DSM 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 DSM 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 DSM's relevant facility in the absence of an agreement between the parties to transfer to an alternate DSM facility. Upon termination of the DSM 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 DSM Agreement, except in certain circumstances, and will have the right to require DSM to assist with a transfer of the Omidria manufacturing process to a new manufacturer other than DSM, at our sole discretion and cost.

We have also entered into agreements with Hospira Worldwide, Inc., or 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 commercial requirements of liquid OMS103, if approved for marketing. Pursuant to our 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 the 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 Omidria and OMS103. We have not yet signed commercial agreements with suppliers for the supply of all of our anticipated commercial quantities of these APIs, although we intend to do so prior to the commercial launch of the applicable product if we do not otherwise have a sufficient quantity on hand to satisfy our projected requirements. Given the large amount of these APIs manufactured annually by these and other suppliers, we anticipate that we will be capable of attaining our commercial API supply needs for Omidria and OMS103.

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

## **Competition**

The pharmaceutical industry is highly competitive and characterized by a number of established, large pharmaceutical companies, as well as smaller companies like ours. If our competitors' market products that are less expensive, safer or more effective than any future products developed from our products, or that reach the market before our products receive regulatory approval, we may not achieve commercial success. We are not aware of any products comprised of two or more APIs that directly compete with our PharmacoSurgery products that are approved for intraoperative delivery in irrigation solutions during surgical procedures; however, our PharmacoSurgery products 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 an NSAID intraoperatively to reduce inflammation and postoperative pain.

Although we are not aware of any companies developing similar combination approaches for intraoperative pupil dilation and postoperative pain reduction, such strategies may develop once Omidria is marketed in the U.S. In addition, the level of reimbursement that surgeons receive for the administration of our products, including Omidria, could represent an impediment to the adoption of one or more of those products.

Our other clinical and preclinical products 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<sup>®</sup> is the only complement inhibitor approved for commercial use, and our lead MASP-2 inhibitor OMS721 will have to compete with Soliris<sup>®</sup> if it is approved for any indication(s) for which Soliris<sup>®</sup> is also approved. Additionally, the The Nordic Group is currently authorized to market Trasylol<sup>®</sup> in Europe for patients undergoing coronary artery bypass graft surgery. In September 2011, the marketing authorization for Trasylol<sup>®</sup> was also reinstated in Canada, with additional safety warnings, for patients undergoing coronary artery bypass graft surgery. Any product that we develop in our Plasmin program for the same indication would directly compete with Trasylol<sup>®</sup> in any countries in which Trasylol<sup>®</sup> 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. 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.

## **Intellectual Property**

As of February 15, 2014, we owned or held worldwide exclusive licenses to a total of 51 issued or allowed patents and 51 pending patent applications in the U.S. and 245 issued or allowed patents and 230 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 others, delivered locally and intraoperatively to the site of any medical or surgical procedure. As of February 15, 2014, our patent portfolio included 18 U.S. and 74 foreign issued or allowed patents, and eight U.S. and 23 foreign pending patent applications, directed to our PharmacoSurgery products and development programs. Our issued PharmacoSurgery patents have terms that will expire as late as September 24, 2022 for OMS103 and July 30, 2023 for Omidria, and, if currently pending patent applications are issued, August 3, 2032 for OMS103, October 23, 2033 for Omidria and March 17, 2026 for OMS201.

Our initial issued patents in our PharmacoSurgery portfolio are directed to combinations of agents, drawn from therapeutic classes such as pain and inflammation inhibitory agents, spasm inhibitory agents, restenosis inhibitory agents and tumor cell adhesion inhibitory agents. We expanded our initial patent position with a series of patent applications directed to

what we believe are the key physiological and technical elements of selected surgical procedures, and to the therapeutic classes that provide opportunities to improve clinical benefit during and after these procedures. Accordingly, 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 preferred for use 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.

- *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 15, 2014, we owned two issued U.S. Patents and three pending U.S. Patent Applications and 28 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 15, 2014, we owned six issued U.S. Patents, three pending U.S. Patent Applications, and 41 issued patents and 17 pending patent applications in foreign markets (Argentina, Australia, Brazil, Canada, Chile, China, Europe, Hong Kong, India, Indonesia, Israel, Japan, Mexico, New Zealand, Norway, Russia, Singapore, South Africa South Korea and International Patent Cooperation Treaty) 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 15, 2014, we owned three issued U.S. Patents, two pending U.S. Patent Applications, and an additional 35 issued patents and five pending patent applications in foreign markets (Australia, Brazil, Canada, China, Europe, Hong Kong, India, Japan, Mexico, Norway, Russia, Singapore and South Korea) that are directed to OMS201.
- *PDE10 Program - OMS824*. As of February 15, 2014, we own five issued patents and one pending patent application in the U.S., and one issued patent and 23 pending patent applications in foreign markets (Australia, Brazil, Canada, China, Chile, Europe, India, Indonesia, Israel, Japan, Mexico, New Zealand, South Korea and South Africa) that are directed to proprietary PDE10 inhibitors.
- *PPAR $\gamma$  Program - OMS405*. As of February 15, 2014, we owned one issued patent and three pending patent applications in the U.S. and seven issued patents and 26 pending patent applications in foreign markets (Australia, Brazil, Canada, China, Europe, India, Japan, Mexico, New Zealand, Russia and South Korea) directed to our recent discoveries linking PPAR $\gamma$  and addictive disorders.
- *MASP-2 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, Medical Research Council at Oxford University and Helion. As of February 15, 2014, we exclusively controlled seven issued patents and 17 pending patent applications in the U.S., and 16 issued patents and 90 pending patent applications in foreign markets (Australia, Brazil, Canada, Chile, China, Hong Kong, Europe, India, Indonesia, Israel, Japan, Mexico, New Zealand, Russia, South Africa, South Korea and International Patent Cooperation Treaty) related to our MASP-2 program.
- *PDE7 Program - OMS527*. As of February 15, 2014, we owned one issued patent and two pending patent applications in the United States, and two issued patents and 23 pending patent applications in foreign markets (Australia, Brazil, Canada, China, Europe, India, Japan, Mexico, New Zealand and Russia) directed to our discoveries linking PDE7 to movement disorders, as well as two issued patents and one pending patent application in the U.S. and 16 pending patent applications in foreign markets (Australia, Brazil, Canada, Chile, China, Europe, India, Indonesia, Israel, Japan, Mexico, New Zealand, Russia, South Africa and South Korea) 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 (Australia, Brazil, Canada, China, Europe, Hong Kong, Hungary,

India, Japan, Korea, Mexico, New Zealand and Russia) that are directed to proprietary PDE7 inhibitors. For a more detailed description of our agreement with Daiichi Sankyo, see "Business-Preclinical Programs-PDE7 Program."

- *Plasmin Program - OMS616*. We hold worldwide exclusive licenses to a series of antifibrinolytic agents from The Regents of the University of California. As of February 15, 2014, we exclusively controlled two issued patents and three pending patent applications in the U.S. and 21 issued and five pending patent applications in foreign markets (Australia, Canada, Europe and Japan) that are directed to these proprietary agents.
- *GPCR Platform*. As of February 15, 2014, we owned five issued patents and 10 pending patent applications in the U.S., and 43 issued patents and eight pending patent applications in foreign markets (Australia, Canada, China, Europe, Hong Kong, India, Japan, Macao, Mexico, New Zealand and Russia), 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 15, 2014, we owned and/or held worldwide exclusive license rights from the University of Washington to three pending U.S. Patent Applications, four foreign patent applications (Australia, Canada, Europe, Japan) and one International Patent Cooperation Treaty Patent Application directed to our antibody platform. Additionally, we owned one issued U.S. Patent, two pending U.S. Patent Applications and eight pending foreign applications (Australia, Canada, Europe, Japan) 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 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 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 manufacturing, marketing and distribution rights for each of our products and programs. Some of our products 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-Preclinical Programs-PDE7 Program."
- *MASP-2 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 MRC and Helion. For more detailed descriptions of these licenses, see "Business-Clinical Programs-MASP Program."



- *PPAR $\gamma$  Program.* We acquired the patent applications and related intellectual property rights for our PPAR $\gamma$  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-Clinical Programs- PPAR $\gamma$  Program."
- *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-Preclinical Programs-Plasmin Program."
- *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 University of Washington. For a more detailed description of this agreement, see "Business-Preclinical Programs-Antibody Platform."

## 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 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 are regulated by the EMA as drugs or biologics under the rules governing medicinal products in the EU as well as national regulations in individual countries. Our products are in various stages of testing and none has received marketing approval from the FDA or EMA.

The steps required before a product may be approved for marketing by the FDA or EMA 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 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 EMA approval of an MAA.

*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 such a case, 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 in the form of an MAA, requesting approval to market the product for a specified indication. In Europe, an MAA may be submitted for approval across the EU (centralized procedure) or 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.

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 will 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 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 candidate products 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.

Some of our products, 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 the Centers for Medicare & Medicaid Services, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice, state Attorneys General, and other state and local government agencies. 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 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. 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 of the DQSA, which was enacted in November 2013, amends the FDCA to establish a distinct category of drug compounders known as “outsourcing facilities.” Compounders who elect to register with FDA as an outsourcing facility are 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. FDA has identified compounding as an enforcement priority in 2014, 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**

In both U.S. and foreign markets, our ability to commercialize our products successfully, and to attract commercialization partners for our products, depends in significant part on the availability of adequate financial coverage and reimbursement from third-party payors, including, in the U.S., managed care organizations, private health insurers and governmental payors such as the Medicare and Medicaid programs. Third-party payors 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. Even with the availability of such studies, third-party payors may not provide coverage and reimbursement for our product candidates, in whole or in part.

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, including 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.

We will be seeking to apply for coverage and reimbursement from the U.S. Center for Medicare and Medicaid Services, or CMS, under provisions that allow for transitional separate payment for Omidria as opposed to having Omidria be included as part of the existing packaged payment for cataract surgery paid by CMS. Other third-party payors often follow the reimbursement methodology adopted by CMS. Although we believe we will meet the criteria for transitional separate payment, we cannot predict how long CMS will take to process our application, and there is no assurance that CMS will eventually approve our application. Even if our application is approved, separate payment will be for a period not greater than three years and we will have to re-apply for continued separate payment by CMS. Since the majority of patients undergoing cataract surgery are covered by Medicare in the U.S., if we do not receive approval for separate payment by CMS, we may need to adjust our pricing and our revenue could be lower than if we had received a positive decision by CMS on separate payment for Omidria. Even if we receive transitional separate payment from CMS, if we cannot receive continuation of separate payment once it expires, we would expect to be classified within the packaged payment for the cataract procedure and, at that time, may need to adjust our pricing accordingly. In addition to CMS, we will need to arrange for reimbursement from private payors that may, or may not, reference our CMS reimbursement status in their coverage decisions.

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 \$36.3 million, \$31.9 million and \$23.7 million in 2013, 2012 and 2011, respectively.

## Employees

As of February 28, 2014, we had 75 full-time employees, 57 of whom are in research and development and 18 of whom are in finance, legal, business development and administration, including 4 with M.D.s and 20 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 Key Employees

The following table provides information regarding our executive officers and key employees as of March 13, 2014:

Name	Age	Position(s)
<i>Executive Officers:</i>		
Gregory A. Demopoulos, M.D.	55	President, Chief Executive Officer and Chairman of the Board of Directors
Michael A. Jacobsen	55	Vice President, Finance, Chief Accounting Officer and Treasurer
Marcia S. Kelbon, J.D., M.S.	54	Vice President, Patent and General Counsel and Secretary
<i>Key Employees:</i>		
Timothy M. Duffy	53	Vice President, Business Development
Kenneth M. Ferguson, Ph.D.	58	Vice President, Development and Chief Development Officer
George A. Gaitanaris, M.D., Ph.D.	57	Vice President, Science and Chief Scientific Officer
Patrick W. Gray, Ph.D.	62	Scientific Fellow
Michael K. Inouye	58	Vice President, Commercial Operations
Catherine A. Melfi, Ph.D.	55	Vice President, Regulatory Affairs and Quality Systems
J. Steven Whitaker, M.D., J.D.	58	Vice President, Clinical Development and Chief Medical Officer
Albert S. Yu, M.D.	57	Vice President, Clinical Development

*Gregory A. Demopoulos, M.D.* is one of our founders and has served as our president, chief executive officer and chairman of the board of directors since June 1994 and, in an interim capacity, as our chief financial officer and treasurer from January 2009 to October 2013. He also served as our chief medical officer from June 1994 to March 2010. Prior to founding Omeros, Dr. Demopoulos completed his residency in orthopedic surgery at Stanford University and his fellowship training at Duke University. Dr. Demopoulos currently serves on the board of directors of Onconome, Inc., a privately held company developing

biomarkers for early cancer detection. Dr. Demopoulos received his M.D. from the Stanford University School of Medicine and his B.S. from Stanford University. Dr. Demopoulos is the brother of Peter A. Demopoulos, 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 us, 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.

*Michael K. Inouye* has served as our vice president, commercial operations since October 2013. Prior to joining Omeros, Mr. Inouye served as a consultant to life sciences companies from March 2008. Mr. Inouye served as Senior Vice President, Corporate and Commercial Development of Pharmacyclics, Inc. from May 2007 through February 2008. From March 2006 through February 2007, Mr. Inouye was Senior Vice President of Commercial Operations of Telik, Inc. From May 2005 through February 2006, Mr. Inouye was working as an independent pharmaceutical industry consultant. Mr. Inouye was a worldwide commercial operations executive at Gilead Sciences, Inc. from August 1995 to April 2005, where he led the global product launches of leading HIV therapeutics and hepatitis B virus therapeutics. Before joining Gilead Sciences, he served in

sales, marketing and business development roles at Merck & Co. and American Home Products. In addition, From 2005 through its acquisition by Gilead in 2012, Mr. Inouye served on the board of directors of Pharmasset Inc. Mr. Inouye received a B.S. in Food & Science Technology from the University of California at Davis and an M.B.A. from California State Polytechnic University, Pomona.

*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 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.

*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.

*Albert S. Yu, M.D.* has served as our vice president, clinical development since October 2012. He previously served as a consultant to Omeros from November 2011 to October 2012. From August 2007 to May 2011, Dr. Yu served as vice president of clinical affairs and chief medical officer of Calistoga Pharmaceuticals, Inc., a biotechnology company that was acquired by Gilead Sciences, Inc. Before Calistoga, he served at ICOS Corporation as head of clinical affairs, where he led the early clinical development of Cialis®. Dr. Yu received his M.D. from the University of Washington and his B.S. from the Massachusetts Institute of Technology.

## **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.omeros.com](http://www.omeros.com). We make available, free of charge through our web site, 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, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the U.S. Securities and Exchange Commission, or SEC. Our web site 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**

**We are focusing a significant portion of our activities and resources on Omidria and our success may largely depend on our ability to obtain regulatory approval.**

We are a biopharmaceutical company with no products approved for commercial sale and we have not generated any revenue from product sales. We have incurred, and expect to continue to incur, significant costs relating to the development of our lead PharmacoSurgery product, Omidria, for use during ILR procedures. We intend to focus a significant portion of our activities and resources on gaining regulatory approval for Omidria, and we believe a substantial portion of the value of our company relates to our ability to obtain marketing approval for this product.

We have submitted an NDA with the FDA and an MAA with EMA for Omidria, and both are currently under substantive review. The regulatory process is subject to substantial agency discretion and risks, including those described later in these risk factors. Either agency may decide not to approve our application, requiring us to obtain additional data regarding Omidria and to resubmit our marketing application(s), further delaying our ability to market and generate revenue from the sale of Omidria.

If there are any negative decisions or delays in the regulatory process, the market price of our common stock could decline significantly.

**Even if we receive regulatory approval for Omidria or our other products, we cannot be certain that we will successfully commercialize these products.**

We have invested a significant portion of time and financial resources in the development of Omidria and our other products. We anticipate that our ability to generate revenues will depend on the commercial success of our products, including Omidria, if approved, which in turn will depend on several factors, including our ability to:

- generate commercial sales of our products, if approved, through our own sales force, collaborations with pharmaceutical companies or contract sales organizations, that we may establish;
- establish effective marketing programs and build brand identity;
- obtain acceptance of our products by physicians, patients and third party payors and obtain and maintain distribution of our products;
- establish and maintain agreements with distributors on commercially reasonable terms; and
- demonstrate commercial manufacturing capabilities necessary to meet the commercial demand for a product and maintain commercial manufacturing arrangements with third-party manufacturers.

We will continue to incur significant and increasing costs as we continue to support the potential commercial launch of Omidria, if approved. If we fail to successfully commercialize this product or the other products in our pipeline, if approved, or we are significantly delayed in doing so, we may be unable to generate sufficient revenues to grow our business and our business, financial condition and results of operations will be materially and adversely affected.

**Our existing and future products, including Omidria and OMS103, may never achieve market acceptance.**

Even if we receive regulatory approvals for the commercial sale of one or more of our existing or future products, including Omidria and OMS103, the commercial success of these products will depend on, among other things, their acceptance by physicians, patients, third-party payors and other members of the medical community. If our products fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. Market acceptance of, and demand for, any product that we may develop and commercialize will depend on many factors, including:

- our ability to provide acceptable evidence of safety, efficacy and product quality;
- the availability and relative cost and efficacy of alternative and competing treatments;
- the effectiveness of our marketing and distribution strategy to, among others, hospitals, surgery centers, physicians and/or pharmacists;
- the prevalence of the condition for which the product is approved or frequency of the related surgical procedure;
- the acceptance by physicians of each product as a safe and effective treatment;
- the perceived advantages over alternative treatments;
- the relative convenience and ease of administration;
- the availability of adequate reimbursement by Medicare and other third parties;
- the frequency and severity of adverse side effects; and
- publicity concerning our products or competing products and treatments.

Further, the number of operations in which any of our PharmacoSurgery products, if approved, would be used may be significantly less than the total number of such operations performed. If our products do not receive sufficient levels of acceptance from physicians, patients, third-party payors and other members of the medical community, it is unlikely that we



will ever become profitable. If we are unable to increase market penetration of our products, our growth prospects would be significantly harmed.

**We are subject to extensive government regulation, including the regulations associated with approval for marketing of our products.**

Both before and after approval of our products, we, our products, 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; 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 being exposed to an unacceptable health risk or because of the way in which the investigators on which we rely carry out the trials.

The FDA has not approved any of our products for sale in the U.S. Obtaining FDA approval 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 a timely basis, if at all.

The FDA may decide that our data are insufficient for approval of our products and require additional preclinical, clinical or other studies or additional work related to chemistry, manufacturing and controls. As we develop our products, we periodically discuss with the FDA clinical, regulatory and manufacturing matters, and our views may, at times, differ from those of the FDA. For example, the FDA regulates our products that consist of two or more active ingredients as combination drugs under its Combination Drug Policy. The Combination Drug Policy requires that we demonstrate that each active ingredient in a drug product contributes to the product's claimed effect. The FDA has maintained questions regarding whether available data and information provided to the FDA demonstrate the contribution of each active ingredient in OMS103. We have not yet reached agreement with the FDA regarding clinical trial design, data analysis, and proposed label claims for OMS103. If we are unable to resolve these questions, we may be required to provide additional information, which may include the results of additional preclinical studies or clinical trials.

If we are required to conduct additional clinical trials or other testing of our products beyond that which we currently contemplate for regulatory approval, if we are unable to successfully complete 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 be delayed in obtaining marketing approval for our products, or may never obtain marketing approval.

Even if regulatory approval of a product 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 product. Even after approval, discovery of previously unknown problems with a product, manufacturer, or facility, such as previously undiscovered side effects or adverse effects, may result in restrictions on any product, manufacturer, or facility, including, among other things, a possible withdrawal of approval of the product.

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

We intend to have our products 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. Although we have filed for regulatory approval of Omidria in the EU, we may be unable to file for regulatory approvals in other non-U.S. geographies and may not receive necessary approvals to commercialize Omidria or any of our other products in any market. The 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 may vary from country to country. The time required to obtain regulatory approval outside the U.S. and EU may differ from that required to obtain FDA or EMA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA or EMA approval discussed in these "Risk Factors." We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA or EMA 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. The failure to obtain these approvals could harm our business.

**If we are unable to obtain adequate reimbursement from governments or third-party payors for any products that we may develop or if we are unable to obtain acceptable prices for those 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 availability of adequate reimbursement for the use of our approved products, including Omidria, from governmental and other third-party payors, 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 payor may depend on a number of factors, including the third-party payor's determination that use of a product is:

- a 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 a product from each government or third-party payor can be a time-consuming and costly process that will require the build-out of a sufficient staff and could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. Because none of our products has been approved for marketing, we can provide no assurances at this time regarding their cost-effectiveness and the amount, if any, or method of reimbursement. Further, we can provide no assurance that the amounts, if any, reimbursed to surgical facilities for utilization of our surgery-related products or to surgeons for the administration and delivery of these products will be considered adequate to justify the use of these products. There may be significant delays in obtaining reimbursement coverage for newly approved products and we may not be able to provide data sufficient to gain acceptance with respect to reimbursement. Even when a payor 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. Increasingly, third-party payors who reimburse healthcare costs, such as government and private payors, 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. 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 we are able to obtain for any product we develop is inadequate in light of our development and other costs or is significantly delayed, our business could be materially harmed.

**We cannot be certain that OMS103 will receive regulatory approval or be successfully commercialized.**

We have an ongoing Phase 3 clinical program evaluating OMS103 in patients undergoing arthroscopic partial meniscectomy. We are redesigning the program to include postoperative pain reduction as the primary endpoint. 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 may find it difficult to prevent compounders from preparing compounded formulations of products that may compete with our products when commercialized, including Omidria and OMS103.**

In November 2013, President Obama signed the Drug Quality and Security Act, which provided for the oversight of compounded human drugs. The law permits a compounding pharmacy to voluntarily register with the FDA as an outsourcing facility and create compounded products, subject to certain requirements including compliance with cGMPs and FDA inspection. Registered outsourcing facilities will be permitted to compound products in large quantities instead of pursuant to individual patient prescriptions. Outsourcing facilities may not engage in wholesale selling of compounded drugs, compound a drug that is essentially a copy of a commercially available drug, or compound drugs that the FDA identifies as prohibited for compounding. Outsourcing facilities will still be subject to potential liability for patent infringement by compounding patented drugs. It is not clear how many compounding pharmacies will register with the FDA as outsourcing facilities, or how

aggressively the FDA will implement the new law. It is also not clear to what extent traditional compounding pharmacies that do not register as outsourcing facilities will continue to produce compounded drugs without individual patient prescriptions. We may be unable to prevent a registered outsourcing facility or traditional compounding pharmacy from preparing a compounded formulation in large quantities that is similar to Omidria or OMS103 but outside the scope of the claims of our issued patents, or may be unsuccessful in enforcing our issued patents against outsourcing facilities or traditional compounding pharmacies who prepare compounded formulations that are within the scope of our issued patents. Because these patent violations may be sporadic and dispersed, we may not be able to easily identify the violations. Such actions may hinder our ability to generate enough revenue to achieve profitability and adversely affect our margins.

**If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our products, we may be unable to generate product revenue.**

Omeros has never sold, marketed or distributed any biopharmaceutical product. Developing an internal sales force is expensive and time-consuming, and a delay in hiring and training an internal sales force could impact the timing or effectiveness of any product launch. If we enter into arrangements with third parties to perform sales and marketing services, our product revenues are likely to be lower than if we market and sell any approved products ourselves. Factors that may inhibit our efforts to commercialize any approved products 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, particularly before our planned market launch of Omidria, if approved, in the second half of 2014;
- the inability of sales personnel to sell our product(s) to adequate numbers of hospitals, surgery centers, physicians and/or pharmacists;
- our inability to develop and maintain adequate internal 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; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unsuccessful in building a sales and marketing infrastructure or unable to partner with one or more third parties to perform sales and marketing services for our products, we will have difficulty commercializing our products, which would adversely affect our business and financial condition.

In the EU, we plan to out-license Omidria marketing rights to a third-party that has capabilities to promote to ophthalmologic surgeons, facilitate distribution and reimbursement, and 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 such agreements on terms acceptable to us, or if we are unable to enter into such agreements at all, we would not expect to see sales of Omidria in those territories, which could adversely affect our business and financial condition.

**We have a history of operating losses, and we may not achieve or maintain profitability.**

We have not been profitable and have generated substantial operating losses since we were incorporated in June 1994. We had net losses of approximately \$39.8 million, \$38.4 million and \$28.5 million for the years ended December 31, 2013, 2012 and 2011, respectively. As of December 31, 2013, we had an accumulated deficit of approximately \$254.4 million. We do not anticipate generating revenue from the sale of our products until the second half of 2014 at the earliest and expect to incur additional losses for at least the next several years and cannot be certain that we will ever achieve profitability. As a result, our business is subject to all of the risks inherent in the development of a new business enterprise, such as the risks that we may be unable to obtain additional capital needed to support the preclinical and clinical expenses of development and commercialization of our products, to develop a market for our products, to successfully transition from a company with a research and development focus to a company capable of commercializing products and to attract and retain qualified management as well as technical and scientific staff.

**Our independent registered public accounting firm has indicated that our financial condition raises substantial doubt as to our ability to continue as a going concern.**

Our financial statements have been prepared assuming that we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. However, our independent registered public accounting firm has included in its audit opinion for the year ended December 31, 2013 a statement that there is substantial doubt as to our ability to continue as a going concern as a result of our recurring losses and

financial condition on December 31, 2013. Our ability to continue as a going concern will require us to obtain additional financing, enter into strategic alliances or sell assets in order to fund our operations. The reaction of investors to the inclusion of a going concern statement by our auditors, our current lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital, enter into strategic alliances and/or make our scheduled debt payments on a timely basis or at all. If we become unable to continue as a going concern, we may have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.

**If we are unable to raise additional capital when needed or on acceptable terms, we may be unable to complete the development and commercialization of Omidria, OMS103 or our other products, or continue our other preclinical development programs.**

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to:

- prepare for the potential commercialization of Omidria;
- continue the Phase 3 clinical program of OMS103 for use in arthroscopic partial meniscectomy surgery;
- continue the clinical development of OMS824 and OMS721;
- continue our development efforts in our GPCR program to advance this program for potential partnering or for internal development of products targeting GPCRs;
- scale-up and produce clinical and commercial supplies of products, and conduct clinical studies for our products, including for Omidria, OMS103, OMS824, OMS721, and products being developed in our PDE7 and Plasmin programs;
- continue research and development in all of our programs;
- make principal and interest payments when due under our debt facility with Oxford and MidCap;
- initiate and conduct clinical trials for other products;
- make milestone payments to our collaborators;
- undertake development activities and make the required payments to maintain our exclusive licenses to our MASP-2 program; and
- launch and commercialize any products for which we receive regulatory approval.

If we do not raise additional capital, we may be unable to commercialize Omidria, if it is approved, or complete all of the clinical trials in our Phase 3 clinical program for OMS103, which would prevent us from generating sales revenue for one or both of those products. Furthermore, we may need to raise additional capital to continue the clinical development of OMS824, OMS721 and other clinical programs, and to advance one or more of our preclinical programs into clinical development. Also, our clinical trials may be delayed or we may need to conduct additional trials for many of the reasons discussed in these "Risk Factors," which would increase our development expenses and may require us to raise additional capital to complete the clinical development and commercialization of our products and to decrease spending on our other development programs. If we are unable to raise sufficient capital to commercialize Omidria, complete the clinical development of OMS103 or advance the development of one or more of our other programs, our business and prospects could be harmed and our stock price could decline significantly.

**If our clinical trials are delayed, we may be unable to develop our products on a timely basis, which will increase our development costs and delay the potential commercialization of our products and the subsequent receipt of revenue from sales, if any.**

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, poorly executed testing, a failure of a clinical site to adhere to the clinical protocol or an unacceptable study design;
- an insufficient supply of product materials or other materials necessary to conduct our clinical trials;

- the need to qualify new suppliers of product 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 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;
- 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 contract research organizations, or 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. 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 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 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 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 products.**

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 obtain regulatory approval for our products.

**We have no capacity to manufacture clinical or commercial supplies of our products and intend to rely solely on third parties to manufacture clinical and commercial supplies of all of our products.**

We do not intend to manufacture our products for our clinical trials or on a commercial scale and intend to rely on third parties to do so. With the exception of our agreements with DSM for the commercial supply of Omidria and Hospira Worldwide, Inc. for the commercial supply of liquid OMS103, we have not yet entered into any agreement for the commercial supply of any of our products, and can provide no assurance that we will be able to do so on commercially reasonable terms, if at all. Our agreement with DSM for the supply of Omidria has a term extending through December 31, 2015, which term could be terminated early by either party upon the occurrence of certain specified events, including any mandate from a regulatory authority prohibiting manufacture at DSM's relevant facility in the absence of an agreement with DSM to transfer the manufacture of Omidria to an alternative DSM facility. If DSM is unable to manufacture Omidria at its planned facility, or if our supply agreement with DSM is terminated, we will have to transfer the Omidria manufacturing process to another facility or manufacturer. The cost of transferring the Omidria manufacturing process to an alternate DSM manufacturing facility or a different manufacturer, or any significant delays in the timely completion of the transfer of the Omidria manufacturing process, could materially harm our business and prospects. Any significant delays in the manufacture of clinical or commercial supplies of our other products could materially harm our business and prospects.

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

Contract manufacturers that we select to manufacture our products 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 commercialization of our products. 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. 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 such supply arrangements may not be available on commercially reasonable terms, if at all.

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 products 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 product approval, product seizure or recall or withdrawal of product approval. If the safety of any product 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 one or more of our products, 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 products to patients in our clinical trials or on a commercial scale would be

jeopardized. Any delay or interruption in the supply of clinical trial supplies 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. If we need to change to other commercial manufacturers, the FDA and comparable foreign regulators must first approve these manufacturers' facilities and processes, which could require new testing and compliance inspections, and the new manufacturers would have to be educated in or independently develop the processes necessary for the production of our products.

**Ingredients necessary to manufacture our PharmacoSurgery products may not be available on commercially reasonable terms, if at all, which may delay the development and commercialization of our products.**

We must purchase from third-party suppliers the active pharmaceutical ingredients necessary for our contract manufacturers to produce our PharmacoSurgery products for our clinical trials and, if approved, for commercial distribution. Suppliers may not sell these ingredients to us at the time we need them or on commercially reasonable terms, if at all. 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 for our PharmacoSurgery products, we have not yet entered into agreements for the supply of all such ingredients 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 in a timely manner or in the minimum guaranteed quantities. If we are unable to obtain and then supply these active pharmaceutical ingredients to our contract manufacturers for our clinical trials or for the manufacture of commercial supplies if products, such as Omidria, are approved, potential regulatory approval of our products or, if approved, commercialization of our products, would be delayed, significantly impacting our ability to develop and commercialize our products, which would materially affect our ability to generate revenue from the sale of our products.

**We may need licenses for active ingredients from third parties so that we can develop and commercialize some products from some of our current preclinical programs, which could increase our development costs and delay our ability to commercialize products.**

Should we decide to use active pharmaceutical ingredients in any of our products that are proprietary to one or more third parties, we would need to obtain licenses to those active ingredients from those third parties. For example, we intend to use proprietary active ingredients that we have exclusively licensed from Daiichi Sankyo Co., Ltd. for our PDE7 program. 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 products from these programs by either accessing or developing alternate active ingredients, resulting in increased development costs and delays in commercialization of these products. 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 products from these programs.

**Our agreements with Vulcan and 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, should we elect to proceed with either of such transactions.**

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, that 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, such as Oxford and MidCap, 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 may not be successful in partnering new drug targets made accessible by our GPCR program.**

To fully exploit the developments arising from our GPCR program, we intend to partner or out-license our proprietary rights associated with some of the new drug targets made accessible by our GPCR program. There can be no assurance that we will enter into any such agreements and, even if we do, that the terms of any such agreements will be favorable to us. For example, potential partners may require that we first advance the development and optimization of functionally active compounds identified from our high-throughput screening of orphan GPCRs prior to entering into a licensing or other partnering arrangement, requiring us to invest substantial resources without any certainty that we will successfully optimize one or more of the compounds or recover our investment. Potential partners may also require that we obtain the issuance of patents protecting the new drug targets and compounds that interact with those targets. We may not be successful in obtaining the issuance of such patents for the targets and compounds we intend to partner or for the targets and compounds we intend to develop ourselves and, even if we do, the breadth of our patent rights may be inadequate or may be viewed as inadequate by potential partners. Further, if we are unable to secure the issuance of patents or patents of adequate breadth, we may be unable to exclude competitors from developing and commercializing compounds that interact with GPCR targets, limiting our ability to successfully commercialize these targets either independently or with a partner.

**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 pay Helion up to \$6.9 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 products from our MASP-2 and Plasmin programs depends on third-party developers and manufacturers of biologic drug products.**

Any product from our MASP-2 or Plasmin programs would be a biologic drug product and we do not have the internal capability to sequence, hybridize or clone biologics or to produce them for use in clinical trials or on a commercial scale. 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 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 products that are suitable for clinical trials or that can be successfully commercialized or generate revenue through partnerships.**

Any products from our preclinical programs, including our PDE7, Plasmin and GPCR 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 products that are suitable for clinical testing. For example, we have not yet generated any products from our GPCR program. We may discover that there are fewer drugable 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 products that successfully complete preclinical or clinical testing. If we are unable to develop products, potential corporate partners may be



unwilling to enter into partnership agreements with us. We also cannot be certain that any products 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 development programs and are considering a variety of products, we may expend our limited resources to pursue a particular product or products and fail to capitalize on products or indications that may be more profitable or for which there is a greater likelihood of success.**

Because we have limited resources, we must focus on clinical and preclinical development programs and products that we believe are the most promising. As a result, we may forego or delay pursuit of opportunities with other products or other indications that later prove to have greater commercial potential and may not be able to progress development programs, including our GPCR program, as rapidly as otherwise possible. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Further, if we do not accurately evaluate the commercial potential or target market for a particular product, 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, 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 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. 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, such as for 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 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;
- we may not be able to generate sufficient data to fully support 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 that are not patentable and which are unlikely to be adequately protected through trade secrets if, for example, a competitor were to independently develop 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 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 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 advisors 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.

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. 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 or may 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 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, programs, technologies or methods do not exist, have not been filed, or could not be filed or issued.

Because some patent applications in the U.S. may be maintained in secrecy until the patents are issued, because patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our patents, our licensors' patents, our pending applications or our licensors' pending

applications, or that we or our licensors were the first to invent or the first to file patent applications for inventions embodied in our technologies. Our competitors may have filed, and may in the future file, patent applications covering technologies similar to ours. Any such patent application may have priority over our or our licensors' patent applications and could further require us to obtain rights to issued patents covering such technologies. If our or our licensors' pending patent applications issue as patents, we can provide you no assurances that the patents will not be challenged in post-grant review or inter-parties review proceedings. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in interference derivation proceedings declared by the USPTO to determine priority of invention in the U.S. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions. Similar patent opposition proceedings in other countries and regions may also be costly and could result in the loss of patent rights in those countries and regions.

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. We refer to this loan and security agreement as the Oxford/MidCap Loan Agreement. 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.

**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.

**Our research programs have been partially supported by grant funding provided by the National Institutes of Health and our ability to utilize future grant funding may be limited.**

Our preclinical research programs have been partially supported by grant funding from the National Institutes of Health, or NIH. NIH is conducting an administrative review of our financial systems related to the allocation of expenditures to cost categories during administration of our NIH grants. The outcome of this review could result in constraints on the manner in which we administer any future NIH grants that we may receive.

**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. Section 404 requires us to perform system and process evaluation and testing of our internal control over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting for each fiscal year. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses.

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.

## 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 market than products or any future products that we may develop. 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 OMS824, and these companies may be further along in development and have the resources to develop their products 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 any 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.**

Any product for which we obtain marketing approval, 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 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 our products or their manufacture, 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 our products 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. 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 and maintain such insurance on acceptable terms or that we will be able to secure increased coverage if the commercialization of our products progresses, or that future claims against us will be covered by our product liability insurance. Although we currently have product liability insurance coverage for our clinical trials, our 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, 2013, our stock traded as high as \$13.76 per share and as low as \$3.65 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:

- FDA or EMA actions related to our NDA and MAA submissions for Omidria;
- results from our clinical development programs, including the data from our ongoing clinical development programs evaluating Omidria, OMS103, OMS824, OMS721 and OMS405;
- FDA or foreign regulatory actions related to any of our other products;
- announcements regarding the progress of our preclinical programs, including without limitation our GPCR program;
- failure of any of our products, if approved, to achieve commercial success;
- 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 our products;
- 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;
- 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 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 our product and products 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 to seek additional capital, we cannot be certain that it will be available to us on acceptable terms, if at all. 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 development or commercialization of one or more of our products 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.

**If we sell additional shares of our common stock under the Sales Agreement with MLV, our existing shareholders will experience immediate dilution and, as a result, our stock price may go down.**

We and MLV & Co. LLC, or MLV, entered into an at-the-market sales agreement, or Sales Agreement, in December 2012. Under the Sales Agreement, we may sell shares of our common stock by any method deemed to be an "at-the-market" offering under SEC rules. In October 2013, we sold 373,700 shares of our common stock under the Sales Agreement and received \$4.9 million in net proceeds. If we sell additional shares under the Sales Agreement, such sales will dilute our existing shareholders and could cause the market price of our common stock to decline significantly. Although MLV is precluded from shorting our stock during the term of the Sales Agreement, the ability to sell shares under the Sales Agreement, should we elect to use it further, could encourage short sales by third parties, which could cause or contribute to the decline in our stock price.

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

Approximately 9.5 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. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

**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 your sole source of potential gain in the foreseeable future, and you should not rely on an investment in our common stock for dividend income.



## 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 5,200 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 \$3.2 million for 2014, \$4.0 million for 2015 and \$4.1 million for 2016 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 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

Effective October 26, 2012, Omeros Corporation and Gregory A. Demopoulos, M.D., our chairman, chief executive officer, and president, and Richard J. Klein, our former chief financial officer and treasurer, entered into a settlement agreement and release settling and releasing all of the parties' respective claims in the lawsuit captioned *United States of America, ex. rel. Richard J. Klein v. Omeros Corporation and Gregory Demopoulos*, No. C09-1342 JCC. This lawsuit is described in Part II, Item 1 of our Quarterly Report on Form 10-Q filed with the SEC on August 7, 2012. Under an order filed by the U.S. District Court for the Western District of Washington on November 5, 2012, all claims asserted by Omeros, Dr. Demopoulos and Mr. Klein were dismissed with prejudice and all of Mr. Klein's claims asserted against Omeros on behalf of the U.S. Government under the Federal False Claims Act, or the Qui Tam Claims, were dismissed without prejudice to the U.S. Government, which had declined to intervene and thus was not a party to the proceeding.

Effective October 2, 2013, Omeros and Dr. Demopoulos entered into a settlement agreement and release with Carolina Causality Insurance Company, or CCIC, related to CCIC's defense of, and coverage obligations related to, the above-described lawsuit filed by Mr. Klein settling and releasing all of the parties' respective claims in the lawsuit captioned *Carolina Casualty Ins. Co. v Omeros Corp., et al*, No. 2:12-CV-00287. This lawsuit was filed by CCIC in 2012 as a declaratory judgment action in the U.S. District Court for the Western District of Washington relating to its coverage obligations under Omeros' directors, officers and corporate liability insurance policy that was in effect at the time Mr. Klein's employment with us was terminated. In connection with this lawsuit, Omeros and Dr. Demopoulos filed counterclaims against CCIC alleging that CCIC breached its duty to defend under the insurance policy, acted unreasonably and in bad faith, and unreasonably denied a claim for coverage in violation of Washington law. Pursuant to the terms of the settlement agreement, the parties settled and released all of their respective claims in the CCIC litigation and CCIC was required to make a one-time payment of \$12.5 million to Omeros, which was paid on October 24, 2013. On October 31, 2013, all claims asserted by Omeros, Dr. Demopoulos and CCIC in this lawsuit were dismissed with prejudice. While Dr. Demopoulos released all of his claims in exchange for this settlement, he elected to receive no portion of the settlement funds and to have all proceeds be paid to Omeros.

In connection with the administrative review by NIH of the two grants that were the subject of the Qui Tam Claims, we recognized \$900,000 in the first quarter of 2013 and \$164,000 in the third quarter of 2013 as selling, general and administrative expense. In October 2013, we repaid to NIH the \$1.064 million previously accrued. The administrative review will be complete following a review of Omeros' financial systems related to the allocation of expenditures to cost categories for use by Omeros

in current and any future grants. The outcome of this review could result in constraints on the manner in which we administer any future NIH grants that we may receive.

**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, 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
Year Ended December 31, 2012	High	Low
4th Quarter	\$11.85	\$5.08
3rd Quarter	\$10.34	\$8.17
2nd Quarter	\$13.45	\$8.51
1st Quarter	\$10.88	\$3.96

#### Holdings

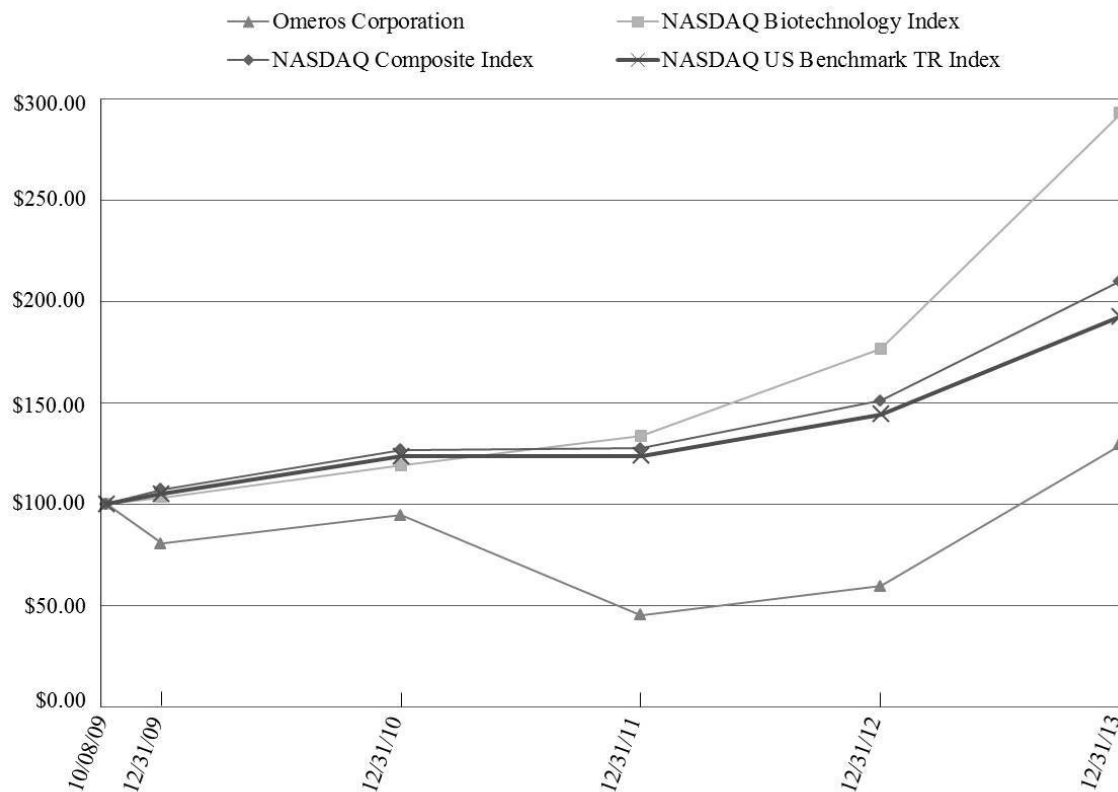
As of February 28, 2014, there were approximately 161 holders of record of our common stock.

#### 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, the NASDAQ Biotechnology Index, the NASDAQ Composite Index and the NASDAQ US Benchmark TR Index for the period beginning October 8, 2009 (the date of our initial public offering) and ending December 31, 2013. This graph assumes that \$100 was invested on October 8, 2009 in our common stock, the NASDAQ Biotechnology Index, the NASDAQ Composite Index and the NASDAQ US 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.



We are presenting the NASDAQ US Benchmark TR Index for the first time and expect that this index will replace the NASDAQ Composite Index in the performance graph for our Annual Report on Form 10-K for the year ending December 31, 2014. We are making this change as a result of a change in the total return data made available to us by NASDAQ beginning January 1, 2014. NASDAQ has identified NASDAQ US Benchmark TR Index as its proprietary index that most closely compares to NASDAQ Composite Index.

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.

**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,				
	2013	2012	2011	2010	2009
	(In thousands, except share data)				
<b>Consolidated Statements of Operations and Comprehensive Loss Data:</b>					
Revenue	\$ 1,600	\$ 6,022	\$ 4,524	\$ 2,105	\$ 1,444
Operating expenses:					
Research and development	36,297	31,922	23,718	23,465	16,929
Selling, general and administrative	15,819	10,985	8,216	8,746	5,273
Total operating expenses	52,116	42,907	31,934	32,211	22,202
Loss from operations	(50,516)	(36,885)	(27,410)	(30,106)	(20,758)
Litigation settlement	12,500	—	—	—	—
Investment income	12	40	51	167	214
Interest expense	(2,366)	(1,729)	(1,884)	(1,535)	(2,202)
Loss on extinguishment of debt	—	—	—	(296)	—
Other income (expense), net	574	130	697	2,519	1,657
Net Loss	<u>\$ (39,796)</u>	<u>\$ (38,444)</u>	<u>\$ (28,546)</u>	<u>\$ (29,251)</u>	<u>\$ (21,089)</u>
Basic and diluted net loss per share	<u>\$ (1.39)</u>	<u>\$ (1.59)</u>	<u>\$ (1.29)</u>	<u>\$ (1.37)</u>	<u>\$ (2.92)</u>
Denominator for basic and diluted net loss per share	<u>28,560,360</u>	<u>24,155,690</u>	<u>22,212,351</u>	<u>21,420,883</u>	<u>7,218,915</u>

	As of December 31,				
	2013	2012	2011	2010	2009
	(In thousands)				
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and short-term investments	\$ 14,101	\$ 22,350	\$ 24,570	\$ 41,993	\$ 60,305
Working capital	2,944	16,341	6,963	27,880	49,574
Total assets	16,535	26,575	26,982	45,704	62,062
Notes payable, net of discount	20,498	20,103	19,446	10,255	12,758
Accumulated deficit	(254,373)	(214,577)	(176,133)	(147,587)	(118,336)
Total shareholders' (deficit) equity	(18,384)	(6,531)	(5,554)	20,470	43,145

**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 clinical-stage biopharmaceutical company committed to discovering, developing and commercializing products targeting inflammation, coagulopathies and disorders of the central nervous system. Our most clinically advanced product, OMS302, or Omidria™, for lens replacement surgery, is derived from our proprietary PharmacoSurgery® platform designed to improve clinical outcomes of patients undergoing ophthalmological, arthroscopic, urological and other surgical and medical procedures. Our PharmacoSurgery platform is based on low-dose combinations of 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. In addition to Omidria, we have six other clinical-stage programs in our pipeline. We also have a deep and diverse pipeline of preclinical programs as well as two additional platforms: one capable of unlocking new G protein-coupled receptor drug targets and the other used to generate antibodies. For each of our products and programs, we have retained all manufacturing, marketing and distribution rights.

### *Products and Development Programs*

Omidria, our lead PharmacoSurgery product, previously completed a successful Phase 3 clinical trial that evaluated the product in patients undergoing intraocular lens replacement, or ILR. In November 2013, the FDA conditionally accepted Omidria as the proposed brand name for OMS302 in the U.S. and in December 2013, the EMA accepted Omidria as the proposed brand name for OMS302 in the EU. These acceptances are subject to final determination prior to approval of the respective marketing applications. We submitted for Omidria an NDA to the FDA in July 2013 and an MAA to the EMA in September 2013 to allow us to market and sell Omidria in the U.S. and the EU, respectively, for use in patients undergoing ILR. In October 2013, we announced that the FDA accepted the NDA for Omidria for filing and that the MAA for Omidria was validated by the EMA. Assuming approval of Omidria by the FDA within approximately one year of our initial submission of the NDA, we expect to begin marketing Omidria in the U.S. in the second half of 2014. 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, facilitate distribution and reimbursement, and manage pharmacovigilance and clinical support. Assuming approval of Omidria by the EMA and the out-licensing of Omidria marketing rights to one or more third parties, we anticipate the initiation of EU marketing and sales of Omidria in late 2014 or the first half of 2015. We have discussed with the FDA and EMA the design for pediatric studies for Omidria, which may afford Omidria an additional six months of exclusivity if completed successfully. In addition, we are evaluating the potential role of Omidria in the management of intraoperative floppy iris syndrome, or IFIS.

In addition to Omidria, we have a pipeline of other development programs targeting pain, inflammation, coagulopathies and disorders of the central nervous system. We have the following six additional clinical-stage programs in our pipeline: (1) OMS103 for reducing inflammatory pain following arthroscopic partial meniscectomy surgery, which has completed one Phase 3 trial, (2) our lead PDE10 inhibitor OMS824 for the treatment of schizophrenia, which is in a Phase 2 clinical program for patients with stable schizophrenia, (3) our lead PDE10 inhibitor OMS824 for the treatment of Huntington's disease, which is in a Phase 2 clinical program, (4) our lead MASP-2 antibody OMS721 for the treatment of thrombotic microangiopathies, which has completed dosing in a Phase 1 clinical trial and a Phase 2 clinical program is underway, (5) our PPAR $\gamma$  program, in which three Phase 2 clinical trials are being conducted by our collaborators to evaluate a PPAR $\gamma$  agonist, alone or in combination with other agents, for treatment of addiction to opioids and to nicotine and (6) our PharmacoSurgery product 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.

OMS103, our second PharmacoSurgery product, is being developed for use during arthroscopic procedures, including partial meniscectomy surgery. In December 2012, we completed a Phase 3 clinical trial in which the pre-specified primary endpoint was the Symptoms Subscale of the Knee Injury and Osteoarthritis Outcome Score (KOOS)-a patient-reported measure that is comprised of questions about knee swelling, clicking, catching and stiffness. 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, as was seen in the Phase 2 trial in patients undergoing arthroscopic partial meniscectomy, achieved statistically significant reduction of postoperative pain. We are redesigning our Phase 3 clinical program in arthroscopic partial meniscectomy surgery 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.

We have two IND applications for OMS824 filed at the FDA, one for schizophrenia and one for Huntington's disease, and each is currently in a Phase 2 clinical program. We are also conducting an ongoing Phase 1 clinical program evaluating the safety, tolerability and pharmacokinetics of OMS824 in healthy subjects, as well as a clinical trial to evaluate target occupancy of OMS824 using PET scans in healthy subjects by measuring the extent to which OMS824 binds to PDE10 in the striatum. 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. We also are seeking Fast Track designation for OMS824 for schizophrenia.

OMS721 is in a Phase 2 clinical program, and we submitted an IND application to the FDA in March 2014 to begin a Phase 2 clinical trial to evaluate OMS721 for the treatment of TMAs. If the IND application is cleared by the FDA, we intend to initiate this Phase 2 clinical trial in the second quarter of 2014. OMS721 has received Orphan Drug designation for the prevention of complement-mediated TMAs.

Our preclinical programs 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), (3) our GPR17 program in which we are optimizing compounds against GPR17, an orphan GPCR linked to myelin formation and (4) our proprietary *ex vivo* antibody platform.

In our GPCR platform, we are working to complete high-throughput surrogate de-orphanization of orphan GPCRs, identifying small-molecule compounds that bind and functionally interact with the receptors and to develop products that act at these new potential drug targets. As of February 28, 2014, we had publicly announced that we had identified and confirmed sets of small-molecule compounds that interact selectively with, and modulate signaling of, 52 Class A orphan GPCRs and two Class B GPCRs (glucagon-like peptide-1 receptor, or GLP-1R, and parathyroid hormone 1 receptor, or PTH-1R).

### *Financial Summary*

We recognized net losses of \$39.8 million, \$38.4 million, and \$28.5 million for the years ended December 31, 2013, 2012 and 2011, respectively. These losses are principally from expenses incurred in connection with research and development activities, consisting primarily of clinical trials, preclinical studies and manufacturing services associated with our current research and development programs. We expect our net losses to increase for the year ended 2014 as we continue to prepare for the planned commercial launch of Omidria in the U.S., if approved, in the second half of 2014, advance our clinical trials, and expand our other research and development efforts. As of December 31, 2013, our accumulated deficit was \$254.4 million and total shareholders' deficit was \$18.4 million.

## **Results of Operations**

### *Revenue*

	Years Ended December 31,		
	2013	2012	2011
	(In thousands)		
Vulcan Inc.	\$ 970	\$ 4,677	\$ 2,000
Life Science Development Fund Authority (LSDF)	—	624	2,028
Small Business Innovative Research Grant (SBIR)	630	721	266
Other Revenue	—	—	230
Total Revenue	<u>\$ 1,600</u>	<u>\$ 6,022</u>	<u>\$ 4,524</u>

Historically, our revenue has consisted of grant funding and revenue recognized in connection with funding received from third parties. Other than grant funding, we do not expect to receive any revenue from our products unless we receive regulatory approval and commercialize our products or enter into collaborative agreements for the development and commercialization of our products. Omidria, our most advanced product, is currently under review for marketing authorization by both the FDA and the EMA. We do not expect Omidria to be commercially available, if at all, before the second half of 2014 in the U.S. and late in 2014 or in the first half of 2015 in Europe. With respect to the EU, we do not expect to begin marketing Omidria until we have secured a partner with European commercial operations. We continue to pursue government and private grant funding as well as collaboration funding for our products and research programs.

Revenue was \$1.6 million and \$6.0 million for the years ended December 31, 2013 and 2012, respectively. The decrease was primarily due to lower revenue recognized from our GPCR program funding agreements with Vulcan and LSDF. We recognized the remaining revenue associated with these agreements during the first quarters of 2013 and 2012.

Revenue was \$6.0 million and \$4.5 million for the years ended December 31, 2012 and 2011, respectively. The increase was primarily due to higher revenue recognized from the Vulcan agreement and NIH grants for preclinical research. This increase was partially offset by a decrease in revenue recognized under our agreement with LSDF given that all remaining revenue under this agreement was recognized during the first quarter of 2012.

#### *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,		
	2013	2012	2011
	(In thousands)		
Direct external expenses:			
Clinical research and development:			
Omidria (OMS302)	\$ 4,477	\$ 8,622	\$ 4,663
OMS721	1,996	—	—
OMS103	404	2,773	3,558
OMS824	7,265	990	12
Other clinical programs	35	52	60
Total clinical research and development	<u>14,177</u>	<u>12,437</u>	<u>8,293</u>
Preclinical research and development	4,149	6,019	5,005
Total direct external expenses	<u>18,326</u>	<u>18,456</u>	<u>13,298</u>
Internal, overhead and other expenses	14,383	11,275	9,601
Stock-based compensation expense	3,588	2,191	819
Total research and development expenses	<u>\$ 36,297</u>	<u>\$ 31,922</u>	<u>\$ 23,718</u>

Direct external clinical research and development expenses consist primarily of expenses incurred pursuant to agreements with third-party manufacturing organizations, contract research organizations, or 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 not directly tied to any individual research project and are deployed across multiple clinical and preclinical projects 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 products. 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 clinical success of each product as well as on-going assessments of each product's commercial potential. In addition, we cannot forecast with any degree of certainty which products 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 products 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. We do not expect any of our current products to be commercially available before the second half of 2014, if at all. 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.



The increase in total research and development expenses during the year ended December 31, 2013 compared to 2012 was due primarily 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 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. We expect our research and development expenses to increase for the year ended December 31, 2014 as we continue to advance Omidria through the regulatory approval process, OMS824 and OMS721 through clinical development and our preclinical programs toward the clinic.

The increase in total research and development expenses for 2012 compared to 2011 was primarily due to higher expenses related to our Omidria Phase 3 clinical program, advancing our OMS824 and OMS721 programs into and toward the clinic, respectively, our GPCR program, and increased legal costs and employee compensation, including non-cash stock-based compensation. These increases were partially offset by lower expenses in our OMS103 program and in several of our preclinical programs, including our PDE7 and Plasmin programs.

#### *Selling, General and Administrative Expenses*

	Years Ended December 31,		
	2013	2012	2011
	(In thousands)		
Selling, general and administrative, excluding stock-based compensation expense	\$ 13,155	\$ 8,895	\$ 7,108
Stock-based compensation expense	2,664	2,090	1,108
Total selling, general and administrative expenses	<u>\$ 15,819</u>	<u>\$ 10,985</u>	<u>\$ 8,216</u>

The increase in 2013 was primarily due to legal matters, including expenses incurred in connection with the CCIC matter (see Part I, Item 3 - Legal Proceedings) and patent fees related to our products, 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 in the second half of 2014, expenses related to non-cash stock-based compensation, employee costs and non-cash rent expense associated with the lease of our new facilities. We expect our selling, general and administrative expenses to increase for the year ended December 31, 2014 as we prepare for the potential commercial launch in the U.S. of Omidria in the second half of 2014.

The increase in selling, general and administrative expenses during the twelve months ended December 31, 2012 compared to the same period of 2011 was primarily due to higher legal costs, marketing expenses tied to the potential 2014 commercial launch of Omidria and employee compensation, including non-cash stock-based compensation.

#### *Litigation Settlement*

Litigation settlement is the \$12.5 million payment we received from our former insurer CCIC, related to CCIC's defense of, and coverage obligations related to, the Klein lawsuit. See Part I, Item 3 - Legal Proceedings.

#### *Interest Expense*

	Years Ended December 31,		
	2013	2012	2011
	(In thousands)		
Interest Expense	\$ 2,366	\$ 1,729	\$ 1,884

Interest expense was \$2.4 million and \$1.7 million for the years ended December 31, 2013 and 2012, respectively. The increase in 2013 compared to 2012 was due to a higher interest rate and a higher average balance on our Oxford notes. Interest expense was \$1.9 million for the year ended December 31, 2011, with the decrease in 2012 from 2011 being due to a lower average balance on our Oxford notes.

*Other Income (Expense), Net*

	Years Ended December 31,		
	2013	2012	2011
	(In thousands)		
Other Income (Expense), Net	\$ 574	\$ 130	\$ 697

Other income (expense) principally includes sublease rental income and costs associated with warrant modifications we have made for the years ended December 31, 2013 and 2012. 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. The decrease during the year ended December 31, 2012 compared to 2011 is due to \$511,000 of warrant modification expense recognized in the first quarter 2012.

**Financial Condition - Liquidity and Capital Resources**

As of December 31, 2013, we had \$14.1 million in cash, cash equivalents and short-term investments and working capital of \$2.9 million. 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.

We believe that our existing cash, cash equivalents and short-term investments, together with capital that we may be able to raise through one or more corporate partnerships, equity offerings, debt financings, collaboration and licensing arrangements or asset sales, will be sufficient to fund our anticipated operating expenses, capital expenditures and note payments for at least the next 12 months. The company's operating plans for the next 12 months call for cash expenditures to exceed available cash, cash equivalents, and short-term investments due to the continued advancement of our clinical and preclinical programs as well as U.S. prelaunch sales and marketing activities associated with Omidria. To help meet these capital requirements, in March 2014, we terminated our existing loan agreement with Oxford and entered into the Oxford/MidCap Loan Agreement, whereby we received \$12.6 million in incremental funds and deferred the repayment of any principal under the new loan agreement until April 1, 2015. We may also have the opportunity to raise additional capital through corporate partnerships, public or private stock sales, debt financings, or through the pursuit of collaborations and licensing arrangements related to certain of our programs.

Corporate partnerships, public or private equity sales, additional debt financings, corporate collaboration and licensing arrangements or asset sales may not be available on terms that are acceptable to us, if at all, and any further equity financing would dilute the ownership of our existing shareholders. If we are unable to raise capital as and when needed, such failure could have a negative impact on our financial condition and ability to continue as a going concern. The audit report covering our 2013 consolidated financial statements contains a "going concern" explanatory paragraph based on our losses and financial condition as of December 31, 2013; however, this report does not take into account, among other things, the opportunity to raise additional funds from one or more of the sources of capital listed above.

	Years ended December 31,		
	2013	2012	2011
	(In thousands)		
<b>Selected cash flow data:</b>			
Cash provided by (used in):			
Operating activities	\$ (29,695)	\$ (34,551)	\$ (25,668)
Investing activities	7,909	(907)	16,909
Financing activities	21,650	32,973	9,486

*Operating Activities.* Expenditures related to operating activities were primarily for research and development and selling, general and administrative expenses in support of our operations. Overall, net cash used in operating activities decreased for the year ended December 31, 2013 by \$4.9 million as compared to the same period in 2012. Our net loss increased by \$1.4 million from 2012 primarily due to a \$4.4 million decrease in revenue and a \$9.2 million increase in operating expenses partially offset by the \$12.5 million we received in the CCIC litigation settlement. Other activities impacting the decrease in net cash used in operating activities between the comparative periods was a \$3.5 million increase in the deferred rent associated with the rent abatement at our new corporate offices, a \$2.0 million increase in non-cash stock compensation, a \$1.6 million decrease in grant and other receivables and a \$1.0 million decrease in deferred revenue.

Net cash used in operating activities increased \$8.9 million for the year ended December 31, 2012 as compared to the same period in 2011. Our net loss increased \$9.9 million from 2011 primarily due to an \$11.0 million increase in our operating expenses partially offset by a \$1.5 million increase in our revenues. Other activities impacting the increase in cash used in operating activities was a \$4.7 million increase in deferred revenue, a \$4.6 million increase in deferred rent including \$3.0 million that was given to us as a cash incentive payment from our landlord, a \$2.4 million increase in non-cash stock compensation and a \$1.1 million increase in grant and other receivables.

*Investing Activities.* Investing activities, other than the purchases and sales of short-term investments, consist primarily of purchases of property and equipment. Cash flows from investing activities primarily reflect cash used to purchase short-term investments and receipts 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, 2013 was \$8.8 million greater than in 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.

Net cash used in investing activities for the year ended December 31, 2012 was \$907,000 while, in 2011, net cash provided from investing activities was \$16.9 million. Of the \$17.8 million of incremental cash used in investing activities between 2012 and 2011, the purchase of short-term investments exceeded the sale of short-term investments by \$265,000 in 2012 while, in 2011, the net sale of investments generated \$18.2 million of cash provided from operations. We also purchased \$599,000 less property and equipment in 2012 than we did in 2011.

*Financing Activities.* Net cash provided from financing activities in the year ended December 31, 2013 was \$21.7 million. We received \$16.1 million of net proceeds from the sale of 3.9 million shares of our common stock in a registered direct offering in May 2013, \$4.9 million from the sale of 374,000 shares of our common stock under our ATM agreement in October 2013 and \$662,000 upon the exercise of employee stock options during the year.

During the year ended December 31, 2012, cash provided by financing activities was \$33.0 million. We received \$32.3 million in net proceeds from the sale of 3.4 million shares of our common stock in a public offering in July 2012. We also received \$369,000 upon the exercise of employee stock options during the year. In December 2012, we received net proceeds of \$6.5 million under the Oxford Loan Agreement and amended the terms of indebtedness under the Loan Agreement to provide for interest-only payments through December 31, 2013.

Net cash provided by financing activities in the year ended December 31, 2011 of \$9.5 million was primarily the result of borrowing an additional \$10.0 million from Oxford in March 2011. We also paid \$1.1 million of principal on the Oxford note and received \$595,000 upon the exercise of employee stock options.

#### *Funding Requirements*

Because of the numerous risks and uncertainties associated with the development and commercialization of our products, and to the extent that we may or may not enter into collaborations with third parties to participate in development and commercialization, 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:

- the progress and results of our preclinical and clinical programs;
- the costs of commercialization activities, including product manufacturing, marketing, sales and distribution;
- the commercial success of Omidria, if and when Omidria is approved for sale in the U.S. and/or the EU;
- the cost, timing and outcomes of the regulatory processes for our products;
- 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 our continued growth
- 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, if approved, becomes cash flow positive, which may be in several years if at all. To meet our future capital requirements, we will need to finance our future cash needs through public or private equity sales, debt financings or corporate collaboration and licensing arrangements. Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If 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.

#### *MLV At-the-Market Agreement*

In December 2012, we entered into an at-the-market issuance sales agreement with MLV. Pursuant to the Sales Agreement, we may sell shares of our common stock with an aggregate offering price of up to the amount available on our currently effective shelf registration statement and which amount would be reduced by any other securities we offer and sell under this shelf registration statement. The Sales Agreement provides that sales may be made directly on The NASDAQ Global Market or through or to a market maker other than on an exchange. With our prior written consent, sales may also be made in negotiated transactions and/or any other method permitted by law. MLV will receive a 2.0% commission from the gross proceeds of any sales. Subject to the terms and conditions of the Sales Agreement, MLV will use its commercially reasonable efforts to sell the shares of our common stock from time to time, based upon our instructions (including any price, time or size limits or other parameters or conditions that we may impose). We are not obligated to make any sales of common stock under the Sales Agreement, and no assurance can be given that we will sell any additional shares under the Sales Agreement, or, if we do sell additional shares, as to the price or amount of shares that we will sell, or the dates on which any such sales will take place. The Sales Agreement expires on April 16, 2014 and may be terminated by either party at any time upon 10 days' notice to the other party, or by MLV at any time in certain circumstances, including the occurrence of a material adverse effect to Omeros. In addition, the Sales Agreement will automatically terminate upon the sale of all common stock subject to the Sales Agreement.

#### *Loan and Security Agreement*

In October 2010, we entered into the Loan Agreement, or the Oxford Loan Agreement, with Oxford Finance LLC, or Oxford, and its affiliates which allowed us to borrow up to \$20.0 million. In December 2012, we amended the Oxford Loan Agreement, or the Amendment, and borrowed an additional \$7.2 million which represented principal payments we had previously made on the Oxford Loan Agreement obligations. This brought the outstanding principal balance to \$20.0 million as of December 31, 2012, and the outstanding principal balance remained at \$20.0 million as of December 31, 2013. The Amendment provided for interest-only payments at an annual rate of 9.25% through December 31, 2013. In connection with the Amendment, we also agreed to pay Oxford a \$1.4 million loan maturity fee. Beginning on January 1, 2014, monthly principal and interest payments of \$638,000 were due through the maturity date of December 1, 2016.

In March 2014, we entered into a Loan and Security Agreement, or the Oxford/MidCap Loan Agreement, with Oxford and MidCap Financial SBIC, LP, or MidCap, pursuant to which the lenders loaned us an aggregate principal amount of \$32.0 million. We used approximately \$19.1 million of the loan proceeds to repay all of the amounts owed by us under the Oxford Loan Agreement. We intend to use the remaining 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%. Payments due under the Oxford/MidCap Loan Agreement are interest-only, payable monthly, in arrears, through March 1, 2015. Beginning April 1, 2015, 36 payments of principal and interest are payable monthly, in arrears under the Oxford/MidCap Loan Agreement. All unpaid principal and accrued and unpaid interest are due and payable on March 1, 2018.

In connection with the execution of the Oxford/MidCap Loan Agreement, we made a one-time up front facility fee payment to the lenders of \$160,000. 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 under the Oxford/MidCap Loan Agreement 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 its obligations under the Oxford/MidCap Loan Agreement, we granted Oxford, as collateral agent for the lenders, a security interest in substantially all of its 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, 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 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 its rights and remedies under the Oxford/MidCap Loan Agreement or related agreements.

#### *Carolina Casualty Insurance Company Litigation and NIH Matter*

On October 2, 2013, Omeros and its chief executive officer entered into a settlement agreement with CCIC related to CCIC's defense of, and coverage obligations related to, the Klein lawsuit. Per the settlement agreement, CCIC paid Omeros \$12.5 million on October 24, 2013. While Dr. Demopolos released all of his claims in exchange for this settlement, he elected to receive no portion of the settlement funds and to have all proceeds be paid to Omeros. See Part I, Item 3 - Legal Proceedings.

In October 2013, in connection with an administrative review by NIH of the grants that were the subject of the Klein lawsuit, Omeros paid NIH the \$1.064 million. See Part I, Item 3 - Legal Proceedings

#### **Contractual Obligations and Commitments**

The following table presents a summary of our contractual obligations and commitments as of December 31, 2013.

	Payments Due Within				Total
	1 Year	2-3 Years	4-5 Years	More than 5 Years	
	(In thousands)				
Operating leases	\$ 3,232	\$ 8,042	\$ 8,411	\$ 42,063	\$ 61,748
License maintenance fees	7	22	30	85	144
Capital leases (principal and interest)	58	43	5	—	106
Notes payable (principal and interest)	7,660	15,320	—	—	22,980
Total	<u>\$ 10,957</u>	<u>\$ 23,427</u>	<u>\$ 8,446</u>	<u>\$ 42,148</u>	<u>\$ 84,978</u>

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, 2013, the remaining aggregate non-cancelable rent payable under the initial term of the lease is approximately \$61.7 million and we have received net lease incentives of \$4.5 million, which were recorded as deferred rent on our accompanying consolidated balance sheet.

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 the Annual Report on Form 10-K for a description of the agreements that include these royalty and milestone payment obligations.

The following table summarizes future principal payments, including regularly scheduled payments on the Oxford Loan Agreement for January 2014 through March 2014 and for periods thereafter, the payments on the Oxford/MidCap Loan Agreement we entered in March 2014.

	Payments Due Within				Total
	1 Year	2-3 Years	4-5 Years	More than 5 Years	
	(In thousands)				
Operating leases	\$ 3,232	\$ 8,042	\$ 8,411	\$ 42,063	\$ 61,748
License maintenance fees	7	22	30	85	144
Capital leases (principal and interest)	58	43	5	—	106
Notes payable (principal and interest)	4,102	22,188	15,320	—	41,610
Total	<u>\$ 7,399</u>	<u>\$ 30,295</u>	<u>\$ 23,766</u>	<u>\$ 42,148</u>	<u>\$ 103,608</u>

### 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 and directors based on estimated fair values. We use the straight-line method to allocate compensation cost to reporting periods over the optionees' requisite service period, 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 the vesting terms. 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.

As stock-based compensation expense is based on options ultimately expected to vest, the expense 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.

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.

#### **Recent Accounting Pronouncements**

There were no recent accounting pronouncements in 2013 whose adoption impacted or is expected to impact our financial statements or related disclosures.

#### **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, 2013, we had cash, cash equivalents and short-term investments of \$14.1 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, 2013. 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, 2013, our principal executive and principal financial officer 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, 2013. 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 (1992 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, 2013.

Ernst & Young LLP has independently assessed the effectiveness of our internal control over financial reporting as of December 31, 2013 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 2013 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, 2013 based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 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, 2013, 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, 2013 and 2012, 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, 2013 of Omeros Corporation and our report dated March 13, 2014 expressed an unqualified opinion thereon that included an explanatory paragraph regarding Omeros Corporation's ability to continue as a going concern.

/s/ Ernst & Young LLP

Seattle, Washington  
March 13, 2014

**ITEM 9B. OTHER INFORMATION**

None.

## 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 2014 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 2014 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 2014 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, 2013:

	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
<i>Equity compensation plans approved by security holders:</i>			
2008 Equity Incentive Plan (1)	5,299,298	\$ 7.99	413,330
Amended and Restated 1998 Stock Option Plan	1,669,567	1.25	—
nura, inc. 2003 Stock Option Plan	438	10.63	—
Total	<u>6,969,303</u>	<u>\$ 6.38</u>	<u>413,330</u>

(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 fiscal year equal to the lower of: (i) five percent of the outstanding shares of our common stock on the last day of the immediately preceding fiscal year; (ii) 1,785,714 shares; and (iii) such other amount as our board of directors may determine. On January 1, 2014, an additional 1,517,975 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 2014 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 2014 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 13, 2014

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ GREGORY A. DEMOPULOS, M.D.</u> Gregory A. Demopulos, M.D.	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	March 13, 2014
<u>/s/ MICHAEL A. JACOBSEN</u> Michael A. Jacobsen	Vice President, Finance, Chief Accounting Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)	March 13, 2014
<u>/s/ RAY ASPIRI</u> Ray Aspiri	Director	March 13, 2014
<u>/s/ THOMAS J. CABLE</u> Thomas J. Cable	Director	March 13, 2014
<u>/s/ PETER A. DEMOPULOS, M.D.</u> Peter A. Demopulos, M.D.	Director	March 13, 2014
<u>/s/ ARNOLD C. HANISH</u> Arnold C. Hanish	Director	March 13, 2014
<u>/s/ LEROY E. HOOD, M.D., PH.D.</u> Leroy E. Hood, M.D., Ph.D.	Director	March 13, 2014

**OMEROS CORPORATION**  
**INDEX TO FINANCIAL STATEMENTS**

	<b>Page</b>
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM	F-2
CONSOLIDATED BALANCE SHEETS	F-3
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS	F-4
CONSOLIDATED STATEMENT OF SHAREHOLDERS' EQUITY (DEFICIT)	F-5
CONSOLIDATED STATEMENTS OF CASH FLOWS	F-6
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS	F-7

## 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, 2013 and 2012, 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, 2013. 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, 2013 and 2012, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2013, in conformity with U.S. generally accepted accounting principles.

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

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, 2013, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) and our report dated March 13, 2014 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Seattle, Washington  
March 13, 2014

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

	<b>December 31,</b>	
	<b>2013</b>	<b>2012</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 1,384	\$ 1,520
Short-term investments	12,717	20,830
Grant and other receivables	379	1,934
Prepaid expenses and other current assets	337	416
Total current assets	14,817	24,700
Property and equipment, net	939	1,037
Restricted cash	679	679
Other assets	100	159
Total assets	\$ 16,535	\$ 26,575
<b>Liabilities and shareholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,329	\$ 2,632
Accrued expenses	3,944	4,757
Deferred revenue	—	970
Current portion of notes payable, net of discount	5,600	—
Total current liabilities	11,873	8,359
Notes payable, net of current portion and discount	14,898	20,103
Deferred rent	8,148	4,644
Commitments and contingencies (Note 8)		
Shareholders' equity:		
Preferred stock, par value \$0.01 per share:		
Authorized shares—20,000,000 at December 31, 2013 and 2012;		
Issued and outstanding shares—none	—	—
Common stock, par value \$0.01 per share:		
Authorized shares—150,000,000 at December 31, 2013 and 2012;		
Issued and outstanding shares—30,359,508 and 25,897,483 at December 31, 2013 and 2012, respectively	304	259
Additional paid-in capital	235,685	207,787
Accumulated deficit	(254,373)	(214,577)
Total shareholders' deficit	(18,384)	(6,531)
Total liabilities and shareholders' equity	\$ 16,535	\$ 26,575

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,		
	2013	2012	2011
Revenue	\$ 1,600	\$ 6,022	\$ 4,524
Operating expenses:			
Research and development	36,297	31,922	23,718
Selling, general and administrative	15,819	10,985	8,216
Total operating expenses	52,116	42,907	31,934
Loss from operations	(50,516)	(36,885)	(27,410)
Litigation settlement	12,500	—	—
Investment income	12	40	51
Interest expense	(2,366)	(1,729)	(1,884)
Other income (expense), net	574	130	697
Net loss	\$ (39,796)	\$ (38,444)	\$ (28,546)
Comprehensive loss	\$ (39,796)	\$ (38,444)	\$ (28,546)
Basic and diluted net loss per share	\$ (1.39)	\$ (1.59)	\$ (1.29)
Weighted-average shares used to compute basic and diluted net loss per share	28,560,360	24,155,690	22,212,351

See notes to consolidated financial statements

**OMEROS CORPORATION**  
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)**  
(In thousands, except share and per share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Deficit
	Shares	Amount			
<b>Balance at December 31, 2010</b>	21,920,836	\$ 219	\$ 167,838	\$ (147,587)	\$ 20,470
Issuance of common stock upon exercise of stock options for cash	509,398	5	590	—	595
Stock-based compensation	—	—	1,927	—	1,927
Net loss	—	—	—	(28,546)	(28,546)
<b>Balance at December 31, 2011</b>	22,430,234	224	170,355	(176,133)	(5,554)
Issuance of common stock in public offering, 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)
<b>Balance at December 31, 2012</b>	25,897,483	259	207,787	(214,577)	(6,531)
Issuance of common stock in direct offering, 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)
<b>Balance at December 31, 2013</b>	30,359,508	\$ 304	\$ 235,685	\$ (254,373)	\$ (18,384)

See notes to consolidated financial statements

**OMEROS CORPORATION**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In thousands)

	Year Ended December 31,		
	2013	2012	2011
<b>Operating activities:</b>			
Net loss	\$ (39,796)	\$ (38,444)	\$ (28,546)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	302	320	435
Stock-based compensation expense	6,252	4,281	1,927
Non-cash interest expense	502	354	352
Warrant modification expense	41	511	—
Changes in operating assets and liabilities:			
Grant and other receivables	1,555	(1,059)	2,254
Prepaid expenses and other current and noncurrent assets	84	(438)	(201)
Accounts payable and accrued liabilities	(1,169)	(2)	339
Deferred revenue	(970)	(4,718)	(2,228)
Deferred rent	3,504	4,644	—
Net cash used in operating activities	<u>(29,695)</u>	<u>(34,551)</u>	<u>(25,668)</u>
<b>Investing activities:</b>			
Purchases of property and equipment	(204)	(642)	(1,241)
Purchases of investments	(47,182)	(49,547)	(9,000)
Proceeds from the sale and maturity of investments	55,295	49,282	27,150
Net cash provided by (used in) investing activities	<u>7,909</u>	<u>(907)</u>	<u>16,909</u>
<b>Financing activities:</b>			
Proceeds from issuance of common stock, net of offering costs	20,988	32,306	—
Net proceeds from borrowings under notes payable	—	6,492	9,942
Payments on notes payable	—	(6,194)	(1,051)
Proceeds from issuance of common stock upon exercise of stock options	662	369	595
Net cash provided by financing activities	<u>21,650</u>	<u>32,973</u>	<u>9,486</u>
Net decrease) increase in cash and cash equivalents	(136)	(2,485)	727
Cash and cash equivalents at beginning of period	1,520	4,005	3,278
Cash and cash equivalents at end of period	<u>\$ 1,384</u>	<u>\$ 1,520</u>	<u>\$ 4,005</u>
<b>Supplemental cash flow information</b>			
Cash paid for interest	<u>\$ 1,709</u>	<u>\$ 1,502</u>	<u>\$ 1,461</u>
Reduction of equipment cost basis due to assets purchased with grant funding	<u>\$ —</u>	<u>\$ 60</u>	<u>\$ 1,689</u>
Property acquired under capital lease	<u>\$ —</u>	<u>\$ 30</u>	<u>\$ —</u>

See notes to consolidated financial statements

**OMEROS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 1—Organization and Significant Accounting Policies**

*Organization*

We are a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing products targeting inflammation, coagulopathies and disorders of the central nervous system. Our most clinically advanced products are derived from our proprietary PharmacoSurgery<sup>®</sup> platform designed to improve clinical outcomes of patients undergoing ophthalmological, arthroscopic, urological and other surgical and medical procedures. Our PharmacoSurgery platform is based on low-dose combinations of therapeutic agents delivered directly to the surgical site throughout the duration of the procedure to preemptively inhibit inflammation and other problems caused by surgical trauma and to provide clinical benefits both during and after surgery. Omidria<sup>™</sup> (OMS302), our most advanced product, is derived from our PharmacoSurgery platform. In addition to Omidria, we have six other clinical-stage development programs in our pipeline. We also have a deep and diverse pipeline of preclinical programs as well as two additional platforms: one capable of unlocking new G protein-coupled receptor drug targets and the other used to generate antibodies. For each of our products and programs, we have retained all manufacturing, marketing and distribution rights.

Omidria is used for patients undergoing intraocular lens replacement surgery. In July 2013, we submitted a New Drug Application (NDA) to the Federal Drug Administration (FDA) and in September 2013, a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for Omidria.

*Basis of Presentation*

Our consolidated financial statements include the accounts of Omeros Corporation and our wholly-owned subsidiaries. All inter-company transactions between and among our subsidiaries have been eliminated. The consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). Deferred rent totaling \$959,000 was reclassified from current liabilities to non-current liabilities for the year ended December 31, 2012 in the accompanying Consolidated Balance Sheets as we did not have the obligation or intention to pay this rent prior to December 31, 2013. The presentation of the related captions on the cash flow statement for the prior year has also been reclassified to conform to the current period presentation.

*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 trial 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 \$39.8 million, \$38.4 million, and \$28.5 million in 2013, 2012, and 2011, respectively, and had an accumulated deficit of \$254.4 million as of December 31, 2013. As of December 31, 2013, the Company had cash, cash equivalents and marketable securities of \$14.1 million and working capital of \$2.9 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 prelaunch sales and marketing activities associated with Omidria. To help meet these capital requirements, in March 2014, we terminated our existing loan agreement with Oxford and entered into a new loan agreement with Oxford and MidCap (see Note 6) whereby we received \$12.6 million in incremental funds and deferred the repayment of any principal under the new loan agreement until April 1, 2015. We may also have the opportunity to raise additional equity capital through public or private stock sales, corporate partnerships, asset sales or through the pursuit of collaborations and licensing arrangements related to certain of our programs.

Public or private equity sales, additional debt financings or corporate collaboration and licensing arrangements may not be available on acceptable terms to the Company, if at all. The Company's inability to raise capital as and when needed could have a negative impact on its financial condition and its ability to continue as a going concern.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern.

### *Financial Instruments and Concentrations of Credit Risk*

Cash and cash equivalents, grant and other 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 and short-term investments. 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, the use of which is restricted and serves as collateral securing a letter of credit for our facility operating lease.

### *Grant and Other Receivables*

Grant receivables 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. Other receivables consist primarily of lease incentives and are stated at the contractual amount due to us. Our receivables are primarily due from the U.S. government or our landlord and, as such, 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.

### *Impairment of Long-Lived Assets*

The carrying amount of long-lived assets, including property and equipment, are 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 our facility 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 our facility operating leases.

### *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 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 and directors based on estimated fair values. We use the straight-line method to allocate compensation cost to reporting periods over the optionees' requisite service period, 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. 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 employee and directors based awards may differ materially from that recorded for existing awards.

### *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, 2013, 2012 or 2011.

### *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*

There were no recent accounting pronouncements whose adoption impacted or is expected to impact the Company's financial statements or related disclosures.

## **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 unrestricted 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, 2013, 2012 and 2011 were computed based on the shares of common stock outstanding during the respective periods. Potentially dilutive securities excluded from the diluted loss per share calculation are as follows:

	Year Ended December 31,		
	2013	2012	2011
Outstanding options to purchase common stock	6,969,303	5,269,353	3,006,567
Warrants to purchase common stock	609,016	609,016	609,016
Total	7,578,319	5,878,369	3,615,583

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

As of December 31, 2013 and 2012, 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, 2013 or 2012. 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.

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

	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

	December 31, 2012			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as cash equivalents	\$ 21	\$ —	\$ —	\$ 21
Money-market funds classified as current restricted cash	193	—	—	193
Money-market funds classified as non-current restricted cash	679	—	—	679
Money-market funds classified as short-term investments	20,830	—	—	20,830
Total	\$ 21,723	\$ —	\$ —	\$ 21,723

Cash held in demand deposit accounts of \$1.2 million and \$1.5 million is excluded from our fair-value hierarchy disclosure as of December 31, 2013 and 2012, respectively. Current restricted cash at December 31, 2012 was held in money-market mutual funds and was included in prepaid expenses and other current assets on the accompanying Consolidated Balance Sheet. There were no unrealized gains and losses associated with our short-term investments as of December 31, 2013 or 2012.

The carrying amounts reported in the accompanying Consolidated Balance Sheets for grant and other 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**

*Grant and Other Receivables*

Grant and other receivables consisted of the following:

	December 31,	
	2013	2012
	(In thousands)	
Grant funding receivables	\$ 308	\$ 402
Lease incentives receivable	—	1,488
Other receivables	71	44
Total grant and other receivables	<u>\$ 379</u>	<u>\$ 1,934</u>

*Property and Equipment*

Property and equipment consisted of the following

	December 31,	
	2013	2012
	(In thousands)	
Computer equipment	\$ 431	\$ 394
Computer software	127	98
Office equipment and furniture	615	500
Capital lease equipment	231	231
Laboratory equipment	1,626	1,603
Total	<u>3,030</u>	<u>2,826</u>
Less accumulated depreciation and amortization	<u>(2,091)</u>	<u>(1,789)</u>
Total property and equipment, net	<u>\$ 939</u>	<u>\$ 1,037</u>

For the years ended December 31, 2013, 2012 and 2011, depreciation expense was \$302,000, \$320,000 and \$435,000, respectively.

*Accrued Liabilities*

Accrued liabilities consisted of the following:

	December 31,	
	2013	2012
	(In thousands)	
Employee costs	\$ 1,346	\$ 458
Clinical trials	596	1,842
Contract research	858	1,447
Consulting & professional fees	649	575
Other accruals	495	435
Total accrued liabilities	<u>\$ 3,944</u>	<u>\$ 4,757</u>



## **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), which allowed us to borrow up to \$20.0 million. We borrowed \$10.0 million in October 2010 and the remaining \$10.0 million in March 2011. In December 2012, we amended the Oxford Loan Agreement (the Amendment) and borrowed an additional \$7.2 million which represented principal payments we had previously made on the Oxford Loan Agreement obligations. This brought the outstanding principal balance to \$20.0 million as of December 31, 2012 and 2013. The Amendment also provided for interest-only payments at an annual rate of 9.25% through December 31, 2013. Beginning on January 1, 2014, monthly principal and interest payments of \$638,000 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 obligations. In addition, we recorded debt issuance costs of \$227,000 as other assets. Both the discounts and the debt issuance costs were being amortized to interest expense using the effective-interest method over the repayment period. When we entered into the Amendment, we paid \$588,000 for the prorated portion of the \$900,000 loan maturity fee with no further obligation for the remaining \$312,000. We accounted for the Amendment as a debt modification and accordingly, the remaining \$71,000 of unamortized debt issue costs associated with the Oxford Loan Agreement as of the date of the Amendment are being amortized to interest expense using the effective-interest method over the amended repayment term. In connection with the Amendment, we also agreed to pay Oxford a \$1.4 million loan maturity fee that 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 through the amended repayment term. As of December 31, 2013, the remaining unamortized discount and debt issuance costs associated with the debt were \$949,000 and \$114,000, respectively. As of December 31, 2013, we were not in default under the Oxford Loan Agreement. The Oxford Loan Agreement had similar terms and covenants as the Oxford/Midcap Loan Agreement described below.

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 the Oxford Loan Agreement. 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 \$160,000 upfront loan initiation fee and 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), 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, increase our interest rate 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.

### *Equipment Financing*

We have capital leases for copier equipment, which have lease terms expiring in July 2015 and October 2017. Equipment related to these capital leases of \$231,000 is included in our property and equipment as of December 31, 2013 and 2012,

respectively. At December 31, 2013 and 2012, accumulated depreciation on this equipment was \$145,000 and \$99,000, respectively.

#### *Future Principal Payments*

Future principal payments as of December 31, 2013 under the Oxford Loan Agreement, as amended, and our equipment financing, based on stated contractual maturities, are as follows:

Year Ending December 31,	Total
	(In thousands)
2014	\$ 6,116
2015	6,683
2016	7,295
2017	5
2018	—
Total future principal payments	\$ 20,099

The principal payments reflected in the table above exclude the unamortized balance of the debt discount and the Oxford/MidCap Loan Agreement, and include the short-term portion of the principal payments on our equipment financings, which are included in accrued liabilities in the accompanying Consolidated Balance Sheet.

The following table summarizes future principal payments, including regularly scheduled payments on the Oxford Loan Agreement for January 2014 through March 2014 and for periods thereafter, the payments on the Oxford/MidCap Loan Agreement we entered in March 2014.

Year Ending December 31,	Total
	(In thousands)
2014	\$ 1,517
2015	7,226
2016	10,400
2017	11,403
2018	3,017
Total future principal payments	\$ 33,563

The principal payments reflected in the table above exclude the unamortized balance of any debt discount and include the short-term portion of the principal payments on our equipment financings.

#### **Note 7—Revenue**

Revenue recognized from grants and other sources are as follows:

	Year Ended December 31,		
	2013	2012	2011
	(In thousands)		
Vulcan Inc.	\$ 970	\$ 4,677	\$ 2,000
Life Science Development Fund Authority (LSDF)	—	624	2,028
Small Business Innovative Research Grant (SBIR)	630	721	266
Other Revenue	—	—	230
Total revenue	\$ 1,600	\$ 6,022	\$ 4,524

In October 2010, we entered into a platform development funding agreement with Vulcan Inc. (Vulcan) pursuant to which we received \$20.0 million for our G protein-coupled receptor (GPCR) program. Of the funds received, \$8.2 million was

recorded as deferred revenue. The deferred revenue balance was recognized as revenue 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, 2012 and 2011, we recognized revenue of \$970,000, \$4.7 million and \$2.0 million, respectively. In addition, we recognized \$60,000 and \$38,000 as cost reductions to assets for the years ending December 31, 2012 and 2011, respectively. 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 in October 2010 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 years ended December 31, 2012 and 2011, respectively, we recognized revenue of \$624,000 and \$2.0 million and recorded cost reductions to property and equipment of \$1.7 million in the year ended December 31, 2011. 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.

We have periodically received Small Business Innovative Research (SBIR) grants from the National Institutes of Health (NIH), which are used to support the research and development of our products. We recorded revenue related to these grants of \$630,000, \$721,000 and \$266,000 for the years ended December 31, 2013, 2012 and 2011, respectively. As of December 31, 2013, \$1.2 million remained available under these grants.

## **Note 8—Commitments and Contingencies**

### *Development Milestones and Product Royalties*

Schizophrenia - 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 a schizophrenia product, 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. We have not paid any such royalties through December 31, 2013.

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 peroxisome proliferators activated receptor gamma (PPAR $\gamma$ ) 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 $\gamma$  activity. We will be required to make payments up to \$3.8 million in total, for both PPAR $\gamma$  agonists and dietary supplements that increase PPAR $\gamma$  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, 2013, 2012 and 2011, 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 are obligated 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, 2012 and 2011, 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 are obligated to make development and sales milestone payments to Helion of up to \$6.9 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 years ended December 31, 2013, 2012 and 2011, 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.

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, 2013, 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. Pursuant to the terms of the Settlement Agreement, we paid \$3.95 million to Mr. Klein, which was recorded as litigation settlement expense in the quarter ended September 30, 2012, and all claims pending in the lawsuit 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. The \$3.95 million settlement cost was reimbursed to us by our insurer Carolina Causality Insurance Company (CCIC), during the quarter ended December 31, 2012 and recognized as a recovery of the previously recorded litigation settlement expense.

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. The administrative review will be complete following a review of our financial systems related to the allocation of expenditures to cost categories for use by us in current and any future grants.

In October 2013, we and our chief executive officer entered into a settlement agreement with CCIC related to CCIC's defense of, and coverage obligations related to, the Klein lawsuit. Per the settlement agreement, CCIC paid Omeros \$12.5 million on October 24, 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.

## 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 (collectively the Lease Amendments) to the Lease. 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 commenced in November 2012 and the Lease Amendments in November 2012 and May 2013, respectively. The Lease and the First Lease Amendment did not require us to pay any base rent until November 2013, but did require us to provide security deposits totaling \$679,000. The deposit is recorded as restricted cash on the accompanying Consolidated Balance Sheet.

In March 2012, BMR paid us a \$3.0 million cash lease incentive and during 2013 and 2012, BMR reimbursed us for \$1.4 million and \$602,000, respectively, in expenses incurred by us in connection with the leased premises. In October 2013, we entered into the Third Amendment to the Lease, which replaced in its entirety the base rent schedule as outlined by the Original Lease Agreement.

As of December 31, 2013, we have received net lease incentives of \$4.5 million which 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 our lease. The deferred rent is being amortized over the initial 15 year term of the Lease.

Rent expense totaled \$4.3 million, \$2.9 million and \$2.2 million for the years ended December 31, 2013, 2012 and 2011, respectively.

We periodically sublease unused office and laboratory space to third party tenants. Rental income received under these subleases was \$550,000, \$635,000 and \$693,000 for the years ended December 31, 2013, 2012 and 2011, respectively. Rental income is recorded as other income in the accompanying Consolidated Statements of Operations and Comprehensive Loss.

We lease laboratory and office space as described above and rent equipment under various operating lease agreements that include certain rent escalation terms. Future minimum payments related to these leases, which exclude common area maintenance and related operating expenses, at December 31, 2013, are as follows:

Year Ending December 31,	Lease Payments	Sublease Income	Net Lease Payments
	(In thousands)		
2014	\$ 3,232	\$ 550	\$ 2,682
2015	3,976	550	3,426
2016	4,066	550	3,516
2017	4,158	480	3,678
2018	4,253	—	4,253
Thereafter	42,063	—	42,063
Total	\$ 61,748	\$ 2,130	\$ 59,618

## Note 9—Shareholders' Equity

### Common Stock

As of December 31, 2013, we had reserved shares of common stock for the following purposes:

Options granted and outstanding	6,969,303
Options available for future grant	413,330
Common stock warrants	609,016
Total shares reserved	7,991,649

MLV At-the-Market Sales Agreement - In December 2012, we entered into an At-the-Market Sales Agreement (the Sales Agreement) with MLV & Co (MLV) pursuant to which we may direct MLV to sell shares of our common stock directly on The

NASDAQ Global Market, through a market maker other than on an exchange or in negotiated transactions. Any sales made under the Sales Agreement are based solely on our instructions and MLV will receive a 2% commission from the gross proceeds. The Sales Agreement expires on April 16, 2014 and may be terminated by either party at any time upon 10 days' notice to the other party or by MLV at any time in certain circumstances including the occurrence of a material adverse change in Omeros.

In October 2013, we sold 374,000 shares of our common stock with a weighted average price of \$13.29 per share under the Sales Agreement and received \$4.9 million in net proceeds.

**Direct Offering** - 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.

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

### *Warrants*

The following table summarizes our outstanding warrants at December 31, 2013:

Outstanding At December 31, 2013	Expiration Date	Exercise Price
197,478	March 29, 2014	\$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
<u>609,016</u>		<u>\$23.85</u>

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.

In March 2012, we extended by one year the expiration dates of warrants to purchase up to 197,478 shares of our common stock at an exercise price of \$12.25 per share. In March 2013, we extended the expiration dates of the same warrants by an additional year. As a result of this extension, the warrants expire on March 29, 2014. We evaluated the fair value of the warrants before and after the modifications and recorded the \$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, 2013 and 2012, respectively.

### **Note 10—Stock-Based Compensation**

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, the 2008 Plan provides for annual increases in the number of shares available for issuance thereunder on the first day of each fiscal year, beginning with the 2010 fiscal year, equal to the lowest of:

- five percent of the outstanding shares of our common stock on the last day of the immediately preceding fiscal year;
- 1,785,714 shares; or
- such other amount as our board of directors may determine.

On January 1, 2014, 2013, and 2012, in accordance with the 2008 Plan annual increase provisions, the authorized shares in the 2008 Plan increased by 1,517,975, 1,294,874, and 1,121,511 shares, respectively. As of December 31, 2013, a total of 7,382,633 shares were reserved for issuance under our stock plans, of which 413,330 were available for future grants. 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. Generally, options vest over a four-year period, but may be granted with different vesting terms.

Compensation cost for stock options granted to employees 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 been reduced for estimated forfeitures. The fair value of each employee option grant was estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions during the periods ended:

	Year Ended December 31,		
	2013	2012	2011
Estimated weighted-average fair value	\$ 6.87	\$ 7.35	\$ 3.31
Weighted-average assumptions:			
Expected volatility	88%	86%	83%
Expected term, in years	5.8	5.7	5.7
Risk-free interest rate	1.66%	0.95%	1.97%
Expected dividend yield	—%	—%	—%

- (A) *Expected Volatility.* Because of our limited trading history, the expected volatility rate used to value stock option grants is based on volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the pharmaceutical and biotechnology industry in a similar stage of development.
- (B) *Expected Term.* We elected to utilize the "simplified" method for "plain vanilla" options to determine the expected term of our stock option grants. 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.
- (C) *Risk-free Interest Rate.* The risk-free interest rate assumption was based on zero-coupon U.S. Treasury instruments that had terms consistent with the expected term of our stock option grants.
- (D) *Expected Dividend Yield.* We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future.

Stock-based compensation guidance requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from estimates. We estimate forfeitures based on our historical experience; separate groups of employees that have similar historical forfeiture behavior are considered separately for expense recognition.

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, 2013, 2012 and 2011, we granted to non-employees options to purchase 40,000, 28,000 and 15,000 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 the accompanying Consolidated Statements of Operations and Comprehensive Loss as follows:

	Year Ended December 31,		
	2013	2012	2011
		(In thousands)	
Research and development	\$ 3,588	\$ 2,191	\$ 819
Selling, general and administrative	2,664	2,090	1,108
Total stock-based compensation expense	<u>\$ 6,252</u>	<u>\$ 4,281</u>	<u>\$ 1,927</u>

In connection with the non-employee options, we recognized expense of \$71,000, \$64,000 and \$62,000 during the years ended December 31, 2013, 2012 and 2011, 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, 2012	5,390,582	\$ 5.18		
Granted	1,943,301	9.52		
Exercised	(185,321)	3.57		
Forfeited and expired	(179,259)	7.52		
Balance at December 31, 2013	<u>6,969,303</u>	<u>\$ 6.38</u>	7.20	<u>\$ 34,262</u>
Vested and expected to vest at December 31, 2013	<u>6,692,208</u>	<u>\$ 6.27</u>	<u>7.12</u>	<u>\$ 33,588</u>
Exercisable at December 31, 2013	<u>4,072,707</u>	<u>\$ 4.57</u>	<u>5.82</u>	<u>\$ 27,385</u>

The total intrinsic value of options exercised during the years ended December 31, 2013, 2012 and 2011 was \$1.1 million, \$578,000 and \$2.1 million, respectively.

Information about stock options outstanding and exercisable is as follows:

Range of Exercise Price	December 31, 2013				
	Options Outstanding			Options Exercisable	
	Number of Options	Weighted- Average Remaining Contractual Life (Years)	Weighted- Average Exercise Price	Number of Options	Weighted- Average Exercise Price
\$0.98 - \$4.10	2,688,757	4.97	\$ 2.31	2,336,148	\$ 2.03
\$4.53 - \$6.42	891,051	6.44	6.13	810,558	6.15
\$7.29 - \$10.19	2,101,090	9.34	9.11	479,382	8.74
\$10.40 - \$13.49	1,288,405	8.90	10.59	446,619	10.48
\$0.98 - \$13.49	<u>6,969,303</u>	<u>7.20</u>	<u>\$ 6.38</u>	<u>4,072,707</u>	<u>\$ 4.57</u>

At December 31, 2013, there were 2,896,596 unvested options outstanding that will vest over a weighted-average period of 2.7 years. Excluding non-employee stock options, the total estimated compensation expense to be recognized in connection with these options is \$15.6 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,	
	2013	2012
	(In thousands)	
Deferred tax assets:		
Net operating loss carryforwards	\$ 68,942	\$ 59,124
Deferred rent	2,770	1,579
Stock-based compensation	3,537	2,183
Research and development tax credits	5,707	3,775
Other	1,866	1,614
Total	<u>82,822</u>	<u>68,275</u>
Less valuation allowance	<u>(82,822)</u>	<u>(68,275)</u>
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2013 and 2012, we had net operating loss carryforwards of approximately \$205.9 million and \$177.0 million, respectively, and research and development tax credit carryforwards of approximately \$5.7 million and \$3.8 million, respectively. Approximately \$3.2 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. Unless previously utilized, our net operating loss and research and development tax credit carryforwards expire between 2019 and 2033.

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 \$14.5 million, \$13.6 million and \$9.5 million in 2013, 2012 and 2011, 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,		
	2013	2012	2011
Statutory tax rate	(34)%	(34)%	(34)%
Permanent difference	3%	2%	1%
Change in valuation allowance	36%	35%	33%
Research and development credit	(5)%	—%	—%
Other	—%	(3)%	—%
Effective tax rate	<u>—%</u>	<u>—%</u>	<u>—%</u>

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 a result of the implementation of this guidance, we identified certain immaterial adjustments to our research and development tax credit, which was accounted for as a reduction to the deferred tax assets. There have been no changes in unrecognized tax benefits for the years ended December 31, 2013, 2012 and 2011. Further, there were no unrecognized tax

benefits that impacted our effective tax rate and accordingly, there was no material effect to our financial position, results of operations or cash flows.

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 2013 and 2012 (in thousands, except per share amounts):

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)

2012	For the Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
Revenue	\$ 1,496	\$ 1,526	\$ 1,417	\$ 1,583
Total operating expenses	9,568	9,770	14,453	9,116
Loss from operations	(8,072)	(8,244)	(13,036)	(7,533)
Net loss	(8,895)	(8,539)	(13,276)	(7,734)
Basic and diluted net loss per share	\$ (0.40)	\$ (0.38)	\$ (0.51)	\$ (0.30)

In October 2013, Omeros and its chief executive officer entered into a settlement agreement with CCIC related to CCIC's defense of, and coverage obligations related to, the Klein lawsuit. Per the settlement agreement, CCIC paid Omeros \$12.5 million on October 24, 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.

Operating expenses for the three-month period ended September 30, 2012 include \$3.95 million related to our Settlement Agreement with Mr. Klein. In November 2012 CCIC reimbursed us the \$3.95 million, which we recorded as a recovery on settlement in operating expenses for the three months ended December 31, 2012.

## EXHIBIT INDEX

Exhibit Number	Footnote Reference	Description
3.1	(1)	Amended and Restated Articles of Incorporation of Omeros Corporation
3.2	(1)	Amended and Restated Bylaws of Omeros Corporation
4.1	(2)	Form of Omeros Corporation common stock certificate
4.2	(3)	Stock Purchase Warrant issued by nura, inc. to Oxford Finance Corporation dated April 26, 2005 (assumed by Omeros Corporation on August 11, 2006)
4.3	(3)	Amended and Restated Investors' Rights Agreement among Omeros Corporation and holders of capital stock dated October 15, 2004
4.4	(4)	Form of Omeros Corporation Stock Purchase Warrant (as of December 31, 2012, warrants in this form were issued to purchase up to a total of 167,885 shares of common stock)
4.5	(4)	Form of Omeros Corporation Stock Purchase Warrant (as of December 31, 2012, warrants in this form were issued to purchase up to a total of 29,593 shares of common stock)
4.6	(4)	Form of Notice of Waiver of Warrant Termination (applicable to Stock Purchase Warrants filed as Exhibits 4.4 and 4.5)
4.7	(5)	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 4.4 and 4.5)
4.8	(23)	Notice Regarding the Extension of the Expiration Date to March 29, 2014 of Warrants to Purchase up to an Aggregate of 197,478 Shares of the Common Stock of the Registrant (applicable to Stock Purchase Warrants filed as Exhibits 4.4 and 4.5)
4.9	(6)	Form of Common Stock Warrant issued by Omeros Corporation to Cougar Investment Holdings LLC, which warrants were subsequently assigned to its affiliate Vulcan Capital Venture Capital II LLC (as of December 31, 2012, warrants in this form were issued to purchase of up to a total of 399,999 shares of common stock)
10.1	(3)*	Form of Indemnification Agreement entered into between Omeros Corporation and its directors and officers
10.2	(3)*	Second Amended and Restated 1998 Stock Option Plan
10.3	(3)*	Form of Stock Option Agreement under the Second Amended and Restated 1998 Stock Option Plan (that does not permit early exercise)
10.4	(3)*	nura, inc. 2003 Stock Plan
10.5	(3)*	Form of Stock Option Agreement under the nura, inc. 2003 Stock Plan
10.6	(7)*	2008 Equity Incentive Plan
10.7	(26)*	Form of Stock Option Award Agreement under the 2008 Equity Incentive Plan
10.8	(8)*	Second Amended and Restated Employment Agreement between Omeros Corporation and Gregory A. Demopulos, M.D. dated April 7, 2010
10.9	(3)*	Offer Letter between Omeros Corporation and Marcia S. Kelbon, Esq. dated August 16, 2001
10.10	(3)*	Technology Transfer Agreement between Omeros Corporation and Gregory A. Demopulos, M.D. dated June 16, 1994

- 10.11 (3) Technology Transfer Agreement between Omeros Corporation and Pamela Pierce, M.D., Ph.D. dated June 16, 1994
- 10.12 (3)\* Second Technology Transfer Agreement between Omeros Corporation and Gregory A. Demopoulos, M.D. dated December 11, 2001
- 10.13 (3) Second Technology Transfer Agreement between Omeros Corporation and Pamela Pierce, M.D., Ph.D. dated March 22, 2002
- 10.14 (3)\* Technology Transfer Agreement between Omeros Corporation and Gregory A. Demopoulos, M.D. dated June 16, 1994 (related to tendon splice technology)
- 10.15 (9) Lease dated January 27, 2012 between Omeros Corporation and BMR-201 Elliott Avenue LLC
- 10.16 (10) First Amendment to Lease dated November 5, 2012 between Omeros Corporation and BMR-201 Elliott Avenue LLC
- 10.17 (22) Second Amendment to Lease dated November 16, 2012 between Omeros Corporation and BMR-201 Elliott Avenue LLC
- 10.18 Third Amendment to Lease dated October 16, 2013 between Omeros Corporation and BMR-201 Elliott Avenue LLC
- 10.19 (12) Amended and Restated Settlement Agreement effective as of October 26, 2012 among Omeros Corporation, Gregory A. Demopoulos, M.D. and Richard J. Klein
- 10.20 Settlement Agreement and Release effective as of October 2, 2013 among Omeros Corporation, Gregory A. Demopoulos, M.D. and Carolina Casualty Insurance Company.
- 10.21 (4)† Commercial Supply Agreement between Omeros Corporation and Hospira Worldwide, Inc. dated October 9, 2007
- 10.22 (4)† Exclusive License and Sponsored Research Agreement between Omeros Corporation and the University of Leicester dated June 10, 2004
- 10.23 (3)† Research and Development Agreement First Amendment between Omeros Corporation and the University of Leicester dated October 1, 2005
- 10.24 (4)† Exclusive License and Sponsored Research Agreement between Omeros Corporation and the Medical Research Council dated October 31, 2005
- 10.25 (3)† Amendment dated May 8, 2007 to Exclusive License and Sponsored Research Agreement between Omeros Corporation and the Medical Research Council dated October 31, 2005
- 10.26 (13)† Funding Agreement between Omeros Corporation and The Stanley Medical Research Institute dated December 18, 2006
- 10.27 (4)† Patent Assignment Agreement between Omeros Corporation and Roberto Ciccocioppo, Ph.D. dated February 23, 2009
- 10.28 (22)† First Amendment to Patent Assignment Agreement between Omeros Corporation and Roberto Ciccocioppo, Ph.D. effective December 31, 2010
- 10.29 (4)\* Omeros Corporation Non-Employee Director Compensation Policy
- 10.30 (14)† License Agreement between Omeros Corporation and Daiichi Sankyo Co., Ltd. (successor-in-interest to Asubio Pharma Co., Ltd.) dated March 3, 2010
- 10.31 (15)† Amendment No. 1 to License Agreement with an effective date of January 5, 2011 between Omeros Corporation and Daiichi Sankyo Co., Ltd.
- 10.32 (24)† Amendment No. 2 to License Agreement with an effective date of January 25, 2013 between Omeros Corporation and Daiichi Sankyo Co., Ltd.

- 10.33 (16)† Exclusive License Agreement between Omeros Corporation and Helion Biotech ApS dated April 20, 2010
- 10.34 (18) At Market Issuance Sales Agreement dated December 14, 2012 between Omeros Corporation and MLV & Co. LLC
- 10.35 (6) Loan and Security Agreement dated October 21, 2010 between Omeros Corporation and Oxford Finance LLC (successor-in-interest to Oxford Finance Corporation)
- 10.36 (22) Consent and First Amendment to Loan and Security Agreement dated February 3, 2011 between Omeros Corporation and Oxford Finance LLC (successor-in-interest to Oxford Finance Corporation)
- 10.37 (25) Form of Subscription Agreement, dated May 9, 2013, between Omeros Corporation and each of the investors in the offering
- 10.38 (19) Second Amendment to Loan and Security Agreement dated March 25, 2011 between Omeros Corporation and Oxford Finance LLC (successor-in-interest to Oxford Finance Corporation)
- 10.39 (22) Third Amendment to Loan and Security Agreement dated June 13, 2011 between Omeros Corporation and Oxford Finance LLC
- 10.40 (22) Fourth Amendment to Loan and Security Agreement dated February 1, 2012 between Omeros Corporation and Oxford Finance LLC
- 10.41 (22) Fifth Amendment to Loan and Security Agreement dated June 23, 2012 between Omeros Corporation and Oxford Finance LLC
- 10.42 (20) Sixth Amendment to Loan and Security Agreement dated December 28, 2012 between Omeros Corporation, Oxford Finance LLC and Oxford Finance Funding Trust 2012-01
- 10.43 (26) Seventh Amendment to Loan and Security Agreement dated May 7, 2013 between Omeros Corporation, Oxford Finance LLC, Oxford Finance Funding Trust 2012-01 and Oxford Finance Funding I, LLC
- 10.44 Eighth Amendment to Loan and Security Agreement dated October 23, 2013 between Omeros Corporation, Oxford Finance LLC, Oxford Finance Funding Trust 2012-01 and Oxford Finance Funding I, LLC
- 10.45 (6) Secured Promissory Note dated October 21, 2010 with a principal amount of \$10,000,000 issued by Omeros Corporation to Oxford Finance Corporation (and subsequently assigned to Oxford Finance Funding Trust 2012-01)
- 10.46 (20) Allonge dated December 28, 2012 to Secured Promissory Note dated October 21, 2012 with a principal amount of \$10,000,000 issued by Omeros Corporation to Oxford Finance LLC (and subsequently assigned to Oxford Finance Funding Trust 2012-01)
- 10.47 (19) Secured Promissory Note dated March 25, 2011 with a principal amount of \$10,000,000 issued by Omeros Corporation to Oxford Finance Corporation (and subsequently assigned to Oxford Finance Funding Trust 2012-01)
- 10.48 (20) Allonge dated December 28, 2012 to Secured Promissory Note dated March 25, 2011 with a principal amount of \$10,000,000 issued by Omeros Corporation to Oxford Finance LLC (and subsequently assigned to Oxford Finance Funding Trust 2012-01)
- 10.49 (20) Secured Promissory Note dated December 28, 2012 with a principal amount of \$4,000,000 issued by Omeros Corporation to Oxford Finance LLC
- 10.50 (20) Secured Promissory Note dated December 28, 2012 with a principal amount of \$3,176,303 issued by Omeros Corporation to Oxford Finance LLC
- 10.51 (21)† Platform Development Funding Agreement between Omeros Corporation and Vulcan Inc. and its affiliate dated October 21, 2010
- 10.52 (21)† Grant Award Agreement between Omeros Corporation and the Life Sciences Discovery Fund Authority dated October 21, 2010

- |           |      |  |
|-----------|------|--|
| 10.53     | (27) | Loan and Security Agreement among Omeros Corporation, Oxford Finance LLC and MidCap Financial SBIC, LP dated March 5, 2014   |
| 10.54     | (27) | Form of Secured Promissory Note issued by the registrant to Oxford Finance LLC dated March 5, 2014   |
| 10.55     | (27) | Form of Secured Promissory Note issued by the registrant to MidCap Financial SBIC, LP dated March 5, 2014  |
| 12.1      |      | Ratio of Earnings to Fixed Charges   |
| 23.1      |      | Consent of Independent Registered Public Accounting Firm   |
| 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 |
| 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 |
| 32.1      |      | Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002  |
| 32.2      |      | Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002  |
| 99.1      |      | Description of Omeros Corporation Securities   |
| 101.INS** |      | XBRL Instance Document   |
| 101.SCH** |      | XBRL Taxonomy Extension Schema Document  |
| 101.CAL** |      | XBRL Taxonomy Extension Calculation Linkbase Document  |
| 101.DEF** |      | XBRL Taxonomy Extension Definition Linkbase Document   |
| 101.LAB** |      | XBRL Taxonomy Extension Labels Linkbase Document   |
| 101.PRE** |      | XBRL Taxonomy Extension Presentation Linkbase Document   |
- 
- (1) Incorporated by reference from the Annual Report on Form 10-K filed by Omeros Corporation on March 31, 2010 (File No. 001-34475).
  - (2) Incorporated by reference from the Registration Statement on Form S-1/A filed by Omeros Corporation on October 2, 2009 (File No. 333-148572).
  - (3) Incorporated by reference from the Registration Statement on Form S-1 filed by Omeros Corporation on January 9, 2008 (File No. 333-148572).
  - (4) Incorporated by reference from the Registration Statement on Form S-1/A filed by Omeros Corporation on September 16, 2009 (File No. 333-148572).
  - (5) Incorporated by reference from the Current Report on Form 8-K filed by Omeros Corporation on March 29, 2012 (File No. 001-34475).
  - (6) Incorporated by reference from the Current Report on Form 8-K filed by Omeros Corporation on October 25, 2010 (File No. 001-34475).
  - (7) Incorporated by reference from the Registration Statement on Form S-1/A filed by Omeros Corporation on April 1, 2008 (File No. 333-148572).
  - (8) Incorporated by reference from the Current Report on Form 8-K filed by Omeros Corporation on April 12, 2010 (File No. 001-34475).
  - (9) Incorporated by reference from the Current Report on Form 8-K filed by Omeros Corporation on February 1, 2012 (File No. 001-34475).
  - (10) Incorporated by reference from the Quarterly Report on Form 10-Q filed by Omeros Corporation on November 9, 2012 (File No. 001-34475).
  - (11) Incorporated by reference from the Current Report on Form 8-K filed by Omeros Corporation on September 28, 2012 (File No. 001-34475).

- (12) Incorporated by reference from the Current Report on Form 8-K filed by Omeros Corporation on November 1, 2012 (File No. 001-34475).
- (13) Incorporated by reference from the Registration Statement on Form S-1/A filed by Omeros Corporation on May 15, 2009 (File No. 333-148572).
- (14) Incorporated by reference from the Quarterly Report on Form 10-Q filed by Omeros Corporation on May 12, 2010 (File No. 001-34475).
- (15) Incorporated by reference from the Quarterly Report on Form 10-Q filed by Omeros Corporation on May 10, 2011 (File No. 001-34475).
- (16) Incorporated by reference from the Quarterly Report on Form 10-Q filed by Omeros Corporation on August 10, 2010 (File No. 001-34475).
- (17) Incorporated by reference from the Current Report on Form 8-K filed by Omeros Corporation on May 10, 2011 (File No. 001-34475).
- (18) Incorporated by reference from the Current Report on Form 8-K filed by Omeros Corporation on December 14, 2012 (File No. 001-34475).
- (19) Incorporated by reference from the Current Report on Form 8-K filed by Omeros Corporation on March 31, 2011 (File No. 001-34475).
- (20) Incorporated by reference from the Current Report on Form 8-K filed by Omeros Corporation on January 2, 2013 (File No. 001-34475).
- (21) Incorporated by reference from the Annual Report on Form 10-K filed by Omeros Corporation on March 15, 2011 (File No. 001-34475).
- (22) Incorporated by reference from the Annual Report on Form 10-K filed by Omeros Corporation on March 18, 2013 (File No. 001-34475).
- (23) Incorporated by reference from the Current Report on Form 8-K filed by Omeros Corporation on March 29, 2013 (File No. 001-34475).
- (24) Incorporated by reference from the Quarterly Report on Form 10-Q filed by Omeros Corporation on May 9, 2013 (File No. 001-34475).
- (25) Incorporated by reference from the Current Report on Form 8-K filed by Omeros Corporation on May 10, 2013 (File No. 001-34475).
- (26) Incorporated by reference from the Quarterly Report on Form 10-Q filed by Omeros Corporation on November 7, 2013 (File No. 001-34475).
- (27) Incorporated by reference from the Current Report on Form 8-K filed by Omeros Corporation on March 5, 2014 (File No. 001-34475).

\* Indicates management contract or compensatory plan or arrangement.

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

†† Portions of this exhibit are redacted in accordance with a request for confidential treatment.

\*\* XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under those sections.

## SEC FORM 10-K

Copies of Omeros' Annual Report on Form 10-K for the fiscal year ended December 31, 2013, including financial statements, are available on the Company's web site at [www.omeross.com](http://www.omeross.com) or by written request to:

### Investor Relations

**Omeros Corporation**  
The Omeros Building  
201 Elliott Avenue West  
Seattle, WA 98119

## TRANSFER AGENT AND REGISTRAR

### Computershare

P.O. Box 30170  
College Station, TX 77842-3170  
Toll Free Number: 866.282.4938 (U.S.)  
Outside the U.S.: 201.680.6578  
TDD for Hearing Impaired: 800.490.1493 (U.S.)  
Outside the U.S.: 781.575.4592  
[www.computershare.com/investor](http://www.computershare.com/investor)

## INVESTOR RELATIONS AND MEDIA CONTACT

### Investor Relations

**Omeros Corporation**  
The Omeros Building  
201 Elliott Avenue West  
Seattle, WA 98119  
[ir@omeross.com](mailto:ir@omeross.com)

## FORWARD-LOOKING STATEMENTS

This annual report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, which are subject to the "safe harbor" created by those sections. Forward-looking statements are based on management's beliefs and assumptions and on information available to management only as of the date of this annual report. All statements other than statements of historical fact are "forward-looking statements." Terms such as "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would," and similar expressions and variations thereof are intended to identify forward-

## INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

**Ernst & Young LLP**

## CORPORATE HEADQUARTERS

**Omeros Corporation**  
The Omeros Building  
201 Elliott Avenue West  
Seattle, WA 98119  
[www.omeross.com](http://www.omeross.com)

## STOCK LISTING

Omeros' stock trades on The NASDAQ Global Market under the symbol OMER. For more information, please visit [www.omeross.com](http://www.omeross.com).

## 2014 ANNUAL MEETING

The 2014 Annual Meeting of Shareholders of Omeros Corporation will be held May 23, 2014, beginning at 10:00 A.M. (local time), at:  
**Bell Harbor International Conference Center**  
2211 Alaskan Way  
Pier 66  
Seattle, WA 98121

looking statements, but these terms are not the exclusive means of identifying such statements. Omeros' actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including, without limitation, the risks, uncertainties and other factors described under the heading "Risk Factors" in this annual report. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, and Omeros assumes no obligation to update these forward-looking statements publicly, even if new information becomes available in the future.

## BOARD OF DIRECTORS

### Ray Aspiri

Former Chairman of the Board  
Tempress Technologies, Inc.

### Thomas J. Cable

Chairman of the Board  
Washington Research Foundation

### Gregory A. Demopoulos, M.D.

Chairman and President, Chief Executive Officer  
Omeros Corporation

### Peter A. Demopoulos, M.D.

Cardiologist  
Swedish Heart and Vascular Institute

### Arnold C. Hanish

Former VP and Chief Accounting Officer  
Eli Lilly & Company

### Leroy E. Hood, M.D., Ph.D.

President  
Institute for Systems Biology

### Michael A. Jacobsen

Vice President, Finance  
Chief Accounting Officer and Treasurer

### Marcia S. Kelbon, J.D.

Vice President, Patent  
General Counsel and Secretary

## KEY EMPLOYEES

### Timothy M. Duffy

Vice President, Business Development

### Kenneth M. Ferguson, Ph.D.

Vice President, Development  
Chief Development Officer

### George A. Gaitanaris, M.D., Ph.D.

Vice President, Science  
Chief Scientific Officer

### Patrick W. Gray, Ph.D.

Scientific Fellow

### Michael K. Inouye

Vice President, Commercial Operations

### Catherine A. Melfi, Ph.D.

Vice President, Regulatory Affairs and Quality Systems

### J. Steven Whitaker, M.D., J.D.

Vice President, Clinical Development  
Chief Medical Officer

## EXECUTIVE OFFICERS

### Gregory A. Demopoulos, M.D.

Chairman, President  
Chief Executive Officer







# OMEROS

201 ELLIOTT  
AVENUE WEST  
SEATTLE  
WASHINGTON  
98119

[WWW.OMEROS.COM](http://WWW.OMEROS.COM)